

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

The LC-MS/MS system is intended to use to support confirmation analysis for Pharmaceutical Laboratory and must minimally comply with the following requirements:

SECTION A – ULTRA PERFORMANCE LIQUID CHROMATOGRAPHY

A.1 Binary gradient solvent delivery system

1. The system shall be equipped with two solvent selection valves to enable the choice of 2-6 different mobile phase solvents.
2. There shall be a switching valve to divert the mobile phase flow to waste, without going through the analytical column, for regular flushing of the system.
3. It shall have a flow rate range of at least 0.001 – 8 ml/min, in 1 µl/min increments.
4. Flow rate accuracy shall be $\pm 0.1\%$ or better.
5. Flow rate precision shall be $\leq 0.05\%$ RSD or ≤ 0.01 min SD, whichever is greater.
6. The gradient accuracy shall be $\pm 0.2\%$ of full-scale or better.
7. The gradient precision shall be $\leq 0.15\%$ SD.
8. The pump must have a maximum operation pressure of 103 MPa (1034 bar) at < 5 ml/min and a maximum operation pressure of 80 MPa (800 bar) at > 5 ml/min.
9. The pump shall have an adjustable purge function and automatic purging available through an autosampler.
10. The pump shall offer finger-tight fitting systems for tool-free maintenance of externally accessible tubing
11. The pump shall be equipped with an electronic leak sensor.

A.2 Autosampler/ injector

1. The autosampler shall be able to operate at pressures in the range of 2 – 103 MPa (20 – 1034 bar).
2. The linearity of the autosampler shall be $r > 0.99999$ (caffeine in water).
3. The autosampler shall offer automated barcode recognition of the type of sample rack or well-plate and detection of empty sample segments.
4. The autosampler shall offer safety features, including leak sensor, automatic sample rack recognition, empty segment detection, and internal monitoring of all mechanical operations.
5. The autosampler temperature accuracy shall be $-2^{\circ}\text{C} / +4^{\circ}\text{C}$ from the set temperature or better.
6. The injection range of the autosampler is 0.01–25 µL with a min. step of 0.01 µL. There shall have an option to extend the injection range up to at least 100 µL. Tenderer shall quote for the option to purchase the sample loop in **Annex C to Part 3 – Price and Submission Information**.
7. The autosampler shall provide an injection volume accuracy of $\pm 0.5\%$ or better at 10 µL water.
8. The autosampler shall be able to operate with a minimum sample volume of 2 µL at 1 µL injection volume.
9. The injection volume precision of the autosampler shall be $< 0.25\%$ area RSD for 1 µL (caffeine in water), typically $< 0.5\%$ area RSD for 0.5 µL (caffeine in water).
10. The carryover of the autosampler shall be $\leq 0.002\%$ with caffeine

A.3 Thermostatted column compartment

1. The operational temperature should range from at least 25-60°C.
2. The temperature shall have accuracy within $\pm 0.5^\circ\text{C}$, stability/precision within $\pm 0.1^\circ\text{C}$.
3. It should have the capacity of holding at least 4 analytical columns with 2.1 mm ID and column length of at least 10 cm, and each with guard columns.
4. It shall have solvent leak sensor and real time temperature monitoring.

SECTION B – QUADRUPOLE MASS SPECTROMETER (MS/MS)

B.1 Ion Source

1. The system shall be equipped with Electrospray Ionization (ESI) source as the standard, operable at both positive and negative polarity.
2. Changing or maintaining the ion source shall be possible without braking the vacuum and simple for the user to perform (without specific tools).

B.2 Mass Spectrometer

1. The system shall be a segmented linear quadrupole ion trap mass spectrometer.
2. The system shall be able to perform full scan MS and selected ion monitoring and Selected Reaction Monitoring.
3. The system shall be capable of rapidly switching between positive and negative ion detection.
4. The system shall be capable of **MSⁿ** multi-stage MS experiments with no low mass cut-off.
5. The system shall be able to perform ultra-high resolution slow scanning for resolutions up to a minimum of 20,000.
6. The mass spectrometer shall be supplied with a divert valve that is under fully automated data system control.
7. The mass spectrometer shall have an integrated syringe to allow for automated infusion under data system control.
8. The mass spectrometer shall have automatic system calibration and optimization.
9. The detector polarity shall be able to switch between alternate scans in not more than 100 msec.
10. The system shall operate at the mass range (m/z) of m/z 15 – 200; m/z 50 – 2000 and m/z 20 – 4000.
11. The system shall be able to isolate ions down to 0.3 Da, up to m/z 1000 and 1 Da isolation width for up to m/z 200.
12. ESI Full scan MS/MS Sensitivity Signal-to-Noise ratio: The S/N shall be higher than 100:1 for 250 femtogram reserpine injection on column.
13. ESI MSⁿ full scan Sensitivity Signal-to-Noise ratio: The S/N shall be higher than 25:1 for 250 femtogram reserpine injection on column.

SECTION C – DATA MANAGEMENT SYSTEM

C.1 Computer and Accessories

1. Operating System: Microsoft Windows 10 (latest build version) which is compatible with the data management software and supported Microsoft Office 365 (licence to be provided by Authority)
2. Processor: Intel® Core™ 9th Gen i7 Processor or better

EQUIPMENT 2: ULTRA PERFORMANCE LIQUID CHROMATOGRAPH TANDEM QUADRUPOLE MASS SPECTROMETER (LC-MS/MS) SYSTEM**LOCATION: PHARMACEUTICAL LAB**

3. Monitor: Minimum 22" IPS LED Monitor with resolution 1280 x 1024 dpi
4. Hard Disk: 1TB 7200 rpm SATA 6Gb/s HDD or better
5. Memory: Minimum 16GB DDR4 RAM
6. Available Network Interface Ports: Shall be built-in to the computer board or PCI card based with minimum 2 ports. (Depending on system requirements; 1 of the ports will be used for connecting to HSA Network)
7. DVD-ROM drive
8. 104 key Keyboard
9. Optical mouse and mouse pad
10. Must be able to support HSA supplied managed AV.
11. Printer: Black and white Laser printer

C.2 Software

1. The software must be compatible with Microsoft Office 365 software.
2. The NIST 2020 MS library which includes both the EI and MSMS tandem spectra libraries shall be provided.
3. The software shall be a Windows-based data system that provides full digital system control, automatic tuning, automated SRM optimizer, data acquisition, qualitative and quantitative analysis, report creation and diagnostics.
4. Data acquisition, peak integration, calibration, quantification and QC calculation shall be fully automated.
5. The software shall update ion ratios and retention times automatically.
6. It shall be able to acquire data, integrate, review and report on an actively running sample
7. Shall be able to import/export sample sequence or calibration information minimally to Excel.
8. Output for importation to LIMS system shall be possible for result uploading.
9. shall allow user to view system status, user information, and monitor runs.
10. The software shall be able to control the system 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.
11. The Tenderer 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
12. The system software shall be able to interface with HSA's LIMS for the following:
 - a) Raw Data Files archival & retrieval.
 - b) System test result report output to PDF for archival.
 - c) System test result report for result uploading.
 - d) To accept work list upload from HSA's LIMS, if applicable.
13. System shall be able to import and run a sequence file generated by the LIMS. The sequence file generated is shall be in csv or txt file format.
14. The Tenderer shall work with HSA personnel for the following:
 - a) To define and assign a Hostname and/or PC name given by has IT infrastructure team to facilitate the system management on HSA network

- b) To define the Raw Data file structure & directory assigned by HSA to facilitate the automation of electronic archival and retrieval of files.
 - c) To perform SIT and UAT to ensure the integration to HSA's LIMS system is running fine.
15. For the system report printing and extraction, the Tenderer shall work with Laboratory to ensure the seamless integration and interface with HSA's LIMS.

C.3 Information/ Details to be included in the report

- 1. The report to be generated by the software for qualitative and quantitative analysis must be customisable by lab and Contractor shall assist the user to customise the report parameters.
- 2. The software must be available for user to customize or modify the report format.
- 3. In general, the report must include basic sample information such as sample name, operator, acquisition date and time, sample vial position, injection volume, data file name/path, acquisition and data analysis method as well as any user comment.

SECTION D – MISCELLANEOUS

D.1 Training, Warranty and Support

- 1. 3 days' in-house training for at least 4 staffs shall be provided and shall minimally include routine hardware maintenance and troubleshooting, software to operate the system and basic and advance data analysis.
- 2. The price quoted shall include Installation Qualification and Operation Qualification (IQ/OQ) to be performed for the LCMS/MS system
- 3. The system shall come with at least two (2) years warranty. Tenderer shall quote for option to purchase post warranty comprehensive maintenance contract for the system for 3 years and another further 2 years.
- 4. The warranty and post warranty comprehensive maintenance contract shall cover both hardware and software that minimally include the following:
 - (a) At least 1 preventive maintenance (PM) per year inclusive of PM kit;
Note: Commissioning of the equipment is not considered as a PM.
 - (b) Provision of unlimited breakdown calls, on-site services, troubleshooting and repairs during Office Hours i.e. 8am to 5:30pm from Monday to Friday excluding Saturday, Sunday and Public Holidays. Please refer to **Section D – Miscellaneous, Clause D.2 (d)** for the response time;
 - (c) Provision of repair consumables/ wear and tear parts for corrective maintenance during unforeseen breakdown
 - (d) Supply of all replacement parts; and
 - (e) Provide system update or upgrade of software version.
- 5. The Contractor shall guarantee that the spare parts, consumables and services for the system will be available for a period of 7 years from the date of discontinuation of the system.
- 6. The Contractor must have at least 1 hardware engineer and 1 application chemist locally for the provision of technical support of the proposed system. Please provide the list of trained engineers & chemists of the proposed system in **Annex C – Price and Submission Information** for reference.
- 7. For post warranty comprehensive maintenance contract, Contractor shall invoice after PM is successfully carried out.

D.2 Performance of Services during warranty and post warranty comprehensive maintenance contract

The Services to be performed by the Contractor shall consist of Preventive Maintenance and Corrective Maintenance as described below.

Preventive Maintenance

- a) The Preventive Maintenance shall consist of:

Routine maintenance of the System, including but not limited to the testing of functions and inspecting of the condition of the System in order to keep the System safe for use and in Good Working Order; and Adjustment and/or repair of any defect in or malfunction of the System discovered by the Contractor's representatives during the course of routine maintenance checks.

- b) The Preventive Maintenance performed shall be in compliance with the maintenance procedures and safety tests specified by the manufacturer.
- c) The Preventive Maintenance shall be carried out and completed during Office Hours.

Corrective Maintenance

- d) Upon receipt of oral or written notice from the Authority, the Contractor shall use its best endeavours to ensure that the Contractor's suitably qualified and duly authorised representatives attends to the Authority, within the response time of not more than 24 hours upon receipt of oral/written notification if the request is made on a Working Day. If the request is made on a non-Working Day, the Contractor shall respond within the next Working Day.

D.3 Replacement and Purchase of Components

- a) The Contractor shall inform the Authority of any part or component of the System that needs to be replaced. Prior written approval must be issued by the Authority before the replacement may be effected unless the replacement required is deemed urgent by the Authority in which case a verbal approval (which shall subsequently be confirmed in writing) obtained from an authorised officer of the Authority shall suffice.
- b) The Contractor shall use all reasonable endeavours to supply only original or genuine replacement components, which are required to maintain the System in good working order. All replacement components shall not be chargeable during the period of warranty period and post warranty comprehensive maintenance contract

Please indicate any non-compliance to requirement specifications here.

Reference To	Remarks