



## INSTALLATION QUALIFICATION PROTOCOL FOR BOD INCUBATOR

#### **Pre - Execution Approval**

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



## PHARMA DEVILS MICROBIOLOGY DEPARTMENT

#### INSTALLATION QUALIFICATION PROTOCOL FOR BOD INCUBATOR

#### 1.0 Objective:

The purpose of installation qualification is as follows

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

#### 2.0 Scope:

#### Scope is limited to the following

Equipment / System Name	BOD Incubator
ID Number	
Location	Incubation Room

#### 3.0 Equipment / System Description:

BOD Incubator are used for incubation of culture media, culture organisms at set temperature. It internal surface is consist 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.



#### INSTALLATION QUALIFICATION PROTOCOL FOR BOD INCUBATOR

#### **5.0 Checklist for Installation verification:**

Installation of BOD 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:




#### MICROBIOLOGY DEPARTMENT

### INSTALLATION QUALIFICATION PROTOCOL FOR BOD INCUBATOR

#### 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

#### **10.0** Abbreviations:

IQ	:	Installation Qualification
DQ	:	Design Qualification



## PHARMA DEVILS MICROBIOLOGY DEPARTMENT

## INSTALLATION QUALIFICATION PROTOCOL FOR BOD INCUBATOR

#### Post execution approval:

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



MICROBIOLOGY DEPARTMENT

### INSTALLATION QUALIFICATION PROTOCOL FOR BOD 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 Indl. 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	Instrument Manual submitted by the vendor		



MICROBIOLOGY DEPARTMENT

### INSTALLATION QUALIFICATION PROTOCOL FOR BOD INCUBATOR

#### Annexure - II

#### **Checklist for Installation Verification**

S.No.	System Data	Acceptance Criteria	Actual	Remarks
А.		Equipment /Instrume	nt specific details	
1.	Capacity	Should be 165 Ltrs		
2.	Internal Chamber (MOC)	Should be SS 304, Mirror polish		
3.	Internal Chamber Dimension (WXDXH)	Should be 600 X 600 X 900 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		



MICROBIOLOGY DEPARTMENT

## INSTALLATION QUALIFICATION PROTOCOL FOR BOD INCUBATOR

S.No.	System Data	Acceptance Criteria	Actual	Remarks
А.		Equipment /Instrume	nt 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 3 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 100ohrms RTD Sensor.		



MICROBIOLOGY DEPARTMENT

## INSTALLATION QUALIFICATION PROTOCOL FOR BOD INCUBATOR

S.No.	System Data	Acceptance Criteria	Actual	Remarks	
А.		Equipment /Instrume	nt specific details		
14.	Relay	Electric circuit breaker Should be provided			
15	Communication	PC communication via 485 (13050) should be provided			
16.	Cooling System	CFC free compressor should be provided			
17.	Heating System	Electric Heater should be provided			
В.		Location su	itability		
1.	Location	Should be place in Incubation Room - 1			
C.	Utilities				
1.	Electrical Supply	230 VAC, 50HZ – 16A, ± 5 %, 1400 Watts Supply should be provided			



## PHARMA DEVILS MICROBIOLOGY DEPARTMENT

## INSTALLATION QUALIFICATION PROTOCOL FOR BOD INCUBATOR

S.No.	System Data	Acceptance Criteria	Actual	Remarks
D.		Safet	y	
1.	Alarm	Heater & compressor On/off; Over temp condition alarm should be provided		
E.	MOC Certificates	Should be provided		
F.	Calibration Certificates	Should be provided		
G.	Testing Certificates	Should be provided		
Н.	Drawing Details	Drawing No.		
1.	Not Applicable	Not Applicable		



MICROBIOLOGY DEPARTMENT

### INSTALLATION QUALIFICATION PROTOCOL FOR BOD INCUBATOR

#### Annexure - III

#### List of Changes / Deviations

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

Verified By:

**Approved By:** 



MICROBIOLOGY DEPARTMENT

#### INSTALLATION QUALIFICATION PROTOCOL FOR BOD INCUBATOR

#### 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