PERFORMANCE QUALIFICATION PROTOCOL FOR STEAM STERILIZATION USING VERTICAL AUTOCLAVE

1.0 Objective:

To demonstrate that the Autoclave, when operated within specified parameters is capable of sterilizing the load using an overkill approach by establishing that:

1.1 The unit passes the safety checks.

1.2 All automatic controls are operational.

1.3 All instruments and recorders are calibrated.

1.4 Empty chamber heat distribution meets the requirement.

1.5 The thermometric test carried out in garments load are within acceptable limit.

1.6 The Chemical and Biological indicator used in garment should show satisfactory results.

2.0 Scope:

Applicable to Vertical Autoclaves used in Production Department.

3.0 Justification:

Justification for performing the validation to be recorded in the validation report.

4.0 Site of the Study:

Location: to be recorded in Report

5.0 Responsibility:

Representatives from

Production :
Engineering :
Quality Control :
Quality Assurance :
(Individuals name to be recorded in the report)

6.0 Description of the Equipment to be used:

Equipment: AUTOCLAVE (Moist heat steriliser). *

Code No: to be recorded in the report.

** Date of Equipment Qualification done as per protocol to be recorded in report.*

7.0 Standard Operating Procedure (SOP) to be followed:

7.1 SOP for operating Autoclave: SOP No. To be recorded in report.

7.2 SOP for prepration of Sterile Garments: SOP No. to be recorded in the report.

7.3 Microbiological method for use of biological indicators: Reference MM number to be recorded in the report.

8.0 Control:

8.1 Requirements:

8.1.1 Positive and negative controls of chemical indicators and biological indicators (spores of *Geobacillus stearothermophlilus*) Strips/ ampoules.

8.1.2 Biological Indicators should be tested and released by Quality Control.

8.1.3 Batch No. of chemical indicators (strips/ampules) to be recorded in the report.

8.1.4 Batch No. and spores concentration (as per analysis done by micro) of biological Indicator should be recorded in the report.

8.1.5 Auto control through PLC (if applicable) for temperature, time, pressure and sequence of operations.

8.1.6 Not less than 12 calibrated sensors.

8.2 Calibration:

8.2.1 Calibrated thermograph chart recorder code number and calibration details to be recorded in Report.

8.2.2 Calibrated temperature Data Logger and sensor- Code number and Calibration Details to be recorded in Report.

8.2.3 Calibrated pressure gauges- Code number and calibration Details to be recorded in Report.

8.2.4 Calibrated G-tek microprocessor for digital display: Code number and Calibration details to be recorded in the report.

8.3 Training:

8.3.1 Training details of Personnel involved in the validation study to be recorded in the validation report.

8.4 Precautions:

8.4.1 Safety aspects while operation of equipment and process must be ensured.

9.0 Validation Procedure:

Reason for validation: (To be recorded in the report).

Date of validation: (To be recorded in the report).

9.1 Automatic Control Test:

Run all the cycle as per SOP and check all Automatic controls (i.e. sequence of operations) are satisfactory and all safety features are operational. (To be attached with the report)

9.2 Heat distribution in empty chamber:

9.2.1.1 Place at least 12 temperature sensor of the data logger in the following position:

9.2.1.2 One sensor near the controller probe (reference probe)

9.2.1.3 One sensor near the exhaust.
9.2.1.4 One at the approximate center of the chamber.
9.2.1.5 Rest of the sensor should be distributed uniformly throughout the chamber

9.3 Start the sterilization cycle as per SOP and Record the actual time when the reference temperature sensors and the sensors of the digital temperature controller and of the thermograph chart recorder reaches 121°C.

9.4 Acquire the data collected in the cycle from the datalogger and verify the distribution of temperature. Record the equilibration time and the F_o value.

9.5 Chemical indicator and Biological indicator to be placed at the same position as that of the temperature sensor in each of the sterilization cycle and additional four chemical indicators are to be placed randomly in the chamber.

9.6 Repeat the exercise for further two cycles.

9.7 Heat penetration study in Garments and Accessories load:
9.7.1 Place at least 12 temperature sensor of the data logger in the following position:
9.7.1.1 One sensor near the controller probe (reference probe)
9.7.1.2 One sensor near the exhaust.
9.7.1.3 Place the remaining sensor, one in each of the garment and duster, so as to cover all surface and such that they are uniformly distributed throughout the load.

9.7.2 Prepare the garments and accessories load separately as per SOP and keep that load in the autoclave chamber. Place at least 12 temperature sensors at the same location as in the cycle for Heat distribution study – Empty chamber. Care must be taken the ends of the temperature sensors do not come in contact with the wall of the chamber. Note down the location of the temperature sensors with the help of a schematic diagram.

9.7.3 Start the sterilization cycle as per SOP and record the actual time when the reference temperature sensor and the sensors of the digital temperature controller and of the thermograph chart recorder riches 121°C.

9.7.4 Acquire the data collected in the cycle from the datalogger and verify the distribution of Temperature. Record the F_0 value and the equilibration time

9.7.5 Chemical and biological indicator to be placed at the same position as that of the temperature sensor in each of the sterilization cycle and additional four chemical indicators are placed randomly in the chamber.

9.7.6 Incubate Biological Indicators along with the positive control as per the storage condition mentioned in the respective MM. After incubation check the biological indicator strip for turbidity or growth by comparing with positive control.

9.7.7 Perform each cycle separately for Accessories and Garment load.

9.8 Acceptance Criteria:
9.8.1 Automatic control (if applicable):

9.8.1.2 Visual display should indicate cycle completion.
9.8.1.3 During the whole of the cycle, variables as shown on the recorder are within the acceptable limits.

9.8.2 Heat distribution in empty chamber:

9.8.2.1 The hold time, as determined from the measured temperature is not less than the time defined in SOP.

9.8.2.2 Any point during hold period of sterilization cycle, the temperature of all probes should be between the ranges specified in SOP.

9.8.2.3 The equilibration time is not more than 30 second.

9.8.2.4 F_0 value of all sensors should be calculated and minimum F_0 value should be mentioned in the report.

9.8.2.5 At the end of cycle the temperature sensors have remained in position.

9.8.2.6 The chemical indicators show change in colour from purple to green in at least three quadrants.

9.8.3 Heat penetration study in Garments load:

9.8.3.1 The hold time, as determined from the measured temperature is not less than the time defined in SOP.

9.8.3.2 At any point during sterilization hold period, the temperature of all probes should be between the ranges specified in SOP.

9.8.3.3 The equilibration time is not more than 30 second.

9.8.3.4 At the end of the cycle the temperature sensors should remain in position.

9.8.3.5 At the end of drying stage the load should be sensibly dry.

9.8.3.6 F_0 value of all sensors should be calculated and minimum F_0 value should be mentioned in the report.

9.8.3.7 The requirements of the microbiological test should be met as per respective MM.

9.8.3.8 The chemical indicator should show change in colour from purple to green in at least three quadrants.

9.8.3.9 The calibration of all probes after completion should be within the limit.

9.9 Non Compliances:

9.9.1 Details of Deviation:

9.9.1.1 If any of the probes gets opened during validation run, the data from the said probe should not be considered. The total no. of such probes should not be more than 8.

9.9.1.2 Any other deviation should be recorded in the report.

9.9.2 Out of specification:

9.9.2.1 Any out of specification observed should be investigated and reported.

10.0 Type of validation:

10.1 Concurrent / Revalidation (To be recorded in the report)

11.0 Frequency:

11.1 For new load – 3 successful run.

11.2 One validation exercise per six months.

11.2.1 Covering all the load patterns once per year for heat penetration studies.

11.2.2 Covering all the load patterns once per two years for bio – revalidation.

11.3 After major change in equipment, load configuration and process parameters or after any major maintenance of the autoclave.

12.0 Results/Observations:

12.1 Record the observations during the study and results obtained from Quality Control department in the Validation Report.

13.0 Summary of findings of experiment (Inference):

13.1 Summarize the findings of the Validation Study to draw an inference.

14.0 Recommendation:

14.1 Record the recommendations based on the interpretation of the results of the Validation Report.

15.0 Team Approval:

15.1 The individuals who have performed the Validation Study, supervised the validation, completed the records, performed the testing of the product should approve the Validation Report.

16.0 Review:

16.1 The Validation Report should be reviewed by Unit Quality Assurance and Unit Head.

16.2 The report should include any follow-up action if required.

17.0 Protocol Approval:

17.1 Validation protocol and report should be finally approved by Unit Quality Assurance and Unit Head.

18.0 Attachments (if any):

18.1 Annexures (if any) attached to the Validation Report should be recorded.

19.0 Abbreviations:

SOP	:	Standard Operating Procedure
MM	:	Microbiological Method
NRVP	:	Non Routine Validation
SSVA	:	Steam Sterilization using Vertical Autoclave
No.	:	Number

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^{O}C: Degree Centigrade