USER REQUIREMENT SPECIFICATION

Name of Item: Karl Fischer Apparatus	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 1 of 2

1.0 **Purpose:** To describe the specific requirement of K F apparatus for measurement of water contents.

2.0 **Scope:** This specification is applicable to the KF apparatus to be installed at quality control laboratory.

3.0 **System Description:** KF apparatus shall be used for determining the water content in raw materials, finished products, in process samples etc. during routine quality control activities. The water contents are critical factors during manufacturing process; therefore to determine the water content the instrument is required. Moreover the pharmacopeias mention the requirement of water contents in the listed official monographs. Sometimes the analysis is required in the drug product during stability sample analysis. Therefore, the equipment shall have the following minimum listed specifications. Before purchasing the equipment additional features shall also be considered.

3.1 The equipment should have compact design and should be suitable for determining very small quantities of water present in the test sample. It should have the provision for cleaning of the equipment after usage. It should have the design in such a way that no unnecessary dismantling have to be done for cleaning thus avoiding carryovers from one sample to the other while analyzing multiple samples.

3.2 It should have the automated system for filling of all the solvents. The system should be capable of reproducing the results.

3.3 The instrument should be controlled through the software, which has facility to store all the generated methods for future usage. The software should be 21 CFR Part 11 compliant for data recording. The software should be capable of performing all the calculations and storing the data.

3.4 When taking printouts the software shall have the facility to customize the report as per user requirement or standard format could be made as per the final standard format.

3.5 The manufacturer/ supplier should provide complete documentation for validation of the equipment.

3.6 It should have provision for future up-gradation.

3.7 After sales service back up should be from approachable distance so as to minimize breakdown time, if any.

4.0 Documentation: Supplier/Manufacturer shall provide the following document.

- Test certificate of the material used for calibration or validation of the equipment certificates.
- Qualification (DQ, IQ, OQ, PQ) documentation.
- Operator's manual

5.0 Other Considerations: The manufacture/ supplier shall have the commonly used spares in stock. If not, the manufacture/ supplier shall have the provision to arrange at the earliest, if required. The manufacture/ supplier shall provide the general maintenance support to the Engineering section.

Prepared By:
Date:

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Date: