USER REQUIREMENT SPECIFICATION (URS)

FOR

HIGH PERFORMANCE LIQUID CHROMATOGRAPH (HPLC)

Department : Quality Control

URS no. ……..

Supersede : Nil

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Issued to mfg / supplier by purchase department _____

1.0 Approval:

Activity detail	Name of person	Designation	Signature	Date
Prepared By				
Reviewed By				
Approved By				

2.0 Change History:

Revision number	Revision Details	Date of revision

3.0 Purpose:

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

4.0 Scope:

4.1 This document is applicable for HPLC to be procured for manufacturing plant.

4.2 The specification and criteria given in this document is to be considered but should not be limited to this.

5.0 Specifications:

5.1 Description of equipment / system:

HPLC shall have following components.
(a) Mobile phase reservoir (b) Pump (c) Auto-Injector (sampler) (d) column holding compartment (e) column oven (f) detector (g) Data handling software

The detail description of the components is as follows;

5.1.1 Mobile phase reservoir

- Facility to keep 5 solvent bottles of 1-liter capacity.

5.1.2 Pump

- Analytical Quaternary Gradient system.
- Flow rate range: 0.1 to 10 ml/minute
- Pressure: up to 5000 psi

5.1.3 Auto-Injector (sampler)

- Sample volume range: 10 µl to 100 µl
- Provision of auto injection and flushing of syringe.
- Sample vial compartment: at least 100 sample vials with inbuilt cooling facility.
- Programmable auto sampler

5.1.4 Column holding compartment and column oven

- Provision to connect chromatographic column of length 100 mm to 300 mm.
- Inbuilt column oven for temperature up to 80°C.

5.1.5 Detector

- UV –visible detector (Range 190 to 380 nm)
- Diode array detector (Range 190 to 700 nm)

5.1.6 Data handling software

- Capable to program the HPLC and can provide long period of unattended operation.
- Facility to receive and store detector output and print out of chromatograms.
- Software should have streamlined series of operations like Method preparation, sequence, and processing, reporting, reviewing and approving data.
- System suitability calculation according to BP/USP/Ph.Eur.
- Facility of multiple user log in, authorization for privileges, audit trail.

5.2 Identification number and location:

Equipment Name	Identification Number	Location
HPLC-1	Q/058	Instrument room
HPLC-2	Q/059	
HPLC-3	Q/060	
HPLC-4	Q/061	

5.3 Intended use:

5.3.1 Operation of equipment depends upon the production output; the equipment should be designed to work continuously for 3 shifts per day.

5.3.2 Shall be used for quantitative quality control analysis of drug compounds, impurities and method validation work.

5.3.3 The expected range of analyte concentration is 0.005 to 100%.

5.4 Intended type of material to be handled:

This will include handling of;

- Solid & Liquid pharmaceutical starting materials (API & excipients)
- Ophthalmic dosage forms
- Liquid injectable

5.5 Construction:

The parts of liquid chromatograph must be non-reactive with commonly used solvents and chemicals in HPLC analysis.

5.6 Capacity:

Not applicable

5.7 Electrical construction:

Not applicable

5.8 Control parameters:

Operating variables of pump, injector, auto sampler, detector must be controlled through software.

5.9 Acceptable tolerance for control parameters:

Pump flow rate: accuracy ± 5 % of set flow rate
Injection volume: accuracy ± 1% of set injection volume.
Detector wavelength: accuracy ± 1% of set wavelength
Column Oven Temperature: ± 5% of set temperature.

5.10 Type of control System:

Data handling software.

5.11 Feasible parameters to be set:

Purging, Flushing auto sampler syringe, Pump flow rate, Injection volume, detector wavelength, Method setup, and Sequence setup, Temperature, Shutdown Procedure.

5.12 Parameters to be indicated by control systems:

Wavelength, Temperature, Flow rate, Name of method, Name of sequence, Analysis details during Current Run.

5.13 Available utilities:

Bench for keeping HPLC in an instrument room.
Electrical utilities to start HPLC.
Chemicals and solvents.

5.14 Limitations / constraints:

Not Applicable

5.15 Regulatory requirements:

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

5.16 Delivery Address:

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6 .0 Safety:

In case of power cut off, the data of running analysis shall not be lost.

7 .0 Vendor Scope:

7.1 Spare Parts:

A suggested spare parts listing with their part number to be provided by vendor 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:

7.2.1 Start-up support shall consist of full time assistance on the User's site for installation, start-up and commissioning.
7.2.2 Vendor must provide familiarization and training.
7.2.3 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.
7.2.4 Technical support shall be available as and when required.
7.2.5 Any other information related to safety and utilities is to be provided by vendor.

8 .0 Documentation:

S.No.	Document	Mode
1.	User manual	Paper or .pdf
2.	Software guide	Paper or .pdf
3.	Qualification documents	Paper
4.	Spare parts list	Paper
5.	Certificates for compliance	Paper
6.	List of users	Paper

9 .0 References:

9.1 Unite states pharmacopoeia, British pharmacopoeia
9.2 Book on HPLC by P. D. Sethi
9.3 In house