USER REQUIREMENT SPECIFICATION

Name of Item: Polarimeter	**Protocol No**.:.....
Functional Area: Quality Control	**Page No.:** 1 of 8

Name of Instrument: Polarimeter

Document Reference No.: ……..

Effective Date: ……..

USER REQUIREMENT SPECIFICATION	
Name of Item: Polarimeter	**Protocol No**.:.....
Functional Area: Quality Control	**Page No.:** 2 of 8

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**

USER REQUIREMENT SPECIFICATION

Name of Item: Polarimeter	**Protocol No**.:.....
Functional Area: Quality Control	**Page No.:** 3 of 8

2.0 Table of Content:

3.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for a polarimeter. The URS is provided to aid the user through the important components.

The URS is provided to the supplier to provide a price quote for the, polarimeter including design and manufacture of the equipment.

The URS will be recognized as the integral part of the procurement agreement with the selected instrument vendor. The instrument supplier or vendor will abide by the information and condition set forth by this document as well as purchasing and delivery terms and condition of the Client.

The polarimeter shall be installed in Instrument Room of QC Department.

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

4.0 OVERVIEW DEFINITION:

4.1 The Polarimeter shall have the following features:

4.1.1. The polarimeter should have software for the operation.

4.1.2. The polarimeter should have reproducibility 0.002º Arc.

4.1.3. The polarimeter should be interface with PC and should have auto validation facility.

4.1.4. The polarimeter should design to meet the requirement of IP,BP, USP.

4.1.5. The polarimeter should have Tungsten-halogen 6V 20W, Average 2,000 hr. life

4.2 The polarimeter shall be used for:

The poralimeter shall be used for the measuring of optical rotation of optical active substances.

4.3 Technical Specifications:

Detailed Instrument Specifications for instrument are as follows:

ITEM	SPECIFICATIONS
Measuring Mode	Optical Rotation Specific Rotation Concentration User Defined Scale
Measuring Scale	Degree Arc

USER REQUIREMENT SPECIFICATION

Name of Item: Polarimeter	**Protocol No**.:.....
Functional Area: Quality Control	**Page No.:** 5 of 8

ITEM	SPECIFICATIONS
	% Concentration
Measuring Range	± 89°C Arc Optical Rotation, ± 999.99° Arc Specific Rotation, 0-99.99 ° Concentration
Resolution	0.001° Arc Optical Rotation, 0.001° below 100° Arc, and 0.01° Between 100 to 999.99° Arc Specific rotation, 0.001% Concentration
Reproducibility	0.002° Arc
Accuracy	0.002° up to 1° 0.2% up to 5° 0.01% above 5°
Optical Wavelength	325nm, 365nm, 405nm, 436nm, 546nm, 589nm, 633nm (other wavelength available)
Response Time	1°/sec. Slewing rate & 2 sec. nominal setting time
Light Source	Tungsten-halogen 6V 20W, Avg 2,000 hr. life
Sample chamber	Accepts sample tubes up to 200 mm
Communication interface	Two Rs 232 serial ports, one parallel printer port and one auxiliary port
Analog Output	0.1% resolution 0-10 volt full range (optional)
Calibration	Automatic calibration by push button
Display	Graphics LCD, 320 x 240 dots cold fluorescent back lit
Automatic sensitivity control	Permits measurement for sample transmittance as low as 0.01% or up to O.D. 4.0
Input power	100 V, 50/60 Hz

ITEM	SPECIFICATIONS
	115 V, 50/60 Hz 220 V, 50/60 Hz
Operating Dimensions	30" W x 9"H x 14" D 769 mm W x 231 mm H x 359 mm D
Shipping Dimensions	36"W x 19"H x 21"D 923mm W x 487 mm H x 538 mm D
Operating weight	70 lbs. (32 Kg)
Shipping weight	100 lbs. (45 Kg)
Temperature Compensation	Temperature of the sample can be corrected to a reference temp.
Temperature Display	Accurate to ±0.5°C Resolution 0.1°C
Calendar / Clock Functions	Battery-backed clock. Time and date sent to computer and printer.

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

4.4.1 Temperature **:** NMT 24°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 instruments operation shall be safe, smooth both from user and environmental stand point.

5.2 POWER FAILURE/RECOVERY:

In the event of a power failure, the system shall shut off automatically and acquire operator involvement to restart.

5.3 SAFETY FEATURE:

The instrument should produce warning or safety symbols to protect the instruments against damage.

5.4 ALARMS AND WARNINGS:

Instruments should give message in case of any wrong data entered

6.0 SALIENT FEATURES

6.1 COMPATIBILITY AND SUPPORT

ELECTRIC CONTROL:

The Supplier shall utilize controller that shall include a communication port.

UTILITIES:

The Supplier shall specify utility requirements. The User shall ensure that the utilities are available and that the utility supply lines and piping are terminated with fittings or connections.

6.2 MATERIAL OF CONSTRUCTION:

Metal and plastic

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, DQ.

8.0 DELIVERY

The polarimeter with all options, equipment, and the documentation listed below, shall be delivered to Client site. Delivery 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.

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