

1 Functional Requirements

The equipment (LC-MS/MS system) is intended to be coupled with automated extraction and sample injection system for the online automated analysis of Amphetamines, Ketamine and O6-Monoacetylmorphine in biological samples. The technical specification for automated extraction and sample injection system is provided in Part 3: Requirement Specifications of Equipment 2.

Tenderer is required to state the model and name of manufacturer of Online Automated Extraction and Sample Injection System that can be coupled with the proposed LC-MS/MS system:

2 Technical Requirements

2.1 The system must be a Quadrupole Mass Spectrometer (MS/MS) coupled with an ultra-high performance liquid chromatograph (UHPLC), and must meet the configurations and requirements as follows:

Part A: Liquid Chromatograph mainframe

1. Binary gradient pump
2. Thermostatted Column Manager

Part B: Quadrupole Mass Spectrometer (MS/MS)

1. Ion source
2. Mass Analyser

Part C: Data Management System

1. Computer hardware and accessories
2. Acquisition and processing software

Part D: Instrumental Setup and Miscellaneous

1. Online automated sample extraction and injection system
2. Other requirements
3. Accessories

Part E: Warranty & Post Warranty Comprehensive Maintenance Services

2.2 The system must be able to operate on these conditions:

- Ambient operating temperature: at least 15 - 35 °C.
- Ambient operating humidity: 5 - 95% (Non-condensing).
- Line voltage requirements: 230V ± 10%, and
- Conforms to minimally one the following safety standards: CSA, IEC, EN.
- Conforms to ISO9001 quality management standard

3 Technical Requirements

Part A – Ultra High Performance Liquid Chromatography

A.1 Binary Gradient Pump

- The dimension of the binary gradient pump must not exceed the length of 55 cm, width of 50 cm width and height of 30 cm.
 - The pump system must be equipped with at least two solvent selection valves to enable the choice of at least four (4) solvents, in combination of two.
 - The solvent delay volume must be less than 100 µL.
 - The flow rate must be settable within range of 10 µL/min to 3mL/min in minimum 1 µL/min increments.
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- The flow precision must be less than 0.1% RSD.
- The flow accuracy must be within $\pm 1\%$.
- The gradient composition accuracy must be within $\pm 0.5\%$.
- The gradient composition precision must be less than 0.2% RSD.
- The system must be able to tolerate high pressure working conditions with at least 1200 bar.
- The system must be able to perform high pressure binary mixing with settable range from 0.0% to 100%.
- The system must be equipped with automatic purge and seal wash.

A.2 Thermostatted Column Manager

- The temperature must be settable between 20°C to 100°C.
- The temperature stability must be within ± 0.1 °C.
- The temperature accuracy must be within ± 0.5 °C.
- The column manager must be able to hold at least 4 columns.
- The column manager must be able to hold columns of up to 20 cm in length.

Part B – Quadrupole Mass Spectrometer (MS/MS)**B.1 Ion Source**

- The system must be equipped with a source housing that is able to host interchangeable atmospheric pressure chemical ionization (APCI) probe and Electrospray (ESI) probe.
- The ESI should incorporate a heated gas flow aimed towards the probe nebulizer for efficient desolvation.
- The ionization voltage must be user selectable from -4.5 kV to +5.5 kV.
- The system must be compatible with the flow rate from 5 $\mu\text{L}/\text{min}$ to 3000 $\mu\text{L}/\text{min}$.
- The probe must incorporate the ability to adjust the sprayer tip position to allow easy optimisation of ionisation.
- Samples should be allowed to be introduced by direct infusion in solution using infusion syringe pump.
- The sampling cone must be removable by hand, without the need for specified tools.
- The desolvation and cone gas must be supplied via digitally controlled mass flow meters and be controlled via the data system.
- Positive and negative ionization capabilities must be included on the instrument.
- All source voltages must be under data system control and must incorporate active read backs.

B.2 Mass Analyzer

- The dimension of the mass spectrometer must not exceed the length of 90 cm and width of 90 cm.
- The instrument must incorporate two quadrupole mass analyzers (MS1 and MS2) each having a mass (m/z) range of at least 5-2000 Da.
- The instrument must have a maximum scan speed of 10,000 Da/sec or above in triple quadrupole mode.
- The instrument must have a mass stability of 0.1 Da or less at m/z 906.7 for at least 12 hours at operating conditions, or equivalent.
- The MRM dwell time must be at least 1 msec.
- The system must have no significant cross talk for infused reserpine while monitoring two MRM transitions with a dwell time of 1 msec and inter-MRM pause time of 3 msec, or equivalent.
- Positive Mode MRM Sensitivity: the signal-to-noise must be higher than 40,000:1 for 1 pg reserpine injection on column for the transition m/z 609 to 195 at unit mass resolution of 0.7 ± 0.1 Da at half height, or equivalent.

- Positive mode MRM Reproducibility: The system must have standard deviation of peak area less than 10% for the transition m/z 609 to 195 for 10 replicate injections of 10 fg resperine on column, or equivalent.
- The system must have a linear ion trap incorporated at MS2 for activation of ion trap scan mode.
- The linear ion trap must have a mass range (m/z) of at least 50 to 2000 Da in linear ion trap mode.
- The linear ion trap must have a maximum scan speed 20,000 Da/sec or above in linear ion trap mode.
- The linear ion trap must be able to scan at least 80 MRM transitions followed by a precursor scan and a neutral loss scan followed by two Enhanced Product Ion scans in less than 2 seconds, or equivalent.
- The system must be able to perform Multiple Reaction Monitoring (MRM), Full scan MS, selected ion monitoring for both MS1 and MS2, product ion scan and precursor ion scan.
- The system must be able to switch ionization polarity via user settable software controls.

Part C – Data Management System

C.1 Computer hardware and Accessories

- The computer system must have a minimum configuration of Intel Core i5 3.2Ghz, 16 GB RAM, 1 TB hard drive, 3 LAN network cards, DVD RW (CD RW capable), USB optical scroll mouse, keyboard, 20 to 22" widescreen LCD monitor.
- Windows operation system that best fit the software involved in the integration of the online automated sample extraction and injection system and the LC-MS/MS system (E.g. Windows 7 64 bit or above).
- Must include Microsoft office software.
- A network laser printer with at least 1200 x 1200 dpi resolution and capable of double side printing.
- The PC(s) must come with at least 3-year full warranty and accompanied with their system recovery CDs or DVDs.

C.2 Acquisition and processing software

- The software must have the ability of working with Multiple Reaction Monitoring (MRM), Full scan MS, selected ion monitoring for both MS1 and MS2, product ion scan and precursor ion scan modes.
- Data Acquisition, Peak Integration, Calibration, Quantification and QC calculations must be fully automated and can be performed in a multiple batch analysis mode.
- The software must be able to provide a platform for simultaneously processing of quantitative data and acquiring of sample data.
- The MS acquisition method editor must have a facility to enable the setting of MRM dwell time, inter-channel delay and inter-scan delay times, based on the expected average chromatographic peak width to ensure optimal data acquisition rates are maintained for the highest quality of analyte qualification.
- The software must have the facility to generate a report in PDF format for viewing or exporting to a third party system. The report should be stored and able to be reprocessed independently of the original raw data, on another PC with similar software.
- The software must update ion ratios and retention times automatically from any sample specified in the sample sequence.
- The software must be able to set calibration for quantitation and define peak integration criteria.
- This software must calculate the concentrations for a group of compounds in the same RT window.
- The software must flag samples when the ion ratios fall out of the user-defined values.

- The software must be able to seamlessly integrate with software of the automated sample extraction and injection system such that it can process the sample sequence and sequence actions generated by the software of the automated sample extraction and injection system for data acquisition.

Part D - Miscellaneous

The proposed system shall include and fulfil the following requirements.

Part D – Instrument Setup and Miscellaneous**D.1 Online automated sample extraction and injection system**

- The system as a whole (Part A, B and C) must be fully compatible and able to seamlessly integrate with the automated sample extraction and injection system.
- The Tenderer must have prior experiences with such setup. The Tenderer must demonstrate their ability and knowledge in setting up such system. Please provide the list of previous setups of LC-MS/MS coupled with online automated sample extraction and analysis system in Annex E to Part 3 – Performance Summary.

D.2 Other requirements

- **Electrical Requirements**

- i. The unit shall operate directly on the Authority's existing electrical switched socket of rating 230V ac $\pm 10\%$, 50 Hz ± 2 Hz, single phase/triple phase ac supply.
- ii. The unit shall be protected from transient power disruption during use. The
- iii. disruption shall not affect the unit's performance.

- **Delivery, installation, commissioning**

The Tenderer must oversee overall systems integration, site preparation, installation and necessary configuration of the system.

- **Risk Assessment**

- i. The contractor must perform on-site risk assessment. Risk Assessment Report in 5x5 matrix shall be submitted and approved prior to the delivery of the unit.

D.3 Accessories

- A syringe pump must be supplied for direct infusion of sample.
- Uninterrupted Power Supply (UPS) which enables the system to operate for at least 15 minutes without external power must be supplied.
- A roughing pump must be supplied.

D.4 Option to Purchase

- The Tenderer shall quote for Atmospheric Chemical Ionisation (APCI) probe in Annex D Price Schedule as an option.

Part E - Warranty and Post warranty maintenance**E.1 Warranty and Maintenance**

- The system shall come with at least one (1) year warranty for the whole system that comprises equipment hardware, software, UPS and etc.
- The warranty shall take effect after successfully of commissioning and full integration with Equipment 2: Online Automated Extraction and Sample Injection system.
- The warranty must include the following at no additional cost:
 - (i) Annual preventive maintenance (PM) with PM kit;
 - (ii) 1 preventive maintenance for UPS for each warranty year;

- (iii) Unlimited breakdown calls and on-site services during Operating Hours i.e. Monday to Friday from 8:30 am to 6pm excluding Saturday, Sunday and Public Holiday;
 - (iv) Supply of replacement of parts;
 - (v) Update and/or upgrade of software version and mass spectral library
- The Tenderer must ensure service parts and consumables are readily available and provide assurance that all parts can be obtained at least 10 years after delivery of the instrument.

E.2 Training and Technical Support

- Contractor must provide after-sales support from service engineers and application chemists in Singapore.
- Contractor shall provide technical support to ensure the proposed LC-MS/MS system to be fully integrated with Equipment 2: Online Automated Extraction and Sample Injection System.
- Approximate 1 month upon successful of commissioning, on-site basic training for users (4 – 6 staffs) should be provided. The training shall be conducted by trained personnel, and topics should include theory, equipment overview, method setup, data acquisition, data processing, report formatting and general maintenance. A proposed training schedule and agenda must be appended with the tender submission.
- Advanced training should be provided within one (1) year from the completion of on-site basic training including advanced functions of the system and software, troubleshooting and advanced maintenance of the system for approximately 4 staffs.

E.3 Post warranty maintenance

- The Tenderer is required to quote comprehensive maintenance contract for five (5) years after the warranty period. The comprehensive maintenance contract shall provide coverage for overall system including hardware and software and UPS. The price quoted shall minimally include the following:
 - (i) provision of unlimited breakdown calls and on-site services during Operating Hours;
 - (ii) provision of replacement parts
 - (iii) to provide two (2) preventive maintenance per year
 - (iv) any software or library revisions

E.4 Performance of Services

E4.1 The Services to be performed by the Contractor shall consist of Preventive Maintenance and Corrective Maintenance as described below.

E4.1.1 Preventive Maintenance

- a) The Preventive Maintenance shall consist of:

Routine maintenance of the Equipment, including but not limited to the testing of functions and inspecting of the condition of the Equipment in order to keep the Equipment safe for use and in Good Working Order; and

Adjustment and/or repair of any defect in or malfunction of the Equipment 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 during Operating Hours.
- d) The contractor shall give the Authority a minimum of three (3) days' notice before carrying out the Preventive Maintenance at the Authority's premises.

E4.1.2 Corrective Maintenance

- a) Upon receipt of oral or written notice from the Authority, the Contractor shall use its best endeavors 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 first twenty-four (24) hours of the beginning of the next Working Day (if extended coverage is not provided).
- b) The Contractor shall complete any repair, or replacement or adjustment of components within 5 working days if parts are available locally or 10 working days if parts are not available locally from and including the date on which the Contractor was given notice pursuant to Clause E4.1.2(a), unless the Authority had agreed in writing to have the time period extended.
- c) If the repair, or replacement or adjustment of components for longer than 30 working days, corresponding extension of the warranty and comprehensive maintenance contract must be offered for the affected period.

E.5 Replacement and Purchase of Components

E5.1 The Contractor shall inform the Authority of any part or component of the Equipment that needs to be replaced.

E5.2 The Contractor shall use all reasonable endeavours to supply only original or genuine replacement components, which are required to maintain the equipment in good working order.

E.6 Guarantee

E6.1 The Contractor hereby warrants that all the Equipment and every part or unit thereof serviced by the Contractor shall conform to the requirements of this Contract and be free from any defect or deficiency in their performance or workmanship for a period of three (3) months from the date of acceptance of the Services by the Authority (hereinafter referred to as "the Equipment Guarantee Period"). The Contractor hereby also warrants that all materials and every part or unit thereof, used for the Services shall be free from any defect in manufacture or any defect arising out of design, workmanship or materials used or any failure or malfunction due to quality of material, workmanship, design, assembly, installation or integration for a period of three (3) months from the date of acceptance of the materials by the Authority (hereinafter referred to as "the Materials Guarantee Period"). The Equipment Guarantee Period and the Materials Guarantee Period shall collectively be known as the "Guarantee Period".

E6.2 Where during the Guarantee Period, any part or unit of the Equipment serviced by the Contractor or materials used for the Services or supplied therefor are found to be defective of any of the reasons specific in Clause E6.1 above, the Contractor shall at the written request of the Authority replace the same at the expense (including freight charges, transportation costs or other incidental charges) of the Contractor or if the Authority so agrees make good or repair the same at the expense (including freight charges, transportation costs and other

PART 3: REQUIREMENT SPECIFICATIONS**HSA000ETT18300055****Equipment 1:** Liquid Chromatography Tandem Quadrupole Mass Spectrometer (LC-MS/MS) Systems**Location:** Analytical Toxicology Laboratory, Drug Abuse Testing**Quantity:** 1

incidental charges) within a Guarantee Turn-Around-Time of 7 days. The Equipment or materials or part or unit thereof so replaced or repaired shall be subject to the Guarantee under this Clause for the Authority or three (3) months whichever is later and such balance of the Guarantee Period shall begin to run only from the date of receipt of the part or unit so replaced or repaired by the Authority.

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	<u>Remarks</u>