PERFORMANCE QUALIFICATION OF STEAM STERILIZER

PERFORMANCE QUALIFICATION PROTOCOL OF STEAM STERILIZER (ANTICANCER LYOSECTION)

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PERFORMANCE QUALIFICATION PROTOCOL OF STEAM STERILIZER (ANTICANCER LYOSECTION)

1.1 PROTOCOL APPROVAL:

1.2 Protocol Prepared by:

Executive - QA Department is responsible for the preparation of protocol for Performance Qualification of Steam Sterilizer

NAME	DESIGNATION	SIGNATURE	DATE

1.3 Protocol Checked by:

Validation Core Committee Member responsible to review the Protocol for performance qualification of Steam Sterilizer located in Anticancer Lyo section.

NAME	DESIGNATION	SIGNATURE	DATE

1.4 Protocol Approved by:

Manager – QA is responsible to approve the performance qualification protocol.

NAME	DESIGNATION	SIGNATURE	DATE

PERFORMANCE QUALIFICATION PROTOCOL OF STEAM STERILIZER (ANTICANCER LYOSECTION)

2.0 OBJECTIVE:

2.1 The objective of this protocol is to establish sufficient data to assure that the Steam Sterilizer (Autoclave) supplied by M/s …….. is suitable for steam sterilization of Filtration items, Filling items, Seals and Garments. In addition, this validation protocol is intended to assure the Sterility of the items when the equipment is operated in accordance with SOP.

3.0 SCOPE:

3.1 These procedures are to be performed after the installation and operational qualification have been completed and approved.

3.2 These procedures are to be performed, as per the schedule given to assure that the system performance is consistent between the period, after completion of performance qualification study and before conducting a revalidation study.

3.3 These procedures are to be performed after any major modification of the equipment or relocation and for revalidation during appropriate intervals.

3.4 Any change in cycle parameters (set parameters).

3.5 To show that the Autoclave installed in the Sterilisation area of the Anticancer Lyo section performs for its intended use.

4.0 RESPONSIBILITY:

4.1 A plan to carry out the validation shall be prepared in the form of a protocol by the Task Force Leader.The validation team members shall be responsible to carry out the validation.

5.0 ACCOUNTABILITY

5.1 Head – Quality Assurance.

PERFORMANCE QUALIFICATION PROTOCOL OF STEAM STERILIZER (ANTICANCER LYOSECTION)

6.0 METHOD:

6.1 VALIDATION TEAM MEMBERS:

S.No.	Name	Department	
1.			
2.			
3.			
4.			
5.			
6.			

6.2 ACCEPTANCE CRITERIA:

6.2.1 The steam sterilizer should be capable of achieving a temperature of 121^0C in direct contact with saturated steam with approximately 1.2 Kg/cm^2 pressure.

6.2.2 The steam sterilizer should be capable of maintaining uniform temperature through out the chamber within the range of 121.0^0 to 124.0^0C during sterilization holding period.

6.2.3 F_0 value of lowest heating probe should be not less than that of F_0 value of Biological Indicator.

6.2.4 The Bowie-Dick Test indicator should show a uniform color change.

6.2.5 The bacterial load should be reduced on steam sterilization by more than 12 logs when challenged with ***Geobacillus stearothermophillus*** spores having spore population of 10^6 spores per strip.

6.3 VALIDATION PLAN AND METHODOLOGY:

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

6.3.1.1 Calibration of Instruments.

6.3.1.2 Clod Chamber Leak Test.

6.3.1.3 Hot Chamber Leak Teat.

6.3.1.4 Steam Qualification Tests (Non Condensable Gases Test, 3 trials on 3 different days).

6.3.1.5 Bowie –Dick Test for Steam penetration (3 trials).

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

6.3.1.7 Loaded Chamber heat penetration studies (3 trials, HPHV) for each sterilization load with temperature mapping probes inside the innermost possible layer of the load subjected for sterilization.

6.3.1.8 Bio-Challenge studies using *Geobacillus stearothermophillus* spore strips (containing more than 10^6 spores) during the loaded chamber heat penetration studies.

6.3.1.9 Estimation of the F_0 value achieved during the sterilization hold period at each temperature-mapping probe.

To qualify the equipment above tests 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.

6.4 CALIBRATION OF INSTRUMENTS:

Instruments required for equipment qualification shall be calibrated at the start and at the end of qualification study as per the respective standard operating procedure of instrument calibration.

Instruments required for qualification

a) Data logger.

b) Thermocouples

Note: Attach the copy of the calibration record.

6.5 COLD CHAMBER LEAK TEST:

6.5.1 Objective

6.5.1.1 Objective of this test is to ensure that the rate of vacuum drop is with in the acceptable limits when the steam sterilizer is operated as per SOP.

6.5.2 Procedure

6.5.2.1 Place minimum 12 no. of Temperature mapping probes (flexible RTDs) into chamber through the validation port of the sterilizer.

6.5.2.2 Seal the port with silicon sealant so that steam leakage does not take place. Place one probe in drain point.

6.5.2.3 Locate the probes in the chamber in such a way that probes do not touch any metallic surface.

6.5.2.4 Connect the probes to a suitable data logger, which can scan temperature from different locations with respect to time at 1-minute interval.

6.5.2.5 Operate Autoclave as per SOP.

6.5.2.6 Ensure the cycle parameters are as follows.

Pre vacuum	: -0.800 bar
Delay time	: 5 minutes
Hold time	: 10 minutes
Process end pressure	: -0. 080bar
Acceptance limit	**: 0.013 bar**

6.5.2.7 Start the Cold Chamber Leak Test and also start the chartless recorder.

6.5.2.8 During vacuum leak test equipment operates in the following steps

1st: Reaches the vacuum level up to – 0.800 Bar and note the reading (P1)

2nd: Hold the vacuum for 5 minutes

3rd: Note the reading (P2) after 5 minutes delay period

4th: Continue holding of vacuum for further 10 minutes

5th: Note the reading (P3) of vacuum after the 10 minutes

6th: Vacuum break starts and reach up to -0.070 Bar

6.5.2.9 Take the print out of vacuum leak test from the equipment printer

6.5.2.10 Equipment operator is to note the pressure of P1, P2 and P3 from print out

6.5.2.11 Calculate the rate of vacuum drop as per the following formula

$$\text{Rate of vacuum drop} = \frac{(P3 - P2) \times 1000}{10}$$

6.5.2.12 Restore the print out and chart to support the vacuum leak test report. Identify the print out and strip chart record with cycle detail i.e. date and cycle code.

NOTE – The vacuum leak test should be performed only when the sterilization chamber is empty, dry and at room temperature.

6.5.2.13 Take three trials of vacuum leak test in three different days.

6.5.3 **Acceptance Criteria:** The rate of vacuum drop should not be more than 1.3 m bar/minute.

6.5.4 **Observation & Results:**
Record the observations in the prescribed format as given in Annexure-I (Summary Report) and enclose reports in Validation Report.

6.6 HOT CHAMBER LEAK TEST:

6.6.1 **Objective**

6.6.1.1 Objective of this test is to ensure that the rate of vacuum drop is with in the acceptable limits when the steam sterilizer is operated as per SOP.

6.6.2 **Procedure**

6.6.2.1 Operate Autoclave as per SOP.

6.6.2.2 Ensure the cycle parameters are as follows.

Pre vacuum	: - 0.200 bar
Delay time	: 3 minutes
Hold time	: 10 minutes
Acceptance limit	**: 0.013 bar**
Process end pressure	: - 0. 080bar

6.6.2.3 Start the Hot Chamber Leak Test and also start the chartless recorder.

6.6.2.4 During vacuum leak test equipment operates in the following steps.

1st : Reaches the vacuum level up to – 0.200 Bar and note the reading (P1)

2nd : Hold the vacuum for 3 minutes

3rd : Note the reading (P2) after 3 minutes delay period

4th : Continue holding of vacuum for further 10 minutes

5th : Note the reading (P3) of vacuum after the 10 minutes

6th : Vacuum break starts and reach up to -0.070 Bar

6.6.2.5 Take the print out of vacuum leak test from the equipment printer

6.6.2.6 Equipment operator is to note the pressure of P1, P2 and P3 from print out

6.6.2.7 Calculate the rate of vacuum drop as per the following formula.

$$\text{Rate of vacuum drop} = \frac{(P3 - P2) \times 1000}{10}$$

6.6.2.8 Restore the print out and chart to support the vacuum leak test report. Identify the print out and strip chart record with cycle detail i.e. date and cycle code.

NOTE – Perform the hot chamber leak test when the chamber is in hot condition.

6.6.2.9 Take three trials of hot chamber leak test in three different days.

Acceptance Criteria: The rate of vacuum drop should be NMT 0.013 bar/minute.

6.6.3 **Observation & Results**

Record the observations in the prescribed format as given in Annexure-II (Summary Report) and enclose reports in Validation Report.

6.7 STEAM QUALITY TESTS (Non-Condensable Gases Test):

6.7.1 **Objective**

6.7.1.1 Objective of this test is to ensure that, the steam, which comes from the boiler of the High Pressure High Vacuum Steam Sterilizer, does not contain non-condensable gases more than the desire level (NMT 3.5%) when measured on-line during the sterilization cycle.

6.7.2 **Procedure**

6.7.2.1 **Test Apparatus:** The apparatus is shown and described in Figure No.1.

6.7.3 **Assembling of the test apparatus:**

6.7.3.1 Connect the needle valve (f) to the steam service pipe as shown in Figure No.1.

6.7.3.2 Assemble the apparatus so that condensate will drain freely from the long rubber (i) tube into the glass sampling pipe (e) with 'U' type end as shown in Figure No 1.

6.7.3.3 Fill the container (d) with cold water until it overflows. Fill the burette (a) and funnel (b) with cold water, invert them and place them in the container (d). Draw out any air that has collected in the burette.

6.7.3.4 While keeping the steam sampling pipe (e) out of the container, open the needle valve and allow steam to purge the air form the pipe.

6.7.3.5 Place the pipe in the container, locate the end within the funnel, and add more cold water until it flows through the overflow pipe (k).

6.7.3.6 Place the empty measuring cylinder (g) under the container overflow.

6.7.3.7 Adjust the needle valve to allow a continuous sample of steam into the funnel sufficient to cause a small amount of "Steam Hammer" to be heard.

6.7.3.8 Ensure that all the steam is discharged into the funnel and does not bubble out into the container.

6.7.3.9 Note the setting of the needle valve. Close the valve.

6.7.3.10 Place a thermometer (j) to dip the tip in the water of container.

6.7.3.11 Ensure that the container is topped up with cold water and that the measuring cylinder is empty. Draw out any air present in the burette. Note the Burette reading.

6.7.4 **Testing:**

6.7.4.1 Ensure that the sterilizer chamber is empty except for the usual chamber furniture. Select and start the operating cycle.

6.7.4.2 When the steam supply to the chamber first opens, open the needle valve (f) to the previously noted setting, allowing a continuous sample of steam into the funnel sufficient to cause a small amount of steam hammer to be heard.

6.7.4.3 Allow the steam sample to condense in the funnel. Any non-condensable gases will rise to the top of the burette. Overspill formed by the condensate and the water displaced by the gases will collect in the measuring cylinder.

6.7.4.4 When the temperature of the water in the container reaches 70-75ºC close the needle valve. Note the reading of the Burette. Note the volume of gas collected in the burette (Vb) as difference between initial and final reading and the volume of water collected in the measuring cylinder (Vc).

6.7.4.5 Calculate the fraction of non-condensable gases as a percentage as follows.

Fraction of non-condensable gases = 100 x (V b/V c).

Note: Carry out the three tests in three different days.

6.7.5 **Acceptance Criteria:**

6.7.5.1 The test should be considered satisfactory if the fraction of non-condensable gases does not exceed 3.5 %.

6.7.5.2 The test should be done two more times to check consistency. If the results of the three tests differ significantly, then the cause should be investigated before proceeding further.

6.7.6 **Observation & Results**

6.7.6.1 Record the observations in the prescribed format as given in Annexure-III (Summary Report) and enclose reports in Validation Report.

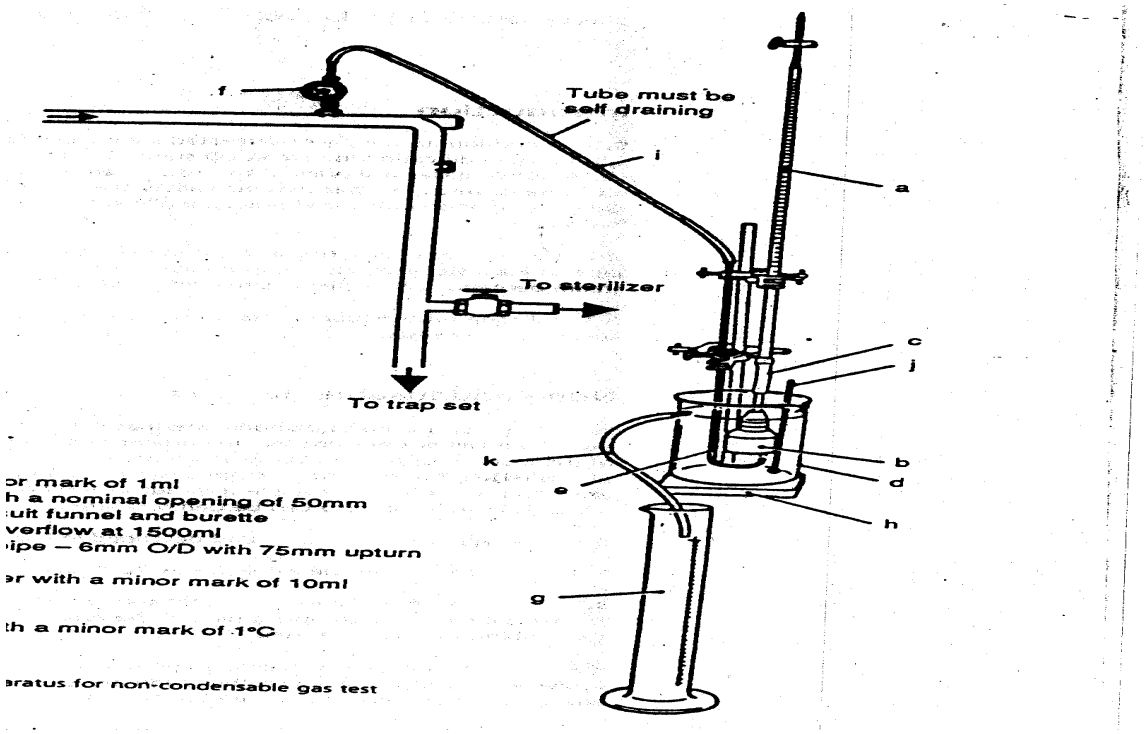

Figure No. 1

6.8 BOWIE – DICK TEST FOR STEAM PENETRATION:

6.8.1 **Objective**

6.8.1.1 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.

6.8.2 **Procedure**

6.8.2.1 Place one Bowie-dick Test Pack in the center of the sterilization chamber Supported approximately 100 to 200 mm above the sterilization chamber Base.

6.8.2.2 Start Chartless Record.

6.8.2.3 Operate the Steam Sterilizer as per the SOP. Ensure the cycle parameters are as follows

Pre Vacuum	:	- 0.75bar
Pre Heat	:	100°c
No. of Pre pulses	:	2 No.s
Ster. Hold Temp.	:	121.3°c
Ster. Hold Time	:	30 minutes.
Over shoot Temp	:	124.0°c
Ster. Stop temp	:	121.0°c
Ster. Reset temp	:	119.0°c
Temp. Control	:	0.3°c
Process end pressure	:	0.08 bar

6.8.2.4 To support the test result preserves equipment print out, chart, Exposed Bowie – Dick test paper.

6.8.3 **Acceptance Criteria**

6.8.3.1 The Bowie-Dick test indicator should show a uniform color change. No change or non-uniform change or air entrapment (bubble) spot on the pattern indicates inadequate air removal from the sterilization chamber.

6.8.3.2 If air is present in the chamber, it will collect within the Bowie-Dick test pack as a bubble. The indicator in the region of the 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.

6.8.4 **Observations & Results.**

6.8.4.1 Record the observations in the prescribed format as given in Annexure – IV. (Summary Report) and enclose reports in Validation Report.

6.9 EMPTY CHAMBER HEAT DISTRIBUTION STUDY:

6.9.1 Types of loads:

3 HPHV - Minimum Load & Maximum load of Empty Chamber.

6.9.2 **HIGH PRESSURE HIGH VACUUM CYCLE:**

6.9.2.1 **Objective**

6.9.2.1.1 To ensure the uniform heat distribution within the empty chamber when ‘HPHV process 1’ is selected for autoclave operation.

6.9.2.2 **Procedure**

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

6.9.2.2.2 Location of the probes are shown in the diagram attached as Attachment.

6.9.2.2.3 Select HPHV Cycle from MMI. Ensure the cycle parameters are as follows:

Pre vacuum	: -0.700 bar
Pre Heat	: 100ºc
No. of pulses	: 2
Sterilization temp	: 121.3ºc
Sterilization time	: 30 min
Temperature control	: 0.5ºc
Over shoot temperature	: 124ºc
Sterilization stop temp	: 121.0ºc
Sterilization reset temp	: 119.0ºc
Post vacuum	: -0.700 bar
Vacuum hold time	: 30 min
Post pressure	: -0.100bar
Post pulses	: 1No.
Process end pressure	: -0.080bar

6.9.2.2.1 Operate the High Pressure High Vacuum Steam Sterilizer as per SOP and also start the data logger to record temperatures with in the sterilization chamber with respect to time.

6.9.2.2.2 When the sterilization cycle completes, collect the printout of the sterilizer and preserve.

6.9.2.2.3 Download the data from chartless recorder into the computer for chart and take the printout.

6.9.2.2.4 Download the data from data logger into the computer for data-analysis and printing.

6.9.2.3 **Acceptance Criteria:**

6.9.2.2.1 The High Pressure High Vacuum Steam Sterilizer should be capable of attaining a temperature of 121ºC during the

sterilization hold period of 35 minutes with steam pressure of approximately 1.2 kg/cm².

6.9.2.2.1 Temperature spread should be uniform in the chamber within the range of 121ºC to 124ºC during sterilization cycle.

Note: The Location(s) where the sterilization temperature of 121ºC achieves lately compare to other locations is called as cold spot. Do not keep any load in cold spot area.

6.9.2.3 **Observations & Results.**

Record the observations in the prescribed format as given in Annexure VI and enclose reports in Validation Report.

6.10 LOADED CHAMBER HEAT PENETRATION STUDIES:

6.10.1 Loaded chamber shall be checked for heat penetration study. If there is any change in the type and number of articles to be loaded, loading diagram will be changed before revalidation. As per the revalidation result the diagrams will be established for routine cycles and accordingly SOP will be changed. In this case protocol will not be revised, as Validation method will be remaining same.

6.10.2 Types of loads:

6.10.2.1 3 HPHV - Minimum Load & Maximum load of Filling Items/Garments/ Filtration Items/Seals.

6.10.3 **HIGH PRESSURE HIGH VACUUM CYCLE:**

6.10.3.1 **Objective:**

6.10.3.1.1 To ensure the uniform heat penetration within the articles placed in chamber when equipment is operated as per standard operating procedure.

6.10.3.2 **Procedure:**

6.10.3.2.1 Record the set parameters for the sterilization cycle to be operated during the test for loaded chamber heat penetration study.

6.10.3.2.2 Place the probes within the loads as deepest position to attain temperature and in the chamber. Location of the probes and load pattern are shown in the diagram attached as Attachment

6.10.3.2.3 Also place biological indicators strips along with locations of temperature mapping probes

(**Spores:** *Geobacillus stearothermophillus*, Spore count: more than per strip)

6.10.3.2.4 Select HPHV process 1 from MMI. Ensure the cycle parameters are as follows:

Pre vacuum	: -0.500 bar
Pre pressure	: 0.500 bar
No. of pulses	: 2
Sterilization temp	: 121.5ºc
Sterilization time	: 30 min.
Temperature control	: 0.5ºc
Over shoot temperature	: 124ºc
Sterilization stop	: 121.0ºc
Sterilization reset temp	: 120.0ºc
Post vacuum	: -0.700 bar
Vacuum hold time	: 30 min
Post pressure	: -0.100bar
Post pulses	: 1No.
Process end pressure	: -0.070bar

6.10.3.2.4 Operate the High Pressure High Vacuum Steam Sterilizer as per SOP and also start the data logger to record temperatures with in the sterilization chamber with respect to time.

6.10.3.2.5 When the sterilization cycle completes, collect the printout of the sterilizer and preserve.

6.10.3.2.6 Download the data from chartless recorder into the computer for chart and take the printout.

6.10.3.2.7 Download the data from data logger into the computer for data-analysis and printing.

6.10.3.2.8 Collect the exposed biological indicators and perform the sterility of Biological indicator with following condition:

Media: Soyabean casein Digest Media

Incubation period: 7 days

Incubation temperature: 57.5±2.5°C

Positive control: Unexposed *Geo Bacillus stearothermophillus* inoculated in Soyabean Casein Digest media incubated at 57.5±2.5°C. Growth should be observed.

Negative control: Sterilized Soyabean casein digest media incubated at 57.5±2.5°C for 14 days. No growth should be observed.

Calculate the Fo value of each location where temperature is monitored by Thermocouples as per the following formula

$$Fo = dt \times \sum 10^{(T-121)/Z}$$

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

6.10.3.4 **Acceptance Criteria**

6.10.3.4.1 The High Pressure High Vacuum Steam Sterilizer should be capable of attaining a temperature of 121ºC during the sterilization hold period of 35minutes with steam pressure of approximately 1.2 kg/Cm2.

6.10.3.4.1 Temperature spread should be uniform in the chamber within the range of 121ºC to 124ºC during sterilization cycle.

6.10.3.4.1 No growth should be observed in all inoculated SCDM tubes.

6.10.3.4.1 Fo value calculated from the temperature data obtained from individual temperature mapping probe should indicate 12 log reduction of bioburden or should be more than the value as calculated as below.

$$Fo = D_{121} \times (\text{Log } A - \text{Log } B)$$

Where

D_{121} : D Value of the Biological Indicator used in the study

A : Spore population in each biological indicator strip

B : Sterility Assurance Level i.e. 10^{-6}

Note: 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.

6.10.3.5 **Observations & Results**

6.10.3.5.1 Record the observations in the prescribed format as given in Annexure VIII and enclose reports in Validation Report.

Note: Study the sterilization cycle duration with in the load with respect to chamber sterilization cycle.

6.10.3 **DETERMINATION OF F_0 VALUE:**

6.10.3.1 The actual observations obtained during the heat distribution and heat penetration studies at different temperature sensing locations were compiled in the table and the observed temperatures were subjected for calculation for F_0 values at that particular location. The calculations are done by using the following formula and the lethality factor computed (during the sterilization period) are given below.

$$F_0 = dt \sum 10^{(T-121)/Z} \quad \text{.....(a)}$$

$$F_0 = dt \sum \text{(Sum of lethality factors)}$$

Where,

dt = The time interval between successive temperature measurements.

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 (10^0C)

6.10.3.2 The minimum F_0 value {by equation (a)} should be more than the biological F_0 for the biological indicator strip exposed for the bio-challenge study. The biological F_0 value for biological indicator strip exposed during the sterilization can be calculated as follows.

$$F_0 = D_{121} (\log A - \log B) \quad \text{..... (b)}$$

F_0 = D value of the biological indicator at 121^0C

A = Biological concentration or spore concentration

B = Desired level of non – sterility

6.10.3.3 **Acceptance criteria:** The minimum calculated F_0 value required for more than 12 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.

6.10.4 **Observations & Results**

6.10.4.1 Record the observations in the prescribed format and enclose reports in Validation Report.

6.10.4.2 Study the sterilization cycle duration with in the load with respect to chamber sterilization cycle.

6.10.5 **Action To Be Taken In Case of Failure:**

6.10.5.1 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:

6.10.5.2 Engineering department will be informed to check the calibration of instruments like temperature indicating probe, Digital temperature indicator, Data logger, 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.

6.10.5.3 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.

6.10.5.4 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

6.10.5.5 If the failure occurred with the cycle of media it will be considered as critical failure as media used for all microbiological testing (e.g. sterility testing), so there is a chance to false interpretation of results.

6.10.5.6 If the failure occurred with the cycles of garments it will be considered as Major failure because it may hamper the environmental conditions of sterility testing area.

6.10.5.7 If failure occurred with the cycles of SS buckets it will be considered as Minor failure because SS containers are used for sanitization purpose only.

6.10.5.8 In case of any failures, cause of failure will be investigated in detail as given below.

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

6.10.7.1 If any probe located inside the media shows the temperature below 121°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.

6.10.7.2 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

6.10.7.3 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.

6.10.8 **Action to be taken in case of major failure:**

6.10.8.1 If any probe located inside the load of Garment shows the temperature below 121°C, data of 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 show required 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.

6.10.7.2 In case the biological indicator shows positive growth, the personnel monitoring data and environmental monitoring data and garment sterilization records of the batches manufactured since last re-validation will be reviewed. If the data and sterilization record is well within the acceptable limits and cycle will be repeated to establish the sterilization parameters.

6.10.9 **Action to be taken in case of minor failure:**

6.10.8.1 If any probe located inside the load of SS buckets shows the temperature below 121°C, data of 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 show required 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.

6.10.8.2 In case the biological indicator shows positive growth, the cycle will be revalidated for reestablishment of sterilization parameters.

6.10.10 **FREQUENCY OF REVALIDATION:**

6.10.10.1 **REVALIDATION SCHEDULE:**

STUDY	VALIDATION FREQUENCY
Calibration of all instruments e.g. Pressure gauge, Temperature gauge.	For Every Six months
Cold Chamber Leak Test	Every Six months three trials
Hot Chamber Leak Test	Every Six months three trials
Test for the presence of non-condensable gases in pure steam used for steam sterilization	Every Six months three trials
Bowie Dick Test (3 Trails)	Every Six months three trials
Empty chamber heat distribution studies (3 cycles)	Every Six months three trials
Loaded chamber heat penetration studies (3 cycles each with specific loading pattern)	Every Six Months three trials for each type of load.

6.10.10.2 **UNSCHEDULED REVALIDATION:**

- 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 promptly documented.
- Revalidation shall be carried out in case of the following.
- Major Maintenance of Major parts.
- Change of cycle program.
- Inclusion of new load.
-

PERFORMANCE QUALIFICATION PROTOCOL OF STEAM STERILIZER (ANTICANCER LYOSECTION)

7.0 RECORDING:

7.1 After completion of each study, a report shall be prepared by the validation team members which shall include the following information.

7.1.1 Tabulated Data.

7.1.2 Trend Analysis Plots.

7.1.3 Validation Team Members and their Signatures.

7.1.4 Conclusions.

7.1.5 Quality Assurance Department Certification.

7.2 Summary Report, which contains

7.2.1 Post Approval

7.2.2 Objective

7.2.3 Brief Validation methodology

7.2.4 Result Summary

7.2.5 Conclusion

8.0 ABBREVIATIONS:

8.1 SCDM → Soyabean Casein Digest medium.

8.2 RTD → Resistance Temperature Device.

8.3 SS → Stainless Steel.

8.4 NMT → Not More Than.

8.5 NLT → Not Less Than.

8.6 SCDM→ Soybean Casein Digest Medium.

8.7 EPQ → Equipment Performance Qualification.

9.0 REFERENCES:

9.1 SOP → Standard Operating Procedure of Autoclave - D

PERFORMANCE QUALIFICATION PROTOCOL OF STEAM STERILIZER (ANTICANCER LYOSECTION)

10.0 REVISION OF PROTOCOL:

10.1 Protocol has been changed due to the incorporation of new protocol numbering system

10.0 ANNEXURES:

10.1 Annexure – I → DATA SHEET FOR HEAT DISTRIBUTION STUDIES

10.2 Annexure – II → DATA SHEET FOR HEAT PENETRATION STUDIES