USER REQUIREMENT SPECIFICATION

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

Name of Equipment: HPLC Shimadzu

Document Reference Number: ……

Effective Date:

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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**

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3.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for the HPLC.

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

The HPLC system shall be located at instruments lab of Quality control area.

HPLC system is very important instruments in pharmaceutical industries and used to find out assay, purity of material, identification and chromatographic impurities.

The HPLC system shall be interfaced with following components.

1. Programmable quaternary gradient pump.
2. Four channel UV –VIS Detector
3. Auto sampler with chiller
4. column compartment
5. Chromeleon –pcs-1 software
6. Solvent Rack SOR 100
7. Mains cord

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

The unit shall be feasible to be installed in the current building facility.

4.0 OVERVIEW DEFINITION:

4.1 The High Performance Liquid Chromatographer shall have the following features:

4.1.1. The HPLC system is used for testing the all finish and raw material.

4.1.2. The HPLC system should have auto sampler for automatic sampling & it should have sample chiller which can provide temperature in the range 0 to 25°C.

4.1.3. The instrument should have column compartment to provide set and constant temperature to the column in the range 0 to 65°C.

4.1.4. The HPLC system should provide a LPG programmable quaternary pump with flow rate accuracy $\pm$ 1%.

4.1.5. The HPLC gradient pump should have high quality degasser to avoid pressure fluctuations.

4.2 The HPLC shall be used primarily for:

To find out the assay & chromatographic impurities.

4.3 Technical Specifications:

Detailed Instrument Specifications for instrument are as follows:

4.3.1 Low Pressure programmable quaternary gradient pump:

Flow rate accuracy:	±0.1% at 1 ml/min.
Pressure range:	0.1-50 MPa (7250 psi)
Pressure ripple:	Typically less than 1% or less than 1 bar whichever is greater
Proportioning accuracy:	± 0.5% at 2 ml /min
Proportioning reproducibility:	± 0.5% at 2 ml /min
No. of solvents:	Four
Degasser:	Built-in 4-channel degasser
Power Requirement:	200-240 V, 50 Hz.

4.3.2 Variable Wavelength Detector:

Optical design:	Dual-beam photometer (monochromator) Multiple wavelength UV/VIS detector
Wavelength range:	190 nm to 900 nm, programmable.
Wavelength accuracy:	+/- 2.0 nm, Internal calibration with zero order and D-alpha line of the deuterium lamp. Internal verification with holmium oxide filter.
Light source:	Deuterium lamp and tungsten lamp
Flow cell:	Standard: 11 µL, 10 mm path length or alternative flow cell, if available.
Linearity:	NLT 0.999
Signal Outputs:	Dual wavelength

4.3.3 Thermostat Column Compartment

Temp. range:	5º C to 85 º C
Temp. accuracy:	+/- 0.5º C
Temp. stability:	+/- 0.1º C
Temp. precision:	+/- 0.1º C
Column capacity:	6 columns; max. 30 cm length
Column preheating	With eluent heater
Heat Up/Cool-down time:	15 min. from 20ºC to 50 ºC/15min from 50ºC to 20ºC.
Power requirements:	Max. 150 VA

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

4.4.1 Room Temperature**:** 24± 2 °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 system shall operate with a minimum of operator involvement. Operation shall be safe both from an operator and environmental standpoint.

5.2 POWER FAILURE/RECOVERY:

In the event of a power failure, the system shall stop automatically upon loss of electricity and retain all the acquired data. The systems need operator intervention to re-start

5.3 SAFETY FEATURE:

The HPLC system shall have protection against Electrical failure

5.4 ALARMS AND WARNINGS:

The HPLC system should produce alarm in case of any parameter goes up and down from the set and tolerance limit. System should also provide warning at time wrong entry or operation.

6.0 SALIENT FEATURES:

6.1 COMPATIBILITY AND SUPPORT:

ELECTRIC CONTROL:

Power : Single Phase, 230V ± 10% 50 Hz

UTILITIES:

The Supplier shall specify utility requirement. The User shall ensure that the utilities are available.

6.2 MATERIAL OF CONSTRUCTION:

MS powder coated, rust free outer body or equivalent

6.3 Instruments & controls: Software

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. Design qualification.

8.0 DELIVERY:

The HPLC with all options, equipment, and the documentation listed below, shall be delivered to Client Site.

Delivered 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