**USER REQUIREMENT SPECIFICATION**

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| **Name of Item:** Potentiometer | **Protocol No.:**..... |
| **Functional Area:** Quality Control | **Page No.:** 1 of 2 |

**1.0 Purpose:** To describe the specific requirement of Potentiometer.

**2.0 Scope:** This specification is applicable to the potentiometer to be installed at Quality Control laboratory.

**3.0 System Description:** Potentiometer shall be used for assay of raw materials and sometimes in the assay of in process as well as assay of finished products during routine quality control activities. As per different pharmacoepias i.e. Indian Pharmacoepia, British Pharmacoepia, European Pharmacoepia, United States Pharmacoepia the assay method involves the use of potentiometer. To comply with the assay procedure the instrument is required. Moreover, it shall also be required for preparation of working standards in the routine analysis in quality control laboratories. To comply with the international regulatory agencies with respect to assay, the equipment used shall have the following minimum listed specifications. Before purchasing the equipment additional features shall also be considered.

The potentiometer shall have the following listed features.

**3.1** The equipment should have compact design and should be suitable for carrying out aqueous as well as non-aqueous titration.

**3.2** It should have provision for multiple end point titrations.

**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.

**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 attachment of KF apparatus of similar make and the KF apparatus could be controlled through the same software.

**3.7** It should have provision for future up-gradation.

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

**4.0** **Documentation:** Supplier/Manufacturer should provide the following document.

- Test certificate of the material/ solution used for calibration or validation of the equipment.
- Software validation certificate.
- 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. The manufacture/ supplier shall provide the general maintenance support to the Engineering section.

**Prepared By:**
**Date:**

**Approved By:**
**Date:**