



OPERATIONAL QUALIFICATION PROTOCOL FOR BACTERIOLOGICAL INCUBATOR

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	Bacteriological Incubator
ID Number
Location	Incubation Room

3.0 Checklist for Operational verification:

Operation of Bacteriological Incubator 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, sanitization and monitoring of Bacteriological Incubator 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, Sanitization and Monitoring of Bacteriological Incubator	



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6.0 Training

The List of QC (Microbiology) person trained during the operation qualification of Bacteriological Incubator 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.	Main Power Switch on the front panel of the instrument	To start the Instrument		
3.	Red Light Indicator	To indicate that Incubator is start		
4.	Digital Temperature controller	After start of incubator Digital Temperature controller display the last set temperature as green and actual temperature as red colour		
5.	▲ (Up key)	For Increasing the temperature		
6.	▼ (Down Key)	For Decreasing the temperature		
7.	◀ (Shift Key)	For shifting from one digit to another digit		
8.	Set Key	To save the change		



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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:

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