



OPERATIONAL QUALIFICATION PROTOCOL FOR STATIC PASS BOX

Pre - Execution Approval

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



OPERATIONAL QUALIFICATION PROTOCOL FOR STATIC PASS BOX

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	Static Pass Box
ID Number
Location	Cooling Zone to Sterility Testing Room

3.0 Checklist for Operational verification:

Operation of Static Pass Box 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 Pass Box 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 Pass Box

6.0 Training



OPERATIONAL QUALIFICATION PROTOCOL FOR STATIC PASS BOX

The List of QC (Microbiology) person trained during the operation qualification of Static Pass Box cabinet is listed as per Annexure - III.

7.0 Recommendations and Conclusions:

.....
.....
.....
.....

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				
Reviewed By				
Reviewed By				
Approved By				



OPERATIONAL QUALIFICATION PROTOCOL FOR STATIC PASS BOX

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 power (Red indication)		
3.	Release Door Button	To Release the door		
4.	Null Alarm	For Alarm		
5.	Door Locked Indicator	Red indication of door locked		
6.	Door Release Indicator	Green indication of door release		
7.	Opposite Door open Indicator	Indicate that opposite door is open		
8.	U.V.Light Button	To Start the U.V.Light		



OPERATIONAL QUALIFICATION PROTOCOL FOR STATIC PASS BOX

Annexure - II

List of Changes / Deviations

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

Verified By:

Approved By:



OPERATIONAL QUALIFICATION PROTOCOL FOR STATIC PASS BOX

Annexure - III

Training Detail

S.No.	Name of Trainee	Name of Trainer

Verified By:

Approved By: