



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

OPERATIONAL QUALIFICATION PROTOCOL FOR HORIZONTAL AUTOCLAVE

Pre - Execution Approval

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



OPERATIONAL QUALIFICATION PROTOCOL FOR HORIZONTAL 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	AUTOCLAVE
ID Number
Location	Media Preparation Room

3.0 Checklist for Operational verification:

Operation of 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 vendor 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 Moist Heat Sterilizer 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 Moist Heat Sterilizer



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6.0 Training

The List of QC (Microbiology) person trained during the operation qualification of 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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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 Knob ON/OFF	For start the control panel of autoclave		
2.	Door -1 Gasket Seal On / OFF	For On or Off the gasket seal of Door - 1		
3.	Door - 2 Gasket Seal On / OFF	For On or Off the gasket seal of Door - 2		
4.	Door -1 Gasket Release On / OFF	For Releasing of Door - 1gasket		
5.	Door - 2 Gasket Release On / OFF	For Releasing of Door - 2 gasket		
6.	Steam to Gasket On / OFF	For supply of steam to Gasket		
7.	Steam to Chamber On / OFF	For supply of steam to Chamber		
8.	Venting On / OFF	For Venting		
9.	Condensate ON / OFF	For Releasing of condensate		



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S.No.	Operating Parameters	Function	Observation	Remarks
A.	Control Panel Testing			
10.	Vacuum Release ON / OFF	For Releasing of Vacuum from Chamber		
11.	Chamber Vacuum ON / OFF	For Supply of Vacuum in Chamber		
12.	Vacuum Pump ON / OFF	For Supply of Vacuum in Chamber		
13.	Door -1 Open / Close	For opening and closing of door -1		
14.	Door - 2 Open / Close	For opening and closing of door - 2		
15.	Green Push Button (Door - 1 Open)	For opening of Door - 1		
16.	Red Push Button (Door - 1 Close)	For closing of Door - 1		
17.	Red Push/Turn Button (Emergency)	For stop in case of emergency		
18.	Yellow Press Button (Skip)	For skip the setting in operation mode		
19.	Red Indicator (Opposite Door Open)	Indicator show that opposite door is open		
20.	Auto / Manual	For operate the autoclave in Auto or in Manual Mode		



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S.No.	Operating Parameters	Function	Observation	Remarks
B.	PID Controller			
1.	▲	For increasing value		
2.	▼	For decreasing the value		
3.	◀	For shifting from one value to other value		
4.	F/S	For Set the change value		
C.	PLC Control panel			
1.	Shift	For given command to the cycle		
2.	Enter	To save the changes		
3.	Esc	To come in to previous menu or screen		
4.	▲	For movement from one parameter to next parameter		
5.	▼	For movement from one parameter to next parameter		



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S.No.	Operating Parameters	Function	Observation	Remarks
D.	Chart Recorder			
1.	RCD	To start printing on graph		
2.	DISP (Esc)	To display of various parameter		
3.	Print ▲	To scroll for next setting		
4.	FED ▶	To scroll for next setting		
5.	CH UP ▲	To save the changes		



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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: