



**PHARMA DEVILS**  
QUALITY CONTROL DEPARTMENT

**USER REQUIREMENT SPECIFICATION**

**Name of Item:** Refractometer

**Protocol No.:**.....

**Functional Area:** Quality Control

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

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

**System Description:** Refractometer shall be used to measure the refractive index of a liquid sample. Refractive index is the inherent property of a compound and specific for a compound at a temperature. The refractive index is used for identification test of different compounds and is listed in different pharmacopeias shall be used for maintaining the temperature of the sample inside the sample compartment of the equipment. The samples where the maintaining of temperature is required are refractometer and viscometer. All these instruments are involved in testing of the critical parameters for testing of finished or raw material testing. The tests can alter the quality of the product in a significant way.

Based on the requirements listed above the refrigerated water bath shall consist of the following listed features. However, additional features shall also be considered.

**2.1** Capacity for water tank 5-10 ltrs of circulating water.

**2.2** Material of construction: The equipment should be made of stainless steel both from outside and inside to avoid any problem related to rusting or shedding of paint from the surface.

**2.3** It should have provision for circulation of the water from the bath to the instrument as a built in system or some external circulating device.

**2.4** It should have provision for temperature from 5°C to 50°C. The walls of the unit shall be insulated to minimize heat loss.



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**2.5** The cooling system should consist of a branded compressor and CFC free cooling gas filled inside the cooling system.

**2.6** It should have digital display of temperature. The temperature should be maintained through an efficient electronic device. The temperature uniformity should be there for effective temperature control.

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

**2.8** The manufacturer/ supplier should provide the following calibration certificates:

**2.8.1** Temperature display unit, with traceability.

**2.8.2** Any other measuring device, if any.

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

**3.0 Documentation:** Supplier/Manufacturer shall provide the following document.

- Circuit diagrams for electrical connections.
- Calibration certificates for all gauges or measuring devices with trace-ability.
- Test and guarantee certificates.
- Qualification (DQ, IQ, OQ, PQ) documentation
- Individual part certificates, if any.
- Operator's manual

**4.0 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 technical guidance to the Engineering section for general



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maintenance of the refrigerated water bath unit. The lab analysts should be trained for usage of the equipments.

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

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