PERFORMANCE QUALIFICATION REPORT 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 is within acceptable limit.

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

2.0 Scope:

Applicable to Autoclaves used in Production Department.

3.0 Justification:

4.0 Site of the Study:

Location: _____

5. Responsibility:

Representatives from

Production : _____

Engineering : _____

Quality Control : _____

Quality Assurance : _____

6.0 Description of the Equipment to be used:

Equipment: AUTOCLAVE (Moist Heat Sterilizer).

Code No.: _____

Equipment qualification done on date: _____

7.0 Standard Operating Procedure (SOP) to be followed:

7.1 For operating autoclave: SOP No.: _____.

7.2 SOP for preparation of Sterile garments: SOP No.: _____.

7.3 MM for use of biological indicators. _____

Reference MM validation protocol number: _____.

8.0 Control:

8.1 Requirements:

Positive and negative controls of chemical (Steamclox) and biological (ampoules / strips of *Geobacillus stearothermophlilus*) indicators.

i) Biological indicators tested and released by Quality Control.

	Chemical indicator	Biological Indicator (Ampoules/ Strips)
Manufacturers name		
Lot No.		
Mfg. Date.		
Exp. Date		
A.R No.	-----	
Spore concentration	-----	

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

8.2 Calibration:

i) Calibrated thermograph chart recorder-Code no.: _____; Calibration Done on: _____, due on: _____

ii) Calibrated temperature data logger
Code No.: _____ ;
Calibration Done on: _____, Due on: _____

iii) Calibrated temperature sensors-
Before validation: _____ After Validation:_____

iv) Calibrated pressure gauges / Digital Pressure Indicator.

Code no.: _____ ;

Calibration Done on: _____, Due on: _____

All calibration reports are attached as an annexure no._____

8.3 Training:

Name	Training status	Training report availability	Checked by

8.4 Precautions:

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

Checked By/ Date:_____

9.0 Validation Procedure:

9.1 Carry out the Validation Procedure as per the Protocol No: .....

Date of validation:_____

10.0 Acceptance Criteria:

10.1 Automatic control:

10.1.1 A visual display should indicate cycle completion.

10.1.2 During the whole of the cycle, variables as shown on the recorder should be within the acceptable limits.

10.2.0 Heat distribution in empty chamber:

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

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

10.2.3 Equilibrium time is not more than 30 second.

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

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

10.2.6 Chemical indicators show change in colour from purple to green in at least three quadrants.

10.3.0 Heat penetration study in Garments and Accessories load:

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

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

10.3.3 The equilibration time is not more than 30 second.

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

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

10.3.6 The requirements of the microbiological test as per MM_____ should be met.

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

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

11.0 Non Compliances :

11.1 Details of Deviation:

Deviation Report dated	Checked by

11.2 Out of specification:

OOS Report dated	Checked by

12.0 Type of validation:
Concurrent / Revalidation.

13.0 Frequency:

13.1 New load – 3 successful run.

13.2 One validation exercise per six months.

13.2.1 Covering the entire load patterns once per year for heat penetration Studies.

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

13.3 After major change in equipment, load configuration and process parameters.

(OR)

13.4 Any major maintenance of the autoclave.

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14.0 Results/Observations:

Equipment No. :_____

Date/s of Validation : _____

14.1 Automatic control test:

14.1.1 All cycle run as per SOP No.: _____.

Found satisfactory / not satisfactory.

14.1.2 Visual display of cycle complete: Yes / No

14.2 Heat distribution in empty chamber:
Load description_____

Parameter	**Cycle I** Date: _____		**Cycle II** Date: _____		**Cycle III** Date: _____	
	From	**To**	**From**	**To**	**From**	**To**
1. Cycle description						
Cycle started at	_____	____	_____	____	_____	____
Sterile hold start	_____	____	_____	____	_____	____
Sterile hold completed	_____	____	_____	____	_____	____
Cycle completed at	_____	____	_____	____	_____	____
2. Sterile hold period						
3. Time of First probe to reach at121^{o}C temperature						
4. Time of Last probe to Reach at 121^{o}C temperature						
5. Equilibrium Time. (NMT 30 sec)						
6. Temperature range During hold period (121^{o}C-124^{o}C)						
7. Indicated and recorded chamber pressure (NLT 15 PSI)						
8. Minimum F_0 value						
9. sensor are in position after cycle						
10. Thermograph chart recorder is attached as	Annexure No. _____		Annexure No. _____		Annexure No. _____	
11. Schematic and data of Temperature reading of data logger is attached as	Annexure No. _____		Annexure No. _____		Annexure No. _____	
12. Observation on chemical indictor strip for required colour change is attached as	Annexure No. _____		Annexure No. _____		Annexure No. _____	

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Parameter	Cycle I Date: _____	Cycle II Date: _____	Cycle III Date: _____
13. Result of exposed biological indicator after incubation is attached as	Annexure No. _____	Annexure No. _____	Annexure No. _____
14. Checked By			

14.3 Heat penetration study in Garments load:

Load description _____

Parameter	Cycle I Date: _____		Cycle II Date: _____		Cycle III Date: _____	
	From	**To**	**From**	**To**	**From**	**To**
1. Cycle description						
Cycle started at	_____	____	_____	____	_____	____
Sterile hold start	_____	____	_____	____	_____	____
Sterile hold completed	_____	____	_____	____	_____	____
Cycle completed at	_____	____	_____	____	_____	____
2. Sterile hold period						
3. Time of First probe to reach at121^{o}C temperature						
4. Time of Last probe to Reach at 121^{o}C temperature						
5. Equilibrium Time. (NMT 30 sec)						
6.Temperature range During hold period (121^{o}C-124^{o}C)						
7.Indicated and recorded chamber pressure (NLT 15 PSI)						
8.Minimum F_0 value						
9.sensor are in position after cycle						
10.Thermograph chart recorder is attached as	Annexure No. _____		Annexure No. _____		Annexure No. _____	
11.Schematic and data of Temperature reading of data logger is attached as	Annexure No. _____		Annexure No. _____		Annexure No. _____	
12.Observation on chemical indictor strip for required colour change is attached as	Annexure No. _____		Annexure No. _____		Annexure No. _____	
13. Result of exposed biological indicator after incubation is attached as	Annexure No. _____		Annexure No. _____		Annexure No. _____	
14. Checked By						

14.4 Heat penetration study in Accessories load:

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Load description _____

Parameter	Cycle I Date: _____	Cycle II Date: _____	Cycle III Date: _____
	From To	**From To**	**From To**
1. Cycle description Cycle started at Sterile hold start Sterile hold completed Cycle completed at	_____ ____ _____ ____ _____ ____ _____ ____	_____ ____ _____ ____ _____ ____ _____ ____	_____ ____ _____ ____ _____ ____ _____ ____
2. Sterile hold period			
3. Time of First probe to reach at 121°C temperature			
4. Time of Last probe to Reach at 121°C temperature			
5. Equilibrium Time. (NMT 30 sec)			
6. Temperature range During hold period (121°C-124°C)			
7. Indicated and recorded chamber pressure (NLT 15 PSI)			
8. Minimum F_0 value			
8. sensor are in position after cycle			
10. Thermograph chart recorder is attached as	Annexure No. _____	Annexure No. _____	Annexure No. _____
11. Schematic and data of Temperature reading of data logger is attached as	Annexure No. _____	Annexure No. _____	Annexure No. _____
12. Observation on chemical indictor strip for required colour change is attached as	Annexure No. _____	Annexure No. _____	Annexure No. _____
13. Result of exposed biological indicator after incubation is attached as	Annexure No. _____	Annexure No. _____	Annexure No. _____
14. Checked By			

15.0 Summary of findings of experiment (Inference):

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16.0 Recommendation:

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17.0 Team Approval:

_____	_____	_____	_____
Production	Quality Control	Engineering	Quality Assurance

Date:

18.0 Review (inclusive of follow up action if any):

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19.0 Approved by: **Noted by:**

_____	_____
UNIT QUALITY ASSURANCE HEAD	UNIT HEAD

Date:

20.0 Annexures (if any):

21.0 Abbreviations:

No.	:	Number
SOP	:	Standard Operating Procedure
NLT	:	Not Less Than
MM	:	Microbiological Method
PLC	:	Programmable Logic Control
QC	:	Quality Control
Mm	:	Millimeter
^0C	:	Degree Centigrade
WFI	:	Water for Injection
Mm Hg/min	:	Millimeter of mercury per minute
Kg/cm^2	:	Kilogram per square centimeter
NRVR	:	Non Routine Validation Report
Mfg	:	Manufacturing
A.R.	:	Analytical Report
Exp.	:	Expiry
Ver.	:	Version
OOS	:	Out of Specification
PSI	:	Per Square Inch
NMT	:	Not More Than

sec : Second