



INSTALLATION QUALIFICATION PROTOCOL FOR BACTERIOLOGICAL INCUBATOR

Pre - Execution Approval

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



INSTALLATION QUALIFICATION PROTOCOL FOR BACTERIOLOGICAL INCUBATOR

1.0 Objective:

The purpose of installation qualification is as follows

- To provide documented evidence that the mentioned Bacteriological Incubator is installed as per design.
- To ensure that the Bacteriological Incubator installed confirms to purchase specifications and manufacturer literature, and to document the information that the Bacteriological Incubator meets the specification.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	Bacteriological Incubator
ID Number
Location	Incubation Room

3.0 Equipment / System Description:

Bacteriological Incubator are used for incubation of culture media, culture organisms at set temperature. Its internal surface consists of SS 304 /Mirror polish. Bacteriological Incubator is equipped with PC communication for continuous monitoring of temperature.

4.0 Checklist for Preinstallation verification:

The purpose of the checklist is to confirm the availability of required documents for installation and to verify the availability of components and parts as per the approved purchase order in presence of the technical personnel of the vendor.

Preinstallation verification checklist is enclosed as Annexure - I.



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5.0 Checklist for Installation verification:

Installation of Bacteriological Incubator shall be verified for the compliance with the critical parameters mentioned in the Functional Design Specification.

The purpose of this checklist is to check and document the received material and installation at site with respect to drawings, details, and data sheets approved during DQ and GEP. GEP considers the basic engineering requirements for skilful maneuvering, means those methods and practices, which the administrator determines to be consistent with scientific and engineering principles.

Installation verification checklist is enclosed as Annexure - II.

6.0 Any Changes identified towards equipment design / lay out.

Refer Annexure - III.

7.0 Recommendations and Conclusions:

8.0 References:

Comparison sheets of incubators (already available with Design Qualification)

Packing list supplied by vendor (Not applicable).

List of spares (Not applicable).

Installation Qualification submitted by vendor.

Impact Assessment analysis.

9.0 Annexure

Annexure - I : Check list for Preinstallation Verification.

Annexure - II : Check list for Installation Verification.

Annexure - III : List of Changes / Deviation.

Annexure - IV : Installation Qualification Submitted by the vendor.

Annexure - V : Impact Assessment Analysis.

Annexure - VI : Summary Report of Installation Qualification



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10.0 Abbreviations:

- IQ** : Installation Qualification
- DQ** : Design Qualification

Post execution approval:

	Name	Designation	Signature	Date
Compiled By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



INSTALLATION QUALIFICATION PROTOCOL FOR BACTERIOLOGICAL INCUBATOR

Annexure - I

Checklist for Preinstallation Verification

S.No.	Main Components Accessories / Documents	Code / Doc No.	Actual	Remarks
1.	Comparison sheets of incubators	Not Applicable		
2.	Vendor's Name	Equichem CIEM Incl. Estate, Malad (W.) Mumbai.		
3.	Instrument Make	EQUICHEM		
4.	Instrument Model No.		
5.	Design qualification Reference	Comparison Sheet and manual provided by the vendor/ supplier		
6	Instrument Manual submitted by the vendor	Instrument Manual submitted by the vendor		



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Annexure - II

Checklist for Installation Verification

S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	Equipment /Instrument specific details			
1.	Capacity	Should be 90 Liters		
2.	Internal Chamber (MOC)	Should be SS 304, Mirror polish		
3.	Internal Chamber Dimension (WXDXH)	Should be 450 X 450 X 450 mm		
4.	Inner Chamber MOC	Should be SS 304		
5.	Inner Door	Should be Magnetic door gasket, inner transparent door		
6.	Outside MOC	Should be SS304, Exhaust vent, test port blocker, door lock studs made of SS304		
7.	Insulation	Should be PUF/Glass wool		



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S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	Equipment /Instrument specific details			
8.	Controller	Should be Microprocessor based temp. Controller, Auto tuning. Dual digital display of output – set and Actual, SSR o/p.		
9.	Trays (No. and MOC)	Should be 2 Nos.SS 304		
10.	Heating	Should be SS encapsulated nichrome wire tubular heater motor shaft made of SS.		
11.	Compressor	Should be Hermetically sealed compressor, Electronic time delay provided to safeguard compressor		
12.	Illumination	Should be provide		
13.	Sensor probe	Should be High responsive and accurate sensing platinum 100hrms RTD Sensor.		



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S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	Equipment /Instrument specific details			
14.	Relay	Electric circuit breaker Should be provided		
15	Communication	PC communication via 485 (13050) should be provided		
16.	Blower	Chamber re - circulation blower should be provided		
17.	Heating System	Electric Heater should be provided		
B.	Location suitability			
1.	Location	Should be place in Incubation Room - I		
C.	Utilities			
1.	Electrical Supply	230 VAC, 50HZ – 16A, ± 5 %, 700 Watts Supply should be provided		



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S.No.	System Data	Acceptance Criteria	Actual	Remarks
D.	Safety			
1.	Alarm	Temperature Overshoot alarm should be provided		
E.	MOC Certificates	Should be provided		
F.	Calibration Certificates	Should be provided		
G.	Testing Certificates	Should be provided		
H.	Drawing Details	Drawing No.		
1.	Not Applicable	Not Applicable		



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Annexure - III

List of Changes / Deviations

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

Verified By:

Approved By:



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Annexure - VI

Summary Report of Installation Qualification

Checks	Observations (Yes / No)	Reviewed By Sign / Date
All test procedures executed and verified as per the protocol.		
All criteria set forth in the installation qualification were met.		
Deviation if any		

Summary:

Summary Report Prepared By:

Date & Sign