



OPERATIONAL QUALIFICATION PROTOCOL FOR HORIZONTAL LAMINAR FLOW UNIT

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 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	Horizontal Laminar Flow Unit
ID Number
Location	Sterility Testing Room

3.0 Checklist for Operational verification:

Operation of Horizontal Laminar Flow unit 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 Laminar Bench 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 Laminar Bench

6.0 Training



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The List of QC (Microbiology) person trained during the operation qualification of Horizontal Laminar Flow unit cabinet 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:

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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 main Power supply of the Instrument		
2.	POWER button	To start the Instrument		
3.	Air Flow Button	To start the Air flow of the Instrument		
4.	Light Button	To start the Light		
5.	U.V. Light Button	To start the U.V. Light		
6.	Fault Acknowledgement Button	To accept or reset the Fault		



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Annexure - II

List of Changes / Deviations

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

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Annexure - III

Training Detail

S.No.	Name of Trainee	Name of Trainer

Verified By:

Approved By: