USER REQUIREMENT SPECIFICATION

Name of Item: BOD Incubator	**Protocol No.:**.....
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1.0 **Purpose:** To describe the specific requirement of BOD incubator used in microbial testing of total fungi count.

2.0 **Scope:** This specification is applicable to the BOD incubator to be installed at quality control laboratory.

3.0 **System Description:** BOD incubator shall be used for microbial testing of water samples, raw material, finished samples and packaging samples in pharmaceutical applications. As per different pharmacopoeias the temperature mentioned for microbial contamination is 22 to 25 for fungal contamination. To attain the required temperature the equipment shall consist of specific features. As per the requirement of international regulatory agencies, the equipment used shall have the following minimum listed specifications. Before purchasing the equipment additional features shall also be considered.

The BOD incubator used in microbial contamination testing shall have the following listed features.

3.1 Capacity 325 ltrs with minimum five perforated shelves to hold microbial media testing plates for incubation. It shall have the provision for expandable space for placing additional shelves, if required.

3.2 Material of construction: Outer SS316 and inner with SS316/SS304 (preferably SS316). The wall should be insulated with PUF / Glass Wool to minimize heat loss and maintenance of temperature uniformity. For inside view of the chamber, it should have clear view window and proper illumination of the chamber without opening the inner chamber.

3.3 It should have rugged heating and cooling systems to avoid frequent breakdowns in the heating system. The heaters should be made of SS or nichrome and the arrangement of the heaters should be such that all the corners and the middle of the inner chamber shall

have the temperature within the specified range. The cooling system should consist of a branded compressor and CFC free cooling gas filled inside the cooling system.

3.4 It should have the safety alarm systems whenever there is temperature display is on upper side and lower side of the set value. It should have the provision for cut -off device in case of temperature shoot up.

3.5 The temperature range should be between 5-50°C with variation of 1°C. It should have provision for regulation of the temperature within the specified values.

3.6 It should have electronic or suitable sensors, fitted at suitable places for monitoring of temperature within the chamber.

3.7 The temperature control should be through a suitable device (microprocessor/PLC). The equipment should have facility for printer attachments for recording of all the values stored in PC or software.

3.8 The software for recording of the data should be 21CFR Compliant for data recording for temperature and any deviation observed in the equipment from the set values.

3.9 The manufacturer/ supplier should provide complete documentation for validation of the equipment.

3.10 The manufacturer/ supplier should provide the following calibration certificates:

3.10.1 For material used for construction.

3.10.2 All the measuring devices including temperature, display units etc.

3.11 After sales service back up should be from approachable distance so as to minimize breakdown time, if any.

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4.0 Documentation: Supplier/Manufacturer shall provide the following document.

- P & I diagram, circuit diagrams which ever applicable
- Calibration certificates for all gauges or measuring devices with trace-ability.
- Test and guarantee certificates.
- Qualification (DQ, IQ, OQ, PQ) documentation
- Individual part certificates, if any.

5.0 Other Considerations: The manufacture/ supplier shall have the commonly used spares in stock. If not, the manufacture/ supplier shall have the provision to arrange at the earliest. The manufacture/ supplier shall provide the validation/ calibration support for the next 3-5 years. The manufacture/ supplier shall provide the written document for the validation support at the time of placing the final order. The manufacture/ supplier shall provide the general maintenance support to the Engineering section.

Prepared By:
Date:

Approved By:
Date: