

MICROBIOLOGY DEPARTMENT

## OPERATIONAL QUALIFICATION PROTOCOL FOR GARMENT STORAGE CUBICLE

### **Pre - Execution Approval**

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

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#### OPERATIONAL QUALIFICATION PROTOCOL FOR GARMENT STORAGE CUBICLE

#### 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	Garment storage Cabinet
ID Number	•••••
Location	Change Room

#### 3.0 Checklist for Operational verification:

Operation of Garment Storage cabinet 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 Cleaning, operation and maintenance of Garment Storage cabinet 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>	SOP Title	SOP Number
1.	Cleaning, Operation and Maintenance Of Garment Storage Cabinet	
6.0 Training	5	

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The List of QC (Microbiology) person trained during the operation qualification of Garment Storage 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				
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Reviewed By				
Approved By				



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## OPERATIONAL QUALIFICATION PROTOCOL FOR GARMENT STORAGE CUBICLE

#### Annexure - I

### **Checklist for Operational Verification**

S.No.	Operating Parameters	Function	Observation	Remarks
Α.		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.	Heater Button	To start the Heating		
5.	U.V Light Button	To start the U.V.Light		



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#### Annexure - II

#### **List of Changes / Deviations**

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

Verified 1	By:
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**Approved By:** 



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#### Annexure - III

#### **Training Detail**

S.No.	Name of Trainee	Name of Trainer

Verified By:

**Approved By:**