



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

PERFORMANCE QUALIFICATION PROTOCOL FOR VERTICAL AUTOCLAVE

Pre - Execution Approval

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



PERFORMANCE QUALIFICATION PROTOCOL FOR VERTICAL AUTOCLAVE

1.0 Objective:

- To establish documented evidence which will provide a High degree of assurance and reliability about the performance of the Vertical Autoclave.
- To determine that the Vertical 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	Vertical Autoclave
ID Number
Location	Wash 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:

- 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 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

Temperature Mapping of Vertical Autoclave					
Cycle No.	Set Temperature	Acceptance Criteria	Temperature Mapping Result	Remarks	Verification Done By

Note:

Remarks: - Performance Verification of Vertical 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: