

PART 3: REQUIREMENT SPECIFICATIONS

HSA000ETT17300002

Equipment 7: Liquid Chromatography - High Resolution Accurate Mass Spectrometer (LC-HRMS-MS) System

Quantity: 1

Location: Pharmaceutical Laboratory (Pharm)

Supply, delivery, installation and commissioning of one unit of Liquid Chromatography- Quadrupole High Resolution Accurate Mass Spectrometer (LC-HRMS-MS) System.

TECHNICAL SPECIFICATIONS**(I) High Performance Liquid Chromatography System****(a) Solvent Rack with Degasser**

- Operate at a maximum flow rate of 5 ml/min per channel
- Have at least 4 independent channels
- Channel volume of 500 µl or more for thorough degassing

(b) Binary Pump

- Two serial dual-piston pumps
- Four solvent lines before the pumps
- Proportioning accuracy of $\pm 0.2\%$ or better
- Proportioning precision is $< 0.15\%$ SD
- Flow-rate range settable from 0.1 to 5.0 ml/min
- Flow rate precision of $< 0.05\%$ RSD or better
- Flow accuracy $\pm 0.1\%$ or better
- Max operating pressure of 15,000 psi or higher
- Includes leak sensor, active rear-seal wash system, excess pressure monitoring
- Biocompatible, no stainless steel in flow path

(c) Thermostatted Column Compartment

- Temperature control range 25 °C to 80 °C
- Temperature accuracy of $\pm 0.5\%$ or better
- Temperature stability of $\pm 0.1\%$ or better
- Temperature precision of $\pm 0.1\%$ or better
- Equipped with humidity and temperature sensor
- Provide finger tight fittings with zero dead volume for easy connection to columns

(d) Well Plate Autosampler

- Injection method using in line split-loop principle
- Sample tray capacity: minimum 100 x 2 ml vials
- Settable injection volume option of 0.01 µl to 50 µl
- Injection volume accuracy of $\pm 0.5\%$
- Injection volume precision of $\leq 0.25\%$ RSD
- Carryover of $\leq 0.005\%$
- Sample thermostating temperature range 4 °C to 45 °C or wider

(II) Quadrupole High Resolution Accurate Mass Spectrometer System**General**

- The mass spectrometer must deliver high resolution and accurate masses at all modes of operation
- The mass spectrometer must be capable of real-time data acquisition and data processing, enabling a high spectrum repetition rate
- The mass spectrometer must be able to perform parallel filling and detection
- The mass spectrometer must not need liquid cooling
- Must provide control software for the HPLC and mass spectrometer

Sensitivity

- Buspirone 1 pg on column yields S/N $\geq$ 200:1 or Reserpine 1 pg on column S/N $\geq$ 200:1
Mass Resolution
- Resolution of 50,000 (full width at half maximum FWHM) or better for all scan modes under both positive and negative polarities

Scan Rate

- Maximum scan rate of 12 scans per second or faster in Full Scan

Mass Accuracy

- $< \pm 3$ ppm RMS (Root mean square) – with external calibration over 24 h and without any kind of mass recalibration
- $< \pm 1$ ppm RMS – with internal calibration

Mass Range

- The mass range must be settable between 50 to 3000 m/z or wider

Polarity Switching

- The mass spectrometer must be capable of fast ionization polarity switching to perform one positive mode full scan and one negative mode full scan within one second while maintaining mass accuracy in one injection

Scan Functions

- Quadrupole mass filter function that can perform multiple precursor ion isolation
- Able to do data-dependent or data-independent MS/MS fragmentation of isolated ions with adjustable energy levels and with high resolution accurate mass detection
- Able to do targeted MS/MS scan at specified time
- Able to do SIM scan or timed SIM scan
- Able to do all ion fragmentation scan

Ionization Source

- ESI ionization source
- Flow operating range (without splitting): 1 μ l/min to 1000 μ l/min or better
- The probe must be capable of temperatures up to 400°C to increase the desolvation efficiency and decrease chemical noise
- Incorporate a safety interlock switch to turn off voltages when the ion source is removed from source housing

Intact Protein Analysis Function

- The MS should have ability to preserve and analyse intact proteins, and provide isotopic resolution of intact proteins up to 28 kDa

Vacuum System

- Differentially pumped vacuum system with final vacuum $< 1 \times 10^{-9}$ Torr
- Rotary rough pump is supplied with sound insulation box to reduce noise
- The pump should be able to automatically shut down after power failures

Uninterrupted Power Supply

- Have battery capacity allowing for at least 10 mins system backup in the case of power outage
- Have external isolation transformer for suitable output to support the LC-HRMS/MS system
- Installation and commissioning must be carried out together with the LC-HRMS/MS hybrid system

(III) Application Software

- Software to provide LC and MS instrument control, including acquisition
- Software to support quantitative analysis and compound identification by accurate mass, isotope pattern & MS² library (can be customised) match
- Software to support unknown screening with the following features: differential analysis, intact mass search against ChemSpider, theoretical fragmentation of parent to annotate daughter ions, finding transformed compounds (eg drug metabolites or drug analogues)
- Software to support intact protein analysis with deconvolution algorithm
- Software to support peptide mapping
- Latest LC-HRMS/MS library of drugs, poisons and their metabolites

(IV) System Control and Data Handling Systems

Two (2) sets of computer and printer are required, for data acquisition and data process respectively.

For data acquisition:

Personal computer with the following *minimum* requirements:

- 2 GHz processor with 8 GB RAM
- DVD-ROM drive
- Video card and monitor capable of 1280×1024 resolution (XGA)
- Screen resolution of 96 dpi
- Not less than 1 TB available on hard disk
- NTFS format
- Windows 7 (64-bit)
- Operation system software with valid licence
- 21" TFT color monitor
- Heavy duty printer (double side printing black and white)

For data process:

- Same as the specification for data acquisition with additional Spectral interpretation software that able to predicts fragmentation and generates mechanistic pathways.

(V) Installation, Commissioning & Warranty

- Prices quoted are to include delivery, installation, commission, LC, MS and other related parts calibration and training of operators.
- The system shall come with at least 3 years warranty on hardware, covering 1 preventive maintenance (includes LC-HRMS-MS PM kit) per year, defective parts replacement and labour support service.
- The quotation must also include Installation Qualification and Operation Qualification (IQ/OQ) to be performed for the LC-HRMS-MS system.
- All 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.
- During the commissioning of the instrument, the technical specialist must validate the LC-HRMS-MS system on-site. A copy of the validation report must be submitted to HSA – Pharmaceutical Division after validation has been carried out on the LC-HRMS-MS system.
- Calibration standards with their certificate of analysis attached shall be supplied, and all other accessories necessary to carry out validation checks and maintenance of the instruments.
- During the installation of the instrument, the Contractor must make sure the instrument is properly connected to the gas pipeline in the laboratory using the necessary tubings, connectors and other

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necessities. The outlet is to be connected to the exhaust properly with the risk assessment done. Risk assessment is to be submitted before delivery.

- Original copy of application software must be provided.
- Free upgrade of the operation system software and spectral interpretation software during the warranty period.

Compulsory Accessories and Consumables

- The instrument shall be delivered with all necessary supplies and accessories required for the installation and start-up including:
- One (1) C-18 column, 250 mm x 2.1 mm, 2.2 µm
- One (1) Core enhanced Phenyl-Hexyl column, 100 mm x 2.1 mm, 2.6 µm

Training

- On-site trainings for users shall be given by trained personnel and topics should include LC-HRMS-MS theory, instrument overview and optimization, data acquisition and general maintenance.
- Tenderer must be able to provide the following training for approx 28 laboratory users
 - a) 1 basic training that shall be conducted within 6 months upon successful of commissioning; and
 - b) 1 refresher training that shall be conducted within the warranty period (After 1st year of warranty).
- In addition to the above, advanced training for at least 4 laboratory users must be provided at Contactor's local training centre.

Technical Support

- The Tenderer must have records of good application and maintenance support through the provision of local technical specialist to assist in method developments, on-site training, factory-trained engineer as well as readily available parts and consumables on demand.
- The LC-HRMS-MS system must be guaranteed to be supported with a service and application support contract for at least 7 years after the date of purchase.
- The qualifications of service engineers, product specialist must be submitted for evaluation.
- Familiarization tutorials featuring video clips on various operations and maintenance of the proposed LC-HRMS-MS system must be available as a reference for new users.

I hereby confirm that I can meet all the Requirement Specifications as stated in Part 3: Requirement Specifications – Equipment 7.

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

Tenderer's official
Stamp:

Authorized Signature

Name:

Designation:

(*Delete whichever is not applicable)

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

Reference To	Remarks