USER REQUIREMENT SPECIFICATION (URS)

FOR

AUTOTITRATOR

Department : Quality Control

URS No. : …….

Supersede : Nil

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Issued to mfg / supplier by purchase department _____

1.0 Approval:

Activity detail	Name of person	Designation	Signature	Date
Prepared By				
Reviewed By				
Approved By				

2.0 Change History:

Revision number	Revision details	Date of revision

3.0 Purpose:

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

4.0 Scope:

4.1 This document is applicable for Autotitrator 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.

5.0 Specifications:

5.1 Description of Equipment / System:

The Autotitrator shall have following components.

- Interchangeable burette unit
- Bottles
- Electrode holder stand
- Electrodes
- Data handling software

The detail description of the components is as follows;

5.1.1 Interchangeable Burette unit

- The instrument must have automatic burets of 10 ml capacity with transparent light protecting cover, dispensing tube and dropping tip and pumping device to suck the titrant from the bottle and to dispense it in to a titration vessel.
- Burete shall be interchangeable depending upon the application.
- This unit shall have facility to keep electrodes in a recommended storage solution while not in use.

5.1.2 Bottles

- Separate bottles of brown colored glass of 1-liter capacity with stopper cock for each application.

5.1.4 Electrode holder stand

- The stand shall be comprises of provision of stand for holding two electrodes, dispensing tube with the facility to adjust the height.
- Stirring device with magnetic stirrer with adjustable speed.

5.1.5 Electrodes

- Electrode for Non Aqueous titration, Electrode for Aqueous Acid Base Titration, Electrode for oxidation-reduction titration and reference electrode.

5.1.6 Data handling software

- In-Built Preprogrammed Standard methods in Memory for using titrator.

- Facility to store at least 50 methods.
- Software shall have facility for user and sample log in, method set up, data acquisition, potentiometric end point determination, and printing.

5.2 Identification number and location:

Equipment Name	Identification Number	Location
Autotitrator	…….	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:

Not applicable.

5.7 Electrical construction:

Not applicable

5.8 Control parameters:

- Minimum 3-point calibration with the choice of pH buffers.
- Burette filling without producing air bubbles.
- Adjustable amount for burette dispensing volume.
- Burette volume accuracy.
- Should prevent the moisture absorption in burette and storage bottle.

5.9 Acceptable tolerance for control parameters:

Resolution: 1/10000 of the nominal volume
Volume accuracy: 0.2%

5.10 Type of control System:

Software must supply as standard and allows controlling, monitoring and managing all functions.

5.11 Feasible parameters to be set:

Method set up shall cover all the operating variables.

5.12 Parameters to be indicated by control systems:

- pH or Mill volt
- Time and date.
- Name of the method
- Analysis details during its run.

5.13 Available utilities:

- Printer
- Balance
- PC
- Utilities required for electric connection shall be provided.
- Reagent.

5.14 Limitations / constraints:

Not Applicable

5.15 Regulatory requirements:

The instrument must comply with GLP requirement.

5.16 Delivery Address:

……..

6.0 Safety:

Proper equipment earthing.

7.0 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
  Vendor must provide familiarization and training.

- 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 as and when required.

8.0 Documentation:

S.No.	Document	Mode
1.	User manual	Paper or .pdf
2.	Software guide	Paper or .pdf
3.	Qualification documents	Paper
4.	Spare parts list	Paper
5.	List of users	Paper
6.	NIST traceable electrode certificate	Paper

9.0 References:

Unite state pharmacopoeia, In –House.