USER REQUIREMENT SPECIFICATION (URS)

FOR

KARL FISCHER TITRATOR

Department : Quality control

URS no. ……

Supersede : Nil

USER REQUIREMENT SPECIFICATION

Name of Item: Karl Fischer Titrator	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 2 of 7

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Issued to mfg / supplier by purchase department _____

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Name of Item: Karl Fischer Titrator	**Protocol No.:**.....
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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 Karl Fischer titrator is:
To define the requirement for selection of Karl Fischer 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 Karl Fischer titrator for intended 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 Karl Fischer titrator shall consist of automatic burets and a tightly covered titration vessel fitted with a necessary electrodes and a magnetic stirrer. In addition to this it shall have following components.

- Exchange unit
- Titration cells
- Bottle holder
- Titration stand
- Titration vessel

The detail description of the components is as follows;

5.1.1 Exchange unit

- Exchange unit with glass cylinder and flat stopcock, reagent bottle made of brown coloured glass
- Exchange unit 10 ml with burette tips for titration and dispensing.

5.1.2 Titration cells

- The KF Titrator contains two titration cells of different sizes. A thermostatic is available for work at elevated temperature.

5.1.3 Bottle holder

- The instrument should have the bottle holder secures the reagent and waste bottles.

5.1.4 Titration stand

- The instrument must have a compact titration stand with magnetic stirrer and integrated pump for adding rinsing solution of solvent and for aspirating the titration vessel contents.

5.1.5 Titration vessel

- Instrument must have Magnetic stirrer with adjustable speed.
- Provision for introducing sample through side arm, which can be closed by a stopper.
- Provision for withdrawal of waste solvents form a vessel to a waste collection bottle.

5.2 Identification number and location:

Equipment Name	**Identification Number**	**Location**
Karl Fischer Titrator	……	Wet chemistry lab

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:
The equipment must comply with GLP regulations, must be easy to clean and low maintenance.

5.9 Acceptable tolerance for control parameters:

- The instrument also incorporates detailed GLP methods that are very useful for instrument validation.
- The results are presented in a GLP compliant manner with designation and serial number of the instrument, software version, date, user and method name.
- Creation and storage of methods.

5.10 Type of control System:

With Magnetic stirrer and pump for addition of solvents and siphoning off contents of titration vessel. Intelligent exchange unit equipped with data chip 10 ml burette. Light protecting cover and waste collection bottle-cap-tube. Memory card as a storage medium for additional connection .Provision for computer connection.

5.11 Feasible parameters to be set:

Name of users on result report, Weight of sample for analysis, Method use for analysis, burette dispensing

5.12 Parameters to be indicated by control systems:

1. LCD screen for comfortable user guidance and display of parameters, real-time curves for viewing reaction kinetics of titration and results.
2. Time and date formatting.
3. Formatting Format for recording data with company's name in header.
4. Analysis details during its run.

5.13 Available utilities:

Utilities required for electric connection can be provided.
Solvents like KF reagent and specially dried methanol can be provided.

5.14 Limitations / constraints:

Not Applicable

5.15 Regulatory requirements:

The equipment should meet the GLP requirement.

5.16 Delivery Address:

……..

6.0 Safety:

KF reagent must be pyridine free used.
Proper equipment earthing shall be provided.

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
  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.

8.0 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

9.0 References:

United state phamacopoeia, British pharmacopeia, In house