



USER REQUIREMENT SPECIFICATION

Name of Item: pH Meter

Protocol No.:.....

Functional Area: Quality Control

Page No.: 1 of 7

Name of Equipment: pH Meter

Document Reference Number:.....

Effective Date:



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

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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 |
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| 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 pH meter.

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

The pH Meter shall be located at wet lab area of Quality control area.

The pH Meter is used to check the degree of acidity or alkalinity of the given aqueous solution.

The pH Meter shall be interfaced with following components.

1. Main Unit.
2. Electrode
3. Temperature Sensor
4. Electrode Stand

4.0 OVERVIEW DEFINITION

4.1 The pH meter shall have the following features:

- 4.1.1. The meter should be designed to check the pH of solution from 1 to 11.
- 4.1.2. The pH meter should be easy to operate having user interactive software in dialog mode for ease of operation with protection against invalid entries.
- 4.1.3. PH meter should have sleek molded cabinet with alphanumeric splash waterproof polyester keyboard with soft keys.
- 4.1.4. PH meter should comply to USP standards.
- 4.1.5. Instrument should have facility of simultaneous measurement of pH, and temperature. SCAN key should be provided for displaying the stored pH or MV values with reading no. and sample name.
- 4.1.6. Password protection should be provided for storage of calibration data and readings.
- 4.1.7. Entries should be alphanumeric of Sample Name, Identification number for authentication.
- 4.1.8. Option for Probe check mode is provided for checking Electrode Aging.
- 4.1.9. Built – In Real time Clock (RTC) for time display and on report printout.
- 4.1.10. Report format should comply the GLP requirement.
 - Report giving the selectable 40 readings of pH and mV.
 - Report of last calibration with date & time.



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- Report of pH logged data with graph (optional).
- Online report of individual pH or mV entered readings and calibration data.

- 4.1.11. 5 point Calibration with auto buffer recognition and slope is determined by linear regression or segmentation (Point to Point) interpolation method.
- 4.1.12. Input Stability indicator should be provided for reproducible results.
- 4.1.13. Error indication should be shown on print out.
- 4.1.14. Data logging function (with graph for pH Kinetic study) facility should be provided.
- 4.1.15. Instrument shall have updated operating knob for operation.

4.2 pH meters shall be used primarily for:

Testing of degree of acidity or alkalinity of the solution.

4.3 Technical Specifications:

- 4.3.1 pH Range** : -2.00 to 19.999
- 4.3.2 Resolution** : 0.001 pH
- 4.3.3 Relative accuracy** : +/- 0.002 pH
- 4.3.4 Slope** : 80 to 120 %
- 4.3.5 Sensor** : Combination pH electrode/Two separate Electrode
- 4.3.6 Calibration** : Auto – calibration up to 5 – buffer recognition and print out of Calibration report.
- 4.3.7 Temperature Range** : 0 to 99.9 °C
- 4.3.8 Sensor** : RTD PT 100
- 4.3.9 Display** : 20 x 2 Line Back lighted LCD display

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

- 4.4.1 Room Temperature** : 24 ± 2 °C
- 4.4.2 Relative Humidity** : NMT 55 %



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4.5 Base Utilities Available:

Electrical : **Single Phase, 230V \pm 10 % 50 HZ**
Magnetic stirrer : **Silicon oil bath with inbuilt magnetic stirrer**

5.0 OPERATIONAL REQUIREMENTS

5.1 OPERATION:

The pH meter shall operate with a minimum of operator involvement. Operation shall be safe both from an operator 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 pH meter apparatus shall have alarm after the completion of the test.

6.0 SALIENT FEATURES:

6.1 COMPATIBILITY AND SUPPORT

ELECTRIC CONTROL:

pH 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:

Base frame : SS 304

6.3 Instruments & controls : Touch screen controller



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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, design qualification.

8.0 DELIVERY:

The Melting point apparatus with all options, equipment, and the documentation listed below shall be delivered to 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