



**DESIGN QUALIFICATION PROTOCOL FOR BOD INCUBATOR**

**Pre - Execution Approval**

|             | <b>Name</b> | <b>Designation</b> | <b>Signature</b> | <b>Date</b> |
|-------------|-------------|--------------------|------------------|-------------|
| Prepared By |             |                    |                  |             |
| Reviewed By |             |                    |                  |             |
| Reviewed By |             |                    |                  |             |
| Approved By |             |                    |                  |             |



## DESIGN QUALIFICATION PROTOCOL FOR BOD INCUBATOR

### 1.0 Objective:

The purpose of Design Qualification of the BOD 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

|                                |                        |
|--------------------------------|------------------------|
| <b>Equipment / System Name</b> | <b>BOD Incubator</b>   |
| <b>ID Number</b>               | .....                  |
| <b>Location</b>                | <b>Incubation Room</b> |

### 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. BOD Incubator is equipped with PC communication for continuous monitoring of temperature.

### 4.0 Checklist for design verification:

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



## DESIGN QUALIFICATION PROTOCOL FOR BOD INCUBATOR

| Parameters                  | User requirement / Technical Specification | Vendor Design / Specification   | Remarks |
|-----------------------------|--|---|---------|
| Model                       | Not Mentioned                              | GMP Compliance  |         |
| Capacity                    | Not Mentioned                              | 165 Ltrs  |         |
| Internal Chamber (WXDXH)    | Not Mentioned                              | SS 304, Mirror polish (600X 600 X 900 mm)   |         |
| Operating Temperature Range | Not Mentioned                              | 7°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                              | Heater & compressor On/off; Over temp condition  |         |
| Temperature Over shoot safety | Not Mentioned                              | Thermostat control with audio alarm  |         |
| Trays                         | Not Mentioned                              | 3 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 100 ohms RTD Sensor.                     |         |
| Relay                         | Not Mentioned                              | Electric circuit breaker   |         |
| Communication                 | Not Mentioned                              | PC communication   |         |



**DESIGN QUALIFICATION PROTOCOL FOR BOD INCUBATOR**

| <b>Parameters</b> | <b>User requirement / Technical Specification</b> | <b>Vendor Design / Specification</b>                        | <b>Remarks</b> |
|-------------------|---|---|----------------|
| Software          | Not Mentioned                                     | Software to log temperature data v/s defined time interval, |                |
| Electrical Supply | Not Mentioned                                     | 230 VAC, 50HZ – 16A, ± 5 %, 1400 Watts                      |                |
| Cooling System    | Not Mentioned                                     | CFC free compressor   |                |
| 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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## DESIGN QUALIFICATION PROTOCOL FOR BOD INCUBATOR

### 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            |

### 9.0 Abbreviations:

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



**DESIGN QUALIFICATION PROTOCOL FOR BOD INCUBATOR**

**Annexure - I**

**List of changes / Deviations**

| S.No. | Description of Change / Deviations | Justification |
|-------|------------------------------------|---------------|
|       |                                    |               |
|       |                                    |               |
|       |                                    |               |
|       |                                    |               |
|       |                                    |               |

**Verified By:**

**Approved By:**



**DESIGN QUALIFICATION PROTOCOL FOR BOD INCUBATOR**

**Post execution approval:**

|             | <b>Name</b> | <b>Designation</b> | <b>Signature</b> | <b>Date</b> |
|-------------|-------------|--------------------|------------------|-------------|
| Compiled By |             |                    |                  |             |
| Reviewed By |             |                    |                  |             |
| Reviewed By |             |                    |                  |             |
| Approved By |             |                    |                  |             |