



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Incubator

Protocol No.:.....

Functional Area: Quality Control

Page No.: 1 of 7

**USER REQUIREMENT SPECIFICATION
FOR
INCUBATOR**

Name of Equipment: Incubator

Document Reference Number:

Effective Date:



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USER REQUIREMENT SPECIFICATION

Name of Item: Incubator	Protocol No.:
Functional Area: Quality Control	Page No.: 2 of 7

1.0 Approval

Signing of this approval page of URS indicates agreement in this document. Should Modifications to the user Requirements Specification approach become necessary, an addendum will be prepared and approved.

Prepared by	Signature	Date
Checked By	Signature	Date
Reviewed By	Signature	Date
Approved By	Signature	Date



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Incubator	Protocol No.:
Functional Area: Quality Control	Page No.: 3 of 7

2.0 Table of Contents:

Table of Contents		Page No.
1.0	Approval	2
2.0	Table of Content	3
3.0	Introduction	4
4.0	Overview Definition	4
5.0	Operational Requirements.	5
5.1	Operation	5
5.2	Power failure / Recovery	5
5.3	Emergency stop	5
5.4	Alarms and Warnings	6
6.0	Salient Features.	6
6.1	Compatibility and support	6
6.2	Material of construction	6
6.3	Instruments & controls	6
7.0	Maintenance	7
8.0	Delivery.	7
9.0	Documentation	7



USER REQUIREMENT SPECIFICATION

Name of Item: Incubator

Protocol No.:.....

Functional Area: Quality Control

Page No.: 4 of 7

3.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for a Microbiological Incubators. The URS is provided to aid the user through the important components, variables and options necessary to procure a functional Microbiological Incubators that meets the User Requirement in the most cost effective method.

The URS is provided to the supplier to provide a price quote for the Microbiological Incubators, including design and manufacture of the equipment.

The URS will be recognized as the integral part of the procurement agreement with the selected instrument vendor. The instrument supplier or vendor will abide by the information and condition set forth by this document as well as purchasing and delivery terms and condition of the Client.

The Microbiological Incubators shall be located in Quality Control laboratory.

The utilities and space involved needs to be discussed prior to the purchase of the equipment.

The unit and its support equipment shall be feasible to be installed in the current building facility.

The document encompasses the normal range of Microbiological Incubators operation. Obviously technology improvements and new applications may require deviations from these specifications. These specifications are to be utilized as a guide for the user to answer the majority of the questions involved in specifying and using the equipment. Amendment may be used to round out the requirements.

4.0 OVERVIEW DEFINITION:

4.1 The INCUBATOR shall have the following features:

- 4.1.1. The Incubator shall have control panel for operations.
- 4.1.2. The Incubator shall have Circulation Blower fan motor.
- 4.1.3. The Incubator shall have insulation thick puff.
- 4.1.4. The Incubator shall have chemical resistant inside MOC and gas kits.
- 4.1.5. The Incubator must be factory tested before installation.
- 4.1.6. The Incubator shall have SS perforated trays.
- 4.1.7. The Incubator shall have a port for the validation purpose.
- 4.1.8. The Incubator shall have a forced air circulating system with fan for better uniformity of temperature.
- 4.1.9. The Incubator shall have Temperature controlled by Microprocessor based Digital Temperature controller.
- 4.1.10. The Incubator shall have temperature controlled PT 100 as sensor & safety thermostat supplied with SS wire mesh shelves & silicon.



USER REQUIREMENT SPECIFICATION

Name of Item: Incubator	Protocol No.:
Functional Area: Quality Control	Page No.: 5 of 7

4.2 The B O D incubator shall be used for:

For the incubation plates, culture slants.

4.3 Technical Specifications:

- 4.4.1 Capacity : 325 liters
- 4.4.2 Size : 600X600X900meters
- 4.4.3 Temperature range : Room temperature to 100 °C
- 4.4.4 Accuracy : $\pm 0.2^{\circ}\text{C}$

4.4 The machine is to be used at the following environmental conditions:

- 4.4.1 Temperature : NMT 24 °C
- 4.4.2 Relative Humidity : NMT 55%

4.5 Base Utilities Available:

Electrical : Single Phase, 230V $\pm 10\%$ 50 HZ

5.0 OPERATIONAL REQUIREMENTS

5.1 OPERATION:

The instruments operation shall be safe, smooth both from user and environmental standpoint.

5.2 POWER FAILURE/RECOVERY:

In the event of a power failure, the system shall shut off automatically. The system will starts automatically after getting the electricity and start functioning according to previous setting.

5.3 SAFETY FEATURE:

The system shall be stop safely in emergency.

5.4 ALARMS AND WARNINGS:

The system shall have an Emergency alarming facility. Incase any parameter goes up or down from set parameter. The incubator should produce wibe sound until further command received or all set parameter comes within the set parameter.



USER REQUIREMENT SPECIFICATION

Name of Item: Incubator

Protocol No.:.....

Functional Area: Quality Control

Page No.: 6 of 7

6.0 SALIENT FEATURES

6.1 COMPATIBILITY AND SUPPORT

ELECTRIC CONTROL:

The Supplier shall utilize PID controller that shall include a communication port.

UTILITIES:

The Supplier shall specify utility requirements. The User shall ensure that the utilities are available and that the utility supply lines and piping are terminated with fittings or connections.

6.2 MATERIAL OF CONSTRUCTION:

- Outer side** : Stainless Steel 304.
- Inner side** : Stainless Steel 304 Mirror Polish
- Racks & Trays** : Stainless steel 316 with mirror polish

7.0 MAINTENANCE

Do's and Don'ts to be provided

- 7.1 Preventive maintenance system and checks to be provided (Maintenance and operation manuals of vendor equipment)
- 7.2 A comprehensive lubrication list and recommended lubrication schedule
- 7.3 A comprehensive recommended maintenance (regular recommended inspection intervals, wear points, recommended spare parts list)
- 7.4 Supplier shall supply 2 Copies of Operation, Installation, and Maintenance manuals., DQ, Electrical drawing

8.0 DELIVERY:

The B O D with all options, equipment, and the documentation listed below, shall be delivered to Client site. Delivery should be confirmation of the purchase order.

9.0 DOCUMENTATION:

- 9.1 The Supplier shall provide the documentation for preliminary review. The Supplier shall provide documentation reflecting "as-built" condition with final delivery.
- 9.2 All final documents shall be shipped with transmittals that identify them as contractually required documents. All final documents and drawings shall reflect "As-Built" condition.



USER REQUIREMENT SPECIFICATION

Name of Item: Incubator	Protocol No.:
Functional Area: Quality Control	Page No.: 7 of 7

- 9.3 All documents shall be in English language and supplied with hard copies and supplied in the format identified for each document:
- 9.4 Design qualification
- 9.5 Installation Qualification
- 9.6 Operational Qualification
- 9.7 Maintenance and service manuals
- 9.8 Instrument listing
- 9.9 Material of construction