



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Karl Fischer Apparatus

Protocol No.:.....

Functional Area: Quality Control

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Name of Equipment: Karl Fischer Apparatus

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.

Prepared by	Signature	Date
Checked By	Signature	Date
Reviewed By	Signature	Date
Approved By	Signature	Date



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INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for the Karl Fischer apparatus.

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 Karl Fischer apparatus shall be located at wet lab area of Quality control area.

Karl Fischer apparatus gives the moisture content of sample.

The Karl Fischer test apparatus shall be interfaced with following components.

1. Basic Unit with bottom
2. Beaker
3. Probe
4. Top Plate Assembly
5. Magnetic stirrer
6. Mains cord

The utilities and space involved needs to be discussed prior to the purchase of the equipment.

4.0 OVERVIEW DEFINITION:

4.1 The auto Karl Fischer apparatus shall have the following features:

- 4.1.1. The Karl Fischer apparatus shall be used to find out the moisture content of raw materials and granules.
- 4.1.2. The Karl Fischer apparatus shall have designed to meet the specification of USP, BP, IP and EUR.
- 4.1.3. The auto Karl Fischer apparatus shall be designed to facilitate effective and rapid determination of moisture content in a sample.
- 4.1.4. The auto Karl Fischer apparatus shall have interface with printer and computer.
- 4.1.5. The auto Karl Fischer apparatus shall have facility to produce wipe sound after the completion of titration.
- 4.1.6. The Karl Fischer apparatus shall be provided the reagent filling arrangement.
- 4.1.7. The Karl Fischer apparatus shall be provided with a amber colored glass bottle for online reagent filling and consumption.



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- 4.1.8. The auto Karl Fischer apparatus shall be provided with solenoid valves for flow controlling during titration.
- 4.1.9. The auto Karl Fischer apparatus shall be provided with a magnetic stirrer.
- 4.1.10. The Karl Fischer apparatus shall be provided LCD screen for the display of Reading.

4.2 The Karl Fischer apparatus shall be used primarily for:

For the determination of moisture content

4.3 Technical Specifications:

4.3.1 Power supply : 230 V AC, 50 Hz, 490 VA

4.3.1 Glass beaker : 500 ml, make – Duron.

4.3.2 Glass bottles : 1000 ml , make – Duron.

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

4.4.1 Room Temperature : 24± 2 °C

4.4.2 Relative Humidity: NMT 55 %

4.5 Base Utilities Available:

Electrical : **Single Phase, 230V ±10 % 50 HZ**

5.0 OPERATIONAL REQUIREMENTS:

5.1 OPERATION:

The auto Karl Fischer apparatus 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 Karl Fischer apparatus shall have alarm after the completion of the test.



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6.0 SALIENT FEATURES:

6.1 COMPATIBILITY AND SUPPORT:

ELECTRIC CONTROL:

Karl Fischer apparatus should consist of electrical on / off switch and software for operation and calibration.

UTILITIES:

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

6.2 MATERIAL OF CONSTRUCTION:

Beaker & Bottles : Glass (Duron)

Body of Instruments : Metals

6.3 Instruments & control: Programmable Operating Screen and Software

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 and DQ.

8.0 DELIVERY:

The Karl Fischer apparatus 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.



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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