



DESIGN QUALIFICATION PROTOCOL FOR BACTERIOLOGICAL INCUBATOR

Pre - Execution Approval

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



DESIGN QUALIFICATION PROTOCOL FOR BACTERIOLOGICAL INCUBATOR

1.0 Objective:

The purpose of Design Qualification of the Bacteriological Incubator is to ensure that all the critical aspects including safety, effective cleaning, maintenance, utility requirement, working space, have been considered while designing the equipment and they are properly documented.

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. It internal surface is consist of SS 304 /Mirror polish. Bacteriological Incubator is equipped with PC communication for continuous monitoring of temperature.



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4.0 Checklist for design verification:

Design of Bacteriological Incubator shall be verified for the compliance with the critical parameters mentioned in the URS/ executed tender.

Parameters	User requirement/ Technical Specification	Vendor Design / Specification	Remarks
Model	Not Mentioned	GMP Compliance	
Capacity	Not Mentioned	90 Ltrs	
Internal Chamber	Not Mentioned	SS 304, Mirror polish (450 x 450 x 450 mm)	
Operating Temperature Range	Not Mentioned	+5°C to 60°C	
Accuracy / Sensitivity	Not Mentioned	± 0.5°C	
Temp uniformity	Not Mentioned	± 2.0°C	
Inner MOC	Not Mentioned	SS 304	
Inner Door	Not Mentioned	Magnetic door gasket, inner transparent door	
Outside MOC	Not Mentioned	SS304, Exhaust vent, test port blocker, door lock studs made of SS304	
Insulation	Not Mentioned	PUF/Glass wool	
Controller	Not Mentioned	Microprocessor based temp. Controller, Auto tuning. Dual digital display of output – set and Actual, SSR o/p.	



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Air circulator	Not Mentioned	Forced heated air circulation	
Alarm	Not Mentioned	Temperature Overshoot alarm	
Temperature Over shoot safety	Not Mentioned	Thermostat control with audio alarm	
Trays	Not Mentioned	2 Nos. SS 304	
Heating	Not Mentioned	SS encapsulated nichrome wire tubular heater motor shaft made of SS.	
Compressor	Not Mentioned	Hermetically sealed compressor, Electronic time delay provided to safeguard compressor	
Illumination	Not Mentioned	Should provide	
Sensor probe	Not Mentioned	High responsive and accurate sensing platinum 100ohrms RTD Sensor.	
Relay	Not Mentioned	Electric circuit breaker	
Communication	Not Mentioned	PC communication	
Software	Not Mentioned	Software to log temperature data v/s defined time interval,	
Electrical Supply	Not Mentioned	230 VAC, 50HZ – 16A, ± 5 %, 700 Watts	



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Blower	Not Mentioned	Chamber re - circulation blower	
Heating System	Not Mentioned	Electric Heater	

5.0 Any Changes identified towards equipment design / lay out.

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6.0 Recommendations and Conclusions:

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7.0 References:

- Comparison sheets of incubators.
- Copy of purchase order.
- Risk assessment.
- Operating manual.

8.0 Documents Attached:

Document Title	Annexure No.
List of changes / deviation	I
Comparison sheets of incubators	II
Copy of purchase order	III
Risk assessment	IV
Operating manual	V



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9.0 Abbreviations:

URS : User requirement specification
SS : Stainless Steel
°C : Degree centigrade
Nos : Numbers
mm : millimeter
% : Percentage



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Annexure - I

List of changes / Deviations

S.No.	Description of Change / Deviations	Justification

Verified By:

Approved By:



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Post execution approval:

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