PERFORMANCE QUALIFICATION PROTOCOL FOR STEAM STERILIZER

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1.0 Pre-Approval:

Signing of this Approval page of Performance Qualification Protocol ……. ., indicates the agreement with the Performance Qualification approach described in this document. Should any Modifications to the Performance Qualification become necessary, an addendum will be prepared and approved.

Written By	Signature	Date

Checked By	Signature	Date

Approved By	Signature	Date

PERFORMANCE QUALIFICATION PROTOCOL FOR STEAM STERLIZER

2.0 OBJECTIVE:

The objective of this VALIDATION PROTOCOL is to provide high degree of confidence in the steam sterilization process that is being exerted by STEAM STERILIZER (Eq.No…….) supplied by M/s …….. located in the Decontamination Room of Microbiology Lab suitable for decontaminating the loads which will be operated under the following heads.

- **Standard Cycle**
  - Used Sterility Test Tubes
  - Tested CFU Plates
  - Microbial Limit Test Sample Plates
  - Enriched Media tubes
  - Environmental Monitoring Plates
  - Settling Exposure Plates
  - Surface Monitoring samples tested m(HPC) plates

2.0 SCOPE OF PROTOCOL:

These procedures are to be performed after any major modification of the equipment or relocation or if there is any change / addition in the load configuration and for revalidation at appropriate intervals.

4.0 STERILIZATION PROCESS (Brief Description):

The Steam Sterilizer consists of the following features. The Sterilization Chamber is made up of SS sheet, which is welded with U-Profile SS Jacket. The Sterilization Chamber is provided with a door, which is also made up of SS. The cylindrical sterilizer as double wall unit with glass wool insulation and an outer cover of stainless steel duly buffed and polished.

The sterilizer is provided with the following:

- Jacket: The jacket is fabricated from stainless steel 304 material.
- Chamber & Back Plate: The chamber and the back plate are made up of SS 316 quality and are duly buffed and polished.
- Door: the door is made up of stainless steel 304 plate , the external door locking arrangements including the shooting bolts hub and hinges are also made up of stainless steel.

The door is fitted with a pressure locking arrangement so that the door does not open when the chamber is under pressure. The door is provided with a silicone gasket.

The sterilizer is provided with a stainless steel electric steam generator working on 440 volts, 3 phase AC and 50 cycles power supply. The sterilizer is supported on a stainless steel tubular stand.

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5.0 AREA DESCRIPTION:

The Steam Sterilizer is located in the decontamination zone of Microbiology Lab with restricted access. The decontamination zone is designed as per the specifications for cleanliness Class D (class 100,000). The equipment is located such that, it can be attended easily for routine operational, monitoring and maintenance purpose. All major components and utility lines are located in the controlled area side, for better accessibility.

6.0 RESPONSIBILITIES:

- Author signature indicates that this document has been prepared in accordance with existing project standards and adequately reflects the tasks and deliverables necessary for performance qualification of the Steam Sterilizer, located in the decontamination zone of the Microbiology Lab.
- Reviewer's signature indicates that, he has reviewed the document and that it accurately and completely reflects the tasks and deliverables necessary for the performance qualification of the Steam sterilizer situated as explained above.
- Quality Assurance Signature indicates that this document complies with the Validation master plan, company standards and regulatory guidelines; and that the documentation and information contained herein complies with applicable regulatory, corporate, departmental requirements, and current Good Manufacturing Practices.
- Microbiologist is responsible for conducting the study according to the prepared and approved protocol and collecting and compilation of the data collected from the study for review and final certification of the equipment being validated.
- Maintenance team is responsible for the equipment smooth and consistent running and providing required help during the performance qualification study by providing necessary technical support and ensures that all the systems and support systems are at the predetermined working standards. And to understand the cycle parameters thereby planning for verification and up gradation of the preventive maintenance procedures and calibration procedures as well as the equipment up gradation itself if required.
- Microbiologist is responsible for the required microbiological validation of the process to prove that the cycle has met the predetermined attributes like sterility assurance level of 12-log reduction in microbial load as per the laid down procedures and standards.

7.0 QUALIFICATION TESTS:

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

The Steam sterilizer will be considered qualified for consistent and reliable performance (Validated) on successful completion of the following tests.

- Empty Chamber Heat Distribution studies (3 trials) with temperature mapping probes at different locations of the sterilizer chamber..

- Loaded Chamber heat penetration studies (3 trials) for each sterilization load of fixed loading pattern, with temperature mapping probes inside the innermost possible layer of the load subjected for sterilization.
- Bio-Challenge studies using Bacillus stearothemophilus spore strips (containing 10^6 or more spores per strip) during the heat distribution & heat penetration studies.
- Estimation of the FO value achieved during the sterilization hold period at each temperature-mapping probe.

To qualify these tests the equipment should fulfill the acceptance criteria described in the individual test procedures. After completion of the qualification tests all the data generated will be compiled together to evaluate ability of the Steam sterilizer to sterilize different components at the set parameters and set-loading pattern.

NOTE: The calibration of the probes will be performed once before the empty chamber and loaded chamber. This data shall be enclosed to the respective attachment.

7.1 HEAT DISTRIBUTION EMPTY CHAMBER:

Objective:
Objective of this test is to ensure that,

- The Steam sterilizer is capable of attaining a temperature of 121ºC during the sterilization hold period with steam pressure of 1.2 kg / Cm^2.

- Temperature spread with in the range of 121ºC to 124ºC for 60 minutes during sterilization cycle will demonstrate the uniform heat distribution within the chamber.

- Any Location(s) where the temperature sensor is placed, not achieving minimum sterilization temperature of 121ºC through out the sterilization temperature hold will be considered as cold spot.

Procedure:

1. Pass minimum 16 no. Temperature mapping probes into chamber through the port of the sterilizer as per the Annexure 1 of Attachment 1.
2. Seal the port with silicone sealant so that steam leakage does not take place.
3. Suspend the probes in the chamber in different position so that probes do not touch any metallic surface, also place biological indicators along with locations of temperature mapping probes in the sterilizer chamber.

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TEMPERATURE SENSOR PLACEMENT IN THE EMPTY CHAMBER

(NOTE: The temperature sensors shall be placed in the pre determined locations with predetermined sensor numbers corresponding to the data logger channels).

Sensor No.	location in the chamber	Sensor No.	Location within the chamber
1.	Chamber Drain	9.	Chamber Right Rear End
2.	Near the back Plate left side	10.	Chamber Right Side Middle
3.	Near the back Plate right side	11.	Chamber Right Side Front
4.	Chamber Left Rear End	12.	At the center of back Plate
5.	Chamber Left Side Middle	13.	Center of the door
6.	Chamber Left Side Front	14.	Within the Chamber at the Center
7.	Near the Door on Left Side	15.	Within the Chamber at the Rear End
8.	Near the Door on Right Side	16.	Within the Chamber at the Front

Justification for the temperature sensor location of choice.

- **Sensor no. 1:** Control sensor of the equipment is located in the condensate drain. This is very important to know the temperature of the drain point to evaluate the cycle set parameters.
- **Sensor no. 2, 3, 12:** To verify the probability of excess temperature at the steam inlet.
- **Sensor no.4, 5, 6, 9, 10, 11:** Heat distribution near the body.
- **Sensor no. 7, 8, 13:** Any conduction of heat from the door which may cause temperature drop at that particular point.
- **Sensor nos. 14, 15, 16:** To check the heat distribution at the center.

1. Connect the probes to a suitable data logger, which can scan and print the actual temperature observed at different locations with respect to time.
2. Operate the steam sterilizer as per SOP**,** and also start the data logger to record actual temperatures with in the sterilization chamber with respect to time

- Download the data from data logger into the computer for data-analysis and printing. Enclose the data printouts as per the Annexure 2 of Attachment- 1
- Aseptically collect the exposed biological indicators and hand over to concerned microbiologist for testing .

If the empty chamber heat distribution studies are acceptable, perform three consecutive replicate runs to demonstrate cycle and sterilizer reproducibility.

Compile the data generated during the qualification test for complete evaluations of the system .

Acceptance Criteria:

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 within the range of 121ºC to 124ºC during the sterilization hold period.

Observations and Results:

Record the observations and results in formats enclosed as Annexure 3 Attachment-1

7.2 HEAT PENETRATION STUDY STERILITY TESTING:

Objective:

Objective of this test is to ensure that,

- The steam is sufficiently penetrating into the innermost portions of the load subjected for complete decontamination to achieve desired temperature of 121ºC during the complete Sterilization hold period with steam pressure of 1.2 Kg/cm^2.

- Temperature spread within the range of 121ºC to 124ºC for 60 minutes during sterilization hold period indicate that, uniform heating process which is achieved in the Loaded chamber heat penetration study is not affected by load. There could be the possibility of lag period for attaining 121ºC during heat penetration trials as the probes are placed deep into the load

- Any Location (S) where the temperature indicator is placed, not achieving minimum sterilization temperature of 121ºC during sterilization temperature hold period will be considered as cold spot.

➢ **Maximum Load Details**

- **Load No. I**
  - 03 No. of Sterility Media tubes
- **Load No II**
  - 02 No. of Used Media Box
- **Load No III**
  - Water Sampled Bottles
  - Enriched Media Bottles during Microbial Limit Test

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LOAD NO 1, STERILITY TEST MEDIA TUBES:

TEMPERATURE SENSOR PLACEMENT DURING HEAT PENETRATION STUDIES

Sensor No.	location in the chamber	Sensor No.	Location within the chamber
1.	Chamber Drain	9.	Chamber Right Rear End
2.	Near the back Plate left side	10.	Chamber Right Side Middle
3.	Near the back Plate right side	11.	Chamber Right Side Front
4.	Chamber Left Rear End	12.	At the center of back Plate
5.	Chamber Left Side Middle	13.	Center of the door
6.	Chamber Left Side Front	14.	Within the Sterility tubes
7.	Near the Door on Left Side	15.	Within the Sterility tubes
8.	Near the Door on Right Side	16.	Within the Sterility tubes

Justification for the temperature sensor location of choice:

- **Sensor no.1:** Control sensor of the equipment is located in the condensate drain. This is very important to know the temperature of the drain point to evaluate the cycle set parameters.
- **Sensor no. 2, 3, 12:** To verify the probability of excess temperature at the steam inlet.
- **Sensor no.4, 5, 6, 9, 10, 11:** Heat distribution near the body.
- **Sensor no. 7, 8, 13:** Any conduction of heat from the door which may cause temperature drop at that particular point.
- **Sensor nos. 14, 15, 16:** To check the penetration within the load.

Procedure:

1. Pass Minimum 16 no. Temperature mapping probe into chamber through the port provided as per Annexure 1, of Attachment no, 2 for the above different loads.
2. Seal the port with silicone sealant so that steam leakage does not take place.
3. Place the probes inside the load components, which are supposed to most difficult points for steam penetration, also place biological indicator strip along with each temperature mapping probe.
4. Connect the probes to suitable data logger, which can scan and print the actual temperature with respect to time.
5. Down load the temperature data as per Annexure 2 of Attachment No. 2
6. Operate the steam sterilizer as per SOP, and start the data logger to record actual temperatures with in the sterilization chamber with respect to time.

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LOAD No. 1I, EXPOSED MEDIA PLATES:

TEMPERATURE SENSOR PLACEMENT DURING HEAT PENETRATION STUDIES

Sensor No.	location in the chamber	Sensor No.	Location within the chamber
1.	Chamber Drain	9.	Chamber Right Rear End
2.	Near the back Plate left side	10.	Chamber Right Side Middle
3.	Near the back Plate right side	11.	Chamber Right Side Front
4.	Chamber Left Rear End	12.	At the center of back Plate
5.	Chamber Left Side Middle	13.	Center of the door
6.	Chamber Left Side Front	14.	Within the used media box
7.	Near the Door on Left Side	15.	Within the used media box
8.	Near the Door on Right Side	16.	Within the used media box

Justification for the temperature sensor location of choice:

- **Sensor no.1:** Control sensor of the equipment is located in the condensate drain. This is very important to know the temperature of the drain point to evaluate the cycle set parameters.
- **Sensor no. 2, 3, 12:** To verify the probability of excess temperature at the steam inlet.
- **Sensor no.4, 5, 6, 9, 10, 11:** Heat distribution near the body.
- **Sensor no. 7, 8, 13:** Any conduction of heat from the door which may cause temperature drop at that particular point.
- **Sensor no. 14, 15, 16:** To check the penetration within the load

Procedure:

1. Pass Minimum 16 no. Temperature mapping probe into chamber through the port provided as per Annexure 3, of Attachment no, 2 for the above different loads.
2. Seal the port with silicone sealant so that steam leakage does not take place.
3. Place the probes inside the load components, which are supposed to most difficult points for steam penetration, also place biological indicator strip along with each temperature mapping probe.
4. Connect the probes to suitable data logger, which can scan and print the actual temperature with respect to time.
5. Down load the temperature data as per Annexure 4 of Attachment No. 2
6. Operate the steam sterilizer as per SOP, and start the data logger to record actual temperatures with in the sterilization chamber with respect to time.

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LOAD NO. III, ENRICHED MEDIA BOTTLES:

TEMPERATURE SENSOR PLACEMENT DURING HEAT PENETRATION STUDIES:

Sensor No.	Location in the chamber	Sensor No.	Location within the chamber
1.	Chamber Drain	9.	Chamber Right Rear End
2.	Near the back Plate left side	10.	Chamber Right Side Middle
3.	Near the back Plate right side	11.	Chamber Right Side Front
4.	Chamber Left Rear End	12.	At the center of back Plate
5.	Chamber Left Side Middle	13.	Center of the door
6.	Chamber Left Side Front	14.	Within the Water sampling bottles
7.	Near the Door on Left Side	15.	Within the enriched media bottles
8.	Near the Door on Right Side	16.	Within the enriched media bottles

Justification for the temperature sensor location of choice:

- **Sensor no. 1** - Control sensor of the equipment is located in the condensate drain. This is very important to know the temperature of the drain point to evaluate the cycle set parameters.
- **Sensor no. 2, 3:** To verify the probability of excess temperature at the steam inlet.
- **Sensor no. 4, 5, 6, 9, 10, 11:** Heat distribution near the body.
- **Sensor no. 7, 8:** Any conduction of heat from the door which may cause temperature drop at that particular point.
- **Sensor no. 12, 13, 14, 15, 16:** To check the penetration within the load.

When the sterilization cycle completes:

1. Place the probes and the biological indicators as per the Annexure 5 of Attachment No. 2.
2. Download the data from data logger into the computer for data-analysis and printing. Record the temperature observed at different locations during different loads in the Annexure - 6 of Attachment-2
3. Aseptically collect the exposed biological indicators and hand over it to concerned microbiologist for testing and the observation sheet.

Compile the data generated during the qualification test for complete evaluation of the system.

Acceptance Criteria:

There should be uniform penetration of heat in the load subjected for sterilization during the sterilization hold period and the temperature at each temperature mapping probe should be with in the range of 121ºC to 124ºC during the complete sterilization hold period.

Observations and Results:

- The steam is sufficiently penetrating into the innermost portions of the Media subjected for sterilization to achieve desired temperature of 121ºC during the complete Sterilization hold period with steam pressure of 1.2 Kg/cm^2.
- If sterilization temperature (121ºC) is not achieved through out the cycle, load configuration or size of the load has to be reviewed and cycles to be repeated.
- Temperature spread within the range of 121ºC to 124ºC during sterilization hold period indicate that, uniform heating process which is achieved in the Loaded chamber heat penetration study is not affected by load. There could be the possibility of lag period for attaining 121ºC during heat penetration trials as the probes are placed deep into the load

8.0 SCHEDULED REVALIDATION:

Study	Frequency	
	Validation	Routine
Calibration of all instruments e.g., Pressure Gauge, Compound Gauges, Timer, DTI, Data logger, Probes.	Every Six Month (pre and post validation)	Every Six Month for dial gauges.
Empty-chamber heat distribution studies (3 cycles)	Once a year three trials for each load	Not required
Loaded chamber heat distribution and heat penetration studies. (3 cycles each with specific loading pattern).	Once a year three trials for each load	Not required

8.1 UN-SCHEDULED REVALIDATION:

Revalidation shall be carried out in case of

- Major maintenance of critical parts.
- Change of cycle program.
- Inclusion of new load.

For unscheduled revalidation Empty chamber and loaded chamber revalidation shall be carried out. The pattern of the study shall be based on case to case basis and properly documented.

8.2 ACTION TO BE TAKEN IN CASE OF FAILURE OF A REVALIDATION STUDY:

If minimum sterilization temperature of 121°C is not achieved in one or more location(s) during sterilization hold period of Empty Chamber Heat distribution cycle following action are taken:

Engineering department will be informed to check the calibration of instruments like temperature indicating probe, Digital temperature indicator, Datalogger, gauges etc. However all the instruments are checked for calibration before validation, hence Engineering departments will be asked to send the reference instruments for re-calibration to Calibration agencies. If fault is found due to error in calibration Steam Sterilization cycles will be repeated.

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 fault is found due to mechanical error, cycle will be repeated putting 2 probes in the location of lower temperature. For further confidence location may be challenged with Biological Indicators and F0 value should be reviewed.

If minimum sterilization temperature of 121°C is not achieved in one or more location(s) during sterilization hold period of Loaded Chamber Heat Penetration cycle following actions are taken:

If the failure occurred with the sterilization cycle during the decontamination media it will be considered as **critical failure** as there is a major chance of survival of the organisms in the media.

- **Action to be taken in case of critical failure**:

  If F0 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.