USER REQUIREMENT SPECIFICATION

Name of Item: Water Purification System	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 1 of 7

Name of Equipment: Water Purification System

Document Reference Number:

Effective Date:

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**

2.0 Table contents:

3.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for a Water Purification Unit. The URS is provided to aid the user through the important components, variables and options necessary to procure a functional Water Purification Unit 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 Water Purification Unit, 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.

The Water Purification Unit shall be located in Quality Control Lab.

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 Water Purification Unit 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. Addendum may be used to round out the requirements.

4.0 OVERVIEW DEFINITION

4.1 The water purification system shall have the following features:

4.1.1. The water purification Unit shall have updated touch key panel. For operating control panel. The various screens shall be as follows:

I. Set screen parameter

II. Operate screen parameter.

4.1.2. The water purification unit should be capable of handling of different type of feed water, at minimum / maximum capacity pressure of the feed water.

4.1.3. All contact parts shall be made up of stainless steel 316 and other approved material.

4.1.4. The water purification unit shall be provided with all accessories to utilize (which are non corrosive, non hazardous and safe) within specific size and requirement as per pharmacopoeia.

4.1.5. The water purification unit shall be provided with powder fuse and safety features to avoid failure and personal safety, which shall have features to avoid failure and personal safety, which shall have feature of wear free drive and self-initialization/self- check. No complicated

operations or chains shall be used for drive mechanism. Water Purification Unit shall require negligible maintenance.

4.1.6. The Water Purification Unit shall be provided with detachable filter facility, built-in controller and programmable software. The Water Purification Unit shall have facility to calibrate as per the set requirements.

4.1.7. The Water Purification Unit shall have facility to adjust, and check / verification externally the following parameters -

1. To check reject water
2. To check conductivity at different stage.
3. To check recovery of the final water.
4. To check filters integrity.
5. To check UV lamp Hours.

4.1.8. The water purification unit shall have MOC of good quality materials.

4.1.9. The water purification unit shall be provided with vibration free mechanism.

4.1.10. The water purification unit shall have digital display of current conductivity values at any instant for ease of control, and checking.

4.1.11. The water purification unit shall give purified water equivalent to HPLC grade.

4.2 The water purification shall be used primarily for:

The water purification unit shall give purified water as per USP Specification.

4.3 Technical Specifications:

4.3.1 Purified water system

I) *Purified Water system:*

Flow Rate :	35 – 40 Lit / Hr.
% Recovery	40 – 45 %
Bacteria	Less than 10 CFU / ml
TOC	< 30 ppb
Conductivity @ 25° C (µS / cm)	0.067 to 0.10µS/cm
Storage tank	60 Ltr.

4.3.2 Ultra pure water system:

Flow Rate :	About 90 Lit / Hr.
Resistively	Minimum 18.0 M Ω.cm @ 25°C Typically 18.2 M Ω.cm @ 25°C
UV Lamp	Dual Wavelength (185 and 254 nm

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

4.4.1 Room Temperature **:** 24± 2 °C

4.4.2 Relative Humidity **:** NMT 55 %

4.5 Base Utilities Available:

Electrical **:** Single Phase, 230V ± 10 % 50 HZ
Feed water **:** Purified water

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 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:

The water purification system shall have alarm if any parameter goes up and down from the desired limit.

6.0 SALIENT FEATURES:

6.1 COMPATIBILITY AND SUPPORT

ELECTRIC CONTROL:

The water purification system should consist of electrical on / off switch and touch screen system for operation.

UTILITIES

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

6.2 MATERIAL OF CONSTRUCTION:

Base frame : SS 304.

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 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

9.8 Instrument listing

9.9 Material of construction