



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Refrigerator

Protocol No.:.....

Functional Area: Quality Control

Page No.: 1 of 6

Name of Equipment: Refrigerator

Document Reference Number:

Effective Date:



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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



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3.0 INTRODUCTION:

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

The URS is thus provided to the supplier to provide a price quote for the Refrigerator, 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 Refrigerator 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 Refrigerator 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 refrigerator system shall have the following features:

- 4.1.1. The refrigerator system shall have temperature control for the operations.
- 4.1.2. The refrigerator shall have insulated door in the front which open able.
- 4.1.3. The refrigerator shall have insulation thick puff in three sides.
- 4.1.4. The refrigerator shall have chemical resistant inside MOC and gas kits.
- 4.1.5. The refrigerator should be factory tested before installation.
- 4.1.6. The refrigerator should have the capacity 300 liters.

4.2 The refrigerator shall be used primarily for:

The refrigerator system shall use to the store the light and temperature sensitive material.

4.3 Technical Specifications:

4.3.1 Temperature range 2°C to 8°C

4.3.2 Accuracy \pm 0.5°C



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4.3.3 Safety controller with alarm system.

4.3.4 Safety electrical sockets and fittings.

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

4.4.1 Room Temperature: $24 \pm 2^\circ\text{C}$

4.4.2 Relative Humidity: NMT 55 %

4.5 Base Utilities Available:

Electrical: Single Phase, 240V ± 10 % 50 HZ

5.0 OPERATIONAL REQUIREMENTS:

5.1 OPERATION:

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

5.2 POWER FAILURE/RECOVERY:

In the event of a power failure, the system will stop automatically and will require operator intervention to re-start.

5.3 SAFETY FEATURE:

The system shall be stop safely in emergency.

5.4 ALARMS AND WARNINGS:

Not applicable

6.0 SALIENT FEATURES:

6.1 COMPATIBILITY AND SUPPORT

ELECTRIC CONTROL:

The refrigerator should consist of electrical on / off switch.

UTILITIES

The Supplier shall specify utility requirement. The User shall ensure that the utilities are available.



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6.2 MATERIAL OF CONSTRUCTION:

Outer body: SS 304.

Interior construction: chemical and heat resistant, fire resistant, smooth integral walls of stainless steel 304 or equivalent.

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 water purification system with all options, equipment, and the documentation listed below shall be delivered to the Client Site.

Delivered 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.
- 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.