

HIGH PERFORMANCE ANALYTICAL LIQUID CHROMATOGRAPHY SYSTEM

The HPLC system shall include the following individual stackable self-contained HPLC modules.

1. Quaternary Solvent Delivery System

- The flow rate should be set between 0.001 to 10 ml/min, or better for full operating pressure range
- Flow rate accuracy should be $\pm 0.1\%$ or $\pm 1\mu\text{l}/\text{min}$ or better
- Flow rate precision should be less than $\pm 0.050\%$ RSD or better.
- Maximum Pressure setting range should be 8000 psi or more.
- The standard gradient mixer should have delay volume of 700 μl or less
- The composition accuracy should be below 0.5%
- The composition precision should be below 0.15% RSD
- Maintenance kit, reservoir tray (with 4 solvent bottles complete with fittings)
- It should have automated seal wash facility.
- It should have built in seal wash facility.
- It must have a leak sensor as safety feature
- It should have functions for maintenance and validation which are accessible by software

2. Degassing Unit

- On line Membrane degassing unit should have four flow lines
- Maximum operating flow rate should be up to 10mL/min or more per flow line

3. Diode Array Detector

- Photodiodes: 1024 diodes

- The Bandwidth should be 4nm
- Light source: Deuterium and Tungsten
- Wavelength range must be from 190nm to 800nm
- The flow cell must be temperature controlled from ambient + 5°C to 40°C
- Wavelength accuracy must be ± 1 nm maximum
- Wavelength reproducibility must be ± 0.1 nm
- Drift should be less than 1×10^{-4} AU/Hour
- Noise level should be $< \pm 10$ μ AU at 254 nm
- Data Collection Rate: 100 Hz or better

4. Manual Injector Kit

- S-S manual injector valve, mounting bracket for valve as well as for columns, 100 microlitre injection syringe, Rheodyne 7725 injector

5. Auto-Sample Injector

- The auto sampler design should be a flow through design with variable injection volume.
- Sample injection volume should be variable between 0.1 μ L to 50 μ L.
- Loop injection using fixed loop [5 μ L] should be available as an option for reducing the delay volume.
- Injection system should be variable injection volume type with zero sample loss during injection
- It must be capable of very fast injection time of 15 S/sample
- The maximum operating pressure must be upto 10,000Psi (60MPa)
- Flow line rinse capability both before and after sampling should be possible
- Temperature setting range should be from 4 to 40°C or better
- The Carry over must be below 0.005 % or better

- Injection volume accuracy must be below 1% or better
- The injection precision should be less than 0.25% of RSD or better
- Number of samples to be processed automatically, random access minimum 100 positions for different volume vial
- It should have safety features like leak sensor and automatic rack and vial recognition.
- Maintenance kit should be available
- It should have functions for maintenance and validation which are accessible by software.

6. Column Oven:

- Column oven temp. should be upto 5 degree C. to 90 degree or better
- Eluent pre-heater and Post column cooler are preferable.
- Temperature accuracy +/- 1°C
- Temperature stability +/- 0.2°C

Temperature Repeatability +/- 1°C

Column Capacity: 5 Column or more

7. System Software

- It should function as a communication bus module with data buffering capability
- It should acquire upto 24 hours for one analysis, at 500ms sampling rate
- It must be controllable from a web-based interface via a network. It allows the system to be controlled, monitored and maintained via Internet Explorer Web browser
- It must be compatible with wireless networking
- It must have an expert function in that if pressure falls below specified value,

the expert function will automatically purge the mobile phase

- It should store up to 20 analysis files

8.COLUMNS

1.C 18 Column 150mmX2.1mmX3.1u-with guard column	1 No
2.C 8 Column 150mmX2.1mmX3.1u- with guard column	1 No
3.C 18 Column 250mmX4.6mmX5u- with guard column	1 No
4.C 8 Column 250mmX 4.6mmX5 u with guard column	1 No

9.Data Management System

Hardware

- § Intel Core i5 Duo processor
- § 4 GB RAM on board or higher
- § 1TB GB hard disk or higher
- § DVD-RW drive
- § 19 " LCD colour monitor
- § 101 keys key board and optical mouse
- § Pre-installed Windows XP/Windows 7
- § Multi functional Duplex Color printer

Software

- § Operation of the system should be easy and intuitive via a state-of-the-art 32 bit Windows 7 software with Graphical User Interface
- § Security features of software must comply fully with FDA 21 CFR Part 11
- § It should cover full digital instrument control, qualitative and quantitative processing, report creation, self-diagnosis and auto-tuning
- § The self-diagnosis feature of the software should enable diagnosis of all detectors and all connected LC units

- § The software must have 'column management' system for recording the column details and column usage.
- § The software should perform customised continuous analyses according to the conditions specified for each sample. Priority samples may be inserted in the queue during automated run.
- § The software should be capable to perform overlapping injections
- § The software should be able to monitor and quantitate 8 different wavelengths simultaneously
- § There should be an on-line help function available for users.
- § Method file should be capable to save all analysis parameters, data processing parameters and report format.
- § The reporting format should be flexible and easy to use in any desired format
- § The data can be converted to other 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 have its own log files for complete audit trails
- § The software must have a safety feature where in when the mobile phase level
- § System suitability as per USP/BP, System security as well as System check functions must be provided which comply with Good Laboratory Practice (GLP) and Regulatory Conformity.
- § It should have the capacity to control multi-vendor GC & HPLC.

10. Sonicator

5 ltr Capacity with Heating Facility or better

11. Sample & solvent filtration kit with vaccum pump

Solvent Filtration

- Filtration Assembly with 1 ltr Bottom flask

- Nylon 66 Membrane Filter

Vacuum Pump:

- Vacuum Pump - 22" Hg (554 mm Hg)

Sample Filtration Kit

- Filter Holder - Dia 13mm, S.S.
- 5 ml Glass Tight Syringe
- Nylon 66 Membrane Filter