

Should your offer be accepted, the Requirement Specifications as set out in this Part and shall govern the Contract between the Authority and your company.

**Specifications for a High-Performance Liquid Chromatograph-Photodiode Array Detector
(Pharmaceutical Laboratory)**

The System shall comprise the following:

- I) Quaternary solvent delivery pump
- II) Integrated degassing unit
- III) Auto-injector
- IV) Thermostat column compartment
- V) Photodiode array (PDA) detector
- VI) Data processing and chromatographic software
- VII) Computer Hardware and Software
- VIII) Installation, Commissioning and training
- IX) Warranty

TECHNICAL SPECIFICATIONS

I) Quaternary Solvent Delivery Pump

- 1. The pump must have a maximum operation pressure of at least 130 MPa (1300 bar) at <3ml/min and a maximum operation pressure of at least 80 MPa (800 bar) at 5 ml/min.
- 2. Preferably have a minimum settable flow range of 0.001 – 5 mL/min, in 0.001 mL/min increments.
- 3. Maximum flow rate of 5 ml/min or better.
- 4. The flow accuracy shall not exceed $\pm 1\%$.
- 5. Flow rate precision: $\leq 0.07\%$ RSD.
- 6. The pump must be able to withstand pH range of at least 1.0 -12.0.
- 7. The precision of composition must be less than 0.6% RSD.
- 8. It must have a leak sensor as safety feature.

II) Integrated Degassing Unit

- 1. Membrane degassing unit for at least 4 flow lines shall be available.
- 2. Maximum operating flow rate of up to 5 ml/min per flow line or better.

III) Auto-Injector

- 1. Maximum operating pressure shall be at least 130 MPa
- 2. Sample injection volume shall be variable, preferably at least between 0.1 μ l to 40 μ l in 0.1 μ l increments, with the option to expand the injection volume to 100 μ l when needed.
- 3. It must come with a flush port or equivalent.
- 4. Sample capacity must be able to hold at least 100 x 2ml vials.
- 5. It must be capable of injection cycle time of preferably not more than 10s.

6. The system must come with thermostat with minimum settable temperature range from 4°C to 40 °C in not more than 1°C increments.
7. It must be capable of a carry-over less than 0.003 %
8. The injection precision shall be less than 0.15% RSD
9. It shall have a leak sensor, automatic rack and vial recognition as safety feature

IV) Thermostat Column Compartment

1. Minimum temperature range shall be at least 10°C below ambient to 80°C.
2. Temperature precision: shall not be more than $\pm 0.1^{\circ}\text{C}$.
3. Temperature accuracy: shall not be more than $\pm 0.5^{\circ}\text{C}$ with calibration.
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 be more than: 5 min from ambient $\rightarrow 40^{\circ}\text{C}$; and 10min from $40^{\circ}\text{C} \rightarrow 20^{\circ}\text{C}$

V) Photodiode Array (PDA) Detector

1. Detection must be via 1024-element photodiode array or equivalent to demonstrate similar resolution.
2. The temperature operating range must be at least from 4°C to 40°C.
3. Linearity shall be typically 2.5 AU with 5% deviation.
4. Wavelength accuracy shall not be more than $\pm 1 \text{ nm}$ for self-calibration.
5. Wavelength precision not more than $\pm 0.1 \text{ nm}$.
6. Wavelength range must be at least 190-600 nm, settable in 1 nm increments.
7. Maximum data acquisition rate must be at least 240Hz.
8. Signal noise must be less than $\pm 2 \times 10^{-6} \text{ AU/cm}$
9. Signal drift much be $\leq 0.5 \times 10^{-3} \text{ AU/h}$.

VI) Data processing and chromatographic software

1. Must be a Windows-based data system that provides system control and data analysis and able to view system status, user information, and monitor runs.
2. The software shall be able to control the LC through local area network (LAN) technology. The internet protocol (IP) address used on the system shall be in accordance to the standards of HSA network plan.
3. Contractor shall ensure that the PC/notebook provided with the system is network ready and be able to connect to the HSA's network for interfacing with HSA's LIMS (Laboratory Information Management Software) system, e.g. LISA, LabWare, etc.
4. The system software must be able to interface with HSA's LIMS for the following:
 - Raw data files archival & retrieval.
 - System test result report output to PDF for archival.
 - System test result report for result uploading.
 - To accept work list upload from HSA's LIMS, if applicable.
5. System shall be able to import and run a sequence file generated by the LIMS. The sequence file generated shall be in ".csv" or ".txt" file format.
6. Contractor shall work with HSA personnel for the following:

- To define and assign a Hostname and/or PC name given by HSA IT infrastructure team to facilitate the system management on HSA network.
 - To define the raw data file structure & directory assigned by HSA to facilitate the automation of electronic archival and retrieval of files.
 - To perform SIT and UAT to ensure the integration to HSA's LIMS system is running fine.
7. For the system report printing and extraction, the Contractor shall work with Laboratory to ensure the seamless integration and interface with HSA's LIMS.
 8. The Computer system shall supply with Microsoft Windows Operating system that support Microsoft Active Directory Domain infrastructure.
 9. The Computer system supplied shall use active directory-based user accounts without the requirement of having domain administrator privileges.
 10. The Computer system together with the operation of the required scientific shall not require the use of local system privilege's account or rights for its functional use.
 11. Lab Diagnostic software to allow continuous monitoring of LC in real time to alert user maintenance needs and system problems.
 12. The software must be able to fully control the system using pre-stored methods of all the operating parameters.
 13. The system shall have the capability for method transfer between different LC models.
 14. Must be mutually compatible with the current in-house UV spectral library.
 15. If conversion of library be required, it must be user friendly and can be done by user.
 16. The conversion must not cause any loss in information such as substance loss or UV spectra loss.
 17. Must be able to load and read data from existing LC systems (Agilent 1200, 1260 and 1290) in the laboratory. Acquired data from proposed system shall also be accessible in all LC systems with or without additional software. If additional software is required for the above function, Tenderer shall quote for the software and to specify in **the Annex C Price and Submission Information - Price Schedule**.
 18. Must provide free update of the PC operation system and software during warranty period.
 19. All systems proposed shall be compliant to Good Laboratory Practice (GLP) with system suitability, system and sequence logbook.
 20. User-friendly, intuitive software to facilitate efficient data analysis. Selection of spectra and chromatogram, magnification of spectra and chromatogram, integration, background subtraction, library search shall be completed in a minimum number of clicks compared to the existing LC software.
 21. Must have the ability to run in a fully automated manner, while also providing for manual data evaluation.
 22. Must be able to acquire data, integrate, review and report on an actively running sample.
 23. Must have the feature to protect testing methods from being tampered.
 24. Original copy of application software must be provided. Electronic licenses are accepted.
 25. It shall cover full digital system control, qualitative and quantitative processing, report creation and self-diagnosis.
 26. There shall be an on-line help function.
 27. The report format to be generated via software must be customizable by the Laboratory.
 28. The data can be converted to other formats i.e. ".doc", ".xls", "pdf" and "csv" files.
 29. The software must allow the setting of accessibility to folders and data for different user roles.
 30. Software must have its own log files.

31. Tenderer shall submit the screenshot on the steps required (refer to **Clause VI (20)** for the following for evaluation:

- a) Adding spectra into the library after data acquisition; and
- b) Quantitation workflow using existing calibration data.

VII) Computer Hardware and Software

1. A data acquisition/processing computer and a Laser printer shall be provided with equivalent or better configurations as follows:

PC specifications:

- Operating System: Microsoft Windows 10 (latest build version) and Microsoft Office software 365 which is compatible with the data management software.
- Processor: Intel® Core™ 9th Gen i7 Processor or better
- Monitor: Minimum 22" IPS LED Monitor with resolution 1280 x 1024 dpi
- Hard Disk: 1TB 7200 rpm SATA 6Gb/s HDD or better
- Memory: Minimum 16GB DDR4 RAM
- Available Network Interface Ports: Shall be built-in to the computer board or PCI card based with minimum 2 ports.
- DVD-ROM drive
- 104 key Keyboard
- Optical mouse and mouse pad
- Must be able to support HSA supplied managed AV.

Printer specifications:

- Monthly duty cycle: 3000-5000 pages per month
- Memory: 128MB
- Speed: at least 40 pages per minute
- Size: A4
- Duplex: Yes (Automatic)
- Paper Tray: 500 sheets
- Print Technology: Monochrome Laser
- Print resolution: 1200 x 1200 dpi
- Network printer: yes

VIII) Installation, Commissioning and Training

1. On-site trainings for operating the system and basics performing maintenance must be provided for approximately 30 laboratory staffs. Due to Covid-19 situation, Tenderer must be able to accommodate the training arrangement for laboratory staffs based on MOH's guidelines.
2. Comprehensive maintenance and troubleshooting training must be provided for at least 2 lab staffs at Contractor's training centre or on-site.
3. The price quoted shall include Installation Qualification and Operation Qualification (IQ/OQ) to be performed for the HPLC-DAD system.

4. Proper documentation is to be supplied along with the delivery of the system. These shall include the equipment operating manuals and service manuals.
5. Contractor shall submit Risk Assessment Report in 5x5 matrix prior to the delivery of the System.

IX) Warranty

1. System must come with at least two (2) year warranty upon successful commissioning. Warranty shall minimally include:
 - 1 preventive maintenance (PM) per year;
 - PM kit (if applicable);
 - Replacement of ALL defective parts for hardware and software;
 - Provision of repair consumables for unforeseen breakdown;
 - Unlimited breakdown calls and onsite support service during Office Hours i.e. 8am to 6pm from Monday to Friday excluding Saturday, Sunday and Public Holidays; and
 - Provision of updates for all software including operating software.
2. A service report shall be provided upon completion of each PM.

Please indicate any non-compliance to requirement specifications here should there be any.

Reference To	Remarks