

SECTION 3: REQUIREMENT SPECIFICATIONS**HSA000ETT16000054****Equipment: High Performance Liquid Chromatography****Location: Pharmaceutical Lab****Quantity: 1 unit**

SCOPE OF TENDER

To supply, delivery, installation and commissioning of one unit of High Performance Liquid Chromatography (HPLC) System.

The High Performance Liquid Chromatography unit shall be equivalent, if not better capabilities, than the stated specifications below.

TECHNICAL SPECIFICATIONS**Quaternary Gradient Solvent Delivery Pump**

1. The instrument must have an operation pressure of at least 130 MPa (1300 bar) from 0-2ml/min and an operation pressure of 80 MPa (800 bar) at 3-5 ml/min.
2. Must have a minimum settable flow range of 0.001 – 5 mL/min, in 0.001 mL/min increments
3. Flow precision must be ≤ 0.07 % RSD.
4. The flow accuracy shall not exceed $\pm 1\%$.
5. The settable mobile-phase composition must be from 0-100%.
6. The precision of mobile phase composition must be ≤ 0.15 % RSD.
7. The delay volume must not be more than 350 μL .
8. The instrument must provide extensive information for diagnostic purposes and built-in tests independent of data system used as for example:
 - Leak test - built-in troubleshooting test designed to demonstrate the leak-tightness of the pump
 - Pressure test - quick, built-in test designed to demonstrate the pressure-tightness of the system
 - Records, log files
 - Pump solvent delivered
9. Active seal wash kit must be included for improved seal life if buffer solvent is used.
10. Instrument must be able to notify the lab when the maintenance is due, early maintenance feedback to be included for continuous tracking of instrument usage in terms of seal wear and volume of pumped mobile phase with pre-defined and user settable limits and feedback messages. Electronic records of maintenance and errors.

On-line Degassing Unit

1. Membrane degassing unit for at least four flow lines.
 2. Maximum operating flow rate must be 5 ml/min per flow line or better.
 3. Each channel has an internal capacity of not less than 12 mL that allows a better stabilization process.
 4. It must have a leak sensor as a safety feature.
 5. Low noise and other environmental friendly features preferred.
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Auto-Injector

1. The autosampler design must offer a flow through design with variable injection volume to reduce the carry over.
2. Carryover must be less than 0.004 % (40 ppm) with needle wash.
3. It must come with a flush port.
4. The autosampler must be able to withstand high pressure at a minimum of 1300 bar.
5. The autosampler should be capable for automated injection of sample volumes of at least 0.1-50 µL in 0.1µL increments.
6. Should have a precision $\leq 0.25\%$ RSD from 5-100µL; $\leq 1\%$ RSD from 0.1-5µL.
7. Injection cycle time shall not more than 18 seconds.
8. Sample capacity must be able to hold more than 200 x 2ml vials.
9. The system must come with thermostat with minimum settable temperature from 4°C to 40 °C in 1 °C increments.
10. The injection program must be able to perform automated pre-column derivatization.

Thermostated Column Compartment

1. Temperature range is at least 4°C to 70°C
2. Temperature stability: should not more than $\pm 0.03^\circ\text{C}$.
3. Temperature accuracy: should not more than $\pm 0.5^\circ\text{C}$.
4. Column Capacity: must be able to hold a minimum of three columns with minimum length of 30 cm.
5. Warm up/Cool down time must not more than:
5 min from ambient $\rightarrow 40^\circ\text{C}$
10min from $40^\circ\text{C} \rightarrow 20^\circ\text{C}$
6. The system must incorporate with Leak detection and safe leak handling feature.

Diode Array Detector (DAD)

1. Detection must be via 1024-element photodiode array.
2. Diode width: minimum 1 nm and must be programmable
3. Linearity should be greater than 2.0 AU (shall not exceed $\pm 5\%$).
4. Wavelength accuracy should not be more than ± 1 nm for self-calibration.
5. Wavelength range must be at least 190-700 nm, settable in 1 nm increments.
6. Full spectral data acquisition rate must be at least 80 Hz.

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7. Standard flow cell that meets the following specification shall be included.
 - can hold 12-15 uL volume; and
 - 10 mm cell path length; and
 - can withstands at least 120 bar pressure.
8. Signal noise must be less than $\pm 7 \times 10^{-6}$ AU
9. Wavelength drift must be less than 0.9×10^{-3} AU/h.

Data processing

1. Background subtraction must be able to be performed in the same chromatogram at any time-point.
2. The instrument must be able to generate multiple wavelengths library search results in one report for a single injection.
3. Software must be easy to use for library matching i.e. the matching on screen shall not more than 2 steps.
4. The instrument must be mutually compatible with the lab existing in-house library. The Library search report for standards must be able to give a matching factor of ≥ 950 (Base factor = 1000 for 100% match) or equivalent.

Others

1. All modules in HPLC system must be able to communicate with each other.
2. The supplier must provide chromatographic software with PC monitor and printer. Minimum 8.0GB RAM and minimum 1TB Hard disk shall be provided
3. Printer should at least meet the following requirements:
 - Monthly duty cycle : 3000-5000 pages per month
 - Memory : 128MB
 - Speed : at least 20 pages per minute
 - Size : A4
 - Duplex : Yes
 - Paper Tray : 500 sheets
 - Print Technology : Monochrome Laser
 - Print resolution : 600dpi
 - Network printer : yes
4. System must come with at least two-year warranty upon successful commissioning, covering 1 preventive maintenance per year, defective parts replacement and labour support service. All relevant warranty coverage must be clearly explained.
5. At least 2 on-site training for operating the system and performing maintenance must be provided respectively. Supplier shall provide comprehensive training for equipment at Supplier's Training Centre.
6. The reporting format must be customisable by the laboratory.
7. System settings must be able to link up to OpenLAB Enterprise Content Manager which the Lab is currently using for data archival.
8. The price quoted shall include Installation Qualification and Operation Qualification (IQ/OQ) to be performed for the HPLC system.

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9. Proper documentation is to be supplied along with the delivery of the equipment. These shall include the operator's manuals/software manual, equipment manuals, electrical circuits/ manuals and service manuals.
 10. Original copy of application software must be provided.
 11. Free update of the operation system software must be provided during warranty period.
 12. The software must allow the setting of accessibility to folders and data for different user roles.
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I hereby confirm that I can meet all the Requirement Specifications as stated above.

Supplier's (as *Principal/Agent)
Company or Business Registration No:

Supplier's official
Stamp:

Authorized Signature

Name:

Designation:

(*Delete whichever is not applicable)

Please indicate any non-compliance here should there be any.

Reference To	Remarks