USER REQUIREMENT SPECIFICATION (URS)

FOR

REFRACTOMETER

Department :

URS no.

Supersede :

USER REQUIREMENT SPECIFICATION

Name of Item: Refractometer	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 2 of 7

TABLE OF CONTENT

Issued to mfg / supplier by purchase department _____

1. Approval:

ACTIVITY DETAIL	NAME OF PERSON	DESIGNATION	SIGNATURE	DATE
Prepared By				
Reviewed By				
Approved By				

2. Change History:

REVISION NUMBER	REVISION DETAILS	DATE OF REVISION

3. Purpose:

The purpose of the user requirement for Refractometer is:
To define the instruction for selection of Refractometer for intended use
To provide a specification to the vendors for their submission of quotation.
To ease the selection process of vendors

4. Scope:

4.1 This document is applicable for Refractometer intended to 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. Specifications:

5.1 Description of equipment / system:

The Refractometer shall have following components.

- Temperature Control
- LCD
- Yet Flexible

The detail description of the components is as follows;

5.1.1 Temperature Control

- The instrument eliminates the expense and contaminitation associated with using circuling water baths to control and maintain the sample temperature.
- Built-in cooling and heating in both the presser head and surrounding the prism.

5.1.2 LCD

- LCD allows the scale, sample temperature, set temperature, time, and date status to be easily viewed.
- All functions are activated through a touch screen panel, which will not wear out, or to get misplaced like traditional or detachable keypads.

5.1.3 Yet Flexible

- The instrument should have with simple as placing a sample on the prism, closing the presser and reading the answer all in just a few seconds.
- The instrument should have the lockout function, like calibration and other functions are all password protected.

5.2 Identification number and location:

Equipment Name	Identification Number	Location
Refractometer		Instrument room

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;

- Liquid pharmaceutical raw materials
- Ophthalmic dosage forms
- Liquid injectable

5.5 Construction:

Not Applicable

5.6 Capacity:

The Refractometer must be capable for routine laboratory analyses as well as those involved in research and development.

5.7 Electrical construction:

Control panel includes all control equipment and switch cabinet will contain all high voltage equipment, the cabinet will provide the sterilizer with either 440 VAC, 50 Hz, 3Phase. Cabinet enclosure- Protection category will be IP/54, IP/55.

5.8 Control parameters:

Measurement modes, Optical wave length, Scales, Calibration, Prism, Response time, Light source, Display, Temperature measurement and control, Temperature resolution, Temperature sensor, sample temperature, ambient temperature, temperature accuracy.

5.9 Acceptable tolerance for control parameters:

Measurement scales	: Refractive index (RI), BRIX(% sucrose), Temperature corrected BRIX, Temperature corrected RI and 10 user programmable scales.
Calibration	: 1,2,3 or full multi-point calibration
Prism	: Sapphire
Response time	: Sample can be cooled to 20± 0.5 ℃ and measured in 20 seconds.
Light source	: LED (life:. 100,000 hours)
Temp.measurement & control	: 0- 100ºC
Temp. resolution	: 0.0001 RI and 0.01 BRIX

Temp. sensor	:	High class sensor for controlling of temp.
Sample temperature	:	0 - 80ºC
Ambient temperature	:	0- 40ºC
Temperature accuracy	:	0.05
Optical wave length	:	589.3 nm

5.10 Type of control System:

Software must supplied as standard and allows to control.
Instrument gets the security functions like password protection.
User-friendly touch screen.
Different measurement programs.
Prism dish is easy-to-clean and prevents sample spillage.
Measurements are not influenced by colour or turbidity.
Data out put of all important settings and measurements.
Full GLP capability

5.11 Feasible parameters to be set:

Name of users, Name of sample for analysis.

5.12 Parameters to be indicated by control systems:

1. LCD screen for Sample temp., set temp., etc.
2. Time and date formatting.
3. Formatting Format for recording data with company's name in header.

5.13 Available utilities:

1. Utilities required for electric connection can be provided.
2. Reagent for Calibration can be provided.

5.14 Limitations / constraints:

Not Applicable

5.15 Regulatory requirements:

Software employed for having a control on Refractometer, must be complying with 21 CFR part 11 regulation of USFDA.

5.16 Delivery Address:

……..

6 Safety:

Proper equipment earthing shall be provided.

7 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 Documentation:

S.No.	Document	Mode
1.	User manual	Paper or .pdf
2.	Software guide	Paper or .pdf
3.	Design specification	Paper
4.	Qualification documents	Paper
5.	Spare parts list	Paper

9 References: