



**PHARMA DEVILS**  
QUALITY CONTROL DEPARTMENT

**USER REQUIREMENT SPECIFICATION**

**Name of Item:** Conductivity Meter

**Protocol No.:**.....

**Functional Area:** Quality Control

**Page No.:** 1 of 7

**Name of Equipment:** Conductivity Meter

**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.

<b>Prepared by</b>	<b>Signature</b>	<b>Date</b>
<b>Checked By</b>	<b>Signature</b>	<b>Date</b>
<b>Reviewed By</b>	<b>Signature</b>	<b>Date</b>
<b>Approved By</b>	<b>Signature</b>	<b>Date</b>



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QUALITY CONTROL DEPARTMENT

## USER REQUIREMENT SPECIFICATION

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**3.0 INTRODUCTION:**

This document is generated for the purpose of specifying the user requirements for a Conductivity Meter. The URS is provided to aid the user through the important components, variables and options necessary to procure a functional Conductivity Meter 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 Conductivity Meter, 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 Conductivity Meter 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 Conductivity Meter 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 Conductivity Meter shall have the following features:**

- 4.1.1. Conductivity Meter shall have updated touch key panel for operating control panel. Various screens shall be as follows:
  - I. Set Screen Parameters.
  - II. Operate Screen Parameters.
- 4.1.2. The Conductivity meter should be capable of handling of different Conductivities and type of samples, at minimum / maximum capacity of the Conductivity Meter selected.
- 4.1.3. All Contact parts shall be made up of Stainless Steel 316 and other approved material.
- 4.1.4. The Conductivity meter shall be provided with all accessories to utilize which shall facilitate to measure Conductivity of any products and liquids (which are non corrosive, non hazardous and safe for testing Conductivity) within specific size and requirement as per pharmacopoeia.
- 4.1.5. The Conductivity Meter shall be provided with power fuse and safety features to avoid failure and personal safety, which shall have feature of wear free drive and self – initialization / self –



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check. No complicated operations or chains shall be used for drive mechanism. Conductivity Meter shall require negligible maintenance.

4.1.6. The Conductivity Meter shall be provided with detachable electrode facility, built – in controller and programmable software. The Conductivity Meter shall have facility to calibrate as per the set requirements.

4.1.7. The Conductivity Meter shall have facility to adjust and check / verification externally the Calibration parameters.

4.1.8. The Conductivity Meter shall have MOC of good quality materials.

4.1.9. The Conductivity Meter shall be provided with vibration free mechanism.

The Conductivity Meter shall have digital display of current Conductivity values at any instant for ease of control and checking.

**4.2 pH meters shall be used primarily for:**

To measure the Conductivity of Purified water

**4.3 Technical Specifications:**

- |              |                        |   |  |
|--------------|------------------------|---|--|
| <b>4.3.1</b> | <b>Measuring Range</b> | : | 0.001 $\mu$ S/cm to 20S/cm<br>(Depending on the Cell used 0.1/0.1/10.0K) |
| <b>4.3.2</b> | <b>Temperature</b>     | : | -170 to + 500 °C   |
| <b>4.3.3</b> | <b>Resolution</b>      | : | 0.01 (Displayed)   |
| <b>4.3.4</b> | <b>Accuracy</b>        | : | 0.5 %  |

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

**4.4.1** Room Temperature : 24 $\pm$  2 °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 Conductivity meter shall operate with a minimum of operator involvement. Operation shall be safe both from an operator and environmental standpoint.



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**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 Conductivity meter apparatus shall have alarm in case of mishandling.

**6.0 SALIENT FEATURES:**

**6.1 COMPATIBILITY AND SUPPORT:**

**ELECTRIC CONTROL:**

Conductivity meter should consist of electrical on / off switch for operation.

**UTILITIES**

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

**6.2 MATERIAL OF CONSTRUCTION:**

SS – 316 or Powder coated or equivalent antistatic, stain proof.

**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



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**8.0 DELIVERY:**

The Conductivity Meter 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

9.8 Instrument listing

9.9 Material of construction