STEAM STERILISATION USING AUTOCLAVE FOR POROUS AND NON POROUS LOADS

1.0 Objective:

To demonstrate that the Autoclave, when operated within specified parameters is capable of sterilizing the load by establishing that -

1.1 The steam meets the limits of purified water when analysed for chemical and microbial parameters.
1.2 The unit passes the safety checks of pressure vessel.
1.3 All automatic controls are operational.
1.4 All instruments and recorders are calibrated.
1.5 The Vacuum Leak rate test carried out at ambient temperature meets the requirement.
1.6 The Chamber wall temperature test (Empty Chamber Heat Distribution) meets the requirement.
1.7 The thermometric tests carried out in porous and non-porous load are within acceptable limits.
1.8 The Microbiological test carried out in porous and non porous load are within acceptable limits.
1.9 Bowie-Dick test for steam penetration passes.
1.10 F_o value is NLT 30 minutes for porous load and NLT 12 minutes for non-porous loads.

2.0 Site of study:

Unit and Department Name should be recorded in the report.

3.0 Validation Team

Representative from:
Quality Control
Engineering
Quality Assurance
Safety
(Individuals names to be recorded in the report)

4.0 Description of the Equipment to be used :

Equipment: AUTOCLAVE (Moist heat sterilizer).*
Code No: to be recorded in the report.
Calibration: Details to be recorded in the Report.

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

5.0 Standard Operating Procedures (SOP's) and Microbiological methods (MM's) to be followed:

5.1 SOP for testing of steam condensate: SOP No. to be recorded in the report.
5.2 SOP for operating autoclave: SOP No. to be recorded in the report.
5.3 SOP for preparation of Garments for Core Areas: SOP No to be recorded in the report.
5.4 Microbiological method for use of biological indicators: Reference MM number to be recorded in the report.

6.0 Controls :

6.1 Calibrated strip chart recorder- Code number and calibration details to be recorded in Report.

6.2 Calibrated temperature Data Logger- Code number and calibration Details to be recorded in Report. (with not less than 12 sensors).

6.3 Calibrated pressure and temperature gauges- Code number and calibration Details to be recorded in report.

6.4 Calibrated Digital temperature controller: Code number and Calibration details to be recorded in the report.

6.5 Chemical Indicators and positive and negative control of biological indicators (strips / ampoules of Bacillus stearothermophilus). Details of chemical and Biological indicators strips /ampoules to be recorded in the report.

6.6 Auto control through PLC for temperature, time, pressure and sequence of operations.

6.7 After the completion of the cycle only opposite door (Unloading side) opens.

6.8 Ensure that probes do not touch the wall of autoclave and other items in empty chamber and does not touch the side of flask in non porous load.

6.9 All the sensors should be placed in a way that the orientation of probe is in upward direction.

6.10 16 calibrated sensors (NLT 12 sensors should work accurately during validation cycle).

7.0 Procedure:

Reason for validation: (to be recorded in the report)

Date of validation: (to be recorded in the report)

7.1 **Steam Quality:**

7.1.1 Test the steam at the inlet of the Autoclave for Chemical, microbiological analysis as per QC specification for purified water. Record the results in report.

7.1.2 Ensure that all instruments have been calibrated.

7.2 **Automatic Control Test:**

7.2.1 Run all the cycle as per SOP and check all Automatic controls (i.e. sequences of operations) are satisfactory and all safety features are operational.

7.3 **Vacuum leak rate test:**

7.3.1 Carry out leak rate test as per SOP. If leak test passes carry out further steps as per SOP. If leak test fails, rectify leakage before proceeding.

7.4 **Bowie Dick Test for steam penetration:**

7.4.1 Remove the wrapping of a standard Bowie Dick test pack and place the indicator paper in the sheet located nearest to the center of the pack. Reassemble and secure the pack and replace the wrapper. (Alternatively use a ready-made 3 M Bowie-Dick Test pack).

7.4.2 Pack the test pack in the chamber with the bottom of the pack supported 200 mm above the center of the chamber base.

7.4.3 Run the HPHV cycle with a hold time of 16.9 minutes (16.8-17.0) at 121°C.At the end of the cycle remove the indicator tape from the test pack and look for colour change.

7.5 **Chamber wall thermometric and microbiological test: Heat distribution in empty chamber:**

Place 16 temperature sensors in the following positions:

7.5.1 One in an active drain (approximately 10 mm depth from chamber).

7.5.2 Five on chamber side walls (one at the approximate center and four adjacent to the corner positions of the usable chamber space).

Note : Mark the position of the sensor and probes in a detailed schematic diagram so as to replicate the exercise on any future occasion.

7.5.3 One on the plane of the usable chamber space at a point nearest to the steam inlet port.

7.5.4 Chemical & biological indicator ampoules placed at the same positions as that of the temperature sensor in each of the sterilization cycle.

7.5.5 Select the operating cycle that has to be validated and run the same.

7.5.6 Ensure that the recorder fitted to the sterilizer is recording the parameters.

7.5.7 If, the test is satisfactory, repeat two more times to check for reproducibility and establish permitted tolerances.

7.6 **Thermometric test and Microbiological test: Heat penetration study in porous load:**

Load the chamber as per the loading pattern for porous loads in the SOP.
Place temperature sensors in the following positions.

7.6.1 One in active drain (at depth of approximately 10 mm from the chamber) and other probes to be placed at the location depending on the load configuration (Refer annexure)

7.6.2 Locate 15 sensors in different position in the load in different items such that the most difficult to reach location (steam) are covered. eg. Inside of garments, in between the garments, inside of bulbs, tips of pipettes etc.

7.6.3 20 biological indicators (strips of Bacillus stearothermophilus) / chemical indicator to be placed in following manner,

(a) 16 adjacent to the probes.
(b) 4 in the load (at different location from the probe)

7.6.4 Select and start the operating cycle as indicated in the SOP.

7.6.5 Calculate the F_o value of individual sensors. Attach printout of PLC, data logger and strip chart and record to the report. Review the data and fill the report for each cycle. If the test is satisfactory, repeat two more times.

7.6.6 Recalibrate the sensors after completion of validation (If validation is carried on campaign basis for different load, then calibration can be performed after the completion of campaign).

7.7 Thermometric test and Microbiological test : Heat penetration study in non porous load:

Load the chamber as per the loading pattern for nonporous loads in the SOP. Place temperature sensors in the following positions.

7.7.1 One in active drain (at depth of approximately 10 mm from the chamber)
7.7.2 One in each of flasks/bottles which are slowest to attain sterilization temperature (1 litre flask with 600 ml media at different location) in the load.
7.7.3 One in each of the flask / bottles which are fastest to attain sterilization temperature.
7.7.4 Others in different items with in the load, which are slowest to cool at 80°C.
7.7.5 20 biological indicators (ampoules of Bacillus stearothermophilus) to be placed in following manner.
(a) 16 adjacent to the probes.
(b) 4 in the load (at different location from the probe)
7.7.6 Select and start the operating cycle as per SOP.
7.7.7 If the test is satisfactory repeat the exercise twice to establish repeatability.

Note:

- The sensors should be inserted in such a way that they penetrate into medium to be sterilized, do not touch any surface of the container and do not allow steam to penetrate into the containers .
- Biological indicator ampoules to be placed inside the container dipped in the medium.
- The Heat penetration study to be conducted for every load pattern as mentioned in SOP
- Minimum 3 runs for every load pattern to be conducted to establish reproducibility.
- Incase of revalidation where there is no change in load pattern, or process parameters the minimum and maximum loads (worst cases) to be conducted and other loads to be repeated such that all loads are covered in the span of one year.
- The number of sensors used, to depend on the number of items being sterilize sufficient numbers to be used to map all critical items in the load, in case of small load.
- All the cycle should start when temperature of medium under sterilization is at normal loading temperature and at the end of cooling cycle i.e. below 80ºc in the container / items.

8.0 Acceptance criteria:

8.1 **Steam quality:**
The steam condensate should pass when tested as per purified water specification.

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8.2 **Automatic control:**

8.2.1 A visual display should indicate cycle completion.

8.2.2 During the whole of the cycle. Variables as shown on the recorder are within the acceptable limits

8.3 **Vacuum leak rate test:**

8.3.1 The vacuum leak rate does not exceed 1.3 mbar/min.

8.4 **Bowie-Dick test for steam penetration:**

The colour of the indicator spot in the pack should be uniformly black.

8.5 **Chamber wall thermometric and microbiological test: Heat distribution in empty Chamber:**

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

8.5.2 At any point during hold period of sterilization cycle, the temp. of all probes should be between 121-124°C.

8.5.3 The span of temperature during hold period should not be more than 2°C.

8.5.4 The indicated and recorded chamber temperatures are within 1°C of the temperature in active discharge.

8.5.5 F_o value of all sensors should not be less than 12 for 20 minute cycle (hold time).

8.5.6 The temperature sensors have remained in position.

8.5.7 The requirements of the microbiological test as per MM-07 are met.

8.5.8 The chemical indicators show change in colour, from yellow to purple.

8.5.9 The calibration of probes after completion should be within the limit (Ref. Attached annexure).

8.6 Thermometric and Microbiological test : Heat penetration in porous load:

8.6.1 The hold time, as determined from the measured temperature is not less than the hold time mentioned in SOP (set in the operating cycle).

8.6.2 At any point during hold period of sterilization cycle, the temp. of all probe should be between 121-124°C.

8.6.3 The span of temperature during hold period should not be more than 2°C.

8.6.4 The indicated and recorded chamber temperatures are within 1°C of the temperature in active discharge.

8.6.5 Equilibration time is not more than 30 sec.

8.6.6 F_o value of all sensors should not be less than 30 min.

8.6.7 The temperature sensors have remained in position at the end of the cycle.

8.6.8 The items containing sensors are intact at the end of the cycle.

8.6.9 The requirements of the microbiological test are met.

8.6.10 The chemical indicators show change in colour, from yellow to purple.

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

8.7 **Thermometric and Microbiological test: Heat penetration in non-porous load:**

8.7.1 The requirement of the automatic control test are met i.e. the PLC control the cycle automatically as per the sequence and all the relevant control values and instruments functions as desired.
8.7.2 The holding time is not less than specified in the SOP / PLC setting for that load.
8.7.3 During hold time the measured temperature is the sterilization band of 121°C-124°C.
8.7.4 The measured temperatures are within 1°C of each other.
8.7.5 The indicated and recorded chamber temperatures are within 1°C of the temperature measured in the active drain.
8.7.6 F_o value of all sensors should not be less than 12.
8.7.7 The temperature sensors have remained in position at the end of the cycle.
8.7.8 The items containing sensors are intact at the end of the cycle.
8.7.9 The requirements of the microbiological test as per MM-07 are met.
8.7.10 The chemical indicators show change in colour, from yellow to purple.
8.7.11 The calibration of probes after completion should be within the limit.

8.8 **At the end of the cycle :**

8.8.1 The temperature sensors has remained in position.
8.8.2 The container containing the sensors have not cracked, broken.
8.8.3 The temperature measured in the bottles is not greater then 80°C.
8.8.4 The total cycle is consistence in all three times.

9.0 Non compliance:

9.1 **Deviation:**

9.1.1 If any of the probe gets opened (electrically) during validation run, the data from the said probe should not be considered.
9.1.2 The total no. of such probes should not be more than 4 out of 16 probes.
9.1.3 An initial over shoot of temperature upto 5°C can be considered acceptable.
9.1.4 Any other deviation should be recorded in the report.

9.2 **Out of Specification:**

Any out of specification observed should be investigated and reported.

10.0 Training:

Personnel involved in the execution of this protocol should been trained.

11.0 Type of validation:

Concurrent validation.

12.0 Frequency:

12.1 For new load – 3 successful run
12.2 One validation exercise per six months. (OR)

12.3 After major change in equipment, load configuration and process parameters. (OR)
12.4 After any major maintenance of the autoclave.

13.0 Summary of Findings of Experiment (Inference):
Summarize the reports of all the runs of the validation campaigns and make a report tabulating the critical variables.

14.0 Results:
Record the observations during the study.

15.0 Team approval:
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 (inclusive of follow up action, if any):
The Validation Report should be reviewed by Unit Quality Assurance and Unit Head. The report should include any follow up action, if required.

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

18.0 Abbreviations:
18.1) EOP- Equipment operating procedure.
18.2) SOP- Standard operating procedure.
18.3) PLC- Programmable logic control.

19.0 Reference:
I EOP / SOP of Autoclave operation No. _____.
ii Health Technical Memorandum 2010 , Bowie–Dick test for Steam penetration 13.39
iii Microbiological Method for Biological indicator.
Iv Microbiological Method for Media Preparation.