PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZATION IN PLACE SYSTEM MODULE I

(CYTOTOXIC STERILE LIQUID DOSAGE SECTION)

Revision Index

Revision	Date	Reason for revision
00		New Document

PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZATION IN PLACE SYSTEM MODULE 1 (CYTOTOXIC STERILE LIQUID DOSAGE SECTION)

TABLE OF CONTENTS

PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZATION IN PLACE SYSTEM MODULE 1 (CYTOTOXIC STERILE LIQUID DOSAGE SECTION)

1.0 APPROVAL SIGNATURES:

Signing of this protocol indicates agreement with the Performance Qualification of **SIP System - I** for Cyto Sterile Injectable Facility. Further if any changes in this protocol are required, protocol will be revised and duly approved.

Prepared by		
Name/ Designation	**Signature**	**Date**

Checked by		
Name/ Designation	**Signature**	**Date**

Approved by		
Name/ Designation	**Signature**	**Date**

PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZATION IN PLACE SYSTEM MODULE 1 (CYTOTOXIC STERILE LIQUID DOSAGE SECTION)

2.0 OBJECTIVE

This protocol is designed to establish sufficient data, to assure that the SIP System supplied by M/s .....is suitable for sterilizing the following Vessels:

A. 12 L Compounding Vessels

B. 100 L Compounding Vessels

C. 250 L Compounding Vessels

D. 600 L Compounding Vessels

In addition, this validation protocol is intended to assure the sterility of the items and to maintain the reliability and repeatability of the SIP System when operated in accordance with the established Standard Operating Procedure SOP.

3.0 SCOPE:

This protocol provides a documented evidence for qualification of SIP System used in Cytotoxic Sterile Injectable Preparation.

4.0 REFERENCE DOCUMENT:

Following documents are referred during preparation of the protocol

Document Name	Document Number
Operational SOP of SIP System	

5.0 EQUIPMENT DESCRIPTION:

Process Equipment Description:

The purpose of the Equipment should be able to perform Sterilization in Place for vessels on Set Temperature and time basis and fill them with Filtered Air.
Capacity - Sterilization In Place Vessels Range: 25 - 600 Litres.

Equipment consists of:

- SS 304 trolley with 4 Nos 50 mm Ø X 32 mm PU Swivel castor wheels.
- SS 316 L condensate line with 4 nos condensate ports + 1 No PT 100 Simplex temperature

- Sensor + Float type steam trap with Air Vent.
- SS 304 Electrical control panel consisting of PLC + Touch screen Display + Main switch + Control key + Mains ON lamp + Hooter.
- Clean steam inlet with electrically operated diaphragm valve and sanitary pressure gauge.
- Filtered Compressed Air inlet with electrically operated diaphragm valve.
- Epson Make Printer - LX 300 + II

Safety parameters:

All lines with fittings are Hydro tested at 4.5 Kgs/cm².

6.0 RESPONSIBILITY:

Responsibilities of different department/ personnel involved in different activities related to the performance qualification of SIP System are defined below

6.1 Quality Assurance (Validation):

- To prepare and approve the performance qualification protocol
- To execute the protocol along with the co-ordination of other departments.
- To review the results and compilation of reports.
- To Coordinate with QA for Preparation of the Performance Qualification Protocol & Report.
- To prepare and approve performance qualification report.
- To prepare trend analysis data

6.2 Quality Control:

- To Coordinate with QA for Preparation of Performance qualification protocol & Report
- To perform the test as per protocol.
- To Prepare Report and submission to Quality Assurance.

6.3 Engineering

- To Coordinate with QA Validation team during the Performance Qualification exercise.
- To Prepare the Preventive Maintenance of Dry Heat Sterilizer as per schedule.
- Rectification of Breakdown during qualification study.

7.0 QUALIFICATION TEST METHOD:

7.1 Pre-Requisites

- Prior to conducting/ executing the Performance qualification protocol following

conditions must be fulfilled.

- System should be safe for execution.
- Approval of Operational Qualification report.

7.2 Pre-Qualification test

- Calibration of all measuring instrument of SIP System.
- Calibration of Test instruments

7.3 Steam Quality Test

1. Steam Non-Condensable Gas Test
2. Steam Superheat Test
3. Steam Dryness Test

7.4 Qualification Test Program

- Recipe Development Cycle
- Thermometric Study of Compounding Vessels connected to the SIP System.
- Bio-challenge studies
- Estimation of the F_0 value

7.5 Test Matrix

Following matrix shall be followed for the initial qualification and re- validation of SIP System.

Pre- Qualification Test			
S.No.	**Test**	**Initial Validation**	**Re-Validation**
1.	Calibration of Measuring Instruments	Once	Once
2.	Calibration of test instrument	Once	Once
3.	Steam Quality Test	Once	Once

PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZATION IN PLACE SYSTEM MODULE 1 (CYTOTOXIC STERILE LIQUID DOSAGE SECTION)

Qualification Test			
1.	Recipe Development Cycle	One Trial	X
2.	Thermometric Study of Compounding Vessels 12 Lts.	One Run	One Run
3.	Thermometric Study of Compounding Vessels 100 Lts.	One Run	One Run
4.	Thermometric Study of Compounding Vessels 250 Lts.	One Run	One Run
5.	Thermometric Study of Compounding Vessels 600 Lts.	One Run	One Run
6.	Bio-challenge studies	With each thermometric study	With each thermometric study
7.	Estimation of the F_0 value	With each thermometric study	With each thermometric study

8.0 QUALIFICATION TEST PROCEDURE:

8.1 PRE - QUALIFICATION STUDY:

8.1.1 VERIFICATION OF ALL CALIBRATED MEASURING INSTRUMENTS OF SIP SYSTEM

Ensure that all the instruments attached to the Dry Heat Sterilizer are calibrated before the Qualification.

S.No.	Item Description
1.	Duplex sensors attached to the drain.
2.	Compound Gauge attached in steam supply line.
3.	All Compound Gauges attached to the compounding vessels.
4.	Calibration of Pressure Transmitters

Observations and Results

Record the observations and results in the format enclosed as **Annexure 1.**

8.1.2 CALIBRATION OF TEST INSTRUMENTS:

Ensure that all the instruments used for the performance qualification are precalibrated

S.No.	Item Description
1.	All 14 sensors used for performance qualification.
2.	Data Logger

Observations and Results

Record the observations and results in the format enclosed as **Annexure 1.**

8.2 QUALIFICATION STUDY:

8.2.1 STEAM NON-CONDENSABLE GAS TEST:

Objective:

- Objective of this test is to ensure that,

- The pure steam supply to the Compounding vessel does not contain non-condensable gases than the desired level (NMT 3.5%) when measured on-line during the standard sterilization cycle

Procedure:

- Perform the test as per the Standard Operating Procedure SOP.

Basis of Calculation

- The calculations are done by using the following formula.

Fraction of non-condensable gases = $100 \times \frac{V_b}{V_c}$

Where,

V_b = Volume of gas collected in the burette (i.e difference between the initial & final Burette readings).

V_c = Vacuum of water collected in the measuring cylinder

Acceptance Criteria:

- The concentration of non-condensable gases should not be more than 3.5% when sampled from the main Pure Steam line (just prior to entering the SIP System) during the sterilization cycle

Observations and Results:

- Record the observations and results in the format enclosed as **Annexure 2** with SOP

8.2.2 SUPERHEAT TEST:

Objective

Objective of this test is to ensure that,

- The superheat value of pure steam supply to the Compounding vessel should be within acceptance criteria when measured on-line during the standard sterilization cycle

Procedure

- Perform the test as per the Standard Operating Procedure SOP. Record the observations and results in the format enclosed as **Annexure 2** with SOP**.**

Acceptance Criteria

- The test should be considered satisfactory if the super heat measured in the expansion tubes does not exceed 25 ^{0}C

8.2.3 DRYNESS TEST:

Objective

Objective of this test is to ensure that the Dryness value of pure steam supply to the Compounding vessel should be within acceptance criteria when measured on-line during the standard sterilization cycle.

Procedure

Perform the test as per the Standard operation Procedure SOP and record the observations and results in the format enclosed as **Annexure 4** with SOP.

Acceptance Criteria

The test should be considered satisfactory if the following requirements are met:

The dryness value should not be not lees than 0.90

Through out the operating cycle, the temperature measured in the steam service pipe should be within 3°C.

8.2.4 RECIPE DEVELOPMENT CYCLE:

Objective

Objective of this trial is to ensure that,

A. The SIP System containing Compounding vessel should have proper heat up, sterilization hold and drying phase.

B. The SIP System containing Compounding vessel should be capable of attaining a temperature of 121°C during the sterilization hold period with steam pressure more than 1.2 Kg/cm².

C. Temperature spread with in the range of 121°C to 131°C during sterilization cycle will demonstrate the uniform heat distribution within the vessel.

D. No cold spot should be observed.

Procedure

A. Record the set parameters for the sterilization cycle to be operated during the test for heat distribution study.

B. Perform full loop calibration (probe + data logger) before starting the qualification runs. Attach calibration reports.

C. Prepare at least 14 No. calibrated Temperature Mapping Probe with location and channel tag.

D. Insert Temperature Mapping Probes inside the chamber through the port present on the lid of the vessel. Seal the port with silicone sealant so that steam leakage does not take place. Number of probes depends on the capacity of the vessel. Distribute the probes at different location inside the vessel as per lay out mentioned in Figure - I. Ensure that no probe touches the walls of the vessel.

S.No	Capacity	Probes
1.	12 Litres Vessel	08
2.	100 Litres Vessel	14
3.	250 Litres Vessel	14
4.	600 Litres Vessel	14

Connect the probes to a suitable data logger with a printing interval of 30 seconds.

E. Operate the SIP System as per Standard Operating Procedure SOP and simultaneously start the data logger to record actual temperatures within the vessel with respect to time.

F When the sterilization cycle completes; (1) take the print out of the sterilization cycle of SIP system. (2) Download/ prints the data from data logger and review the data for any discrepancy. Record the temperatures observed at different locations.

G. Perform full loop calibration of probes after completion of thermometric study. Not more than one probe should be out of calibration to accept qualification cycle.

H. Calculate F_0 value of each temperature mapping location as per the section 8.8.

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

J. Prepare summary and conclusion of the performance qualification test and finally approve it by Head - Quality Assurance

Acceptance Criteria

A. There should be uniform distribution of heat in the Compounding vessel during the sterilization hold period and the temperature at each location should be within the range of 121°C to 131°C during the sterilization hold period.

B. The sterilization hold period should not be less than 30 minutes.

C. Temperature uniformity at a given time of temperature recording between all probes during hold period should not be more than ± 5°C.

D. Temperature distribution during hold period at a certain monitoring location should not be more than 5°C.

E. Initial lag period after starting sterilization hold period where temperature uniformity acceptance criteria will not be met, should not be more than 1 minute.

F Should meet the F_0 value, which should be not less than 30 minutes

8.3 THERMOMETRIC STUDY OF COMPOUNDING VESSEL CONNECTED TO SIP SYSTEM :

Objective

Objective of this test is to ensure that,

A. The SIP System containing Compounding vessel should be capable of attaining a

temperature of 121°C during the sterilization hold period with steam pressure more than 1.2 Kg/cm².

B. Temperature distribution should be with in the range of 121°C to 131°C during sterilization cycle that will demonstrate the uniform heat distribution within the chamber of vessel.

C. Any location(s) where the temperature indicator is placed, not achieving minimum sterilization temperature of 121°C through out the sterilization temperature hold will be considered as cold spot.

Procedure

A. Record the set parameters for the sterilization cycle to be operated during the test for heat distribution study.

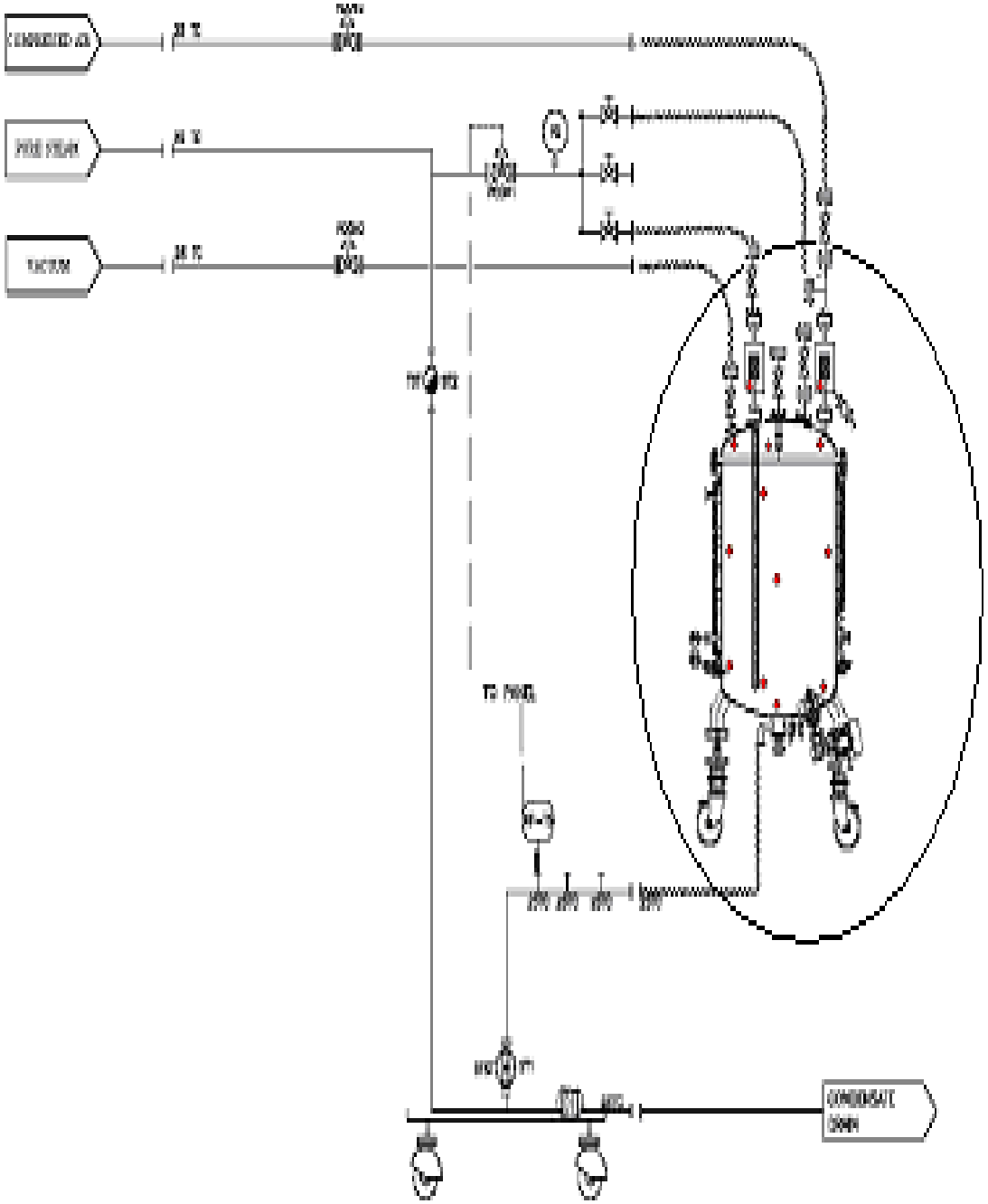
B. Perform full loop calibration (probe + data logger) before starting the qualification cycle. Attach calibration reports.

C. Prepare at least 14 Nos. calibrated temperature mapping probe with location and channel tag.

D. Insert Temperature Mapping Probes inside the chamber through the port present on the lid of the vessel. Seal the port with silicone sealant so that steam leakage does not take place. Number of probes depends on the capacity of the vessel. Distribute the probes at different location inside the vessel as per lay out mentioned in Figure - I. Ensure that no probe touches the walls of the vessel..

E. Attach Biological Indicator and Chemical Indicator to each probe. Record the position of the probes and the Biological indicators along with chemical indicators in a representative schematic form as per the Figure -1

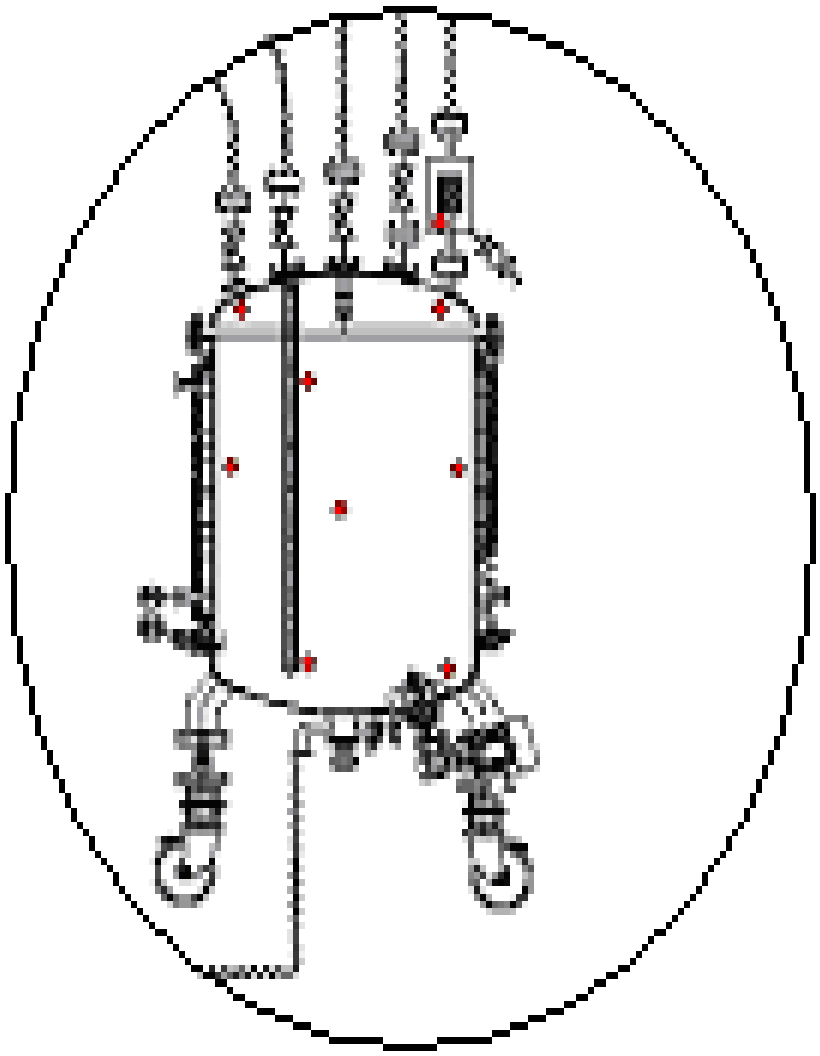
PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZATION IN PLACE SYSTEM MODULE 1 (CYTOTOXIC STERILE LIQUID DOSAGE SECTION)



♦ Location of Probes

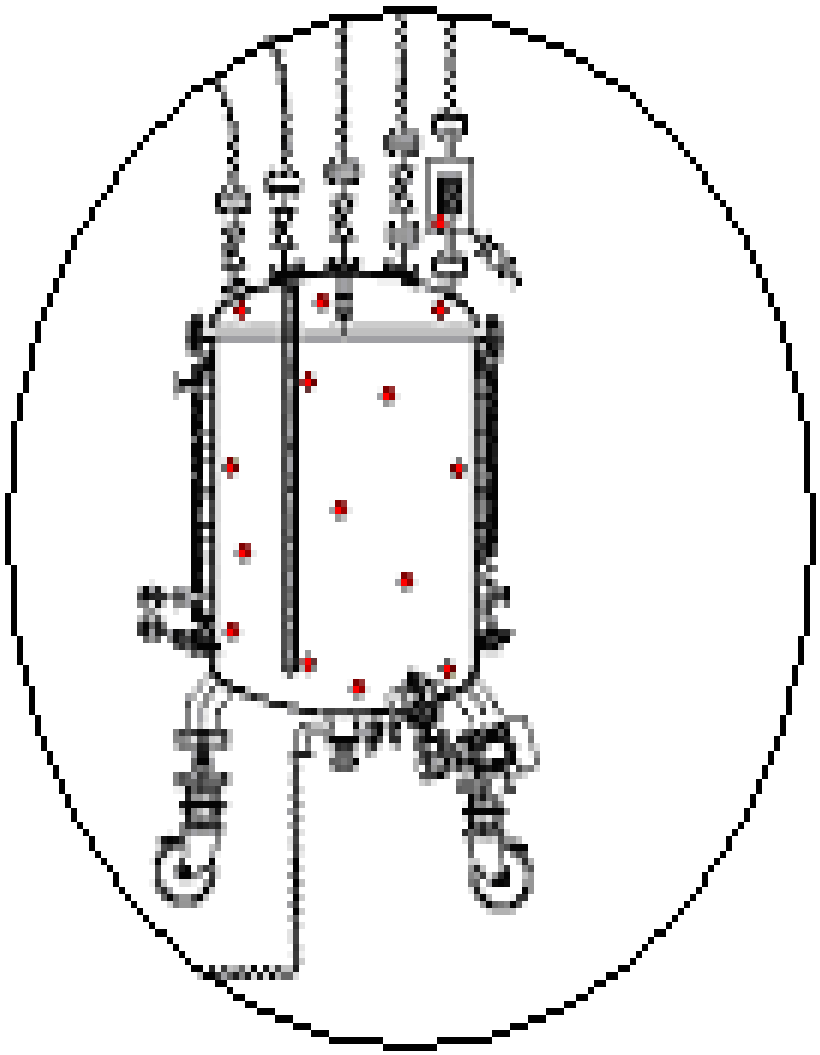
PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZATION IN PLACE SYSTEM MODULE 1 (CYTOTOXIC STERILE LIQUID DOSAGE SECTION)

Location of Probes for 12 Litres Vessel - 08 No.



PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZATION IN PLACE SYSTEM MODULE 1 (CYTOTOXIC STERILE LIQUID DOSAGE SECTION)

Location of Probes for 100, 250, 600 Litres Vessel - 14 No.



F. Connect the probes to a suitable data logger, with a printing interval of 30 seconds.

G. Operate the SIP System as per SOP and simultaneously start the data logger to record actual temperatures within the vessel with respect to time.

H. When the sterilization cycle completes; (1) Collect the print out of the sterilization cycle from SIP system. (2) Download/print the data from data logger and review for any discrepancy. Record the temperatures observed at different locations

I. Perform full loop calibration of probes after completion of thermometric study. Not more than one probe should be out of calibration to accept qualification cycle.

J. Calculate F_0 value of each temperature mapping location and record the results in **Annexure 5**

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

L. Prepare summary and conclusion of the performance qualification test and finally approve it by Head - Quality Assurance

Acceptance Criteria.

- There should be uniform distribution of heat in the Compounding vessel during the sterilization hold period and the temperature at each location should be within the range of 121°C to 128°C during the sterilization hold period.
- The sterilization hold period should not be less than 30 minutes.
- Temperature uniformity at a given time of temperature recording between all probes during hold period should not be more than ± 5°C.
- Temperature distribution during hold period at a certain monitoring location should not be more than 5°C.
- Initial lag period after starting sterilization hold period where temperature uniformity acceptance criteria will not be met, should not be more than 1 minute.
- The biological indicators spores of *Geobacillus Stearothermophillus* should not show any growth after incubation.
- The chemical indicators change the color from pink to green should not be less than 3 compartments.
- Should meet the F_0 value which should be not less than 30 minutes.

Observations and Results

The diagrammatic representation of arrangements of all probes is enclosed as Annexure 7

Record the observations and results in the format enclosed as Annexure 7

8.4 BIO-CHALLENGE STUDIES:

Objective

Objective of this test is to ensure that,

- The steam Sterilization process, when challenged with *Geobacillus*

Stearothermophillus Biological indicator spores having spore population of NLT 10^6 self conaints , should reduce the bacterial load by more than 12-log.

- On incubation of the exposed biological indicator, if growth is observed, then the sterilization cycle parameters to be reviewed.

Procedure

A. Ensure Biological Indicator lots are qualified as per Pharmacopoeial method. Attach the qualification reports.

B. Ensure that the reported D value is within 1.5 to 2.5 min.

C. Open the exposed indicator (during the Thermometric studies) aseptically under laminar air flow and break the ampoule containing medium into the container. Close the container aseptically. Incubate test tube at 55 ± 2°C for 48 hrs.

D. Keep an unexposed ampoule containing medium as negative (-ve) control.

E. Inoculate an unexposed biological indicator containing the medium after breaking the ampoule as positive (+ve) control.

F. Observe for any growth in the containers. Record the observations on daily basis.

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

H. Prepare summary and conclusion of the performance qualification test and finally approve it by Head - Quality Assurance.

Acceptance Criteria

- No bacterial growth should be observed during the inoculation period of 48 hrs. at 55 ± 2°C.

Observations and Results

The diagrammatic representation of arrangements of all Biological Indicators are enclosed as **Annexure 7**.

Record the observations and results in the format enclosed as **Annexure 7**

8.5 ESTIMATION OF F_0 VALUE:

Objective

Objective of this test is to ensure that,

Minimum F_0 value should not be less than 30 minutes, when D Value is 1.5 minutes & Z value is 10°C, but the acceptance criteria should be based on the calculation of

A. the F_0 value for the Biological indicator spore ampoule, which will be used during the Bio-challenge studies. (Biological F_0 should be selected as close as possible to the selected hold period).

B. The calculated F_0 value should not be less than the biological F_0 value at all temperature mapping locations for the sterilization hold period.

Procedure

A. Record the temperatures at all Temperature mapping probes during the sterilization hold period.

B. Calculate the F_0 value at each Temperature mapping probe by using the equation given below.

C. Record the F_0 values (results) accordingly based on the type of study conducted.

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

E. Prepare summary and conclusion of the performance qualification test and finally approve it by Head - Quality Assurance.

Basis of Calculations

- The actual observations obtained during the thermometric studies at different temperature sensing locations should be subjected for calculation of F_0 values at that particular location. The calculations are done by using the following formula.

$$F_0 = dt \sum 10^{\left[\frac{T-121}{Z}\right]} \quad \text{-------- (a)}$$

F_0 = dt ∑ (Sum of lethality rates)

Where,

dt = the time interval between successive temperature measurements (30 sec..).

T = the observed temperature at that particular time (As per the actual temperatures recorded)

Z = the change in the heat resistance of *Geobacillus Stearothermophillus* spores as temperature is changed (10°C).

Acceptance Criteria

The Calculated minimum F_0 value (by equation a) should be more than biological F_0

value for the biological indicator strip exposed for the bio-challenge studies.

The biological F_0 value for the specific biological indicator spore strip can be calculated as follows.

$F_0 = D121 (\log A - \log B)$ -------- (b)

Where,

D_{121} = D value of the biological indicator at 121°C.

A = Biological indicator concentration or spore population.

B = Desired level of non-sterility (10^{-6}).

Therefore, the minimum calculated F_0 value required for more than 6-log reduction of the *Geobacillus stearothermophillus* indicator, which is exposed during the sterilization cycle should not be less than the biological F_0 value for the particular biological spore strip indicator exposed during the bio-challenge studies.

Observations and Results

Record the observations and results in the format enclosed as **Annexure 7.**

9.0 RE QUALIFICATION:

Frequency for Performance Qualification of SIP System is every year.

The Re-qualification should be performed additionally in case of following:

Any major modification in equipment after the last performance qualification. This must be properly documented through a change control system

Adjustments made in the instruments, to correct the non-compliance of operational parameters with respect to specifications.

10.0 DOCUMENTATION:

Results and reports shall be compiled in a binder. Binder shall contain the following sequentially

- Summary Report
- Validation Protocol
- Test Reports

Summary report shall be in narrative form, which describes the work as well as conclusion/certification regarding acceptability. Summary Report shall contain the following

- Post Approval
- Objective
- Acceptance criteria
- Brief validation methodology

- Evaluation of results
- Final result summary
- Deviation, failure investigation reports and corrective actions (if any)
- Conclusion

11.0 CONCLUSION:

Based on the review of results a conclusion shall be drawn and documented in the summary report. Conclusion shall be a clear statement of compliance or noncompliance of the SIP System with the acceptance criteria of the performance qualification protocol.

12.0 ABBREVIATIONS:

ABBREVIATIONS	FULL FORM
PQ	Performance Qualification
OQ	Operation Qualification
IQ	Installation Qualification
µ	Micron
°C	Degree Centigrade

13.0 ANNEXURE:

Annexure 1 : Verification of Calibration Status of instruments

Annexure 2 : Non - Considensable Gas Test

Annexure 3 : SuperHeat Test

Annexure 4 : Dryness Test

Annexure 5 : Recipe Development Cycle

Annexure 6 : Thermometric cycle

Annexure 7 : Sterilization Cycle of SIP System

PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZATION IN PLACE SYSTEM MODULE 1 (CYTOTOXIC STERILE LIQUID DOSAGE SECTION)

ANNEXURE 2
NON-CONDENSABLE GAS TEST

		Done On	

Observations :

Observations	**Readings**		**Difference**
	Initial	**Final**	
Water temperature (°C).			--
Burette (ml).			
Measuring Cylinder (ml).			

The actual observations recorded in the above table are used for calculation of the fraction of non-condensable gases in pure steam as a percentage. The calculations are done by using the following formula.

Fraction of non-condensable gases = 100 X (V_b/V_c)

Where, V_b = Volume of gas collected in the burette (i.e difference between the initial & final burette readings).
V_c = Vacuum of water collected in the measuring cylinder.

Acceptance Criteria :

The fraction of non-condensable gases should not be more than 3.5% in the pure steam used as sterilizing medium for the SIP system.

Calculations :

Fraction of non-condensable gases = 100 X (V_b/V_c)
Fraction of non-condensable gases = 100 X (---------/----------) = _____ **%**

Result :

The fraction of non-condensable gases in pure steam used as sterilizing medium for SIP system is within the acceptable limits.

	Name	**Signature**	**Date**
Done By			
Checked By			

PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZATION IN PLACE SYSTEM MODULE 1 (CYTOTOXIC STERILE LIQUID DOSAGE SECTION)

ANNEXURE 3

SUPERHEAT TEST

Done on	

Observations :

Observations	Readings
Temperature in side expansion tube (°C).	
Temperature in steam service pipe (°C).	
Boiling point of water at local atmospheric pressure	

The temperature in the expansion tube (T_e) when the steam supply to the chamber first opens. The calculation of the superheat in ^oC from the following equation:

Superheat = $T_e - T_o$

Where T_o is the boiling point of water at local atmospheric pressure.

Acceptance Criteria:

The test should be considered satisfactory if the superheat measured in the expansion tube does not exceed 25 ^{0} C.

Calculations:

Superheat = ---------- - ---------- = _____

Result:

The Superheat test of pure steam used as sterilizing medium in the SIP system is within the acceptable limits.

	Name	Signature	Date
Done By			
Checked By			

PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZATION IN PLACE SYSTEM MODULE 1 (CYTOTOXIC STERILE LIQUID DOSAGE SECTION)

ANNEXURE 4

DRYNESS TEST

Done on	

Observations:

Observations	Readings
Initial Temperature of the water in the flask (°C). T_0	
Final Temperature of the water and condensate in the flask (°C). T_1	
Average temperature of steam delivered to the sterilizer (^{0}C) T_s	
Initial mass of water in the flask (kg) M_w	
Mass of the condensate collected (kg) M_c	
Latent heat of dry saturated steam at temperature T_s. (KJ Kg $^{-1}$)L	

When the temperature of the water in the flask is approximately 80^{0}C, disconnect the rubber tube from the pitot tube, agitate the flask so that the contents are thoroughly mixed, and note the temperature of the water (T_1). Weigh the flask and stopper assembly and note the mass The temperature in the expansion tube (T_e).
Weight the flash and stopper assembly and note the mass (M_1)
The initial mass of the water in the flask is given by $Mw = M_2-M_1$
The mass of the condensate collected is given by $Mc = M_3 – M_2$
Calculate the Dryness value of the steam from the following equation :

$$\text{Dryness Value} = \frac{(T_1 - T_o)(4.18M_w + 0.24)}{LM_c} - \frac{4.18(T_s - T_1)}{L}$$

Where,

T_o = Initial Temperature of the water in the flask (°C).
T_1 = Final Temperature of the water and condensate in the flask (°C).
T_s = Average temperature of steam delivered to the sterilizer (^{0}C).
M_w = Initial mass of water in the flask (kg).
M_c = Mass of the condensate collected (kg).
L = Latent heat of dry saturated steam at temperature T_s. (KJ Kg $^{-1}$)

Acceptance Criteria :

The test should be considered satisfactory if the following requirements are met:

- The dryness value is not lees than 0.90 (if metal loads are processed, the dryness value should be below 0.95)

- Through out the operating cycle, the temprature measured in the steam service pipe is within 3°C of that measured during the superheat test.

Calculations :

Dryness Value = $\frac{(\text{-------} - \text{-------})(4.18 \text{ X } \text{-------} + 0.24)}{\text{------- X --------}} - \frac{4.18(\text{--------} - \text{---------})}{\text{--------}} = \text{----------}$

Result :

The dryness Value of pure steam used as sterilizing medium in the steam sterilizer is within the acceptable limits.

	Name	Signature	Date
Done By			
Checked By			