



**PERFORMANCE  
QUALIFICATION REPORT  
FOR  
HPHV STEAM STERILIZER**

<b>REFERENCE PROTOCOL No.:</b>
<b>REVISION No.:</b> 00
<b>REPORT No.:</b>
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**1.0 REPORT APPROVAL:**

**PREPARED BY:**

NAME	DESIGNATION	SIGNATURE	DATE

**REVIEWED BY:**

NAME	DESIGNATION	SIGNATURE	DATE

**APPROVED BY:**

NAME	DESIGNATION	SIGNATURE	DATE



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**2.0 OBJECTIVE:**

To compile the all results during execution of performance qualification Protocol for HPHV Steam Sterilizer in Media Discarding Room used to deactivate the Microbiological growth medium.

**3.0 SCOPE:**

The Scope of this Performance qualification Report is applicable to all results of Performance Qualification for the HPHV Steam Sterilizer installed in the Media Preparation room of Microbiology Section in Quality Control.

**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 Report:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Approval and Compilation of Performance Qualification Report.</li><li>• Verification of Tests &amp; Results.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Performance Qualification Report.</li></ul>
<b>Quality Control (Microbiology Section)</b>	<ul style="list-style-type: none"><li>• Review of Performance Qualification Report.</li></ul>

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	<b>HPHV Steam Sterilizer</b>
<b>Equipment ID.</b>	.....
<b>Manufacturer's Name</b>	
<b>Supplier's Name</b>	
<b>Place of Installation</b>	<b>Media Preparation Area</b>



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**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	

**A) Vacuum Leak Test Cycle**

**B) Bowie Dick Test**

**C) Standard Process**

**D) HPHV Cycle**

**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.



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**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.



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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

**8.0 SITE OF STUDY:**

Media Preparation Room (Microbiology Section, Quality Control).



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**9.0 FREQUENCY OF QUALIFICATION :**

S.No.	Test	Run		Frequency
		Initial Qualification	Periodic Qualification	
<b>Pre – Qualification Test</b>				
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</b>				
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:**

**10.1 Training:**

Refer attached training attendance sheet.

**10.2 Verification of calibration status of measuring and test instruments:**

S.No.	Instrument Name	Instruments ID	Calibration Status	
			Done Date	Due Date
1.	Pressure Gauge			
2.	Temperature Sensor			
3.	Wire Data Logger			
4.	T Type Thermocouple Set			

**10.3 Verification of SOP Status:**

S.No.	Document Name	SOP No.	Effective date	
			From	To
1.	Preparation, Review, Approval, Execution, Compilation of Validation/Qualification Protocols and Reports			





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**10.4 Verification of Pre & Post Calibration of Thermal Sensors**

<b>S.No.</b>	<b>Thermal Sensor ID</b>	<b>Pre-Calibration Date</b>	<b>Post-Calibration Date</b>
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			



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**11.0 TESTS AND CHECKS:**

**11.1 Vacuum Leak Test:**

Name of Cycle	Before Insertion of Sensors	After Insertion of Sensors	After Removal of Sensors	
Date	01/02/15	01/02/15	06/02/15	
Parameters	Set Value	Observed Value		
Process Start Time	NA	08:09	09:07	08:08
Process End Time	NA	08:23	09:20	08:23
Pre Vacuum	- 0.700 bar	- 0.700 bar	- 0.700 bar	- 0.700 bar
Delay before hold	03 min.	03 min.	03 min.	03 min.
Vacuum Hold Time	10 min.	10 min.	10 min.	10 min.
Acceptable Leakage	0.013 bar	0.013 bar	0.013 bar	0.013 bar
Process End Pressure	-0.030 bar	-0.030 bar	-0.030 bar	-0.030 bar
Actual Leakage		0.002 bar/10 min.	0.008 bar/10 min.	0.006 bar/10 min.



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**11.2 Bowie-Dick Test :**

Name of Cycle		Bowie Dick Test
Date		01/02/15
Cycle Start Time		11:07
Cycle End Time		12:09
Parameters	Set Value	Observed Value
Pre Vacuum	-0.600 bar	-0.600 bar
Pre Pressure	0.500 bar	0.500 bar
No. of Pre Pulses	3 Nos.	3 Nos.
Heat Up 1	110.0 <sup>o</sup> C	110.0 <sup>o</sup> C
Heat Up Hold 1	5 min.	5 min.
Heat Up 2	115.0 <sup>o</sup> C	115.0 <sup>o</sup> C
Heat Up Hold 2	4 min.	4 min.
Heat Up 3	119.0 <sup>o</sup> C	119.0 <sup>o</sup> C
Heat Up Hold 3	3 min.	3 min.
Heat Up Control Band	0.2 <sup>o</sup> C	0.2 <sup>o</sup> C
Small Valve Set Point	120.4 <sup>o</sup> C	120.4 <sup>o</sup> C
Sterilization Hold Temp.	121.4 <sup>o</sup> C	121.4 <sup>o</sup> C
Sterilization Hold Time	660 sec	660 sec
Temp. Control Band	0.2 <sup>o</sup> C	0.2 <sup>o</sup> C
Overshoot Temp.	124.0 <sup>o</sup> C	124.0 <sup>o</sup> C
Sterilization Stop Temp.	120.9 <sup>o</sup> C	120.9 <sup>o</sup> C
Sterilization Reset Temp.	120.5 <sup>o</sup> C	120.5 <sup>o</sup> C
Process End Pressure	0.030 bar	0.030 bar
<b>Observation of color change in Bowie Dick Pack</b>	Uniform color changed from Blue to Black in Bowie Dick Pack	

- **Attach the Printout (from Autoclave) for time, temperature & pressure profile (Bowie Dick Pack).**



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**11.3 Heat distribution study (empty chamber):**

**11.3.1 Standard Process- I:**

Name of Cycle	Heat Distribution Study
Type of Cycle	Standard Cycle-I
Date	02/02/15
Process Start Time	10:20
Process End Time	11:03

**Set Parameters:**

Parameters	Set Value	Observed Value
	Standard Cycle	
Pre Vacuum	0.000 bar	0.000 bar
Pre Pressure	0.000 bar	0.000 bar
No. of Pre Pulses	0 nos.	0 nos.
Heat Up 1	110.0 °C	110.0 °C
Heat Up Hold 1	5 min.	5 min.
Heat Up 2	115.0 °C	115.0 °C
Heat Up Hold 2	4 min.	4 min.
Heat Up 3	119.0 °C	119.0 °C
Heat Up Hold 3	3 min.	3 min.
Heat Up Band	0.2 °C	0.2 °C
Small Valve Set Point	120.4°C	120.4°C
Sterilization Hold Temp.	121.4°C	121.4°C
Sterilization Hold Time	20 min.	20 min.
Temp. Control Band	0.2°C	0.2°C
Overshoot Temp.	124.0°C	124.0°C
Sterilization Stop Temp.	120.9°C	120.9°C
Sterilization Reset Temp.	120.5°C	120.5°C
Process End Pressure	0.030 bar	0.030 bar

**Test Instrument Details:**

Make (Data Logger)	G-Tek
Model (Data Logger)	9330-000
No. of Probes to be used with Data Logger	10
Calibration Status of Probes	Calibrated

**Attach the Printout & Thermograph from Autoclave & Data Logger for Standard Cycle-I**



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**Observations of Standard Cycle-I:**

S.No.	Probe No.	Channel No.	Sterilizing Temperature (°C)			Chemical Indicator Status
			Max.	Min.	Average	
<b>Cycle – 1<sup>st</sup></b>						
1.0		CH-01	122.1	121.5	121.7	Uniform color changes from Pink to Green
2.0		CH-02	122.2	121.6	121.9	Uniform color changes from Pink to Green
3.0		CH-03	122.3	121.5	121.9	Uniform color changes from Pink to Green
4.0		CH-04	122.3	121.5	121.8	Uniform color changes from Pink to Green
5.0		CH-05	122.3	121.8	122.1	Uniform color changes from Pink to Green
6.0		CH-06	122.5	121.5	122.0	Uniform color changes from Pink to Green
7.0		CH-07	122.4	121.8	122.1	Uniform color changes from Pink to Green
8.0		CH-08	122.2	121.5	121.8	Uniform color changes from Pink to Green
9.0		CH-09	122.4	121.6	121.9	Uniform color changes from Pink to Green
10.0		CH-10	122.2	121.8	122.2	Uniform color changes from Pink to Green



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**11.3.2 HPHV Cycle:**

Name of Cycle	Heat Distribution Study
Type of Cycle	HPHV Cycle
Date	05/02/15
Process Start Time	12:15
Process End Time	13:15

**Set Parameters:**

Parameters	Set Value	Observed Value
	HPHV Cycle	
Pre Vacuum	-0.600 bar	-0.600 bar
Pre Pressure	0.500 bar	0.500 bar
No. of Pre Pulses	3 nos.	3 nos.
Heat Up 1	110.0 °C	110.0 °C
Heat Up Hold 1	5 min.	5 min.
Heat Up 2	115.0 °C	115.0 °C
Heat Up Hold 2	4 min.	4 min.
Heat Up 3	119.0 °C	119.0 °C
Heat Up Hold 3	3 min.	3 min.
Heat Up Band	0.2 °C	0.2 °C
Small Valve Set Point	120.4 °C	120.4 °C
Sterilization Hold Temp.	121.4 °C	121.4 °C
Sterilization Hold Time	30 min.	30 min.
Temp. Control Band	0.2 °C	0.2 °C
Overshoot Temp.	124.0°C	124.0°C
Sterilization Stop Temp.	120.9 °C	120.9 °C
Sterilization Reset Temp.	120.5°C	120.5°C
Post Vacuum Start Pressure	0.200 bar	0.200 bar
Post Vacuum	-0.600 bar	-0.600 bar
Post Vacuum Hold Time	10 min.	10 min.
Post Pressure	-0.100 bar	-0.100 bar
No. of Post Pulses	1 no.	1 no.
Process End Pressure	-0.030 bar	-0.030 bar

**Test Instrument Details:**

<b>Make (Data Logger)</b>	<b>G-Tek</b>
<b>Model (Data Logger)</b>	<b>9330-000</b>
<b>No. of Probes to be used with Data Logger</b>	<b>10</b>
<b>Calibration Status of Probes</b>	<b>Calibrated</b>



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**Attach the Printout & Thermograph from Autoclave & Data Logger for HPHV Cycle  
Observations of HPHV Cycle:**

S.No.	Probe No.	Channel No.	Sterilizing Temperature (°C)			Chemical Indicator Status
			Max.	Min.	Average	
<b>Cycle – 1<sup>st</sup></b>						
1.0		CH-01	122.6	121.9	122.1	Uniform color changes from Pink to Green
2.0		CH-02	122.8	122.2	122.5	Uniform color changes from Pink to Green
3.0		CH-03	122.7	122.2	122.5	Uniform color changes from Pink to Green
4.0		CH-04	122.9	121.8	122.4	Uniform color changes from Pink to Green
5.0		CH-05	122.6	122.1	122.3	Uniform color changes from Pink to Green
6.0		CH-06	122.8	122.0	122.4	Uniform color changes from Pink to Green
7.0		CH-07	122.7	122.0	122.3	Uniform color changes from Pink to Green
8.0		CH-08	122.8	121.9	122.2	Uniform color changes from Pink to Green
9.0		CH-09	122.7	121.9	122.3	Uniform color changes from Pink to Green
10.0		CH-10	122.9	122.1	122.6	Uniform color changes from Pink to Green



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**11.3.3 Standard Cycle-II:**

Name of Cycle	Heat Distribution Study	
Type of Cycle	Standard Cycle-II	
Date	04/02/15	
Process Start Time	14:13	
Process End Time	14:43	
<b>Set Parameters:</b>		
Parameters	Set Value	Observed Value
	Standard Cycle	
Pre Vacuum	0.000 bar	0.000 bar
Pre Pressure	0.000 bar	0.000 bar
No. of Pre Pulses	0 nos.	0 nos.
Heat Up 1	100.0 °C	100.0 °C
Heat Up Hold 1	4 min.	4 min.
Heat Up 2	105.0 °C	105.0 °C
Heat Up Hold 2	3 min.	3 min.
Heat Up 3	113.0 °C	113.0 °C
Heat Up Hold 3	2 min.	2 min.
Heat Up Band	0.5 °C	0.5 °C
Small Valve Set Point	114.5°C	114.5°C
Sterilization Hold Temp.	115.5°C	115.5°C
Sterilization Hold Time	20 min.	20 min.
Temp. Control Band	0.2°C	0.2°C
Overshoot Temp.	119.0°C	119.0°C
Sterilization Stop Temp.	114.9°C	114.9°C
Sterilization Reset Temp.	114.8°C	114.8°C
Process End Pressure	0.030 bar	0.030 bar

<b>Test Instrument Details:</b>	
<b>Make (Data Logger)</b>	G-Tek
<b>Model (Data Logger)</b>	9330-000
<b>No. of Probes to be used with Data Logger</b>	10
<b>Calibration Status of Probes</b>	Calibrated





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**Attach the Printout & Thermograph (from Autoclave & Data Logger) for time, temperature & pressure profile (Standard Cycle -II)**

**Observations Standard Cycle -II:**

S.No.	Probe No.	Channel No.	Sterilizing Temperature (°C)		
			Max.	Min.	Average
<b>Cycle – 1<sup>st</sup></b>					
1.0		CH-01	122.6	121.9	122.1
2.0		CH-02	122.8	122.2	122.5
3.0		CH-03	122.7	122.2	122.5
4.0		CH-04	122.9	121.8	122.4
5.0		CH-05	122.6	122.1	122.3
6.0		CH-06	122.8	122.0	122.4
7.0		CH-07	122.7	122.0	122.3
8.0		CH-08	122.8	121.9	122.2
9.0		CH-09	122.7	121.9	122.3
10.0		CH-10	122.9	122.1	122.6



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**11.4 Heat Penetration Study :**

**11.4.1 Standard Process – I:**

**11.4.1.1 Solid Load Maximum with Agar Media :**

Name of Cycle	Heat Penetration Study
Type of Cycle	Standard Process - I
Load Type	Solid Load Maximum with Agar Media
Date	02/02/15
Process Start Time	12:33
Hold Start Time	13:00
Hold End Time	13:20
Process End Time	13:24

**Set Parameters:**

Parameters	Set Value	Observed Value
	Standard Process - I	Cycle-1 <sup>st</sup>
Pre Vacuum	0.000 bar	0.000 bar
Pre Pressure	0.000 bar	0.000 bar
No. of Pre Pulses	0 nos.	0 nos.
Heat Up 1	110.0 °C	110.0 °C
Heat Up Hold 1	5 min.	5 min.
Heat Up 2	115.0 °C	115.0 °C
Heat Up Hold 2	4 min.	4 min.
Heat Up 3	119.0 °C	119.0 °C
Heat Up Hold 3	3 min.	3 min.
Heat Up Band	0.2 °C	0.2 °C
Small Valve Set Point	120.4°C	120.4°C
Sterilization Hold Temp.	121.4°C	121.4°C
Sterilization Hold Time	20 min.	20 min.
Temp. Control Band	0.2°C	0.2°C
Overshoot Temp.	124.0°C	124.0°C
Sterilization Stop Temp.	120.9°C	120.9°C
Sterilization Reset Temp.	120.5°C	120.5°C
Process End Pressure	0.030 bar	0.030 bar

**Test Instrument Details:**

Make (Data Logger)	G-Tek
Model (Data Logger)	9330-000
No. of Probes to be used with Data Logger	10
Calibration Status of Probes	Calibrated



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**Observations of Solid Load Maximum with Agar Media:**

S.No.	Probe No.	Channel No.	Sterilizing Temperature (°C)			F <sub>0</sub> Value		Spore Log Reduction		Biological Indicator Status	Chemical Indicator Status
			Max.	Min.	Avg.	Numerical	BI	Desired	Actual		
1.		CH-01	122.5	121.4	122.0	25.67	24.15	12.07	12.83	No Growth	Uniform color changes from Pink to Green
2.		CH-02	122.7	121.6	122.2	27.12				No Growth	Uniform color changes from Pink to Green
3.		CH-03	123.0	121.8	122.3	27.86				No Growth	Uniform color changes from Pink to Green
4.		CH-04	122.7	121.6	122.2	27.21				No Growth	Uniform color changes from Pink to Green
5.		CH-05	122.8	121.5	122.3	27.40				No Growth	Uniform color changes from Pink to Green
6.		CH-06	123.0	121.5	122.1	26.69				No Growth	Uniform color changes from Pink to Green
7.		CH-07	123.2	122.0	122.5	29.09				No Growth	Uniform color changes from Pink to Green
8.		CH-08	122.8	121.6	122.2	27.30				No Growth	Uniform color changes from Pink to Green
9.		CH-09	122.8	121.8	122.2	26.99				No Growth	Uniform color changes from Pink to Green
10		CH-10	123.3	122.0	122.7	30.30				No Growth	Uniform color changes from Pink to Green



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**11.4.1.2 Solid Load Minimum with Agar Media :**

Name of Cycle	Heat Penetration Study
Type of Cycle	Standard Cycle
Load Type	Solid Load Minimum Load with Agar Media
Date	02/02/15
Process Start Time	14:54
Hold Start Time	15:22
Hold End Time	15:42
Process End Time	15:46

**Set Parameters:**

Parameters	Set Value	Observed Value
	Standard Cycle	
Pre Vacuum	0.000 bar	0.000 bar
Pre Pressure	0.000 bar	0.000 bar
No. of Pre Pulses	0 nos.	0 nos.
Heat Up 1	110.0 °C	110.0 °C
Heat Up Hold 1	5 min.	5 min.
Heat Up 2	115.0 °C	115.0 °C
Heat Up Hold 2	4 min.	4 min.
Heat Up 3	119.0 °C	119.0 °C
Heat Up Hold 3	3 min.	3 min.
Heat Up Band	0.2 °C	0.2 °C
Small Valve Set Point	120.4°C	120.4°C
Sterilization Hold Temp.	121.4°C	121.4°C
Sterilization Hold Time	20 min.	20 min.
Temp. Control Band	0.2°C	0.2°C
Overshoot Temp.	124.0°C	124.0°C
Sterilization Stop Temp.	120.9°C	120.9°C
Sterilization Reset Temp.	120.5°C	120.5°C
Process End Pressure	0.030 bar	0.030 bar

**Test Instrument Details:**

Make (Data Logger)	G-Tek
Model (Data Logger)	9330-000
No. of Probes to be used with Data Logger	10
Calibration Status of Probes	Calibrated

**Attach the Printout & Thermograph from Autoclave & Data Logger Solid Load Minimum with Agar Media**



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**Observations of Solid Load Minimum with Agar Media:**

S.No.	Probe No.	Channel No.	Sterilizing Temperature (°C)			F <sub>0</sub> Value		Spore Log Reduction		Biological Indicator Status	Chemical Indicator Status
			Max.	Min.	Avg.	Numerical	BI	Desired	Actual		
1.		CH-01	123.0	122.0	122.6	29.92	24.15	12.07	14.96	No Growth	Uniform color changes from Pink to Green
2.		CH-02	123.4	122.4	123.1	33.32				No Growth	Uniform color changes from Pink to Green
3.		CH-03	123.4	122.2	122.8	30.86				No Growth	Uniform color changes from Pink to Green
4.		CH-04	123.2	122.3	122.9	31.93				No Growth	Uniform color changes from Pink to Green
5.		CH-05	123.4	122.3	123.1	33.01				No Growth	Uniform color changes from Pink to Green
6.		CH-06	123.4	122.0	122.7	30.55				No Growth	Uniform color changes from Pink to Green
7.		CH-07	123.1	122.3	122.7	30.47				No Growth	Uniform color changes from Pink to Green
8.		CH-08	123.5	122.3	123.1	33.05				No Growth	Uniform color changes from Pink to Green
9.		CH-09	123.3	122.2	123.0	32.46				No Growth	Uniform color changes from Pink to Green
10		CH-10	123.6	122.5	123.2	34.30				No Growth	Uniform color changes from Pink to Green



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**11.4.1.3 Liquid Load-I Maximum with Broth Media:**

Name of Cycle	Heat Penetration Study	
Type of Cycle	Standard Process -I	
Load Type	Liquid Load-I Maximum with Broth Media	
Date	02/02/15	
Process Start Time	16:39	
Hold Start Time	17:13	
Hold End Time	17:33	
Process End Time	17:39	
<b>Set Parameters:</b>		
Parameters	Set Value	Observed Value
	Standard Cycle	
Pre Vacuum	0.000 bar	0.000 bar
Pre Pressure	0.000 bar	0.000 bar
No. of Pre Pulses	0 nos.	0 nos.
Heat Up 1	110.0 °C	110.0 °C
Heat Up Hold 1	5 min.	5 min.
Heat Up 2	115.0 °C	115.0 °C
Heat Up Hold 2	4 min.	4 min.
Heat Up 3	119.0 °C	119.0 °C
Heat Up Hold 3	3 min.	3 min.
Heat Up Band	0.2 °C	0.2 °C
Small Valve Set Point	120.4°C	120.4°C
Sterilization Hold Temp.	121.4°C	121.4°C
Sterilization Hold Time	20 min.	20 min.
Temp. Control Band	0.2°C	0.2°C
Overshoot Temp.	124.0°C	124.0°C
Sterilization Stop Temp.	120.9°C	120.9°C
Sterilization Reset Temp.	120.5°C	120.5°C
Process End Pressure	0.030 bar	0.030 bar

<b>Test Instrument Details:</b>	
<b>Make (Data Logger)</b>	<b>G-Tek</b>
<b>Model (Data Logger)</b>	<b>9330-000</b>
<b>No. of Probes to be used with Data Logger</b>	<b>10</b>
<b>Calibration Status of Probes</b>	<b>Calibrated</b>

**Attach the Printout & Thermograph from Autoclave & Data Logger for Liquid Load-I Maximum with Broth Media**



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**Observations of Liquid Load-I Maximum with Broth Media:**

S.No.	Probe No.	Channel No.	Sterilizing Temperature (°C)			F <sub>0</sub> Value		Spore Log Reduction		Biological Indicator Status	Chemical Indicator Status
			Max.	Min.	Avg.	Numerical	BI	Desired	Actual		
<b>Cycle – 1<sup>st</sup></b>											
1.		CH-01	122.5	121.9	122.2	27.29	24.15	12.07	13.64	No Growth	Uniform color changes from Pink to Green
2.		CH-02	122.8	122.1	122.5	28.67				No Growth	Uniform color changes from Pink to Green
3.		CH-03	122.7	121.9	122.4	28.02				No Growth	Uniform color changes from Pink to Green
4.		CH-04	122.7	122.2	122.4	28.57				No Growth	Uniform color changes from Pink to Green
5.		CH-05	122.7	122.2	122.4	28.38				No Growth	Uniform color changes from Pink to Green
6.		CH-06	122.7	122.0	122.4	28.58				No Growth	Uniform color changes from Pink to Green
7.		CH-07	123.1	122.1	122.8	30.89				No Growth	Uniform color changes from Pink to Green
8.		CH-08	123.0	122.3	122.8	31.06				No Growth	Uniform color changes from Pink to Green
9.		CH-09	122.6	122.1	122.4	28.36				No Growth	Uniform color changes from Pink to Green
10		CH-10	123.4	122.4	123.0	32.65				No Growth	Uniform color changes from Pink to Green



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**11.4.1.4 Liquid Load-I minimum Load with Broth Media**

<b>Name of Cycle</b>	Heat Penetration Study
<b>Type of Cycle</b>	Standard Cycle
<b>Load Type</b>	Liquid Load-I Minimum with Broth Media
<b>Date</b>	05/02/15
<b>Process Start Time</b>	14:25
<b>Hold Start Time</b>	14:40
<b>Hold End Time</b>	15:00
<b>Process End Time</b>	15:04

**Set Parameters:**

<b>Parameters</b>	<b>Set Value</b>	<b>Observed Value</b>
	<b>Standard Cycle</b>	
Pre Vacuum	0.000 bar	0.000 bar
Pre Pressure	0.000 bar	0.000 bar
No. of Pre Pulses	0 nos.	0 nos.
Heat Up 1	110.0 °C	110.0 °C
Heat Up Hold 1	5 min.	5 min.
Heat Up 2	115.0 °C	115.0 °C
Heat Up Hold 2	4 min.	4 min.
Heat Up 3	119.0 °C	119.0 °C
Heat Up Hold 3	3 min.	3 min.
Heat Up Band	0.2 °C	0.2 °C
Small Valve Set Point	120.4°C	120.4°C
Sterilization Hold Temp.	121.4°C	121.4°C
Sterilization Hold Time	20 min.	20 min.
Temp. Control Band	0.2°C	0.2°C
Overshoot Temp.	124.0°C	124.0°C
Sterilization Stop Temp.	120.9°C	120.9°C
Sterilization Reset Temp.	120.5°C	120.5°C
Process End Pressure	0.030 bar	0.030 bar

**Test Instrument Details:**

<b>Make (Data Logger)</b>	G-Tek
<b>Model (Data Logger)</b>	9330-000
<b>No. of Probes to be used with Data Logger</b>	10
<b>Calibration Status of Probes</b>	Calibrated

**Attach the Printout & Thermograph from Autoclave & Data Logger for Minimum Load with Broth Media**





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**Observations of Liquid Load-I minimum Load with Broth Media:**

S.No.	Probe No.	Channel No.	Sterilizing Temperature (°C)			F <sub>0</sub> Value		Spore Log Reduction		Biological Indicator Status	Chemical Indicator Status
			Max.	Min.	Avg.	Numerical	BI	Desired	Actual		
1.		CH-01	122.5	121.9	122.1	26.38	25.2	12	12.56	No Growth	Uniform color changes from Pink to Green
2.		CH-02	122.6	122.0	122.3	27.94				No Growth	Uniform color changes from Pink to Green
3.		CH-03	122.7	122.0	122.3	27.66				No Growth	Uniform color changes from Pink to Green
4.		CH-04	122.7	121.9	122.2	27.27				No Growth	Uniform color changes from Pink to Green
5.		CH-05	122.7	122.2	122.5	29.08				No Growth	Uniform color changes from Pink to Green
6.		CH-06	122.9	121.9	122.4	28.22				No Growth	Uniform color changes from Pink to Green
7.		CH-07	122.8	122.2	122.5	29.12				No Growth	Uniform color changes from Pink to Green
8.		CH-08	122.6	121.9	122.2	27.16				No Growth	Uniform color changes from Pink to Green
9.		CH-09	122.8	122.0	122.3	27.56				No Growth	Uniform color changes from Pink to Green
10		CH-10	123.0	122.1	122.6	29.69				No Growth	Uniform color changes from Pink to Green



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### 11.4.2 Standard Process - II

#### 11.4.2.1 Liquid Load –II Maximum:

Name of Cycle	Heat Penetration Study
Type of Cycle	Standard Process - II
Load Type	Liquid Load – II Maximum
Date	04/02/19
Process Start Time	16:56
Hold Start Time	17:07
Hold End Time	17:27
Process End Time	17:30

#### Set Parameters:

Parameters	Set Value	Observed Value
	Standard Cycle	
Pre Vacuum	0.000 bar	0.000 bar
Pre Pressure	0.000 bar	0.000 bar
No. of Pre Pulses	0 nos.	0 nos.
Heat Up 1	100.0 °C	100.0 °C
Heat Up Hold 1	4 min.	4 min.
Heat Up 2	105.0 °C	105.0 °C
Heat Up Hold 2	3 min.	3 min.
Heat Up 3	113.0 °C	113.0 °C
Heat Up Hold 3	2 min.	2 min.
Heat Up Band	0.5 °C	0.5 °C
Small Valve Set Point	114.5°C	114.5°C
Sterilization Hold Temp.	115.5°C	115.5°C
Sterilization Hold Time	20 min.	20 min.
Temp. Control Band	0.2°C	0.2°C
Overshoot Temp.	119.0°C	119.0°C
Sterilization Stop Temp.	114.9°C	114.9°C
Sterilization Reset Temp.	114.8°C	114.8°C
Process End Pressure	0.030 bar	0.030 bar

#### Test Instrument Details:

Make (Data Logger)	G-Tek
Model (Data Logger)	9330-000
No. of Probes to be used with Data Logger	10
Calibration Status of Probes	Calibrated

**Attach the Printout & Thermograph from Autoclave & Data Logger for Liquid Load –II Maximum:**



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**Observations of Liquid Load –II Maximum:**

S.No.	Probe No.	Channel No.	Sterilizing Temperature (°C)			F <sub>0</sub> Value		Spore Log Reduction		Biological Indicator Status
			Max.	Min.	Avg.	Numerical	BI	Desired	Actual	
1.		CH-01	117.6	116.1	117.1	33.37	15.92	25.66	12.25	No Growth
2.		CH-02	117.9	116.2	117.2	34.25				No Growth
3.		CH-03	117.9	116.1	117.2	34.10				No Growth
4.		CH-04	117.9	116.0	117.2	34.30				No Growth
5.		CH-05	117.8	116.2	117.2	33.85				No Growth
6.		CH-06	117.8	116.0	117.2	34.14				No Growth
7.		CH-07	117.7	116.1	117.3	34.61				No Growth
8.		CH-08	117.7	116.0	117.2	34.31				No Growth
9.		CH-09	117.7	116.2	117.2	34.05				No Growth
10		CH-10	118.0	116.1	117.4	35.62				No Growth



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**11.4.2.2 Liquid Load –II Minimum:**

Name of Cycle	Heat Penetration Study
Type of Cycle	Standard Cycle-II
Load Type	Liquid Load –II Minimum
Date	04/02/15
Process Start Time	17:49
Hold Start Time	17:59
Hold End Time	18:19
Process End Time	18:20

**Set Parameters:**

Parameters	Set Value	Observed Value
	Standard Cycle	
Pre Vacuum	0.000 bar	0.000 bar
Pre Pressure	0.000 bar	0.000 bar
No. of Pre Pulses	0 nos.	0 nos.
Heat Up 1	100.0 °C	100.0 °C
Heat Up Hold 1	4 min.	4 min.
Heat Up 2	105.0 °C	105.0 °C
Heat Up Hold 2	3 min.	3 min.
Heat Up 3	113.0 °C	113.0 °C
Heat Up Hold 3	2 min.	2 min.
Heat Up Band	0.5 °C	0.5 °C
Small Valve Set Point	114.5°C	114.5°C
Sterilization Hold Temp.	115.5°C	115.5°C
Sterilization Hold Time	20 min.	20 min.
Temp. Control Band	0.2°C	0.2°C
Overshoot Temp.	119.0°C	119.0°C
Sterilization Stop Temp.	114.9°C	114.9°C
Sterilization Reset Temp.	114.8°C	114.8°C
Process End Pressure	0.030 bar	0.030 bar

**Test Instrument Details:**

<b>Make (Data Logger)</b>	<b>G-Tek</b>
<b>Model (Data Logger)</b>	<b>9330-000</b>
<b>No. of Probes to be used with Data Logger</b>	<b>10</b>
<b>Calibration Status of Probes</b>	<b>Calibrated</b>

**Attach the Printout & Thermograph from Autoclave & Data Logger for Liquid Load –II Minimum:**



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**Observations of Liquid Load –II Minimum:**

S.No.	Probe No.	Channel No.	Sterilizing Temperature (°C)			F <sub>0</sub> Value		Spore Log Reduction		Biological Indicator Status
			Max.	Min.	Avg.	Numerical	BI	Desired	Actual	
1.		CH-01	117.5	115.7	116.9	31.94	15.92	12.25	24.56	No Growth
2.		CH-02	117.7	115.9	117.2	33.87				No Growth
3.		CH-03	117.8	116.1	117.0	32.39				No Growth
4.		CH-04	117.9	116.1	117.1	33.08				No Growth
5.		CH-05	117.8	115.9	117.0	32.76				No Growth
6.		CH-06	117.8	116.0	117.1	33.58				No Growth
7.		CH-07	117.6	115.8	117.0	32.55				No Growth
8.		CH-08	117.7	115.8	117.0	32.98				No Growth
9.		CH-09	117.9	116.0	117.0	32.97				No Growth
10		CH-10	118.0	116.2	117.3	34.64				No Growth



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### 11.4.3 HPHV Process - I

#### 11.4.3.1 Garment Full Load:

Name of Cycle	Heat Penetration Study
Type of Cycle	HPHV Cycle
Load Type	Garment Full Load
Date	05/02/15
Process Start Time	15:25
Hold Start Time	15:40
Hold End Time	16:18
Process End Time	16:32

#### Set Parameters:

Parameters	Set Value	Observed Value
Pre Vacuum	-0.600 bar	-0.600 bar
Pre Pressure	0.500 bar	0.500 bar
No. of Pre Pulses	3 nos.	3 nos.
Heat Up 1	110.0 °C	110.0 °C
Heat Up Hold 1	5 min.	5 min.
Heat Up 2	115.0 °C	115.0 °C
Heat Up Hold 2	4 min.	4 min.
Heat Up 3	119.0 °C	119.0 °C
Heat Up Hold 3	3 min.	3 min.
Heat Up Band	0.2 °C	0.2 °C
Small Valve Set Point	120.4 °C	120.4 °C
Sterilization Hold Temp.	121.4 °C	121.4 °C
Sterilization Hold Time	30 min.	30 min.
Temp. Control Band	0.2 °C	0.2 °C
Overshoot Temp.	124.0 °C	124.0 °C
Sterilization Stop Temp.	120.9 °C	120.9 °C
Sterilization Reset Temp.	120.5 °C	120.5 °C
Post Vacuum Start Pressure	0.200 bar	0.200 bar
Post Vacuum	-0.600 bar	-0.600 bar
Post Vacuum Hold Time	10 min.	10 min.
Post Pressure	-0.100 bar	-0.100 bar
No. of Post Pulses	1 no.	1 no.
Process End Pressure	-0.030 bar	-0.030 bar

#### Test Instrument Details:

Make (Data Logger)	G-Tek
Model (Data Logger)	9330-000
No. of Probes to be used with Data Logger	10
Calibration Status of Probes	Calibrated



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**Attach the Printout & Thermograph from Autoclave & Data Logger for Garment Full Load:**

S.No.	Probe No.	Channel No.	Sterilizing Temperature (°C)			F <sub>0</sub> Value		Spore Log Reduction		Biological Indicator Status	Chemical Indicator Status
			Max.	Min.	Avg.	Numerical	BI	Desired	Actual		
1.		CH-01	122.7	121.9	122.3	41.18	24.34	12.17	20.69	No Growth	Uniform color changes from Pink to Green
2.		CH-02	123.0	122.2	122.7	45.19				No Growth	Uniform color changes from Pink to Green
3.		CH-03	122.8	122.2	122.5	43.61				No Growth	Uniform color changes from Pink to Green
4.		CH-04	123.1	122.2	122.5	43.04				No Growth	Uniform color changes from Pink to Green
5.		CH-05	122.9	122.1	122.7	45.23				No Growth	Uniform color changes from Pink to Green
6.		CH-06	122.8	122.0	122.4	42.39				No Growth	Uniform color changes from Pink to Green
7.		CH-07	123.1	122.0	122.6	43.90				No Growth	Uniform color changes from Pink to Green
8.		CH-08	122.8	122.1	122.5	42.83				No Growth	Uniform color changes from Pink to Green
9.		CH-09	122.9	122.2	122.5	42.90				No Growth	Uniform color changes from Pink to Green
10		CH-10	123.2	122.3	122.9	47.08				No Growth	Uniform color changes from Pink to Green



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**11.4.3.2 Other Accessories Load:**

Name of Cycle	Heat Penetration Study
Type of Cycle	HPHV Cycle
Load Type	Other Accessories
Date	05/02/19
Process Start Time	16:55
Hold Start Time	17:16
Hold End Time	17:46
Process End Time	17:58

**Set Parameters:**

Parameters	Set Value	Observed Value
Pre Vacuum	-0.600 bar	-0.600 bar
Pre Pressure	0.500 bar	0.500 bar
No. of Pre Pulses	3 nos.	3 nos.
Heat Up 1	110.0 °C	110.0 °C
Heat Up Hold 1	5 min.	5 min.
Heat Up 2	115.0 °C	115.0 °C
Heat Up Hold 2	4 min.	4 min.
Heat Up 3	119.0 °C	119.0 °C
Heat Up Hold 3	3 min.	3 min.
Heat Up Band	0.2 °C	0.2 °C
Small Valve Set Point	120.4 °C	120.4 °C
Sterilization Hold Temp.	121.4 °C	121.4 °C
Sterilization Hold Time	30 min.	30 min.
Temp. Control Band	0.2 °C	0.2 °C
Overshoot Temp.	124.0 °C	124.0 °C
Sterilization Stop Temp.	120.9 °C	120.9 °C
Sterilization Reset Temp.	120.5 °C	120.5 °C
Post Vacuum Start Pressure	0.200 bar	0.200 bar
Post Vacuum	-0.600 bar	-0.600 bar
Post Vacuum Hold Time	10 min.	10 min.
Post Pressure	-0.100 bar	-0.100 bar
No. of Post Pulses	1 no.	1 no.
Process End Pressure	-0.030 bar	-0.030 bar

**Test Instrument Details:**

<b>Make (Data Logger)</b>	<b>G-Tek</b>
<b>Model (Data Logger)</b>	<b>9330-000</b>
<b>No. of Probes to be used with Data Logger</b>	<b>10</b>
<b>Calibration Status of Probes</b>	<b>Calibrated</b>





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**Attach the Printout & Thermograph (from Autoclave & Data Logger) for time, temperature & pressure profile (Other Accessories Load):**  
**Observations of Other Accessories Load:**

S.No.	Probe No.	Channel No.	Sterilizing Temperature (°C)			F <sub>0</sub> Value		Spore Log Reduction		Biological Indicator Status	Chemical Indicator Status
			Max.	Min.	Avg.	Numerical	BI	Desired	Actual		
1.		CH-01	122.7	121.9	122.3	41.18	24.34	12.17	20.59	No Growth	Uniform color changes from Pink to Green
2.		CH-02	123.0	122.2	122.7	45.19				No Growth	Uniform color changes from Pink to Green
3.		CH-03	122.8	122.2	122.5	43.61				No Growth	Uniform color changes from Pink to Green
4.		CH-04	123.1	122.2	122.5	43.04				No Growth	Uniform color changes from Pink to Green
5.		CH-05	122.9	122.1	122.7	45.23				No Growth	Uniform color changes from Pink to Green
6.		CH-06	122.8	122.0	122.4	42.39				No Growth	Uniform color changes from Pink to Green
7.		CH-07	123.1	122.0	122.6	43.90				No Growth	Uniform color changes from Pink to Green
8.		CH-08	122.8	122.1	122.5	42.83				No Growth	Uniform color changes from Pink to Green
9.		CH-09	122.9	122.2	122.5	42.90				No Growth	Uniform color changes from Pink to Green
10		CH-10	123.2	122.3	122.9	47.08				No Growth	Uniform color changes from Pink to Green



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**12.0 REFERENCES:**

Document Name	Document Number
Validation Master Plan	
Preparation, Review, Approval, Control, Execution, Compilation of Validation/Qualification Protocol & Report	
Operation & Cleaning of Vertical Autoclave	
Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products	Schedule – M
Health Technical Memorandum	HTM 2010

**13.0 DOCUMENTS 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 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:**

On the basis of all results it is evident that no result deviate acceptance criteria given in Protocol, hence no deviation initiated during execution.

**15.0 CHANGE CONTROL, IF ANY:**

No Change Control initiated during Execution.

**16.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION):**

After reviewing all Test Results it is evident that all test Results are found within pre-defined Acceptance criteria as per protocol.

**17.0 CONCLUSION:**

On the Basis of Review it is evident that all test results meets its pre-defined acceptance criteria during periodic qualification.

**18.0 RECOMMENDATION:**

On the Basis of Review and Conclusion it is recommended that that HPHV Steam Sterilizer is dedicated for Routine operation.



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**19.0 ABBREVIATIONS:**

WHO	:	World Health Organization
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
QC	:	Quality Control
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
BI	:	Biological Indicator
SS	:	Stainless Steel
mm	:	Millimetre
%	:	Percentage
Sr. No.	:	Serial Number
°C	:	Degree Centigrade
Min.	:	Minutes
Sec.	:	Second

**20.0 REVISION HISTORY:**

Revision number	Change control no.	Details of changes	Reason for change	Effective date	Updated by
00	NA		New Report		