



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

OPERATIONAL QUALIFICATION PROTOCOL FOR VERTICAL AUTOCLAVE

Pre - Execution Approval

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



OPERATIONAL QUALIFICATION PROTOCOL FOR VERTICAL AUTOCLAVE

1.0 Objective:

- To determine that the equipment operates according to specifications, and to record all relevant information's and data to demonstrate its functions as intended for.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	Vertical Autoclave
ID Number	
Location	Wash Room

3.0 Checklist for Operational verification:

Operation of Vertical Autoclave is verified for the compliance with the critical parameters mentioned in the Functional Specification. Sequentially prepare the list of operating checks specifying critical parameters, perform them as per operating procedure as mentioned in the vender operating manual & document the same in the attached check list (Annexure - I).

4.0 Any Changes/Deviations identified during operating checks:

Refer Annexure – II

5.0 Identification & preparation of Standard Operating Procedures:

Prepared the SOP for operation, cleaning and calibration of Vertical Autoclave using the actual feedback from the operation checks and vendor-operating manual. The preventive maintenance procedure and schedule shall be applicable as per Annual Maintenance Contract of QC Instrument.

<u>S. No.</u>	<u>SOP Title</u>	<u>SOP Number</u>
1.	Operation, cleaning and calibration of Vertical Autoclave

6.0 Training



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The List of QC (Microbiology) person trained during the operation qualification of Vertical Autoclave is listed as per Annexure - III.

7.0 Recommendations and Conclusions:

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8.0 References:

- Installation Qualification
- Operating Manual submitted by the Vendor.

9.0 Annexure

- Annexure - I : Checklist for Operational Verification.
- Annexure - II : List of Changes / Deviation.
- Annexure - III : Training Detail

10.0 Abbreviations:

- SOP : Standard Operating Procedure
- QC : Quality Control

Post execution approval:

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



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Annexure - I

Checklist for Operational Verification

S.No.	Operating Parameters	Function	Observation	Remarks
A.	Control Panel Testing			
1.	Mains key	To start the machine		
2.	MAINS Button	To start the front panel of the machine		
3.	Program Key	For setting the temperature		
		For setting the Cycle Duration - Time Setting		
		For Calendar Setting (Time/Year/Date)		
		For Setting of Baud Rate		
4.	(▲) UP & (▼) Down Key	For increase or decrease the value of digit		
5.	Start/ Stop Key	For start or stop the cycle		
6.	Enter Key	For accept the change done		



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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:



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Annexure - III

Training Detail

S.No.	Name of Trainee	Name of Trainer

Verified By:

Approved By: