## **TECHNICAL SPECIFICATION FOR HPLC SYSTEM WITH ACCESSORIES**

#### General:

- 1. The system should be all-in-one system with system controller, solvent delivery pump, autosampler, detector and column oven readily available and integrated into a single system.
- 2. The system should also allow further addition of optional detector for simultaneous multiple component analysis.
- 3. Usable solvent types should include both organic and aqueous solutions
- 4. Operable pH range should be 1 to 13
- 5. The system should also be able to auto-shutdown to reduce power consumption
- 6. A built-in system controller should be available for standalone operation functions, with graphical user interface (GUI) and touch-screen functions available are preferred
- 7. System controller GUI should display status of flow line and should synchronize with workstation software using Interaction Communication Mode (ICM)

#### Pump:

Туре	:	Quaternary Gradient
Flow Rate Setting Range	:	0.001 to 10 mL/min with 0.001 increments or better
Flow Rate Accuracy	:	±1% or better
Flow Rate Precision	:	±0.06% RSD or better
Gradient/Composition Range	:	0 to 100% with 0.1% increments or better
Gradient Accuracy	:	±0.5% or better
Gradient Precision	:	±0.1% or better
Solvent Handling Capacity	:	Minimum 4 solvents
Maximum Pressure	:	Not less than 6000 psi
Modes of Operation	:	Isocratic & Gradient flow Programming
Plunger Cleaning	:	Automatic rinsing mechanism
Safety	:	Leak detection and Leak handling features

#### Detector:

Туре	:	Photo Diode Array Detector
Wavelength Range	:	190 nm to 800 nm or more
Light Source	:	A deuterium lamp [D2] should be available as Light Source for UV and visible wavelengths respectively; and tungsten lamp [W] should be available as option
Number of Diodes	:	1024
Slit width	:	1.2 nm, 8 nm
Wavelength Accuracy	:	±1 nm or better
Linearity	:	2.5 AU or Better
Drift	:	500 x 10 <sup>-6</sup> AU/Hour or better
Noise Level	:	$\pm 3 \times 10^{-6}$ AU or better
Flow cell	:	Optical wavelength; 10 mm, Capacity: 10 μL or more,
		Pressure: 12 MPa.
Functions	:	Contour output, spectrum library, MX plotting, Suitable Peak Purity Software, Auto Threshold for Peak Purity
Data Transfer Rate	:	100 Hz or better

Other Facilities :	Detector should come with Dual Temperature control	
		function for better baseline stability control

### Injector – Autosampler with sample cooler:

Injection Volume Setting Range	:	10, 20, 25, 50, 100 μL
Injection Repeatability	:	0.5% RSD or better
Injection Volume Accuracy	:	±1% or better
Carry Over	:	Not more than 0.005%
Injection Volume Linearity	:	0.999 or better
Injection cycle time	:	20 seconds or better
Auto-sampler Temperature Range	:	4 to 40 °C or better
Sample Tray Capacity	:	Minimum 200 vials of 1.5 mL capacity
Other Facilities:		

- Co-injection/ Pre-treatment/ Auto Dilutions shall be available.
- Direct cooling type cooling system, with individual tray cooling capability should be available
- It should have safety features like leak sensor and automatic rack and vial recognition.

#### Degasser:

Туре	:	On-line degasser with 5 channels
Volume	:	10mL/min or better

#### Column Oven:

Туре	:	Forced air circulation type
Temperature Range	:	Ambient –10 °C to 85 °C or better
Temperature Precision	:	±0.1 °C or better
Capacity	:	Shall be able to handle at least two 30 cm length
		column.

## **Columns and Accessories:**

Analytical Column	:	C18, 25 cm x 4.6 mm id, 5u with Guard column to be
		included
Column Switching Valve	e:	Automated multi-column switching valve with minimum 6
		position and all the required accessories should be quoted as
		standard (Programmable through Software)
Vials, Cap & Septa	:	500 nos of 1.5 mL Vials along with caps and septa should be
		quoted as standard

Solvent bottles (4 nos or higher) with caps and accessories should be quoted as standard

#### Chromatography Software and Data Management System:

Platform	:	Windows based
Performance	:	Should cover full one-point digital instrument control,
		qualitative and quantitative processing, report creation and
		self-diagnosis.
Data Reports	:	Shall be customizable
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- Regulatory Compliance Software shall comply with 21 CFR Part 11
  - Help wizard to be available

- Automatic execution of system checks, auto-purge and baseline checks should be available
- Log Files should be available for complete audit trails.

Functions:

- The reporting format should be flexible and easy to use in any desired format
- The data can be converted to other (AIA, ASCII) formats. Spread Sheet software and word-processing software can be readily employed to provide data in tables or graphs through industry standard protocols
- Software must display the online status of instruments (Name, Type, Analysis, Status, User Running, Queued Count, Estimated End time)
- In-built pdf generator feature
- Functions to check PC Information, Software Program Files Check, User List, User Groups, Group Rights, Security Policy, Instrument Connection information from software and printable in pdf format
- It should cover full one-point digital instrument control, qualitative and quantitative processing, report creation and self-diagnosis

## **Computer:**

Company proprietary software should be preinstalled in the computer, which has not less than the following configuration

Computer	:	Branded PC with Genuine OS and Antivirus Protection
Memory and Storage	:	Minimum 8GB RAM & 1 TB Storage
Processor	:	Latest Core i5 processor, 2.4 GHz or better
Monitor	:	20" LED monitor or better

## **Documents Required:**

The following documents should be provided by the supplier:

- Operation Manual & Technical Specifications
- Calibration Certificate
- Equipment Qualification Reports (IQ, OQ and PQ)

## **Standard Warranty:**

Period	:	Not less than 36 months from the date of installation for
		both instrument and computer.
Preventive Maintena	nce:	Minimum 2 preventive maintenance visits per year without
		any additional cost.

## Standard Accessories & Consumables:

All standard accessories, essential consumables and tool kit required for the installation, operation and maintenance of the equipment shall be supplied.

## **Other Requirements:**

Number of Installations	:	Not less than 10 numbers. List of organizations with contact details should be provided.
Performance Certificates	:	Bidder should submit performance certificates from IITs, IISc, IISERs or Government (State/Central) Organizations. At

Service Availability	:	least three must be from IITs, IISc and IISERs Service engineer shall be available in Chennai. Contact details should be provided.
Demonstration	:	Working demonstration of the equipment shall be arranged by the supplier at any installed site. without any additional cost
Training	:	One-day training on operation, application, calibration and trouble-shooting of the equipment shall be provided by the supplier without any additional cost

# Option:

Annual Maintenance contract (AMC) should be quoted as option for 4<sup>th</sup> and 5<sup>th</sup> year.