USER REQUIREMENT SPECIFICATION (URS)

FOR

pH meter

Department :

URS no.

Supersede :

USER REQUIREMENT SPECIFICATION

Name of Item: pH Meter	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 2 of 7

TABLE OF CONTENT

S.No.	Sub Heading	Description	Page No.
1		Approval	**3**
2		Change History	**3**
3		Purpose	**4**
4		Scope	**4**
5		Specification	**4**
	5.1	Description of equipment / system	**4**
	5.2	Identification number & location	**4**
	5.3	Intended use	**4**
	5.4	Intended type of material to be handled	**4**
	5.5	Construction	**4**
	5.6	Capacity	**4**
	5.7	Electrical construction	**5**
	5.8	Control parameters	**5**
	5.9	Acceptable tolerance for control parameters	**5**
	5.10	Type of control system	**5**
	5.11	Feasible parameters to be set	**5**
	5.12	Parameters to be indicated by control systems	**6**
	5.13	Available utilities	**6**
	5.14	Limitations / constraints	**6**
	5.15	Regulatory requirements	**6**
	5.16	Delivery Address	**6**
6		Safety	**6**
7		Vendor Scope	**6**
	7.1	Spare Parts	**6**
	7.2	Support	**6**
8		Documentation	**7**
9		References	**7**

Issued to mfg / supplier by purchase department _____

USER REQUIREMENT SPECIFICATION

Name of Item: pH Meter	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 3 of 7

1. Approval:

ACTIVITY DETAIL	NAME OF PERSON	DESIGNATION	SIGNATURE	DATE
Prepared By				
Reviewed By				
Approved By				

2. Change History:

REVISION NUMBER	REVISION DETAILS	DATE OF REVISION

3. Purpose:

The purpose of the user requirement for pH meter is:
To define the instruction for selection of pH meter for intended use
To provide a specification to the vendors for their submission of quotation.
To ease the selection process of vendors

4. Scope:

4.1 This document is applicable for pH meter intended to use at manufacturing plant.

4.2 The specification and criteria given in this document is to be considered but should not be limited to this.

5. Specifications:

5.1 Description of equipment / system:

The pH meter shall have following components.

- Menu Keys
- LCD Display
- pH electrodes
- Electrode stand
- Function Keys
- Automatic temperature compensation

5.2 Identification number and location:

Equipment Name	Identification Number	Location
pH meter		Instrument room

5.3 Intended use:

Operation of equipment depends upon the production output; the equipment should be designed to work continuously for 3 shifts per day.

5.4 Intended type of material to be handled:

This will include handling of drug products;

- Solid & Liquid pharmaceutical raw materials
- Ophthalmic dosage forms
- Liquid injectable

5.5 Construction:

Not Applicable

5.6 Capacity:

The pH meter must be capable for routine laboratory analyses as well as those involved in research and development.

5.7 Electrical construction:

Control panel includes all control equipment and switch cabinet will contain all high voltage equipment, the cabinet will provide the sterilizer with either 440 VAC, 50 Hz, 3Phase. Cabinet enclosure- Protection category will be IP/54, IP/55.

5.8 Control parameters:

Measuring range(Ph, mv, temp.),Resolution (Ph, mv, temp.), Calibration, Stored measurement, Electrode. Accuracy(Ph, mv, temp.), Environmental condition, Temp. Compensation.

5.9 Acceptable tolerance for control parameters:

Measuring range	
pH	: 0 to 14
mv	: ± 2200
Temp.	: -5 to 105.0
Resolution	
pH	: 0.001
mv	: 0.1
Temp.	: 0.1
Calibration	: Multi point calibration up to 3
Stored Measurement	: Up to 100
Electrode	: Included pH electrode
Accuracy	
pH	: ± 0.002
mv	: ± 0.1
Temp.	: ± 0.3
Environmental Condition	: 15 to 40ºC, Humidity from 0 to 90%
Temp. Compensation	: Automatic & manual: -5 to 105ºC

5.10 Type of control System:

Selected report format for complying with GLP requirements.
Full GLP capability
Large display clearly shows measurement values.
Automatic temp. Compensation.
Error messages clearly explain any problems, helping to ensure accurate measurements.
Results are recorded along with time, date, units, and temp. Indication.
All results are sent to a printer and can easily be recalled.

5.11 Feasible parameters to be set:

Sample identification, sample number, Name of users, etc.

5.12 Parameters to be indicated by control systems:

1. Continuous display of: Actual pH, Temperature, time, date and units.
2. Time and date formatting.
3. Formatting Format for recording data with company's name in header.

5.13 Available utilities:

Utilities required for electric connection can be provided.
Standard buffers for calibration can be provided.

5.14 Limitations / constraints:

Not Applicable

5.15 Regulatory requirements:

Software employed for having a control on pH meter, must be complying with 21 CFR part 11 regulation of USFDA.

5.16 Delivery Address:

……

6 Safety:

Proper equipment earthing shall be provided.

7 Vendor Scope:

7.1 Spare Parts:

A suggested spare parts listing will be provided that includes:

- Consumable wear parts
- Parts that are easily broken
- Parts that can wear out, and are long lead time availability.
- Electronic components those are not readily available from a local source to the user.
- The Supplier will either stock frequently required spare parts, or provide the manufacturer name and part number for those parts.

7.2 Support:

- Start-up Support
  Start-up support shall consist of full time assistance on the User's site for installation, start-up and commissioning.

- Training
  User training shall consist of equipment training by a qualified trainer. Certificates of training shall be provided for each person completing the training program.

- Post Start-up Support
  Post start-up support shall consist of User site visits for a period of 1 year after the completion of commissioning activities as and when required.

- Technical Support
  Technical support shall be available via telephone for a period of 5 years following the completion of commissioning.

8 Documentation:

S.No.	Document	Mode
1.	User manual	Paper or .pdf
2.	Software guide	Paper or .pdf
3.	Design specification	Paper
4.	Qualification documents	Paper
5.	Spare parts list	Paper

9 References: