USER REQUIREMENT SPECIFICATION

Name of Item: Incubator	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.**: 1 of 3

1.0 **Purpose:** To describe the specific requirement of incubators used in testing of microbiological organisms.

2.0 **Scope:** This specification is applicable to the incubators to be installed at quality control laboratory in microbiology section.

3.0 **System Description:** Microbial contamination is one of the important tests for water system validation. Since the existing plant is based on liquid formulation, incubators shall be used for microbiological testing of water samples. In addition these shall also be used for testing of raw material, finished products and packaging material etc. The culture media after inoculation and plates after exposure in the environmental monitoring and area monitoring shall be incubated at specified temperatures. As listed in different pharmacopeias the requirement of temperature for general microbial testing and specific organism testing is as under;

Incubator set at 37° for study of total viable count

Incubator set at 40-45° for study of specific organism during secondary testing

Incubator set at 50-55° for study of specific organism during secondary testing

To fulfill the optimum growth conditions these incubators are required. These are also required for confirmatory test of pathogens. It shall be used for general testing, as mentioned above, as well as testing of specific organisms. The general requirement for incubators for microbiological testing shall be as under:

3.1 Capacity 200 ltrs and 324 ltrs with minimum five perforated shelves to hold plates for microbial testing for 325 ltr incubator and two perforated shelves for 200 ltr capacity incubator. The equipments should 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 inner surface should be mirror polished and outer surface should be with dull smooth buffing. The walls 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 provision for clear inner view and proper illumination of the chamber without disturbing the inner chamber area.

3.3 It should have rugged heating system 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 incubators should have the temperature uniformity within the specified range.

3.4 It should have the safety alarm systems whenever the temperature display is on upper side and lower side of the set value.

3.5 The temperature range should be from ambient to 60°C with variation of 1°C. It should have the provision for cut -off device in case of temperature shoot up.

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 electronic device. The equipment should have facility for printer attachments for recording of all the values stored in PC software.

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

3.9 The manufacturer/ supplier should provide complete documentation for validation and calibration 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.

3.10.3 Software validation

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

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.
- Operator's manual

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. During installation of the equipment the manufacturer/ supplier shall explain the general maintenance procedure for the equipment to the Engineering section.

Prepared By:
Date:

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