Document Name: Performance Qualification Report for Lyophilizer	
Identification number:	**Document Number:**
Effective Date:	**Version Number:** 00

Performance Qualification Report

Lyophilizer

Equipment ID:

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1.0 Post-Approval:

PREPARED BY		
NAME/ FUNCTIONAL AREA	**DESIGNATION**	**SIGNATURE /DATE**
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Unit Head		
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2.0 Objective:

The objective of this Performance Qualification report is to:

- To provide documented evidence that the equipment performance was in accordance with the predefined specifications.
- To demonstrate that the system is performing reproducibly and consistently within its Pre defined operating range.

3.0 Scope:

The document includes the Performance Qualification report of the following system:

In-house name of the equipment	Steam Heat Sterilizer
Equipment identification number	……..
Supplier Name and address	……..
Installation location	
Facility	Sterile Formulations Facility
Floor	……..
Room name and number	Washing & Sterilization Room

4.0 Reference Document:

Following documents are referred during preparation of the report:

Document Name	Document Number
PQ protocol of Steam Heat Sterilizer	

5.0 Performance Qualification Test Plan:

5.1 General Steps and Precaution followed during Qualification Study

5.1.1 Number of load pattern & Validation schedule were decided prior to execution the validation activities.

5.1.2 Temperature sensors were inserted through the validation port into the Steam Heat Sterilizer. 'RTD type' temperature sensors were used.

5.1.3 The Drain/Vent sensor was inserted such that it was in close proximity to the sensor located there.

5.1.4 Criteria for selecting the locations for studies were as per Step 6.4.

5.1.5 In each defined load pattern the thermocouples were positioned / attached at strategic points / locations. Locations least accessible to steam are the areas which are remote from the steam source or have large air spaces within and outside the loaded articles.

5.1.6 The biological indicators were attached to each of the temperature sensors. The Biological indicators used were sent to an external lab for determination of Total viable spore count.

5.1.7 The thermograph, data and chemical indicator strips were attached along with the data of the relevant cycle.

5.1.8 For calculation of F0 value measured temperature value for each probe was taken separately.

5.1.9 The load patterns were validated for combination of maximum number / largest size of items.

5.1.10 As the testing had being done in succession (wherein a cycle is preceded by another cycle), the chamber was allowed to cool to at-least 65°C before starting the next cycle.

5.1.11 All the thermocouples were checked for any damage/ short/ open / faulty, before and after every cycle and no damage was observed in any of the cycle.

5.1.12 The minimum time for which a cycle was operated in sterilization mode was based upon the validation reports cycles, so that each and every location achieves a minimum sterilization hold time.

5.2 Selection Criteria for Locations of Thermocouples, Biological and Chemical Indicators in Loaded Chamber study:

5.2.1 All the Sensors were placed on the same locations which were validated during the initial performance qualification for the said load pattern.

5.2.2 One sensor was placed in the active chamber discharge (Drain).

5.2.3 The temperature sensor located in the active chamber discharge was used a reference probe in the loaded chamber study.

5.3 Calculation of F_0 Values / Sterility Assurance Level:

5.3.1 The F_0 values (mathematical) was calculated at each identified location using the equation**:**

$$F_0 = \Sigma L \times dt = \Sigma\, 10^{(TA-121)/10} \times dt$$

Where –
- F_0 = Equivalent sterilization time (in minutes) at 121°C.
- L = Lethal rate
- T_A = Actual temperature measured.
- dt = Time duration (in minutes) between- 2 successive temperature measurements
- Σ = Summation symbol

5.3.2 The minimum required F_0 value for producing a 12 log reduction of the biological indicator used was calculated using the equation

$$F_0 = D_{121} (\log N_0 - \log N_t)$$

Where –
- F_0 = Equivalent sterilization time (in minutes) at 121°C.
- D_{121} = D Value of the biological indicator used (as given in the manufacturers certificate).
- N_0 = Initial Spore Count of the biological indicator (as determined experimentally).
- N_t = Spore Count of the biological indicator at time‘t’ (determined by sterility testing i.e. $N_t = 0 \cong 10^{-6}$ for obtaining a 12 log reduction).

5.3.3 $SAL_{Desired}$ (Desired sterility assurance level):

$$SAL_{Desired} = 10^{-6}$$

5.3.4 $SLR_{Measurable}$ (Spore log reduction that can be measured by the biological indicator used):

$$SLR_{Measurable} = \log N_0 - \log SAL_{Desired}$$

Where – $SLR_{Measurable}$ = Spore log reduction that can be measured
$SAL_{Desired}$ = Desired sterility assurance level
N_0 = Initial Spore Count of the biological indicator (as determined experimentally)

The desired spore log reduction is ≥ 12

5.3.5 The actual spore log reduction achieved (SLR_{Actual}) was calculated using the equation**:**

$$SLR_{Actual} = \frac{F_0}{D_{121}}$$

Where – SLR_{Actual} = Actual spore log reduction
F_0 = Minimum F_0 value calculated mathematically
D_{121} = D value of the biological indicator (as in the certificate of analysis).

5.3.6 The actual sterility assurance level (SAL_{Actual}) was calculated using the equation

$$SAL_{Actual} = 10^{[(\log N_0) - SLR_{Actual}]}$$

Where – SAL_{Actual} = Actual sterility assurance level.
SLR_{Actual} = Actual spore log reduction
N_0 = Spore Count of the biological indicator (as determined experimentally)

5.4 Equipment Qualification:

The qualification of the Steam Heat Sterilizer was done by verifying / testing the parameters as listed in the following table –

S. No.	Tests	No. of Runs	Remarks
1	Calibration of the data logger & temperature sensors used for temperature profile / thermometric tests	–	Was done initially & then after completion of revalidation
2	Vacuum leak test [Chamber integrity testing]	01 (details in the remarks column)	With probes for profiling / mapping inserted in the chamber This test was repeated on each day of revalidation
3	Bowie-Dick type test	01 (details in the remarks column	
4	Empty chamber study [heat distribution study]	03 (for HPHV)	The location of probes was interchanged in each cycle
		03 (for Standard Process)	The location of probes was interchanged in each cycle
5	Loaded chamber studies with BI – distribution & penetration studies [Thermometric tests]	03 (maximum load)	Separate for maximum load pattern of each defined load pattern [porous / unwrapped instruments / fluid load]
		03 (minimum load)	Separate for minimum load pattern of each defined load pattern [porous / unwrapped instruments / fluid load]
6	Automatic control test	–	Was done as a part of the thermometric tests
7	Vacuum leak test [Chamber integrity testing]	01	With the sensors removed; after completion of all the PQ tests
8	F_0 /…./ sterility assurance level calculation	–	Applicable for the thermometric tests, refer step 5.3 for details of calculations

The above-mentioned tests provided a documented verification of the performance of the machine throughout the representative / anticipated range & ensure that the autoclave is still performing satisfactorily.
The methodology of performing / executing each test along with the observations and results is given below:

5.4.1 Vacuum Leak Test:

5.4.1.1 Steam Heat Sterilizer is equipped with automatic systems that performed the steps below automatically & calculated the leak rate (pressure rise in mbar/min) automatically**.**

5.4.1.2 This test was performed in the following conditions / situations during the revalidation study:-

- 01 run; with sensors for validation study inserted into the chamber and without chamber furniture (carriage).
- 01 run; on each day of revalidation study (was done before start of the activities on the day.

- 01 run; after removing the sensors inserted for the validation study (at the end of the revalidation study).

5.4.1.3 The temperature sensors were inserted through the validation port into the autoclave. The validation port was sealed with silicone sealant so that steam leakage does not occur.

5.4.1.4 Vacuum leak test cycle was selected in the equipment & the equipment was operated as per the SOP "Operation, Cleaning and Maintenance of Steam Heat Sterilizer".

5.4.1.5 This test was carried out without the chamber carriage.

5.4.1.6 As per the set cycle parameters when the chamber temperature had stabilized (the chamber was empty except for fixed furniture and necessary monitoring sensors), the vacuum leak test cycle was initiated.

5.4.1.7 When the pressure (vacuum) in the chamber was –0.85 bar or below, all the valves connected to the sterilizer chamber were closed and the vacuum pump was stopped (step performed automatically).

5.4.1.8 The time (T1) and the pressure (P1) was observed and recorded.

5.4.1.9 A delay time of 300 sec ± 10 sec was maintained so as to allow evaporation of condensed water in the chamber and then the pressure (P2) in the chamber and the time (T2) were again observed and recorded.

5.4.1.10 After a further 600 sec ± 10 sec, the pressure (P3) and the time (T3) were observed and recorded again.

5.4.1.11 The cycle was allowed to proceed normally to completion.

5.4.1.12 The vacuum leak rate was calculated as per the equation below –

$$LR = \left(\frac{P_3 - P_2}{10} \right) mbar.min^{-1}$$

Where- LR = Vacuum leak rate in mbar / minute
P3 = Final pressure in the chamber in mbar
P2 = Pressure in the chamber after stabilization in mbar

The observations & data were recorded and report attached as 3.1.

The above procedure was repeated on each day of the revalidation study (with probes inserted) & the data was attached with **Appendix 3.1.1.**

5.4.2 Bowie Dick Type Test:

5.4.2.1 This test was performed using readymade test pack, at a set sterilization temperature of 121°C.

5.4.2.2 The test pack was placed at a height of 100-200 mm from the drain point of the chamber.

5.4.2.3 The temperature sensors were inserted through the validation port into the autoclave. The validation port was sealed with silicone sealant so that steam leakage does not occur.

5.4.2.4 Bowie- Dick test cycle was selected from the PLC. The sterilization hold time was set as per the values mentioned in the table below and the cycle was started**.**

Sterilization Temperature in °C	Holding time
121	16.54 minutes

5.4.2.5 When the cycle is complete, the indicator paper from the test pack was removed and observed for colour change.

5.4.2.6 The details were marked on the paper viz. the load no., Cycle no., date, etc. & the same was attached to the report.

5.4.2.7 The observations were recorded & data attached as **Appendix 3.2.1**.

5.4.2.8 The procedure was repeated on each day of the revalidation study & the data was attached as per **Appendix 3.2.1**.

5.4.3 Empty Chamber Heat Distribution Study:

5.4.3.1 The temperature sensors were inserted through the validation port into the autoclave. The validation port was sealed with silicone sealant so that steam leakage does not occur.

5.4.3.2 All the sensors were labeled properly with location no. and the indicators with Batch No., Cycle no., Location no. etc. and then the temperature sensors were attached/ positioned at specified locations (as per **Appendix 3.3.1**) along with chemical indicators . It was ensured that the temperature sensors did not touch any metallic surface and chemical indicators were within their expiry period.

5.4.3.3 The locations were recorded in the format of location details. (The locations of the indicators and temperature sensors shall be as per the feasibility of positioning them).

5.4.3.4 The steam heat Sterilizer was operated for HPHV Sterilization Cycle with a hold time of 30 minutes (for 121°C cycle); the settings were recorded in the format for operational parameters (**Appendix 3.3.1**). The data logger was set to record temperatures for all the channels at a frequency of 5 second duration for 121°C cycle.

5.4.3.5 After completion of cycle, the chemical indicators were removed from the autoclave and checked. In case the labels had faded, the same were marked properly again. It was also observed & documented whether the sensors have retained their original positions.

5.4.3.6 The Chemical indicators were observed for the specified colour change and documented as per (**Appendix 3.3.1)**

5.4.3.7 The complete data generated during the qualification test was compiled for complete evaluation of the system. The collected data was examined to identify-

5.4.3.7.1 the locations in the chamber that were fastest and slowest to attain the sterilization temperature

5.4.3.7.2 the locations in the chamber that were hottest and coolest during the sterilization hold time

5.4.3.7.3 the location in the chamber that was slowest to cool to 90°C.

5.4.3.8 If the thermometric data was acceptable, two additional runs for same cycle were performed to demonstrate cycle and sterilizer reproducibility. In the next two runs the locations of the thermocouple were interchanged, so as to verify the thermometric data of a particular location. The data was attached, along with printouts and indicators as **Appendix 3.3.1**.

5.4.3.9 Similarly, the Empty cycle heat distribution study for standard process was performed and the data was attached as per **Appendix 3.3**.

5.4.4 Loaded Chamber Study:

5.4.4.1 The distribution & penetration studies were done as a combined cycle separately for both minimum (3 cycles) and maximum (3 cycle) load pattern of a respective load pattern.

5.4.4.2 It was ensured that there was no leakage from the validation port. It was ensured that there is a temperature sensor located in the chamber free space.

5.4.4.3 The appropriate cycle was selected from the HMI and the validated sterilization parameters & hold time were set.

5.4.4.4 The Steam Heat Sterilizer was loaded & the temperature sensors were attached / positioned at points / locations along with biological and chemical indicator strips after appropriately marking the same (the biological indicators were placed only for the minimum load of each defined load pattern). It was ensured

that the temperature sensors were in good thermal contact with the fluid / device which was being monitored by it.

5.4.4.5 The locations were as specified in (**Appendix 3.4.1**). (The locations of the indicators and thermocouples for the maximum load of any particular load pattern were the same at which the PQ study was performed).

5.4.4.6 The autoclave was operated for validated sterilization hold time as per the respective load pattern. The data logger was set to record temperatures for all the channels at a frequency of 5 second duration for 121°C cycle.

5.4.4.7 The biological indicator strips & chemical indicators were removed from the autoclave and properly marked the location on the same again, in case the earlier marking has been erased.

5.4.4.8 After completion of cycle the position of the sensors were observed so as to verify whether the sensors have retained their original positions and that the items in which the sensors were placed are intact.

5.4.4.9 The Chemical indicators were observed for the specified colour change and documented as per (**Appendix 3.4.1**).

5.4.4.10 The biological indicators were incubated within 2 hrs of completion of cycle. One positive control was also incubated along with each lot of tested biological indicators. The tested biological indicators were incubated at 55-60°C for a period of 48 hours, while the positive control indicator was incubated for a period of 24 hours. The report was attached as **Appendix 3.4.1**.

5.4.4.11 The complete data generated during the qualification test was compiled for complete evaluation of the system.

5.4.4.12 The collected data was examined to identify-

5.4.4.12.1 The locations in the chamber that were fastest and slowest to attain the sterilization temperature.

5.4.4.12.2 The locations in the chamber that were hottest and coolest during the sterilization hold time

5.4.4.12.3 The location in the chamber that was slowest to cool to 90°C.

5.4.4.13 The above procedure was repeated two more times for the minimum load pattern and then one time for the already validated maximum load pattern for all the available and validated Load patterns, as per **Appendix 3.4.1**.

5.4.5 Acceptance criteria:

Test	
Vacuum Leak test	➢ The measured pressure [vacuum] (P_2) should be – 850 mbar (-0.85 bar) or below. ➢ The difference between (P2 – P1) shall not be greater than 20 mbar. ➢ The vacuum leak rate should not exceed 1.3 mbar/min.
Bowie-Dick	➢ Visual indication of the cycle completion should be there at the end of the cycle. ➢ There should be a uniform colour change over the entire pattern of the indicator sheet
Empty Chamber mapping	➢ A visual indication of the cycle completion should be there at the end of the cycle. ➢ At the end of the cycle, the sensors should have retained their original positions. ➢ The holding time is ≥ 30 minutes for 121°C cycle. ➢ All the locations / sensors should achieve the sterilization temperature within 15 seconds. (determined w.r.t the 1st location / sensor achieving the sterilization temperature). ➢ The temperature of an individual sensor does not fluctuate by more than ± 1°C. ➢ The indicated and recorded chamber temperatures are within 2°C of the temperature measured in the active chamber discharge. ➢ The hottest & the coolest locations are identified. ➢ The autoclave door should not open till the cycle is complete.
Loaded chamber mapping	**During the Sterilization Hold Time:-** ➢ The holding time is ≥ 30 minutes for 121°C in case of HPHV cycles & ≥ 25 minutes for 121°C in case of standard cycles . ➢ The temperature is within 121-124°C for 121°C. ➢ The temperature measured in each load item does not fluctuate more than ± 1°C, and does not differ from that in other load items by more than 2°C. ➢ The indicated and recorded chamber temperatures are within 2°C of the temperature measured in the active chamber discharge. ➢ Pressure in the chamber shall be between 1.0 – 1.5 kg/cm^2 **On completion of cycle-** ➢ A visual indication of the cycle completion should be there at the end of the cycle. ➢ At the end of the cycle, the sensors should have retained their original positions ➢ The items containing sensors are intact. ➢ The items containing sensors are intact. ➢ The chemical indicators show a uniform colour change as specified by the supplier at end of cycle. ➢ The biological indicator exposed to sterilization cycle shows no growth at the end of the incubation time and the unexposed inoculated carrier shows growth within 48 hours. ➢ The equilibration time between the drain/ reference probe and

	coldest part of the load for achieving sterilization temperature should not exceed 15 seconds (applicable for Porous loads only). ➢ The actual SAL (Sterility Assurance Level) calculated should be ≥ 10^{-6}. ➢ The F0 value at all the locations/ sensor should be ≥ 30 minutes. ➢ The hottest & the coolest locations are identified. ➢ The autoclave door should not open till the cycle is complete.

6.0 SUMMARY AND CONCLUSION:

6.1 Summary Report:

The following conclusion can be made after execution of PQ and reviewing the annexure.

6.1.1 VACUUM LEAK TEST:

Vacuum leak test was carried out and following results were observed:

Date of test	Cycle Description	Delay before hold Start pressure (in mbar) P1	Leak test Hold Start pressure (in mbar) P2	Leak test Hold End pressure (in mbar) P3	Actual Leakage (mbar/min) $\left(\frac{P3-P2}{10}\right)$	Comply (Yes/ No)
	Initial VLT With Probe	0.760	0.743	0.731	1.2	Yes
	Daily VLT with Probe	0.761	0.745	0.734	1.1	Yes
	Daily VLT with Probe	0.760	0.741	0.728	1.3	Yes
	Daily VLT with Probe	0.759	0.744	0.733	1.1	Yes
	Daily VLT with Probe	0.760	0.741	0.729	1.2	Yes
	Daily VLT with Probe	0.759	0.739	0.726	1.3	Yes
	Daily VLT with Probe	0.759	0.736	0.728	0.8	Yes
	Daily VLT with Probe	0.759	0.735	0.724	1.1	Yes
	Daily VLT with Probe	0.760	0.738	0.728	1.0	Yes
	Daily VLT with Probe	0.759	0.736	0.725	1.1	Yes
	Daily VLT with Probe	0.766	0.744	0.731	1.3	Yes
	Daily VLT with Probe	0.759	0.734	0.723	1.1	Yes
	Daily VLT with Probe	0.759	0.733	0.728	0.5	Yes
	Daily VLT with Probe	0.759	0.736	0.726	1.0	Yes
	Daily VLT with Probe	0.759	0.740	0.729	1.1	Yes
	Daily VLT with Probe	0.759	0.744	0.731	1.3	Yes
	Daily VLT with Probe	0.759	0.741	0.733	0.8	Yes
	Daily VLT with Probe	0.759	0.735	0.722	1.1	Yes
	Daily VLT with Probe	0.759	0.740	0.729	1.1	Yes

6.1.2 BOWIE – DICK TEST:

Following is the summary of the results of the Bowie and Dick test carried out during the execution of PQ:

S.No.	Date of test	Acceptance criteria	Observation	Comply (Yes/ No)
1.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
2.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
3.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
4.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
5.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
6.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
7.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
8.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
9.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
10.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
11.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
12.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
13.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
14.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
15.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
16.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
17.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
18.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes
19.		The indicator paper should show uniform colour change	Uniform Colour change is observed on the indicator paper	Yes

6.1.3 EMPTY CHAMBER HEAT DISTRIBUTION TEST:

Empty chamber heat distribution study was carried out for both HPHV process and Gravity process with the help of 16 nos. of external sensors. 3 runs were taken for each type of process and following is the summary of the cycles:

S. No.	Cycle Type	Trial No.	Date of test	Sterilization Hold Time (min.)		Equilibration time (NMT15 sec.)	Min. F_0 (min.)	Max. F_0 (min)	Min. Temp. during Ster. Hold (≥ 121°C)	Max. Temp. during Ster. Hold (≤124°C)	Max. Fluctuation in individual Channel (≤ 2°C)	Max. Diff. between Indicated and Recorded Temp. (≤ 2°C)	Comply (Yes/ No)
				Set	Actual								
1	HPHV	01		00:30:00	00:30:35	05 sec	39.4	42.7	121.0°C	122.7°C	1.5°C	0.1°C	Yes
2	HPHV	02		00:30:00	00:30:30	05 sec	34.9	39.7	121.0°C	122.8°C	1.4°C	0.1°C	Yes
3	HPHV	03		00:30:00	00:30:30	15 sec	38.1	42.6	121.1°C	122.7°C	1.3°C	0.2°C	Yes
4	Gravity	01		00:30:00	00:30:30	05 sec	35.9	40.7	121.0°C	123.0°C	1.5°C	0.3°C	Yes
5	Gravity	02		00:30:00	00:30:25	10 sec	35.5	40.3	121.4°C	122.7°C	1.0°C	1.0°C	Yes
6	Gravity	03		00:30:00	00:30:25	15 sec	35.9	40.3	121.0°C	122.7°C	1.2°C	0.1°C	Yes

6.1.4 LOADED CHAMBER HEAT DISTRIBUTION AND PENETRATION STUDY:

Loaded chamber heat distribution and penetration study was carried out with the help of 16 nos. of external sensors. These sensors were placed inside the load and in the free space for heat penetration and heat distribution study, respectively. Along with the sensors, BI indicators (ampoules) and chemical indicators were also placed as per the specified location.
3 runs were taken for each defined load pattern and following is the summary of the cycles taken:

Load Pattern No.	Load Details	Type of Cycle	Trial No.	Date of test	Sterilization Hold Time (min.)		Equilibration time (NMT 15 sec.)	Min. F_0 (min.)	Max. F_0 (min)	Min. Temp. during Ster. Hold (≥ 121°C)	Max. Temp. during Ster. Hold (≤124°C)	Max. Fluctuation in individual Channel (≤ 2°C)	Max. Diff. between Indicated and Recorded Temp. (≤ 2°C)	SAL (> 10^{-6})	Comply (Yes/ No)
					Set	Actual									
1	Garments (maximum)	HPHV	01		00:30:00	00:30:35	05 sec.	34.8	39.7	121.0°C	122.7°C	1.4°C	0.3°C	10^{-15}	Yes
			02		00:30:00	00:30:35	10 sec.	33.6	38.8	121.1°C	122.8°C	1.4°C	0.1°C	10^{-15}	Yes
			03		00:30:00	00:30:35	10 sec.	34.3	38.5	121.0°C	122.7°C	1.4°C	0.1°C	10^{-15}	Yes
	Garments (minimum)	HPHV	01		00:30:00	00:30:40	05 sec.	34.7	38.8	121.0°C	122.9°C	1.7°C	0.1°C	10^{-15}	Yes
			02		00:30:00	00:30:25	05 sec.	34.4	38.4	121.3°C	123.0°C	1.4°C	0.1°C	10^{-15}	Yes
			03		00:30:00	00:30:30	00 sec.	34.4	38.6	121.0°C	123.0°C	1.7°C	0.1°C	10^{-15}	Yes
2	Accessories (maximum)	HPHV	01		00:30:00	00:30:35	05 sec.	34.7	39.3	121.1°C	122.6°C	1.2°C	0.3°C	10^{-15}	Yes
			02		00:30:00	00:30:25	00 sec.	34.3	38.9	121.0°C	122.9°C	1.5°C	0.2°C	10^{-15}	Yes
			03		00:30:00	00:30:20	05 sec.	34.5	39.0	121.2°C	122.8°C	1.2°C	0.2°C	10^{-15}	Yes
	Accessories (minimum)	HPHV	01		00:30:00	00:30:25	00 sec.	34.4	38.8	121.1°C	123.1°C	1.6°C	0.3°C	10^{-15}	Yes
			02		00:30:00	00:30:25	00 sec.	34.7	39.1	121.0°C	123.0°C	1.7°C	0.4°C	10^{-15}	Yes
			03		00:30:00	00:30:25	00 sec.	34.9	39.3	121.2°C	123.0°C	1.4°C	0.3°C	10^{-16}	Yes
3	Cleaning	Std.	01		00:30:00	00:22:30	00:09:40	24.3	28.3	121.0°C	122.1°C	0.8°C	0.3°C	10^{-8}	No*[1]

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Load Pattern No.	Load Details	Type of Cycle	Trial No.	Date of test	Sterilization Hold Time (min.)		Equilibration time (NMT 15 sec.)	Min. F_0 (min.)	Max. F_0 (min)	Min. Temp. during Ster. Hold (≥ 121°C)	Max. Temp. during Ster. Hold (≤124°C)	Max. Fluctuation in individual Channel (≤ 2°C)	Max. Diff. between Indicated and Recorded Temp. (≤ 2°C)	SAL (> 10^{-6})	Comply (Yes/ No)
					Set	Actual									
	aids-Fixed load		02		00:40:00	00:32:25	00:10:40	35.8	41.8	121.0°C	122.3°C	0.8°C	0.3°C	10^{-15}	Yes
			03		00:40:00	00:30:10	00:10:25	32.6	39.7	121.0°C	122.4°C	0.9°C	0.3°C	10^{-13}	Yes
			04		00:40:00	00:30:05	00:10:50	34.3	39.0	121.0°C	122.3°C	1.2°C	0.3°C	10^{-14}	Yes
4	Media (Solid-Liquid)-maximum	Std.	01		00:40:00	00:23:20	00:17:30	25.5	30.7	121.0°C	122.5°C	0.8°C	0.4°C	10^{-9}	No*[2]
			02		00:35:00	00:26:10	00:09:45	32.6	36.5	121.0°C	122.6°C	1.3°C	0.4°C	10^{-13}	Yes
			03		00:35:00	00:26:55	00:08:40	33.8	39.5	121.0°C	123.7°C	1.8°C	0.3°C	10^{-14}	Yes
			04		00:35:00	00:27:00	00:08:55	33.4	37.8	121.0°C	122.7°C	1.4°C	0.3°C	10^{-13}	Yes
	Media (Solid-Liquid)-minimum	Std.	01		00:35:00	00:28:45	00:09:25	32.5	39.1	121.0°C	123.6°C	1.4°C	0.2°C	10^{-13}	Yes
			02		00:35:00	00:28:20	00:08:40	34.7	40.7	121.0°C	122.8°C	1.2°C	0.1°C	10^{-14}	Yes
			03		00:35:00	00:27:45	00:09:10	33.6	39.6	121.0°C	122.8°C	1.1°C	0.2°C	10^{-13}	Yes
5	Media (Liquid)-maximum	Std.	01		00:35:00	00:31:30	00:04:30	38.9	46.3	121.0°C	122.8°C	1.2°C	0.7°C	10^{-17}	Yes
			02		00:35:00	00:31:35	00:05:35	37.4	45.9	121.0°C	122.7°C	1.2°C	0.3°C	10^{-16}	Yes
			03		00:35:00	00:30:35	00:05:50	36.6	45.8	121.0°C	122.8°C	1.5°C	0.6°C	10^{-15}	Yes
	Media (Liquid)-minimum	Std.	01		00:35:00	00:31:20	00:05:35	35.9	46.5	121.0°C	123.4°C	1.1°C	0.6°C	10^{-15}	Yes
			02		00:35:00	00:32:25	00:03:35	38.9	51.3	121.0°C	123.6°C	1.1°C	0.7°C	10^{-17}	Yes
			03		00:35:00	00:30:30	00:05:25	36.6	49.2	121.0°C	123.5°C	1.2°C	0.4°C	10^{-15}	Yes

***[1]** In first trial run of Load pattern No.3, minimum sterilization hold time was observed 22 minutes 30 seconds which did not meet the acceptance criteria i.e. minimum sterilization hold time should be 25 minutes, therefore in the second trial sterilization hold time was increased (from 30 minutes to 40 minutes). The Sterilization time thus achieved in the second trial was >25 minutes. So, two more runs were performed at the same cycle parameters, in order to demonstrate the reproducibility. The Hold time achieved in each cycle was > 25 minute.

***[2]** In First trial run of Load pattern No.4 minimum sterilization hold time was observed 23 minutes 20 seconds which did not meet the acceptance criteria i.e. minimum sterilization hold time should be 25 minutes, therefore in the second trial Heat up hold time-2 & 3 was increased from 5 minute 10 minutes, sterilization hold time was decreased (from 40 minutes to 35 minutes to avoid overheating of media) & media quantity decreased in 1000 mL screwed capped bottle (750 mL from 800 mL). The Sterilization time thus achieved in the second trial was >25 minutes. So, two more runs were performed at the same cycle parameters, in order to demonstrate the reproducibility. The Hold time achieved in each cycle was > 25 minute.

6.2 Conclusion:

6.2.1 On the basis of results observed it is concluded that the Steam Sterilizer, is consistently capable for sterilization of articles & reproducibly give the desired results as established in Performance Qualification Protocol.

6.2.2 The Vacuum leak test and Bowie – Dick test taken on each day of the trial were also satisfactory. The Media Sterilized was also found to maintain its Growth promotion qualities.

6.2.3 It is thus concluded that the said equipment, full fills all the acceptance criteria specified in the performance qualification.

Therefore, on the basis of this qualification study the Steam Sterilizer is qualified for sterilization of articles and media at the set parameters at which the trial runs were successfully executed.