PERFORMANCE QUALIFICATION PROTOCOL FOR HORIZONTAL AUTOCLAVE

Pre - Execution Approval

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				

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1.0 Objective:

- To establish documented evidence which will provide a High degree of assurance and reliability about the performance of the Autoclave.
- To determine that the Autoclave performs as intended by repeatedly running the system on its intended schedules and recording all relevant information and data. Results must demonstrate that performance consistently meets predefined specifications under normal conditions and where appropriate for worst case situations.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	**Autoclave**
ID Number	**…….**
Location	**Media Preparation Room**

3.0 Performance Verification Checklist:

Verify the performance of all the critical process/functions as per their respective procedure. Refer Performance Verification Checklist as per Annexure - I.

4.0 Any Changes/Deviations identified during operating checks:

Refer Annexure – II.

5.0 Recommendations and Conclusions:

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6.0 References:

Design Qualification

Installation Qualification

Operational Qualification

Standard Operating Procedure

7.0 Annexure

Annexure - I : Performance Verification Checklist

Annexure - II : List of Changes / Deviation.

Annexure - III : Performance Qualification Protocol and Report.

8.0 Abbreviations:

SOP : Standard Operating Procedure

Post execution approval:

	Name	Designation	Signature	Date
Compiled By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				

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Annexure - I
Checklist for Performance Verification

Performance Verification of Horizontal Autoclave					
S.No.	**Verification Detail**	**Acceptance Criteria**	**Observation**	**Remarks**	**Verification Done By**
1.	Vacuum Leak Test	The vacuum leak rate should not exceed 1.0 mmHg/min.			
2.	Bowie-Dick test for steam penetration	The Bowie-Dick Test indicator should show a uniform colour change, from yellow (Initial) to purple (Final), after sterilization.			
3.	Temperature distribution study in empty chamber at 121°C for 45 minutes (Garment & Component cycle)	During hold period of sterilization cycle, the temp. of all probes should be between 121.0 to 124 ^{0}C.			
4.	Temperature distribution study in empty chamber at 121°C for 30 minutes (Gravity cycle)	During hold period of sterilization cycle, the temp. of all probes should be between 121.0 to 124 ^{0}C.			
5.	Temperature penetration study with Minimum and Maximum loads at 121°C for 45 minutes (Garment and Component cycle)	During hold period of sterilization cycle, the temp. of all probes should be between 121.0 to 124 ^{0}C.			
6.	Temperature penetration study with Minimum and Maximum loads at 121^{0}C for 30 minutes (Gravity cycle)	During hold period of sterilization cycle, the temp. of all probes should be between 121.0 to 124 ^{0}C.			

Note:

Remarks: Performance Verification of Horizontal Autoclave - Complies / Does not comply.

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Annexure - II

List of Changes / Deviations

S.No.	Description of Change / Deviations	Justification based on impact analysis

Verified By:

Approved By: