Qualification Summary Report for Auto Sliding Door Steam Sterilizer

QUALIFICATION PROTOCOL	
EQUIPMENT NAME	**AUTO SLIDING DOOR STEAM STERILIZER**
EQUIPMENT ID. NO.	**……**
LOCATION	**MEDIA PREPARATION ROOM**
REASON FOR QUALIFICATION	**…….**

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

TABLE OF CONTENTS

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

1.0 PROTOCOL APPROVAL:

Signing of this approval page of qualification protocol no. …… indicates agreement with the qualification approach described in this protocol.

Prepared by:

Preparation of qualification protocol is the responsibility of Department Microbiology

Prepared By	Department	Designation	Sign & Date
	Quality Control (Microbiology)		

Reviewed by:

Review of this qualification protocol is the responsibility of Department Microbiology/ Quality Assurance

Reviewed By	Department	Designation	Sign & Date
	Quality Control (Microbiology)		
	Quality Assurance		

Approved by:

Approval of this qualification protocol is the responsibility of the Head of Department.

Approved By	Department	Designation	Sign & Date
	Quality Control		
	Engineering		
	Quality Assurance		

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

2.0 OVERVIEW:

2.1 Objective:

2.1.1 The objective of developing and executing this protocol is to:

2.1.2 Document the verification of all aspects of the equipment that can affect product quality.

2.1.3 To establish, check and document the performance of equipment in the established/ predetermined operating ranges.

2.1.4 The protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the performance of the equipment meets the predetermined acceptance criteria.

2.1.5 The objective of this study is to qualify and certify the performance of Double Door steam sterilizer with Equipment ID. No.: ……., Make: PHARMA LAB, Job. No.:…… and Model No. ……. in Microbiology lab at ……

2.1.6 To evaluate the performance of the equipment/ system under various operational conditions that assures the equipment/ system performance is adequate to support the process, for which it is intended for use.

2.2 Purpose:

2.2.1 The purpose of this protocol is to verify that the equipment produces the desired output.

2.3 Scope:

2.3.1 The Scope of this protocol is limited to the qualification of Auto sliding Door Sterilizer in Media preparation Room of Microbiology laboratory in Quality Control facility.

2.4 Responsibility:

2.4.1 The following shall be responsible:

2.4.2 Quality Control (Microbiology) - Sr. officer/ Executive-For preparation of protocol/ execution

2.4.3 Engineering Head – For execution support and final approval of protocol

2.4.4 Quality Control Head – For execution support and final approval of protocol

2.4.5 Quality Assurance Head – For adequacy and final approval

2.5 Execution Team:

2.5.1 The satisfactory operation of the Auto sliding Door Sterilizer shall be verified by executing the qualification studies described in this protocol. Execution team is responsible for the execution of qualification of Auto sliding Door Sterilizer, Execution team comprises of:

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

Department	Name	Designation	Signature	Date
Quality Control (Microbiology)				
Quality Control (Microbiology)				
Engineering				
Quality Assurance				

3.0 ACCEPTANCE CRITERIA:

3.1 Following are the acceptance criteria for different test that are to be conducted during the qualification procedure.

3.2 **Vacuum Leak Rate Test:** Leak rate should not more than 1mm of Hg/ min.

3.3 **Bowie Dick Test For Steam Penetration:** Bowie Dick test is to be considered successful if Bowie dick TST color changed from pink to black.

3.4 **Empty Chamber Heat Distribution Study of HPHV & Standard Gravity Cycle:**

3.4.1 Chamber temperature should be within 121.2-124°C during the sterilization hold period.

3.4.2 Chemical indicators should show uniform color changes.

3.4.3 During the hold period, the observed temperature variation between all probes should not differ by more than 2°C and within single probe should not differ by more than 1°C.

3.5 **Empty Chamber Heat Distribution Study of RVM/ GN Broth Media Cycle:**

3.5.1 Chamber temperature should be within 115.2-118°C during the sterilization hold period.

3.5.2 During the hold period, the observed temperature variation between all probes should not differ by more than 2°C and within single probe should not differ by more than 1°C.

3.6 **Heat Penetration Study for Garments (Maximum/ Minimum Load Pattern):**

3.6.1 Chamber temperature should be within 121.2-124°C during the sterilization hold period.

3.6.2 During the hold period, the observed temperature variation between all probes should not differ by more than 2°C and within single probe should not differ by more than 1°C.

3.6.3 Chemical indicators should show uniform color change.

3.6.4 Tested biological indicators should not show any growth and positive control should show growth after completion of incubation.

3.7 **Heat Penetration study for Glassware and Accessories Load (Minimum/ Maximum Load Pattern):**

3.7.1 During the hold period, the observed temperature variation between all probes should not differ by more than 2°C and within single probe should not differ by more than 1°C.

3.7.2 Chemical indicators should show uniform color change.

3.7.3 Tested biological indicators should not show any growth and positive control should show growth after completion of incubation.

3.7.4 Chamber temperature should be within 121.2-124°C during the sterilization hold period.

3.8 **Heat Penetration Study In Microbiological Culture Media:**

3.8.1 Chamber temperature for category I to V and VII should be within 121.2-124°C during the sterilization hold period.

3.8.2 Chamber temperature for category VI should be within 115.2 to 118.0°C during the sterilization hold period.

3.8.3 Chemical indicators should show uniform color change.

3.8.4 During the hold period, the observed temperature variation between all probes should not differ by more than 2°C and within single probe should not differ by more than 1°C.

3.8.5 Tested biological indicators should not show any growth and positive control should show growth after completion of incubation.

4.0 RE QUALIFICATION CRITERIA:

4.1 There are any major changes, which affect the performance of the equipment.

4.2 Relocation or transfer of Equipment.

4.3 After major changes in the components of the equipment's.

4.4 As per revalidation date and schedule (Every Year).

5.0 INSTRUCTION FOR FILLING CHECKLIST:

5.1 In case of the compliance of the test write actual observation otherwise use "Does not comply" to indicate non-compliance.

5.2 Give the detailed information in the summary and conclusion part of the qualification protocol.

5.3 Whichever column is blank or not used 'NA' shall be used.

6.0 QUALIFICATION PROCEDURE:

6.1 **General Consideration/ Prerequisite:**

6.1.1 The following Pre-validation requirements should meet before conducting the validation program.

6.1.2 Standard operating procedure of the equipment shall be available.

6.1.3 Issued material like Media, biological indicators and chemical indicator should be available for trial.

6.1.4 The impact analysis of the equipment's shall be recorded in the summary sheet.

6.1.5 All the deficiencies and discrepancies related to the equipment which affect the re qualification procedure should be identified and corrective action taken shall be recorded in the appropriate section of the protocol.

6.1.6 Ensure all the instruments like Pressure gauges, In-Built RTD's, Data logger Flexible RTD's which are associated with equipment qualification are calibrated and within the calibration due date. All calibrations standards shall be traceable to appropriate International/ National Standards.

6.1.7 **Note:** All RTD sensors used for the validation activities should comply the Calibration requirements for pre and post validation. Enter the details in Annexure-II.

6.1.8 Gasket should remain intact tightly and the gasket shall be free from cuts and damages when checked physically.

6.1.9 The spore population of the *Geobacillus stearothermophilus* (ATCC 7953) of ampoules/ Self-contained/ Spore Strips should meet the acceptance criteria as per current version of GTP No……..

6.1.10 All utility requirements for the equipment shall be in place.

6.1.11 Chemical indicators, positive and negative control of biological indicators (Strips/ Ampoules/ Self Contained) details should be verified before they are recorded in the report.

6.1.12 Before starting of the activities, equipment shall be cleaned as per respective cleaning SOP's and released for qualification purpose.

6.1.13 Calibration certificates of data logger and sensor should be verified.

6.1.14 Print Interval of data logger printout should be set at 10 second.

6.2 Equipment Description (Auto Sliding Door Sterilizer):

6.2.1 Steam Sterilizer is located in the Microbiology Laboratory of quality control with restricted access. The equipment is located such that, it can be attended easily for routine operational, monitoring and maintenance purpose. One door of the sterilizer opens into the media preparation Area for loading the media, glassware's, Garment and S.S material and another door opens into unloading room for unloading the materials and media. All major components and utility lines are located in the loading area side, for better accessibility.

6.2.2 **The Steam Sterilizer (Make: Pharma lab) Consists of the Following Features**:

6.2.2.1 The Sterilization Chamber is made up of SS 316L, Plate thickness of 14 mm. The Sterilization Chamber is provided with two vertical sliding doors with pneumatic cylinder.

6.2.2.2 Both doors cannot be opened simultaneously and can be opened only when the set door open pressure in the chamber has been reached.

6.2.2.3 The Steam Sterilizer is provided with the following systems and accessories for the desired functioning.

6.2.2.4 Vacuum is provided with localized vacuum pump.

6.2.2.5 Sterilizing grade vacuum-break filter on the sterile area (unloading side).

6.2.2.6 Chambers compound gauge on the sterile area side (Unloading side) and the on the loading side (Media Preparation Room).

6.2.2.7 Jacket pressure gauge, Safety valve for jacket and chamber, Steam trap with strainer and NRV for chamber and steam trap for jacket, on the media preparation area side (loading side).

6.2.2.8 All the manual controls are provided at Media Preparation side.

6.2.2.9 Online recording of Thermograph.

6.2.2.10

Equipment Details:	
Equipment Name : Double Door Steam Sterilizer	
Equipment ID	**:** ……..
Make	**:** Pharmalab
Capacity	**:** 600(D) x 600(W) x 600(H) (in mm)
Job no.	**:** ……..
Location	**:** QC Microbiology

6.3 Item Preparation for Sterilization:

6.3.1 Porous/ hard goods load item should be prepared for sterilization in a variety of ways.

6.3.2 Item contained in steam and air permeable wrapping (paper or other polymeric wrapping, non-shedding fabric or combination)

6.3.3 Item in closed but not sealed, boxes (these may be stain less steel or anodized aluminium that are perforated to allow steam penetration, air removal and drainage of any condensate).

6.3.4 Item placed on open trays (with or without steam and air permeable wrapping).

6.3.5 Item used in aseptic processing should be packed in order to maintain sterility prior to use.

6.3.6 Wrapping material or containers used in sterilization should be constructed of non-shedding material.

6.4 Qualification Checklist:

Following checks shall be carried out during the qualification of Auto sliding door steam sterilizer

6.4.1 Verification of Functional checks

6.4.2 Verification of Operational sequence

6.4.3 Verification of safety features

6.5 Validation Plan and Methodology:

6.5.1. The steam sterilizer will be qualified (As per the methods outlined in this Protocol) for desired performance and its ability to sterilize different components and/ or loads at the set parameters and set loading patterns, repeatable and consistently.

6.5.2 The steam sterilizer will be considered qualify for consistent and reliable performance (Validated) on successful completions of one run (Minimum and Maximum load whichever is applicable) for the following tests.

6.5.2.1 Empty heat distribution study HPHV cycle with sterilization hold of 30 minutes at 121.2°C.

6.5.2.2 Empty heat distribution study Gravity cycle with sterilization hold of 17 minutes at 121.2° C.

6.5.2.3 Empty heat distribution study Gravity cycle with sterilization hold of 18 minutes at 121.2° C.

6.5.2.4 Empty heat distribution study Gravity cycle with sterilization hold of 20 minutes at 121.2° C.

6.5.2.5 Empty heat distribution study Gravity cycle with sterilization hold of 20 minutes at 115.2° C.

6.5.2.6 For other loaded Heat penetration and heat distribution cycles refer Table-2 and Table-3.

Table-1: Empty Chamber Heat Distribution Study

S.No.	Name of the Cycle	Type of cycle	Sterilization Temperature	Sterilization Hold	No. of Cycles
1.	HPHV Cycle	Empty chamber Heat distribution study	121.2° C	30 minutes	1 no.
2.	Gravity Cycle	Empty chamber Heat distribution study	121.2° C	17 minutes	1 no.
3.	Gravity Cycle	Empty chamber Heat distribution study	121.2° C	18 minutes	1 no.
4.	Gravity Cycle	Empty chamber Heat distribution study	121.2° C	20 minutes	1 no.
5.	Gravity Cycle	Empty chamber Heat distribution study	115.2° C	20 minutes	1 no.

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

Table-2: Loaded Chamber Heat Penetration and Heat Distribution Study for HPHV Cycle

S.No.	Name of the Cycle	Type of cycle	Sterilization Temperature	Sterilization Hold	No. of Cycles
1.	HPHV Cycle	Loaded chamber heat penetration and distribution study for Glassware	121.2° C	30 minutes	1 no. with maximum load
2.	HPHV Cycle	Loaded chamber heat penetration and distribution study for Glassware	121.2° C	30 minutes	1 no. with minimum load
3.	HPHV Cycle	Loaded chamber heat penetration and distribution study for Garments	121.2° C	30 minutes	1 no. with maximum load
4.	HPHV Cycle	Loaded chamber heat penetration and distribution study for Garments	121.2° C	30 minutes	1 no. with minimum load

Table-3: Loaded Chamber Heat Penetration and Heat Distribution Study for Gravity Cycle

S.No.	Name of the Cycle	Type of cycle	Sterilization Temperature	Sterilization Hold	No. of Cycles
1.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-V (10 ml agar and broth media in 25 ml capacity tubes)	121.2°C	17 minutes	1 no. with Maximum Load (Fixed Load)
2.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-III (90-100 ml broth media in 250 ml capacity flasks)	121.2°C	18 minutes	1 no. with Minimum & Maximum Load
3.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-II (45-100 ml broth media in 170 ml capacity tubes)	121.2°C	18 minutes	1 nos. with Minimum & Maximum Load
4.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-I (250-800 ml Solid Agar Media)	121.2°C	20 minutes	1 no. with Minimum & Maximum Load
5.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-IV (990 ml broth media in 2000 ml capacity bottles)	121.2°C	20 minutes	1 no. with Minimum & Maximum Load
6.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-VI (RVM & GNB medium)	115.2°C	20 minutes	1 nos. with Maximum Load

7.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-VII (45/ 50 ml broth media in 170 ml capacity tubes)	121.2°C	18 minutes	1 nos. with Maximum Load
8.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-VII (45/ 50 ml broth media in 170 ml capacity tubes)	121.2°C	18 minutes	1 nos. with Minimum Load
9.	Leak Test cycle	Chamber Leakage Test	NA	NA	03 consecutive cycle
10.	Bowie Dick cycle	Bowie Dick Test	121.2 °C	11 minutes	03 consecutive cycle

6.5.3 Estimation of the F_o value shall be performed for each sterilization cycle for hold period. F_o shall be calculated as per below formula.

$F_o = \Delta t \times$ Lethality rate

Lethality rate = $\text{Log10}^{(Ta-Tb)/Z}$

Where,

Ta = Specific temperature

Tb = Base temperature (121.2°C)

Z = 10 when base temperature is 121.2 °C

Δt = Print interval in minutes.

The F_o Value for all the probes should not less than the sterilization hold period.

6.5.4 Vacuum Leak Rate Test:

6.5.4.1 **Objective:**

6.5.4.1.1 Objective of this test is to ensure that the rate of vacuum drop is within the acceptable limits when the Steam sterilizer chamber is subjected to the vacuum of more than/ equal to 532 mm of Hg.

6.5.4.2 **Procedure:**

6.5.4.2.1 Record the set parameters for the vacuum leak test in the observations column. Operate the empty Steam sterilizer as per the current version of SOP No. ..... Allow the Sterilization chamber temperature to stabilize when cycle is started Vacuum Pump will start, & Vacuum valve will ON. Vacuum will be created within the chamber and when vacuum will reach at set level, vacuum valve will OFF & vacuum pump will stop. This vacuum hold time remain for set value. At the completion of hold period, vacuum break valve will ON (PLC will not

count first 5 minutes for calculation of leak rate calculation. It will count next 10 minutes of leak test hold & total vacuum leak during this 10 minutes period for calculation). This valve will remain open till chamber comes to atmospheric pressure. Vacuum leak test should be performed daily as per the SOP during Re- Qualification.

6.5.4.3 **Acceptance Criteria:**

6.5.4.3.1 Leak rate should not more than 1mm of Hg/ minute.

6.5.4.4 **Observations & Results:**

6.5.4.4.1 Record the observations and results as per the report. Attach data print out along With the report.

6.5.5 Bowie Dick Test For Steam Penetration:

6.5.5.1 **Objective:**

6.5.5.1.1 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 121.2°C). Improper removal of air from steam sterilizer shall be indicated by Bowie-Dick test pack. The indicator in the region of the air bubble will be of different color as compared to the color on the remaining part of the test paper, because of lower temperature, lower moisture level or both. In this condition the cycle parameters to be reviewed and the normal sterilization cycles to be modified accordingly.

6.5.5.2 **Procedure:**

6.5.5.2.1 Place one Bowie-Dick Test Pack near the Drain point. Operate the steam sterilizer as per the current version of SOP No. .....

6.5.5.3 **Acceptance Criteria:**

6.5.5.3.1 The Bowie Dick test to be considered as a successful run if Bowie dick TST color changed from pink to black. No change, and non-uniform change and/ or air entrapment (bubble) spot on the pattern indicates inadequate air removal from the Sterilization chamber.

6.5.5.4 **Observations & Results:**

6.5.5.4.1 Record the observations and results as per the report. Attach data print out along with Bowie Dick test paper.

6.5.6 Procedure for Steam Sterilizer Validation:

6.5.6.1 Before start of the validation activity ensure the sensors and data logger is in calibrated state.

6.5.6.2 Initially insert the 12 no. of sensors inside the steam sterilizer chamber through validation port and sealed with silicon sealant and ensure that there is no leakage from the validation port.

6.5.6.3 Keep the sensors inside chamber as per table of respective cycle with defined procedure. During keeping of sensor care shall be taken the probes do not touch any metallic surface.

6.5.6.4 Connect the sensors with a suitable data logger, which can scan and print the actual temperature, observed at different locations with respect to time.

6.5.6.5 Keep the chemical indicator/ biological indicator along with each sensor as per respective diagram wherever applicable.

6.5.6.6 Load pattern shall be defined for each cycle and articles shall be kept inside the chamber as per locations defined in protocol.

6.5.6.7 Set the 10 second print intervals on data logger and check all parameter before start of the activity.

6.5.6.8 Operate the steam sterilizer as per current version of SOP No. ..... and select the cycle through HMI and also start the data logger to record the actual temperatures within the sterilization chamber with respect to time.

6.5.6.9 Location(s) where the temperature sensor is placed, which is not achieved the minimum sterilization temperature of 121.2°C throughout the sterilization hold will be considered as cold spot.

6.5.6.10 After completion of cycle remove the chemical and biological indicator in sterile area.

6.5.6.11 Biological indicator shall be analysed as per current version of GTP No. ..... and incubated at 55-60°C/ 36-38°C for 24-48 hours for three days or as mentioned in manufacturer COA. The biological indicator observation shall be recorded in Annexure I.

6.5.6.12 Perform the cleaning as per current version of SOP No. .....

6.5.6.13 All the results should be evaluated against the predefined acceptance criteria.

6.5.7 Empty Chamber Heat Distribution Study of HPHV & Standard Gravity Cycle

6.5.7.1 During heat distribution study 12 no. of sensors shall be kept with chemical indicator.

6.5.7.2 The Steam sterilizer should be capable of attaining a temperature of not less than (NLT) 121.2°C during the sterilization hold period with steam pressure of 1.0 - 1.3 kg/ Cm^2.

6.5.7.3 Temperature spread within the range of NLT 121.2°C during sterilization cycle will demonstrate the uniform heat distribution within the chamber.

6.5.7.4 There should be uniform distribution of heat in the sterilizer chamber during the sterilization hold period and the temperature at each temperature mapping probe should be NLT 121.2ºC during the sterilization hold period.

6.5.7.5 Perform the validation as per procedure mentioned above at 121.2°C for HPHV and standard gravity cycle given in the Table-1.

6.5.7.6 Compile the data generated during the qualification test for complete evaluations of the system and record the observations and results in Annexure III. Attach data print out and

chemical indicators along with report.

6.5.7.7 **Acceptance Criteria:**

6.5.7.7.1 Chamber temperature should be within 121.2-124°C during the sterilization hold period.

6.5.7.7.2 Chemical indicators should show uniform color changes.

6.5.7.7.3 During the hold period, the observed temperature variation between all probes should not differ by more than 2°C and within single probe should not differ by more than 1°C.

6.5.8 Empty Chamber Heat Distribution Study for RVM/ GN Broth Media Load:

6.5.8.1 **Objective:**

6.5.8.1.1 Objective of this test is to ensure that, the steam sterilizer is capable of attaining a temperature of NLT 115.2°C during the sterilization hold period (20 minutes).

6.5.8.1.2 Temperature distribution in the chamber should be within the range of 115.2°C – 118.0°C during sterilization hold period that will demonstrate the uniform heat distribution within the chamber.

6.5.8.1.3 Location(s) where the temperature sensor is placed, not achieving minimum sterilization temperature of 115.2ºC throughout the sterilization temperature hold will be considered as cold spot.

6.5.8.2 **Procedure:**

6.5.8.2.1 During heat distribution study 12 no. of sensors shall be kept as per location given in the Table-4.

6.5.8.2.2 Operate the steam sterilizer as per current version of SOP No. ..... and select the cycle through HMI and also start the data logger to record the actual temperatures with in the sterilization chamber with respect to time.

6.5.8.2.3 Compile the data generated during the qualification test for complete evaluations of the system and record the observations and results in Annexure III. Attach data print out along with report.

6.5.8.2.4 Run only 1 cycle for heat distribution empty cycle of RVM media/ GN broth load cycle.

6.5.8.3 **Acceptance Criteria:**

6.5.8.3.1 Chamber temperature should be within 115.2-118°C during the sterilization hold period.

6.5.8.3.2 During the hold period, the observed temperature variation between all probes should not differ by more than 2°C and within single probe should not differ by more than 1°C.

Table-4: Sensor Locations in heat distribution of Empty cycles
(HPHV Cycle, Standard Gravity Cycle and RVM Media/ GN Broth Load cycle)

S.No.	Sensor Location	Sensors Detail	
		Location No.	Channel No.
1	Top left Sterile side	T_{01}	01
2	Top right Sterile side	T_{02}	02
3	Bottom left Sterile side	T_{03}	03
4	Bottom right sterile side	T_{04}	04
5	Middle of Sterile Side	T_{05}	05
6	Top left Non-Sterile side	T_{06}	06
7	Top right Non-Sterile side	T_{07}	07
8	Bottom left Non-Sterile side	T_{08}	08
9	Bottom right Non-sterile side	T_{09}	09
10	Middle of Non-Sterile Side	T_{10}	10
11	Center of Chamber	T_{11}	11
12	Near Drain Point	T_{12}	12

6.5.9 Heat Penetration Study of Garments (Maximum/ Minimum Load pattern):

6.5.9.1 During heat penetration study for garments 12 no. of sensors shall be kept with chemical and biological indicator as per location given in the Table-5 and Table-6 for minimum and maximum load respectively.

6.5.9.2 Perform the validation as per procedure mentioned in the point no. 6.5.6 at 121.2ºC for 30 minutes.

6.5.9.3 Compile the data generated during the qualification test for complete evaluations of the system and record the observations and results in Annexure III. Attach data print out along with report of chemical and biological indicators.

6.5.9.4 **Procedure:**

6.5.9.4.1 Aseptic area gowns shall be packed in sterile pouch/ butter paper/ wrapping paper. One such packet of gown shall have 1 boiler suit, 1 headgear and 1 pair of booties. Lint free mopping dusters shall be packed in sterile pouch/ butter paper/ wrapping paper.

6.5.9.4.2 **Maximum Load:** Maximum load shall be having 20 garments (including boiler suit, headgear and booties) and 20 Lint free dusters.

6.5.9.4.3 **Minimum load:** Minimum load shall be having 05 garments (including boiler suit, headgear

and booties) and 05 Lint free dusters.

6.5.9.4.4 Following precautions are to be taken for preparing loading material: Arrange the load material in order to prevent the localized super heating. Material used to wrap the loaded items should ensure that it does not hinder the removal of air and penetration of steam. Non-permeable wrapping materials should not be used.

6.5.9.5 **Acceptance criteria:**

6.5.9.5.1 Chamber temperature should be within 121.2- 124°C during the sterilization hold period.

6.5.9.5.2 During the hold period, the observed temperature variation between all probes should not differ by more than 2°C and within single probe should not differ by more than 1°C.

6.5.9.5.3 Chemical indicators should show uniform color change.

6.5.9.5.4 Tested biological indicators should not show any growth and positive control should show growth after completion of incubation.

Table-5: Sensors Locations in Heat Penetration Study of Garments (Minimum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side	T_{02}	02
3.	Bottom left Sterile side (Inside the mopper)	T_{03}	03
4.	Bottom right sterile side (Inside the Garment)	T_{04}	04
5.	Middle of Sterile Side	T_{05}	05
6.	Top left Non-Sterile side (Inside the Garment)	T_{06}	06
7.	Top right Non-Sterile side (Inside the Mopper)	T_{07}	07
8.	Bottom left Non-Sterile side	T_{08}	08
9.	Bottom right Non-sterile side (Inside the mopper)	T_{09}	09
10.	Middle of Non-Sterile Side	T_{10}	10
11.	Center of Chamber	T_{11}	11
12.	Near Drain Point	T_{12}	12

Table-6: Sensors Locations in Heat Penetration Study of Garments (Maximum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side	T_{02}	02
3.	Bottom left Sterile side (Inside the Garment)	T_{03}	03
4.	Bottom right sterile side (Inside the Garment)	T_{04}	04
5.	Middle of Sterile Side (Inside the Garment)	T_{05}	05
6.	Top left Non-Sterile side (Inside the Garment)	T_{06}	06
7.	Top right Non-Sterile side	T_{07}	07
8.	Bottom left Non-Sterile side	T_{08}	08
9.	Bottom right Non-sterile side (Inside the Garment)	T_{09}	09
10.	Middle of Non-Sterile Side(Inside the Garment)	T_{10}	10
11.	Center of Chamber	T_{11}	11
12.	Near Drain Point	T_{12}	12

6.5.10 Heat Penetration Study for Glassware and Accessories Load (Minimum / Maximum load Pattern):

6.5.10.1 During heat penetration study, 12 no. of sensors shall be kept with chemical and biological indicator as per location given in Table-8 & Table-9 for minimum and maximum load for glassware and accessories.

6.5.10.2 For load details refer to Table-7 for glass wares and accessories.

6.5.10.3 Perform the validation as per procedure mentioned above at 121.2ºC for 30 minutes as per load defined in protocol to demonstrate cycle and sterilizer reproducibility.

6.5.10.4 Compile the data generated during the qualification test for complete evaluations of the system and record the observations and results in Annexure III. Attach data print out along with report of chemical and biological indicators.

6.5.10.5 **Acceptance Criteria:**

6.5.10.5.1 During the hold period, the observed temperature variation between all probes should not differ by more than 2°C and within single probe should not differ by more than 1°C.

6.5.10.5.2 Chemical indicators should show uniform color change.

6.5.10.5.3 Tested biological indicators should not show any growth and positive control should show

growth after completion of incubation.

6.5.10.5.4 Chamber temperature should be within 121.2-124°C during the sterilization hold period.

Table-7: Load Detail: Minimum/ Maximum Glass wares/ Accessories Load Pattern (Mix Load)

Minimum Load	Maximum Load
20 nos. sampling bottles	40 nos. sampling bottles
05 nos. Spatulas	20 nos. Spatulas
5 nos. test tubes	20 nos. test tubes
1 no. Air sampler Hood	2 nos. Air sampler Hood
5 nos. Scissors	10 nos. Scissors
5 nos. Forceps	40 nos. Forceps
3 nos. Micropipette Tips box (1 no. – 0.1ml tip and 2 no. – 1 ml tip Box) 10x10 ml tips in pkt., 01 Cryobox with vials.	6 nos. Micropipette Tips box (3 nos. – 0.1ml tip and 3 nos. – 1 ml tip Box) 50x10 ml tips in pkt, 03 cryobox with vials.
5 nos. SS swab templates	10 nos. SS swab templates
01 mopper	2 mopper
1 manifolds	2 manifolds
40 Filtration cups	80 Filtration cups
1 Vacuum Flask	2 Vacuum Flask
01 Borer	05 Borer
20 Spreader,5 Autoclavable Goggles	100 Spreader, 10 Autoclavable Goggles
5 Autoclavable Spray Bottles	10 Autoclavable Spray Bottles
1 Compressed air/ Nitrogen assembly	1 Compressed air/ Nitrogen assembly

Table-8: Sensors Locations in Heat Penetration Study of Glassware/Accessories (Minimum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side	T_{02}	02
3.	Bottom left Sterile side (Inside empty bottle)	T_{03}	03
4.	Bottom right sterile side (Inside cryobox)	T_{04}	04
5.	Middle of Sterile Side (Inside vacuum flask)	T_{05}	05
6.	Top left Non-Sterile (Inside empty test tube)	T_{06}	06
7.	Top right Non-Sterile side	T_{07}	07
8.	Bottom left Non-Sterile side	T_{08}	08
9.	Bottom right Non-sterile side (Inside air sampler hood)	T_{09}	09
10.	Middle of Non-Sterile Side	T_{10}	10
11.	Center of Chamber	T_{11}	11
12.	Near Drain Point	T_{12}	12

Table-9: Sensors Locations in Heat Penetration Study of Glassware/ Accessories (Maximum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side	T_{02}	02
3.	Bottom left Sterile side (Inside empty bottle)	T_{03}	03
4.	Bottom right sterile side (Inside cryobox)	T_{04}	04
5.	Middle of Sterile Side (Inside vacuum flask)	T_{05}	05
6.	Top left Non-Sterile (Inside empty test tube)	T_{06}	06
7.	Top right Non-Sterile side	T_{07}	07
8.	Bottom left Non-Sterile side	T_{08}	08
9.	Bottom right Non-sterile side (Inside air sampler hood)	T_{09}	09
10.	Middle of Non-Sterile Side	T_{10}	10
11.	Center of Chamber	T_{11}	11
12.	Near Drain Point	T_{12}	12

6.5.11 Heat Penetration Study in Microbiological Culture Media:

6.5.11.1 During heat penetration study in microbiological media 12 no. of sensors shall be kept with chemical and biological indicators for category-I to category-V and category-VII, whereas only biological indicators shall be kept for category-VI (for respective load pattern refer the table mention below).

6.5.11.2 Perform the validation as procedure mentioned as per point 6.5.6.

6.5.11.3 Run the steam sterilizer for different media categories, with time and temperature as per table-3.

6.5.11.4 For load pattern refer point no. 6.5.6.18.7.

6.5.11.5 Compile the data generated during the qualification test for complete evaluations of the system and record the observations and results in Annexure III. Attach data print out along with report.

6.5.11.6 **Acceptance criteria:**

6.5.11.6.1 Chamber temperature for category-I to category-V and category-VII should be within 121.2-124°C during the sterilization hold period.

6.5.11.6.2 Chamber temperature for category-VI should be within 115.2 to 118.0 °C during the sterilization hold period.

6.5.11.6.3 Chemical indicators should show uniform color change.

6.5.11.6.4 During the hold period, the observed temperature variation between all probes should not differ by more than 2°C and within single probe should not differ by more than 1°C.

6.5.11.6.5 Tested biological indicators should not show any growth and positive control should show growth after completion of incubation.

6.5.6.18.7 **Heat Penetration Study Load Details for Microbiological Culture Media:**

Category Name	Minimum Load	Maximum Load
Category-I (250-800 ml agar media)	5 screw caped bottles of 1000 ml capacity are having 800 ml agar media, 2 screw caped bottles of 500 ml capacity having 250/ 350 ml agar medium	40 screw caped bottles of 1000 ml capacity having 800 ml agar media, 4 screw caped bottles of 500 ml capacity having 250 ml / 350 ml agar medium
Category-II (45-100 ml broth media in Tubes)	48 screw caped test tubes of 170 ml capacity having 45ml/ 50ml/ 90ml/ 100ml broth media.	160 screw caped test tubes of 170 ml capacity having 45ml/ 50ml/ 90ml/ 100ml broth media.
Category-III (90-100 ml broth media in Flasks)	35 conical flasks of 250 ml capacity having 100 ml broth with cotton plugs, inserted with pipette having silicon tubing attached to it.	70 screw caped conical flasks of 250 ml capacity having 90/ 100 ml broth medium
Category-IV (990 ml broth media in Bottles)	5 screw caped bottles of 2000 ml capacity having 990 ml broth media	30 screw caped bottles of 2000 ml capacity having 990 ml broth media
Category-V (10 ml agar and broth media in Tubes)	NA	100 test tubes of 25 ml capacity having 10 ml agar media and 250 screw caped test tubes of 25 ml capacity having 10 ml broth media
Category-VI (10-100 ml RVM & GN Broth in tubes)	NA	500 screw caped test tubes of 25 ml capacity having 10 ml RVM Broth media and 20 screw caped test tubes of 170 ml capacity having 100 ml of GN Broth.
Category-VII (45/ 50 ml broth media in Tubes)	48 screw caped test tubes of 170 ml capacity having 45 ml/ 50 ml broth media	160 screw caped test tubes of 170 ml capacity having 45 ml/ 50 ml broth media

Table-10: Sensors Locations in Heat Penetration Study of Standard Gravity Cycle of Media (Category-I: Maximum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side (Inside the 1000 ml of bottle contain 800 ml of agar media)	T_{02}	02
3.	Bottom left Sterile side	T_{03}	03
4.	Bottom right sterile side (Inside the 500 ml of bottle contains 350 ml of agar media)	T_{04}	04
5.	Middle of Sterile Side	T_{05}	05
6.	Top left Non-Sterile side (Inside the 1000 ml of bottle contain 800 ml of agar media)	T_{06}	06
7.	Top right Non-Sterile side (Inside the 500 ml of bottle contain 250 ml of agar media)	T_{07}	07
8.	Bottom left Non-Sterile side (Inside the 1000 ml of bottle contain 800 ml of agar media)	T_{08}	08
9.	Bottom right Non-sterile side	T_{09}	09
10.	Middle of Non-Sterile Side (Inside the 1000 ml of bottle contain 800 ml of agar media)	T_{10}	10
11.	Center of Chamber	T_{11}	11
12.	Near Drain Point	T_{12}	12

Table-11: Sensors Locations in Heat Penetration Study of Standard Gravity Cycle of Media (Category-I: Minimum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side (Inside the 1000 ml of bottle contain 800 ml of agar media)	T_{02}	02
3.	Bottom left Sterile side	T_{03}	03
4.	Bottom right sterile side	T_{04}	04
5.	Middle of Sterile Side	T_{05}	05
6.	Top left Non-Sterile side (Inside the 500 ml of bottle contain 350 ml of agar media)	T_{06}	06
7.	Top right Non-Sterile side	T_{07}	07
8.	Bottom left Non-Sterile Chamber (Inside the 500 ml of bottle contain 250 ml of agar media)	T_{08}	08
9.	Bottom right Non-sterile side	T_{09}	09
10.	Middle of Non-Sterile Side Chamber (Inside the 1000 ml of bottle contain 800 ml of agar media)	T_{10}	10
11.	Center of Chamber (Inside the 1000 ml of bottle contain 800 ml of agar media)	T_{11}	11
12.	Near Drain Point	T_{12}	12

Table-12: Sensors Locations in Heat Penetration Study of Standard Gravity Cycle of Media (Category-II: Maximum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side (Inside the 38 x 200 mm test tube contains 100 ml of broth media)	T_{02}	02
3.	Bottom right sterile side (Inside the 38 x 200 mm test tube contains 90 ml of broth media)	T_{03}	03
4.	Bottom right sterile side	T_{04}	04
5.	Middle of Sterile Side	T_{05}	05
6.	Top left Non-Sterile side (Inside the 38 x 200 mm test tube contains 45 ml of broth media)	T_{06}	06
7.	Top right Non-Sterile side (Inside the 38 x 200 mm test tube contains 50 ml of broth media)	T_{07}	07
8.	Bottom left Non-Sterile side (Inside the 38 x 200 mm test tube contains 90 ml of broth media)	T_{08}	08
9.	Bottom right Non-sterile side	T_{09}	09
10.	Middle of Non-Sterile Side	T_{10}	10
11.	Center of Chamber	T_{11}	11
12.	Near Drain Point	T_{12}	12

Table-13: Sensors Locations in Heat Penetration Study of Standard Gravity Cycle of Media (Category-II: Minimum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side (Inside the 38 x 200 mm test tube contains 100 ml of media)	T_{02}	02
3.	Bottom right sterile side (Inside the 38 x 200 mm test tube contains 90 ml of broth media)	T_{03}	03
4.	Bottom right sterile side	T_{04}	04
5.	Middle of Sterile Side	T_{05}	05
6.	Top left Non-Sterile side (Inside the 38x200 mm test tube contains 45 ml of broth media)	T_{06}	06
7.	Top right Non-Sterile side (Inside the 38 x 200 mm test tube contains 50 ml of broth media)	T_{07}	07
8.	Bottom left Non-Sterile side (Inside the 38 x 200 mm test tube contains 90 ml of broth media)	T_{08}	08
9.	Bottom right Non-sterile	T_{09}	09
10.	Middle of Non-Sterile Side	T_{10}	10
11.	Center of Chamber	T_{11}	11
12.	Near Drain Point	T_{12}	12

Table-14: Sensors Locations in Heat Penetration Study of Standard Gravity Cycle of media (Category-III: Maximum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side	T_{02}	02
3.	Bottom left Sterile side (Inside the 250 ml capacity conical flask contain 100 ml of broth media)	T_{03}	03
4.	Bottom right sterile side	T_{04}	04
5.	Middle of Sterile Side	T_{05}	05
6.	Top left Non-Sterile side (Inside the 250 ml capacity conical flask contain 90 ml of broth media)	T_{06}	06
7.	Top right Non-Sterile side	T_{07}	07
8.	Bottom left Non-Sterile Chamber (Inside the 250 ml capacity conical flask contain 90 ml of broth media)	T_{08}	08
9.	Bottom right Non-sterile side	T_{09}	09
10.	Middle of Non-Sterile Side	T_{10}	10
11.	Center of Chamber (Inside the 250 ml capacity conical flask contain 100 ml of broth media)	T_{11}	11
12.	Near Drain Point	T_{12}	12

Table-15: Sensors Locations in Heat Penetration Study of Standard Gravity Cycle of media (Category-III: Minimum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side	T_{02}	02
3.	Bottom left Sterile side (Inside the 250 ml capacity conical flask contain 100 ml of broth media)	T_{03}	03
4.	Bottom right sterile side	T_{04}	04
5.	Middle of Sterile Side	T_{05}	05
6.	Top left Non-Sterile side (Inside the 250 ml capacity conical flask contain 100 ml of broth media)	T_{06}	06
7.	Top right Non-Sterile side	T_{07}	07
8.	Bottom left Non-Sterile Chamber (Inside the 250 ml capacity conical flask contain 100 ml of broth media)	T_{08}	08
9.	Bottom right Non-sterile side	T_{09}	09
10.	Middle of Non-Sterile Side	T_{10}	10
11.	Center of Chamber (Inside the 250 ml capacity conical flask contain 100 ml of broth media)	T_{11}	11
12.	Near Drain Point	T_{12}	12

Table-16: Sensors Locations in Heat Penetration Study of Standard Gravity Cycle of media (Category-IV: Maximum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side (Inside the 2000 ml capacity bottle contain 990 ml of broth media)	T_{02}	02
3.	Bottom left Sterile side	T_{03}	03
4.	Bottom right sterile side (Inside the 2000 ml capacity bottle contain 990 ml of broth media)	T_{04}	04
5.	Middle of Sterile Side	T_{05}	05
6.	Top left Non-Sterile side (Inside the 2000 ml capacity bottle contain 990 ml of broth media)	T_{06}	06
7.	Top right Non-Sterile side	T_{07}	07
8.	Bottom left Non-Sterile side (Inside the 2000 ml capacity bottle contain 990 ml of broth media)	T_{08}	08
9.	Bottom right Non-sterile side	T_{09}	09
10.	Middle of Non-Sterile Side	T_{10}	10
11.	Center of Chamber	T_{11}	11
12.	Near Drain Point	T_{12}	12

Table-17: Sensors Locations in Heat Penetration Study of Standard Gravity Cycle of Media (Category-IV: Minimum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side (Inside the 2000 ml capacity bottle contain 990 ml of broth media)	T_{02}	02
3.	Bottom left Sterile side	T_{03}	03
4.	Bottom right sterile side (Inside the 2000 ml capacity bottle contain 990 ml of broth media)	T_{04}	04
5.	Middle of Sterile Side	T_{05}	05
6.	Top left Non-Sterile side (Inside the 2000 ml capacity bottle contain 990 ml of broth media)	T_{06}	06
7.	Top right Non-Sterile side	T_{07}	07
8.	Bottom left Non-Sterile side (Inside the 2000 ml capacity bottle contain 990 ml of broth media)	T_{08}	08
9.	Bottom right Non-sterile side	T_{09}	09
10.	Middle of Non-Sterile Side	T_{10}	10
11.	Center of Chamber	T_{11}	11
12.	Near Drain Point	T_{12}	12

Table-18: Sensors Locations in Heat Penetration Study of Standard Gravity Cycle of Media (Category-V: Maximum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side	T_{02}	02
3.	Bottom left Sterile side	T_{03}	03
4.	Bottom right sterile side (Inside the 25 ml capacity test tube containing 10 ml of media).	T_{04}	04
5.	Middle of Sterile Side	T_{05}	05
6.	Top left Non-Sterile side	T_{06}	06
7.	Top right Non-Sterile side	T_{07}	07
8.	Bottom left Non-Sterile side (Inside the 25 ml capacity test tube containing 10 ml of media).	T_{08}	08
9.	Bottom right Non-sterile side	T_{09}	09
10.	Middle of Non-Sterile Side (Inside the 25 ml capacity test tube containing 10 ml of media).	T_{10}	10
11.	Center of Chamber (Inside the 25 ml capacity test tube containing 10 ml of media)	T_{11}	11
12.	Near Drain Point	T_{12}	12

Table-19: Sensors Locations in Heat Penetration Study of Standard Gravity Cycle of media – RVM/ GN Broth (Category-VI: Maximum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side	T_{02}	02
3.	Bottom left Sterile side	T_{03}	03
4.	Bottom right sterile side (Inside the 25 ml capacity test tube containing 10 ml of broth media).	T_{04}	04
5.	Middle of Sterile side	T_{05}	05
6.	Top left Non-Sterile side	T_{06}	06
7.	Top right Non-Sterile side	T_{07}	07
8.	Bottom left Non-Sterile side (Inside the 170 ml capacity test tube containing 100 ml of broth media).	T_{08}	08
9.	Bottom right Non-sterile side	T_{09}	09
10.	Middle of Non-Sterile side (Inside the 25 ml capacity test tube containing 10 ml of broth media).	T_{10}	10
11.	Center of Chamber (Inside the 25 ml capacity test tube containing 10 ml of broth media)	T_{11}	11
12.	Near Drain Point	T_{12}	12

Table-20: Sensors Locations in Heat Penetration Study of Standard Gravity Cycle of media (Category-VII: Maximum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side (Inside the 38 x 200 mm test tube contains 45 ml of broth media)	T_{02}	02
3.	Bottom right sterile side (Inside the 38 x 200 mm test tube contains 45 ml of broth media)	T_{03}	03
4.	Bottom right sterile side	T_{04}	04
5.	Middle of Sterile Side	T_{05}	05
6.	Top left Non-Sterile side (Inside the 38 x 200 mm test tube contains 45 ml of broth media)	T_{06}	06
7.	Top right Non-Sterile side (Inside the 38 x 200 mm test tube contains 50 ml of broth media)	T_{07}	07
8.	Bottom left Non-Sterile side (Inside the 38 x 200 mm test tube contains 45 ml of broth media)	T_{08}	08
9.	Bottom right Non-sterile side	T_{09}	09
10.	Middle of Non-Sterile Side	T_{10}	10
11.	Center of Chamber	T_{11}	11
12	Near Drain Point	T_{12}	12

Table-21: Sensors Locations in Heat Penetration Study of Standard Gravity Cycle of Media (Category-VII: Minimum Load)

S.No.	Sensor Location	Sensor Detail	
		Location No.	Channel No.
1.	Top left Sterile side	T_{01}	01
2.	Top right Sterile side (Inside the 38 x 200 mm test tube contains 45 ml of broth media)	T_{02}	02
3.	Bottom right sterile side (Inside the 38 x 200 mm test tube contains 45 ml of broth media)	T_{03}	03
4.	Bottom right sterile side	T_{04}	04
5.	Middle of Sterile Side	T_{05}	05
6.	Top left Non-Sterile side (Inside the 38 x 200 mm test tube contains 45 ml of broth media)	T_{06}	06
7.	Top right Non-Sterile side (Inside the 38 x 200 mm test tube contains 50 ml of broth media)	T_{07}	07
8.	Bottom left Non-Sterile side (Inside the 38 x 200 mm test tube contains 45 ml of broth media)	T_{08}	08
9.	Bottom right Non-sterile side	T_{09}	09
10.	Middle of Non-Sterile Side	T_{10}	10
11.	Center of Chamber	T_{11}	11
12.	Near Drain Point	T_{12}	12

6.6 STEPS TO BE TAKEN INCASE OF FAILURE:

6.6.1 If minimum sterilization temperature of 121.2°C/ 115.2°C is not achieved in one or more locations during sterilization hold period of Empty chamber heat distribution cycle following action are taken.

6.6.1.1 Engineering department will check mechanical operation of pneumatic valves, operation of vacuum system, functioning of steam trap, steam supply in jacket, any blockage in the steam or vacuum line, any leakage through door gasket and other joints. If failure observed due to mechanical error, all cycles will be repeated once again.

6.6.2 If minimum sterilization temperature of 121.2°C/ 115.2°C is not achieved in one or more locations during sterilization hold period of loaded chamber heat penetration cycle following actions are taken.

6.6.2.1 If the failure occurred with the standard cycles, it will be considered as critical failure.

6.6.2.2 If the failure occurred with the cycles of garments/ accessories it will be considered as Major

failure.

6.6.3 **Action to be taken in Case of Critical Failure:**

6.6.3.1 If any probe located inside the media shows the temperature below 121.2°C/ 115.2°C, Fo value of the location and Biological Indicator test data will be reviewed. If Fo value is lower than the accepted limit and biological indicator test report shows acceptable reduction in the bacterial population, then the cycle will be repeated and the investigation will be carried out to determine the cause of not attaining the minimum required temperature.

6.6.3.2 In case the biological indicator also shows positive growth investigate the cause of failure and review the following parameters

- Sterilization parameters
- Loading pattern
- Biological indicator qualification

6.6.3.3 Necessary corrective actions will be taken to rectify the known (or identified) defect, and a revalidation of the sterilization cycle will be undertaken before commencement.

6.6.4 **Action to be taken in Case of Major Failure:**

6.6.4.1 If any probe located inside the load of Garment/accessories shows the temperature below 121.2°C/ 115.2°C.

6.6.4.2 Necessary corrective actions will be taken to rectify the known (or identified) defect, and a revalidation of the sterilization cycle will be undertaken before commencement.

6.6.4.3 Download the data from data logger into the computer for data-analysis and printing. Calculate the Fo Value of sterilizer as described below:

$Fo = dt \times \sum 10^{(T-121.2)/Z}$

Where,

dt: Interval of temperature monitoring in a certain location i.e. 1 minute

T: Temperature at a certain time in a certain location during sterilization hold period

Z : Z value of the biological indicator used i.e. Increase in temperature required to reduce the D value by 1 log. For the purpose of this equation Z value is considered as 10.

7.0 TRAINING EVALUATION:

Training has been imparted on the operating procedure and on the qualification study conducted for the autoclave with equipment ID. ..... and same has been understood by the participants.

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

S.No.	Name of Trainee	Sign. & Date
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		

Comments:

_____

_____

Training Given By:
Sign & Date:

Reviewed By:
Sign & Date:

8.0 DOCUMENTATION:

8.1 Result & reports shall be completed in a file which shall contain.

- Qualification Protocol
- Qualification Reports

8.2 Conclusion should be the last paragraph of the report, which should clearly state the compliance or failure to meet the objective of the protocol

9.0 RISK IDENTIFICATION, ANALYSIS AND CONTROL MEASURE:

9.1 At the time of performance qualification following possible risk and its control measure has been identified.

S.No.	Risk Identified	Impact Analysis	Control measure
1.	Static charge	During operation static charge may develop which may cause material burning.	A provision for earthing provided to neutralize the static charge.

10.0 CHALLENGE TEST FOR THE IDENTIFIED RISK:

10.1 The above-identified risk has been challenged and their performance shall be recorded in below table.

Parameters	Method of verification	Acceptance criteria	Observation	Verified By Sign/Date
Earthing	Check Current leakage on Machine with multi meter	No current leakage should observe.		

11.0 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):

Following deficiency was identified and corrective actions taken in consultation with the validation team.

11.1 **Description of Deficiency:**

_____

_____

_____

_____

_____

_____

_____

_____

_____

11.2 **Corrective Action(s) Taken:**

_____

_____

_____

_____

_____

_____

Reviewed By:
Sign & Date

12.0 ANNEXURE (S):

S No.	Annexure No.	Title of Annexure
1.	Annexure-I	Qualification Checklist
2.	Annexure-II	Master Temperature Sensor Pre/ Post Calibration Report
3.	Annexure-III	Sterilization Cycle Verification Data Sheet

13.0 SUMMARY AND CONCLUSION:

13.1 **Summary:**

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Reviewed By:
Sign & Date:

13.2 **Conclusion:**

14.0 ABBREVIATIONS:

ABBREVIATION	FULL FORM
PLC	Programmable Logic Control
°C	Degree Celsius
Min.	Minimum
Max.	Maximum
No.	Number
NLT	Not less than
NMT	Not more than
RTD	Resistant temperature detector
MMI	Man machine Interface
HMI	Human Machine Interface
Acc.	Accessories
Glass	Glassware
Sol.	Solution

15.0 FINAL REPORT APPROVAL:

It has been verified that all tests required by this report are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol (If applicable).Signature in the block below indicates that all items in this qualification protocol have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved. The equipment can be taken for routine production purposes.

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
		QUALITY CONTROL		
		ENGINEERING		
		QUALITY ASSURANCE		

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

ANNEXURE-I
QUALIFICATION CHECKLIST

1.0	INSTRUMENT VERIFICATION CHECKLIST	
S.No.	**Statement**	**Observation**
1.	Verify that there is no observable physical damage.	
2.	Safe electrical connection is provided to the equipment.	
3.	Equipment identification no. visible.	
4.	All supporting utilities available.	
5.	Verify that the control panel is at place.	
6.	Verify that equipment is properly earthed.	
7.	Verify that the RTD sensors used for validation are calibrated before validation cycle.	

Done By:
(Sign & Date):

Checked By:
(Sign & Date):

Verified By:
(Sign &Date)

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

2.0	TEST INSTRUMENTS DETAILS			
	Objectives: This test is intended to describe the test instruments used during the qualification			
Sensor No.	**Channel No.**	**Instrument ID No.**	**Calibration Detail**	
			Calibration Done on	**Calibration Due on**
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
Data logger	N/A			

Done By:
(Sign & Date):

Checked By:
(Sign & Date):

Verified By:
(Sign &Date)

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

3.0	VERIFICATION OF CALIBRATION COMPONENT
	This test is intended to describe the Equipments/instruments and its complete details to have traceability to the national standard, which is to be used for the verification of the operation of the steam sterilizer.

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration valid up to	Certificate No.

Done By:
(Sign & Date):

Checked By:
(Sign & Date):

Verified By:
(Sign &Date):

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

4.0	VERIFICATION OF FUNCTIONAL CHECKS			
S.No.	**Name of System Component**	**Specified Function**	**Method of Verification**	**Observation**
1.	Door open after push the switch for sterile area	To open the door for unloading of material	Physically	
2.	Door open after push the switch for Non sterile area	To open the door for loading of material.	Physically	
3.	Process should not start in auto or manual mode if door is open	Process should not start if any door of steam sterilizer in open condition.	Physically by challenging	
4.	Process should not start in auto or manual mode if door precondition is not fulfilled.	Process should not start in auto or manual mode if door precondition fail.	Physically by challenging	

Done By:
(Sign & Date):

Checked By:
(Sign & Date):

Verified By:
(Sign &Date):

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

5.0	VERIFICATION OF KEY FUNCTIONALITY OF CONTROL PANEL			
S.No.	**Component of Control Panel**	**Specified Function**	**Method of Verification**	**Observation**
1	Main red switch for "ON/OFF" steam sterilizer.	To supply the power to the machine by Turning the knob in to desired mode and machine should start.	Physically by challenging	
2	Emergency switch	To stop the operation immediately at the time of emergency.	Physically by challenging	
4	"GREEN" Colour push button for sterile and non-sterile side	To close the sterile and non-sterile side door.	Physically by challenging	
5	"RED" Colour push button for sterile and non-sterile side	To open the sterile and non-sterile side door.	Physically by challenging	
7.	Sterile side Pressure gauge for Jacket, chamber, NST Gasket, ST Gasket	To monitor the pressure of sterile side jacket, chamber, Non-sterile and sterile side gasket and should be functional.	Physically	
8.	Non-sterile side Pressure gauge for chamber gasket and jacket.	To monitor the pressure of non-sterile side chamber gasket and jacket and should be functional.	Physically	
9.	"Cycle Selection Switch " for non-sterile side	To select the cycle (i.e.121˚C or 115˚C) from non-sterile side.	Physically by challenging	
10.	"ON" and "OFF" switch for non-sterile side	To "ON' and "OFF" the system from non-sterile side.	Physically by challenging	

Done By:
(Sign & Date):

Checked By:
(Sign & Date):

Verified By:
(Sign &Date):

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

ANNEXURE-II
MASTER TEMPERATURE SENSOR PRE/POST CALIBRATION REPORT

STD Reading (MASTER SENSOR)	Unit Under Calibration (UUC) Reading					
STD Reading (MASTER SENSOR)						

PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

Master Instrument Details(Name)	Instrument ID	Make	Range	Calibration done date	Calibration due date

Comments:

_____

_____

_____

_____

_____

_____

Calibration Done By:
Sign and Date:

Calibration Checked By:
Sign and Date:

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

ANNEXURE-III
Sterilization Cycle Verification Data

Date of Cycle: _____

Sterilization Cycle No.: _____

1.0 Cycle Parameter

S.No.	Parameter	Set Values
1.	Name of the Cycle	
2.	Cycle Type	
3.	Load	
4.	Category	
5.	Sterilization Temperature	
6.	Sterilization Hold Period	

2.0 Temperature Mapping Data and Summary:

For Temperature mapping data refer Attachment

Summary

Cycle Started (HR:MIN)	
Sterilization Hold Time Started (HR:MIN)	
Sterilization Hold time completed (HR:MIN)	
Total Hold Time (minutes)	
Cycle completed (HR:MIN)	
Minimum Sterile hold temp (^{0}C)	
Maximum Sterile hold temp (^{0}C)	

3.0 Results Fo Observation:

For Fo Observation refer Attachment

Minimum Fo Value = _____ **Maximum Fo Value =** _____

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

4.0 Biological Indicator Details and Test Report:

For details and test report refer Attached Report

_____

_____

_____

5.0 Observation of Temperature variation between all probes and within the probes

_____

_____

_____

6.0 Exposed Chemical Indicator Strip Details:

Position of the strips	Status
Location 1	
Location 2	
Location 3	
Location 4	
Location 5	
Location 6	
Location 7	
Location 8	
Location 9	
Location 10	
Location 11	
Location 12	

7.0 Deviation (if any):

_____

_____

_____

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

8.0 Summary and conclusion:

Summary:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Conclusion:

_____

_____

_____

_____

_____

_____

_____

Done By:
Sign & Date

Checked By:
Sign & Date

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

Table of Contents

2.0 EXECUTIVE SUMMARY:

This final summary report summarizes the results obtained during the execution of the re qualification protocol for the validation of auto sliding door stem sterilizer with Job no…….. , model no……., Make Pharma lab and Equipment ID no…….. This summary report documents that the auto sliding door steam sterilizer performed in accordance with its intended use as indicated in the functional requirement specification. This summary holds the details of the qualification assignment, and the persons and as an organization involved in the qualification. Protocol No…….is performed for the qualification of the auto sliding door steam sterilizer. Successful completion of the qualification activities described in the protocol demonstrates that theAuto sliding door steam sterilizer performed and operated according to the specification as outlined in the qualification protocol and various parameters listed below.

- Test Case no. I Qualification checklist
- Test Case no. II Test instruments details
- Test case no. III Verification of component calibration
- Test case no. IV Test instruments calibration
- Test case no. V Verification of Functional checks

- Test case no. VI Verification of key functionality of control panel
- Test Case no. VII Verification of safety features
- Test case no. VIII Verification/challenges of utilities/services
- Test case no. IX Qualification Test for various load patterns

Total 27 cycles were run which includes:

- Empty Chamber Heat Distribution Study for HPHV and Gravity – 05 Cycles
- Loaded Chamber Heat Penetration and Heat Distribution Study For HPHV -04 Cycles with defined load pattern
- Loaded Chamber Heat Penetration and Heat Distribution Study For Gravity -12 Cycles under seven categories with defined load pattern
- Leak Test -03 Cycles
- Bowie Dick Test -03 Cycles

Empty Chamber Heat Distribution Study

S. No.	Name of the Cycle	Type of cycle	Sterilization Temperature	Sterilization Hold	No. of Cycles
1.	HPHV Cycle	Empty chamber Heat distribution study	121.2° C	30 minutes	1 no
2.	Gravity Cycle	Empty chamber Heat distribution study	121.2° C	17 minutes	1 no
3.	Gravity Cycle	Empty chamber Heat distribution study	121.2° C	18 minutes	1 no
4.	Gravity Cycle	Empty chamber Heat distribution study	121.2° C	20 minutes	1 no
5.	Gravity Cycle	Empty chamber Heat distribution study	115.2° C	20 minutes	1 no

Loaded Chamber Heat Penetration and Heat Distribution Study for HPHV Cycle

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

S. No.	Name of the Cycle	Type of cycle	Sterilization Temperature	Sterilization Hold	No. of Cycles
1.	HPHV Cycle	Loaded chamber heat penetration and distribution study for Glassware	121.2° C	30 minutes	Maximum –I load
2.	HPHV Cycle	Loaded chamber heat penetration and distribution study for Glassware	121.2° C	30 minutes	Minimum –I load
3.	HPHV Cycle	Loaded chamber heat penetration and distribution study for Garments	121.2° C	30 minutes	1 no. with maximum load
4.	HPHV Cycle	Loaded chamber heat penetration and distribution study for Garments	121.2° C	30 minutes	1 no. with minimum load

Loaded Chamber Heat Penetration and Heat Distribution Study for Gravity Cycle

S.No.	Name of the Cycle	Type of cycle	Sterilization Temperatur	Sterilization Hold	No.of Cycles
1.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-V (10 ml agar and broth media in 25 ml capacity tubes)	121.2° C	17 minutes with lag time of 2 minutes	1 nos. with Maximum Load (Fixed Load)
2.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-III (90-100 ml broth media in 250 ml capacity flasks)	121.2° C	18 minutes with lag time of 3 minutes	Maximum-I Load
3.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-III (90-100 ml broth media in 250 ml capacity flasks)	121.2° C	18 minutes with lag time of 3 minutes	Minimum-I Load
4.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-II (45-100 ml broth media in 170 ml capacity tubes)	121.2° C	18 minutes with lag time of 3 minutes	Maximum-I Load
5.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-II (45-100 ml broth media in 170 ml capacity tubes)	121.2° C	18 minutes with lag time of 3 minutes	Minimum-I Load

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

06.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-I(250-800 ml Solid Agar Media)	121.2° C	20 minutes with lag time of 5 minutes	Maximum-I Load
07.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-I (250-800 ml Solid Agar Media)	121.2° C	20 minutes with lag time of 5 minutes	Minimum-I Load
08.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-IV(990 ml broth media in 2000 ml capacity bottles)	121.2° C	20 minutes with lag time of 5 minutes	Maximum-I Load
09.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-IV(990 ml broth media in 2000 ml capacity bottles)	121.2° C	20 minutes with lag time of 5 minutes	Minimum-I Load
10.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-VI(RVM & GNB medium)	115.2° C	20 minutes with lag time of 5 minutes	1 nos. with Maximum Load
11.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-VII (45/ 50 ml broth media in 170 ml capacity tubes)	121.2° C	18 minutes with lag time of 3 minutes	Maximum-I Load
12.	Gravity Cycle	Loaded chamber heat penetration and distribution study for Category-VII (45/ 50 ml broth media in 170 ml capacity tubes)	121.2° C	18 minutes with lag time of 3 minutes	Minimum-I Load
17.	Leak Test cycle	Chamber leakage Test	NA	NA	03 consecutive cycle
18.	Bowie Dick cycle	Bowie Dick Test	121.2 ° C	11 minutes	03 consecutive cycle

Qualification Summary Report for Auto Sliding Door Steam Sterilizer

Validated Load PatternDetails forMicrobiological Culture Media

Category Name	Minimum Load	Maximum Load
Category-I (250-800 ml agar media)	5 screw caped bottles of 1000 ml capacity are having 800 ml agar media, 2 screw caped bottles of 500 ml capacity having 250/ 350	40 screw caped bottles of 1000 ml capacity having 800 ml agar media, 4 screw caped bottles of 500 ml capacity having 250 ml / 350 ml
Category-II (45-100 ml broth media in Tubes)	48 screw caped test tubes of 170 ml capacity having 45ml/ 50ml/ 90ml/ 100ml broth media.	160 screw caped test tubes of 170 ml capacity having 45ml/ 50ml/ 90ml/ 100ml broth media.
Category-III (90-100 ml broth media in Flasks)	35 conical flasks of 250 ml capacity having 100 ml broth with cotton plugs, inserted with pipette having silicon tubing attached to it.	70 screw caped conical flasks of 250 ml capacity having 90/ 100 ml broth medium
Category-IV (990 ml broth media in Bottles)	5 screw caped bottles of 2000 ml capacity having 990 ml broth media	30 screw caped bottles of 2000 ml capacity having 990 ml broth media
Category-V (10 ml agar and broth media in Tubes)	NA	100 test tubes of 25 ml capacity having 10 ml agar media and 250 screw caped test tubes of 25 ml capacity having 10 ml broth media
Category-VI (10-100 ml RVM & GN Broth in tubes)	NA	500 screw caped test tubes of 25 ml capacity having 10 ml RVM Broth media and 20 screw caped test tubes of 170 ml capacity
Category-VII (45/ 50 ml broth media in Tubes)	48 screw caped test tubes of 170 ml capacity having 45 ml/ 50 ml broth media	160 screw caped test tubes of 170 ml capacity having 45 ml/ 50 ml broth media

Validated Accessories/ Glass wares and Garments Load pattern

Minimum Load	Maximum Load
20 nos. sampling bottles	40 nos. sampling bottles
05 nos. Spatulas	20 nos. Spatulas
5 nos. test tubes	20 nos. test tubes
1 no. Air sampler Hood	2 nos. Air sampler Hood
5 nos. Scissors	10 nos. Scissors
5 nos. Forceps	40 nos. Forceps
3 nos. Micropipette Tips box (1 no. – 0.1ml tip and 2 no. – 1 ml tip Box) 10x10 ml tips in pkt., 01 Cryobox with vials.	6 nos. Micropipette Tips box (3 nos. – 0.1ml tip and 3 nos. – 1 ml tip Box) 50x10 ml tips in pkt, 03 cryoboxwithvials.
5 nos. SS swab templates	10 nos. SS swab templates
01 mopper	2 mopper
1 manifolds	2 manifolds
40 Filtration cups	80 Filtration cups
1 Vacuum Flask	2 Vacuum Flask
01 Borer	05 Borer
20 Spreader,5 Autoclavable Goggles	100 Spreader, 10 Autoclavable Goggles
5 Autoclavable Spray Bottles	10 Autoclavable Spray Bottles
1 Compressed air/ Nitrogen assembly	1 Compressed air/ Nitrogen assembly

3.0 SUMMARY REPORT INTRODUCTION:

3.1 Objective:

To summarize the results obtained during the execution of the Performance re qualification for the validation of Auto sliding door stem sterilizer with Job no. ……, model no. ……., Make Pharma lab and Equipment ID no. ……. To documents that the Auto sliding door steam sterilizer performed in accordance with its intended use as indicated in the functional requirement specification.

3.2 Scope:

This report applies to the validation of the Auto sliding door steam sterilizer and the scopeof this summary report is limited to Auto sliding door stem sterilizer with equipment ID …….. installed in microbiology laboratory.

3.3 Exclusion:

This validation summary applies to Auto sliding door stem sterilizer and not to PLC.

4.0 TESTING SUMMARY:

4.1 General:

The performance re qualification protocol cum report provided the necessary documented verification that all the key aspects of the Auto sliding door stem sterilizer were properly verified and operated. The following items were applied to all the steps in this performance re qualification protocol.

4.1.1 Each test case is read prior to performing the test.

4.1.2 Qualification entries are completed using good documentation practices.

4.1.3 Test steps are followed as listed in each test case.

4.1.4 For each test instruction, results are documented in the actual results column.

4.1.5 For each test instructions complies or does not comply is recorded.

4.1.6 The person performing the test recorded their initials/date on every report.

4.1.7 Any event where there is an inability to meet the approved protocol requirements is addressed on the deviation log.

4.1.8 Adhered to site emergency response and safety procedures.

4.1.9 The acceptance criterion for each individual test procedure is met and all required documentation in this protocol are properly executed.

4.1.10 All test procedures are executed and the corresponding test tables were completed.

4.1.11 No deviation is observed during the re qualification procedure.

4.2 Documentation:

4.2.1 All the qualification reviews and verifications are documented at the time they are performed.

4.2.2 All qualification work required by this protocol are performed.

4.2.3 Each protocol page containing the supporting data is signed and dated.

4.2.4 When applicable all the deviation encountered during the execution of this protocol is documented on the appropriated deviation log.

4.2.5 Pages added to the qualification are properly identified, signed, dated and carried the protocol no.

5.0 RESULTS OF VALIDATION TEST:

5.1 Vacuum Leak Rate Test:

5.1.1 **Objective**: This test is performed to ensure that the rate of vacuum drop is within the acceptable limits when the Steam sterilizerchamber is subjectedto thevacuum of more than/equal to 532 mm of Hg.

5.1.2 **Acceptance Criteria:**Leak rate should not be more than 1mm of Hg/min.

5.1.3 **Test Results:** 03 cycles for 3 consecutive days are run and the test met the expected results listed in the test procedure. The test passed without reported deviations.

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Result	Remarks
1.			10 min.	0.4 mm of Hg/min	Complies
2.			10 min.	0.0 mm of Hg/min	Complies
3.			10 min.	0.0 mm of Hg/min	Complies

5.2 Bowie Dick Test For Steam Penetration:

5.2.1 **Objective:** This test is performed to ensure that the vacuum pulses applied before thesterilization hold period are sufficient to remove the entrapped air or non-condensable gases so as to facilitate rapid and even steam penetration into allparts of the load and maintaining these conditions for the specifiedtemperatureholding time (11 minutes at 121.2^0C).

5.2.2 **Acceptance Criteria:**The Bowie Dick test to be considered as a successful run if Bowiedick TST colorchanged from pink to black.No change, and non-uniform change and/ or air entrapment (bubble) spot on the pattern indicates inadequate air removalfrom theSterilization chamber.

5.2.3 **Test Results:**Consecutive03 cycleswere run and the test met the expected results listed in the test procedure. The test passed without reported deviations.

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Result	Remarks
1.			11 min.	Bowie dick color changed from pink to black	Complies
2.			11 min.	Bowie dick color changed from pink to black	Complies

3.			11 min.	Bowie dick color changed from pink to black	Complies

5.3 Empty Chamber Heat distribution Study:

5.3.1 Objective: This test is performed to ensure that the steam sterilizer is capable of attaining the temperature of NLT 121.2^0C/115.2^0C uniformly throughout the chamber during the sterilization hold period with steam pressure of 1.0-1.3 kg/cm2.

5.3.2 Acceptance criteria:

- Chamber temperature should be within 121.2-124°C/115.2 – 118.0°C during the sterilization hold period.
- Chemical indicators should show uniform color changes.
- During the hold period the observed temperature variation betweenall probes should not differ by not more than 2°C.
- During the hold period the measured temperature within the probe should not differ by not more than 1°C

5.3.3 Test Results: Total 05 cycleswere run one for HPHV cycle at 121.2 °Cfor 30 minutes, one for Gravity cycle at 121.2 °C for 17 minutes,one for Gravity cycle at 121.2 °C for 18 minutes, one for Gravity cycle at 121.2 °C for 20 minutes,one for Gravity cycle at 115.2 °C for 20 minutes, all the test cycles met the expected results listed in the test procedure. The test cycle passed without reported deviations.

5.3.3.1 Empty Chamber Heat Distribution Study (HPHV-30 min)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			30 min.	121.32	122.69	32.43	38.93	Complies	Complies

5.3.3.2 Empty Chamber Heat Distribution Study (Gravity Cycle-17 min)

S. No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			17 min.	121.30	122.68	18.24	21.55	Complies	Complies

5.3.3.3 Empty Chamber Heat Distribution Study (Gravity Cycle-18 min)

S. No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			18 min.	121.48	122.69	20.89	22.74	Complies	Complies

5.3.3.4 Empty Chamber Heat Distribution Study (Gravity Cycle-20 min)

S. No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			20 min.	121.28	122.56	21.85	24.80	Complies	Complies

5.3.3.5 Empty Chamber Heat Distribution Study (Gravity Cycle-20 min 115.2°C)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			20 min.	115.34	116.69	23.53	25.41	Complies	Complies

5.4 Heat Penetration and distribution Study for Garments/Glassware and Accessories:

5.4.1 Objective: To ensure that, the steam is penetrated sufficiently into the inner most part of the load subjected to sterilization. To demonstrate that during sterilization hold time the temperature was between 121.2ºC to 124ºC and steam pressure of 1.1 to 1.3 Kg /cm^2 is achieved and maintained in the innermost part of the loaded material,and also heat distribution and penetration is uniform and uniform heating process, which is achieved in the empty chamber is not affected by load.

5.4.2 Acceptance criteria:

- During the hold period the observed temperature variation between all probes should not differ by not more than 2°C.
- During the hold period the measured temperature within the probe should not differ by not more than 1°C
- Chemical indicators should show uniform color change.
- Tested biological indicators should not show any growth and positive control should show growth after completion of incubation.
- Chamber temperature should be within 121.2-124°Cduring the sterilization hold period.

5.4.3 Test Results: Total 04 HPHV cycles are run at 121.2 °Cfor 30 minutes, all the test cycles met the expected results listed in the test procedure. The test cycles passed without reported deviations.

5.4.3.1 Loaded Chamber Heat Penetration and Distribution Study for Glassware (30 min Min)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			30 min.	121.42	122.74	33.91	39.49	Complies	Complies

5.4.3.2 Loaded Chamber Heat Penetration and Distribution Study for Glassware (30 min Max)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			30 min.	121.43	122.67	34.24	39.37	Complies	Complies

5.4.3.3 Loaded Chamber Heat Penetration and Distribution Study for Garments (30 min Max)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			30 min.	121.27	122.54	32.99	37.29	Complies	Complies

5.4.3.4 Loaded Chamber Heat Penetration and Distribution Study for Garments (30 min Min)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			30 min.	121.28	122.68	32.89	37.12	Complies	Complies

5.5 Heat Penetration and Distribution Study for Microbiological Media:

5.5.1 Objective: To ensure that, the steam is penetrated sufficiently into the inner most part of the load subjected to sterilization. To demonstrate that during sterilization hold time the temperature was between 121.2ºC to 124ºC and steam pressure of 1.1 to 1.3 Kg /cm^2 is achieved and maintained in the innermost part of the loaded material,and also heat distribution and penetration is uniform and uniform heating process, which is achieved in the empty chamber is not affected by load.

5.5.2 Acceptance criteria:

- Chamber temperature should be within 121.2-124°C during the sterilization hold period.
- During the hold period the observed temperature variation between all probes should not differ by not more than 2°C.
- During the hold period the measured temperature within the probe should not differ by not more than 1°C
- Chemical indicators should show uniform color change.
- Tested biological indicators should not show any growth and positive control should show growth after completion of incubation.

5.5.3 Test Results: Total 16 Gravity cycles were run at 121.2/115.2 °C for 17min/18 min/20 minutes. During heat penetration study in microbiological media, 12 no. of sensor were kept with chemical and biological indicator for category I, category-II, category-III, category-IV, category-V, category-VI and category-VII media.All the test cycles met the expected results listed in the test procedure.The test cycles passed without reported deviations.

5.5.3.1 Loaded Chamber Heat Penetration and Distribution Study for Category-V (10 ml Agar and Broth Media in 25 ml Capacity Tubes)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			17 min.	121.31	122.46	18.48	21.47	Complies	Complies

5.5.3.2 Loaded Chamber Heat Penetration and Distribution Study for Category-III (90-100 ml Broth Media in 250 ml Capacity Flasks-Min)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			18 min.	121.30	122.39	20.03	22.32	Complies	Complies

5.5.3.3 Loaded Chamber Heat Penetration and Distribution Study for Category-III (90-100 ml Broth Media in 250 ml Capacity Flasks-Max)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			18 min.	121.44	122.53	20.69	23.05	Complies	Complies

5.5.3.4 Loaded Chamber Heat Penetration and Distribution Study for Category-II (45-100 ml Broth Media in 170 ml Capacity Tubes-Min)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			18 min.	121.37	122.54	20.06	23.20	Complies	Complies

5.5.3.5 Loaded Chamber Heat Penetration and Distribution Study for Category-II (45-100 ml Broth Media in 170 ml Capacity Tubes-Max)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			18 min.	121.28	122.60	18.51	23.14	Complies	Complies

5.5.3.6 Loaded Chamber Heat Penetration and Distribution Study for Category-I(250-800 ml Solid Agar Media-Min)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			20 min.	121.30	122.56	21.09	25.25	Complies	Complies

5.5.3.7 Loaded Chamber Heat Penetration and Distribution Study for Category-I(250-800 ml Solid Agar Media-Max)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			20 min.	121.39	122.46	21.44	24.16	Complies	Complies

5.5.3.8 Loaded Chamber Heat Penetration and Distribution Study for Category-IV(990 ml broth Media in 2000 ml Capacity Bottles-Min)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			20 min.	121.12	122.35	21.67	24.60	Complies	Complies

5.5.3.9 Loaded Chamber Heat Penetration and Distribution Study for Category-IV(990 ml broth Media in 2000 ml Capacity Bottles-Max)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			20 min.	121.26	122.53	20.33	25.53	Complies	Complies

5.5.3.10 Loaded Chamber Heat Penetration and Distribution Study for Category-VI(RVM & GNB Medium-Max)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			20 min.	115.40	116.58	22.26	24.69	Complies	Complies

5.5.3.11 Loaded Chamber Heat Penetration and Distribution Study for Category-VII (45/ 50 ml Broth Media in 170 ml Capacity Tubes-Min)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			18 min.	121.24	122.41	18.96	21.93	Complies	Complies

5.5.3.12 Loaded Chamber Heat Penetration and Distribution Study for Category-VII (45/ 50 ml Broth Media in 170 ml Capacity Tubes)

S.No.	Date of Test	Autoclave Cycle No.	Cycle Hold Time	Min Sterile Hold Temp.	Max. Sterile Hold Temp.	Min F_0	Max F_0	Chemical Indicator Status	Remarks
1.			18 min.	121.38	122.57	19.06	23.46	Complies	Complies

6.0 JUSTIFICATION:

The validation is set up and executed according to the following applicable PDA guidelines (Parental Drug Association) TR1: Validation of moist heat Sterilization Processes. Supplement Volume

PDA Guidelines describes general specifications regarding steam sterilizers and with respect to validation andspecific requirements for porous and non-porous cycles.

These guidelines also describe the actual validation process and the requirements for the measurementequipment used as well as the specific required measurement values and accuracies with regard tothe course of the sterilization process.

The actual execution of the measurements and the processing of the measurement results were donewith the help of Data logger and 12 thermocouple sensor.

The measurement system, Data logger having the make: Eurotherm, Model No. serial no. complies with the requirements set by the standards.

The thermocouple sensors having the range from -50 to 400°C make Tempsens were used to sense the temperature at their defined location where they were placed

A detailed description of this equipment and the accompanying calibration certificates are attached with the detailed report.

7.0 CONCLUSION:

On the basis of qualification activity performed, all sections for auto sliding door steam sterilizer are executed and successfully completed. A total of 27 cycles were run and all the cycles are executed as per validated protocol. No any discrepancy is observed during execution of the qualification activity. The Auto sliding door steam sterilizer functioned in accordance with the approved system specification and adhered to site specific standards to ensure system specification. The steam sterilizer is qualified for desired performance and its ability to sterilize different components and loads at the set parameters and set loading patterns, repeatedly and consistently. Compliance with the guidelines is found. No peculiarities before and after the measurement are observed. The detailed measurement results and their graphical representations, the detected deviations and other measurement details are added and included in the expanded report.The justification of the applied standards is given as well as the used measurement equipment and the persons responsible for the interpretation of the result and the final validation conclusions.The Auto sliding door steam sterilizer is now considered re-qualified and can be used for its intendeduse till the next dateof re qualification that falls in themonth of February 2025.

8.0 FINAL APPROVAL:

		NAME	DESIGNATION	SIGN	DATE
Prepared By	Microbiology				
Reviewed By	Microbiology				
Approved By	Microbiology				
	Engineering				
	Quality Assurance				