

SECTION 3: REQUIREMENT SPECIFICATIONS**HSA000ETT17000052****Equipment 1: LC-HRMS****Quantity: 1 unit****Laboratory/ Location: Food Safety Laboratory**

Supply of New Liquid Chromatograph tandem High Resolution Mass Spectrometry System (LC-HRMS) Location: Food Safety Laboratory Quantity: 1	Compliances (Yes/ No) <i>**If No, please indicate reason of non-compliances.</i>
Tenderer shall offer a system that can fully meet the specification as follows with equivalent or better functions.	
<u>Technical Specifications</u> High Performance Liquid Chromatograph System (A) Solvent Rack with Degasser	Yes/ No
(i) Solvent line purging flow rate must be able to operate at 5ml/min per solvent channel.	Yes/ No
(I) Binary Pumps	Yes/ No
(i) Binary pumps must be able to operate in the pH range of 2-12.	Yes/ No
(ii) Binary pumps must be able to perform gradient proportioning and withstand operating pressure of 1200 bar or higher during analysis.	Yes/ No
(iii) Must have minimum 2 x 2 solvent channels.	Yes/ No
(iv) Proportioning accuracy of $\pm 0.2\%$ or better.	Yes/ No
(v) Proportioning precision is $< 0.15\%$ standard deviation.	Yes/ No
(vi) Flow accuracy of $\pm 0.1\%$ or better.	Yes/ No
(vii) Must have built-in leak sensors, active rear-seal wash system and excess pressure monitoring function.	Yes/ No
(B) <u>Thermostatted column compartment</u>	
(i) Must provide finger tight fittings with zero dead volume for easy connection to columns.	Yes/ No
(ii) Must provide temperature accuracy of $\pm 0.5^{\circ}\text{C}$ or better.	Yes/ No
(iii) Must provide temperature stability of $\pm 0.1^{\circ}\text{C}$ or better.	Yes/ No
(iv) Must support minimum temperature operating range from 5 to 60 $^{\circ}\text{C}$.	Yes/ No
(C) <u>Well Plate Autosampler</u>	Yes/ No
(i) Injection method must use in-line split-loop principle.	Yes/ No
(ii) Must have minimum sample capacity of 100 x 1.5ml HPLC vial.	Yes/ No
(iii) Must have injection cycle time of $\leq 20\text{sec}$ or better	Yes/ No
(iv) Must supply one 20 μl injection loop or higher capacity for sample injection	Yes/ No

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(v) Must have injection volume accuracy of $\pm 0.5\%$.		Yes/ No
(vi) Must have injection volume precision of $\leq 0.25\%$ RSD.		Yes/ No
(vii) Must have carry-over of $\leq 0.004\%$ for caffeine		Yes/ No
(viii) Must have built-in needle wash function.		Yes/ No
(ix) Must have sample thermostating minimally include 4 to 40°C.		Yes/ No
(D) <u>Quadrupole High Resolution Mass Spectrometer System</u>		Yes/ No
(i) Must accommodate space constraint of 100cm x 300cm in laboratory for instrument installation.		Yes/ No
(ii) Must deliver real-time data acquisition and data processing capability.		Yes/ No
(iii) The mass spectrometer must come with single data system for synchronized instrument control and data acquisition.		Yes/ No
(v) The quadrupole mass filter must provide variable and stepless precursor ion isolation width selection from 0.4Da to full mass range.		Yes/ No
(vi) The mass spectrometer must be able to perform parallel filling and detection.		Yes/ No
(vii) The mass spectrometer must be able to operate in compliance to instrument specifications from 22 to 28 °C or wider temperature range.		Yes/ No
(viii) Software must be provided to control Liquid Chromatograph and Mass Spectrometer for Qualitative and Quantitative analyses and batch acquisition. Software must provide information on accurate mass, isotopic pattern and MS/MS library match functions.		Yes/ No
(ix) The mass spectrometer (hardware) must be able to perform intact proteins analysis, together with a separate/built-in software to support data acquisition in real time.		Yes/ No
(x) Sensitivity: 500 fg (femtogram) Buspirone on column must yield S/N > 100:1 for Full MS or 200 fg (femtogram) Reserpine on column must yield S/N > 60:1.		Yes/ No
(xi) Mass Resolution: Must be able to deliver mass resolution of >70,000 at Full Width at Half Maximum (FWHM) for all scan modes for both positive and negative polarities.		Yes/ No
(xii) Must be able to perform concurrent polarity switching in a single scan.		

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(xiii)	The mass spectrometer must be able to operate in the settable mass range from 50 to 3,000 m/z	Yes/ No
(xiv)	Scan Speed: Must be able to perform 10 scans per second or better in Full Scan or MS/MS scan mode.	Yes/ No
(xv)	Mass Accuracy: - < 3ppm RMS with external calibration over 24h and without any kind of mass recalibration; - < 1ppm RMS with internal calibration.	Yes/ No
(xvi)	Polarity Switching: The mass spectrometer must be able to perform ionization polarity switching within one second while maintaining mass accuracy of ≤ 5 ppm in a single injection.	Yes/ No
(xvii)	Scan Functions: - The mass spectrometer instrument set up must allow scheduled setup of different events using a graphical user interface. - Must acquire and display Full Scan mass spectra. - Must acquire and display Selected Ion Monitoring scan data for monitoring selected ions for target compound analysis. - Must acquire and display Full Scan MS/MS spectra. - Must acquire and display Selected Reaction Monitoring/Multiple Reaction Monitoring (SRM/MRM) data sets. - Neutral-loss triggered data dependent MS/MS methodology, selecting predominantly precursor ions for MS/MS fragmentation, which show a predefined neutral loss under fragmenting conditions. - Timed SIM for scheduled data acquisition of target compounds. - Timed MS/MS for scheduled data acquisition of target compound fragment spectra. - Must acquire "data independent acquisition" data sets.	Yes/ No
(xviii)	Other Functions: - Must have automatic gain control to automatically control ion injection time for optimized ion current across the entire chromatographic peak. - Must have dynamic exclusion capability to temporarily exclude an ion, while allowing MS/MS spectra acquisition of minor abundant precursors.	Yes/ No
(xix)	Ion Sources & Probes: API - The API source must have flat tuning and must have ion-optics that enable automated tuning. - The API source must have an automatic tuning program. - The API source must incorporate a safety interlock switch to shut off voltages when probe is removed from source housing.	

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- The API source must incorporate Sweep Gas in order to reduce chemical noise. - The API control must include high-voltage dual-polarity power supply, sheath gas flow control, and auxiliary gas flow control to accommodate a wide variety of applications. - Must include an independently heated ion capillary tube, heated by an external heater capable of temperatures up to 400 °C. - The ion capillary tube must be removable to provide vent-free maintenance. - All voltages for focusing the ion beam in the API source must be controlled through the data System. - Must include a removable ion sweep cone. - Must support interchangeable ESI and APCI ionization sources and probes. ESI Probe - Must be able to perform rapid switchover between APCI and ESI using quick release connecting retainers, and without breaking vacuum. - Must operate at flow rates from 1µl/min to 1 ml/min using 100% water without splitting. - The ESI probe needle must be moveable in the x,y and z dimensions relative to the sampling orifice for optimal tuning. - The probe must be capable of temperatures up to 400 °C to increase the desolvation efficiency and decrease chemical noise. APCI Probe Assembly - Must operate at flow rates from 50 µl/min to 2 ml/min using 100% water without splitting. - Must use ceramic heater. - Must include a feedback-controlled heater capable of operation up to 500 °C to vaporize the solvent and analyte. - The APCI sample nozzle must be moveable in the x,y and z dimensions relative to the sampling orifice for optimal tuning.	
(xx) Vacuum System - Differentially pumped vacuum system with final vacuum < 4 x 10⁻⁹ Torr. - Roughing pump must come in a noise isolation enclosure.	Yes/ No
(xxi) Detection System - The detection system must have digital electronic noise discrimination.	Yes/ No

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(E) <u>Data System</u>	Yes/ No
(i) Two sets of bench-top computer with one printer for data acquisition and data processing with minimum configuration as follows: - Processor, 3.3 GHz - 4096 MB 800 MHz DDR2 RAM - 1 TBB SATA II hard drive - DVD-RW - Network-card 10/100 - 2 PCI- und 1 PCI-Express- slots - Networkchip 10/100/1000 on board - Operating System, English Windows 7 Professional (32Bit OS) - 23 inch TFT flat screen colour monitor - Cross linked-cable or compatible (ii) Both the data acquisition computer and data processing computer must be peer-to-peer connected to enable seamless (one-way) data transfer.	Yes/ No
(F) <u>Furniture (Applicable for Bench-Top models only)</u>	Yes/ No
If the proposed model is a bench top unit, Tenderer must provide with the following: (i) Must custom-make and supply one or more tables to fit space constraints of 100cm (width) x 300cm (length) for LC and HRMS, respectively, where relevant. (ii) Table(s) must come with 3 drawers. (iii) Table(s) height (~76cm) must flush with existing bench at installation site.	Yes/ No
(G) <u>Training and commissioning</u>	Yes/ No
(i) Must provide onsite or off-site for the following: - Theory training (single session, for a total of approximate 34 HSA trainees); - Basic training (4 sessions, for a total of approximate 34 HSA trainees); - Advance training (2 sessions, for a total of approximate 12 HSA trainees); - Maintenance training (1 session for a total of approximate 6 HSA trainees). - At least one theory training, basic training and/or maintenance training must be completed before 31st March 2018.	Yes/ No
(H) <u>Two projects delivery</u>	Yes/ No

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Location: Food Safety Laboratory	Quantity: 1	
(i) Tenderer must be able to develop, validate and transfer one macromolecule and one small molecule analytical methods within 3 months after onsite instrument commissioning.		Yes/ No
(I) Onsite inspection post tender award		Yes/ No
(i) Contractor must perform site readiness inspection and onsite risk assessment for new instrument installation safety compliance.		Yes/ No
(ii) The Contractor must be able to perform risk assessment for the LC-HRMS instrument that is located in the designated laboratory. A risk assessment report in 5x5 matrix must be submitted prior to the delivery of the instrument.		
(J) Accreditation / Certification		
(i) The manufacturer of the product shall preferably ISO 9001 certified or equivalent. A copy of the certificate must be submitted for evaluation upon request.		Yes/ No
(K) Installation, commissioning & warranty		Yes/ No
(i) LC tandem HRMS system must be delivered, unpacked, assembled and fully commissioned before 31 st March 2018, with three-year warranty including annual preventive maintenance. All replacement for hardware and software must be provided. The consumables required to perform the PM shall also be included at no additional charge.		Yes/ No
(L) Post warranty maintenance services		Yes/ No
(i) Tenderer shall also quote for 3-year post warranty comprehensive maintenance contract for the instrument that includes of the following: a) Annual PM b) Unlimited breakdown calls during Office Hours c) Consumables required to execute the PM d) Supply of replacement parts e) Software upgrades if any f) Provision of technical & application support		Yes/ No
(ii) The Contractor shall bill HSA on annual basis upon completion of each PM.		
(M) Application & Technical support (onsite)		Yes/ No
During warranty and post warranty contract coverage period, the tenderer must provide the following:		Yes/ No
(i) Application and technical support with a maximum response time of 4 hours upon receipt of oral/written notification.		
(ii) The Services to be performed by the Contractor shall consist of Preventive Maintenance and Corrective Maintenance as described below.		

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<u>Preventive Maintenance:</u> a) The Preventive Maintenance performed shall be in compliance with the maintenance procedures and safety tests specified by the manufacturer. b) The Preventive Maintenance shall be carried out during Office Hours unless i.e. Monday to Friday 8:30am to 6pm exclude Saturday, Sunday and Public Holiday. c) The Contractor shall give the Authority a minimum of three (3) days' notice before carrying out the Preventive Maintenance at the Authority's premises <u>Corrective Maintenance</u> a) 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 4 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 first four (4) hours of the beginning of the next Working Day. b) The Contractor shall attend to unlimited breakdown calls. For this purpose, the Contractor shall provide the Company with a telephone number through which requests for Corrective Maintenance can be made by the Authority during Office Hours. c) The Contractor shall complete any repair, or replacement or adjustment of components within seven (7) working days from and including the date on which the Contractor was given notice pursuant to Clause-Corrective maintenance (a), unless the Authority had agrees in writing to have the time period extended.	
REPLACEMENT AND PURCHASE OF COMPONENTS a) The Contractor shall inform the Authority of any part or component of the Equipment 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 Equipment in Good Working Order.	Yes/ No
GUARANTEE a) 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 one (1 month) 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	Yes/ No

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of material, workmanship, design, assembly, installation or integration for a period of one (1) month 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". b) 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 Guarantee-(a) 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 incidental charges) within a Guarantee Turn-Around-Time of seven (7) working days. The Equipment or materials or part or unit thereof so replaced or repaired shall be subjected to the Guarantee under this Clause for the Authority or one (1) month 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.	
SAMPLE EVALUATION 1. Test samples in individual 1.5ml HPLC vials will be provided by HSA. These test samples comprised of pure standards and sample extracts spiked with standards and shall be provided once only. Instructions for analytical testing will be provided during sample vials collection. 2. All sample vials must be analysed in a facility located in Singapore only. 3. It is recommended testing be performed within 24 hours to reduce effect (to a minimum) due to degradation, either in solution or in matrix. 4. Tenderer shall collect the sample vials on Wednesday, 26th July 2017 and the report shall be submitted within 2 weeks i.e. 10th August 2017, unless the Authority <u>gives consent</u> in writing <u>for extension of deadline</u>. 5. All test results must be accompanied by analysis date and time stamps. 6. All test sample vials must be analysed using the instrument proposed for the tender. Results obtained by using proxy instruments will not be considered. 7. Tenderers who do not participate in the test sample evaluation phase or who fail to follow the instructions provided for analytical testing will be disqualified from the evaluation. 8. All Tenderers must submit a summary report, in tandem with a comprehensive report that discusses (i) test methods, (ii) individual ion chromatograms, (iii) peak areas, (iv) resolutions, (v) signal to noise ratio, (vi) RSD values (where applicable), (vii) MS/MS spectrum, as well as (viii) application libraries or compound table for identification (if any) purposes, either in hard copy or in digitized pdf format via e-mail.	

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9. Two types of test samples shall be provided as follows: <table border="1" data-bbox="277 457 1092 756"> <thead> <tr> <th data-bbox="277 457 680 516">Small molecules analysis</th><th data-bbox="680 457 1092 516">Macromolecule analysis</th></tr> </thead> <tbody> <tr> <td data-bbox="277 516 680 575">100ng/ml standard of drugs</td><td data-bbox="680 516 1092 575">100ng/ml standard of lantibiotic</td></tr> <tr> <td data-bbox="277 575 680 667">3 levels of concentration for standards</td><td data-bbox="680 575 1092 667">Single level of concentration for standard</td></tr> <tr> <td data-bbox="277 667 680 756">2 unknown test samples for identification</td><td data-bbox="680 667 1092 756">Single unknown test sample for identification</td></tr> </tbody> </table>	Small molecules analysis	Macromolecule analysis	100ng/ml standard of drugs	100ng/ml standard of lantibiotic	3 levels of concentration for standards	Single level of concentration for standard	2 unknown test samples for identification	Single unknown test sample for identification	
Small molecules analysis	Macromolecule analysis								
100ng/ml standard of drugs	100ng/ml standard of lantibiotic								
3 levels of concentration for standards	Single level of concentration for standard								
2 unknown test samples for identification	Single unknown test sample for identification								

COMPLIANCE OF REQUIREMENT SPECIFICATIONS

I hereby confirm that I can meet all the specifications and requirements as stated in Section 3: Requirement Specifications.

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

Tenderer's official
Stamp:

Authorized Signature

Name:

Designation:

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

Reference To	Remarks

SECTION 3: REQUIREMENT SPECIFICATIONS
Equipment 2: LC/MS/DAD
Laboratory/ Location: Pharmaceutical Laboratory

HSA000ETT17000052
Quantity: 1 unit

Equipment 2: Liquid Chromatograph – Single Quadrupole Mass Spectrometer – Diode Array Detector (LC/MS/DAD) System Location: Pharmaceutical Laboratory Quantity: 1 unit	Compliances (Yes/ No) <i>**If No, please indicate reason of non-compliances</i>
General A robust and sensitive bench top/stand-alone liquid chromatograph - single quadrupole mass spectrometer - diode array detector (LC/MS/DAD) shall offer configurations as follows: • Liquid Chromatograph (LC) mainframe • Auto Sampler • Column Compartment • Fraction Collector • Diode Array Detector (DAD) • Single Quadrupole Mass Spectrometer with ESI Source • Computer Hardware and Software • Data Management Software System • Installation, Commissioning and Warranty • Training • Technical Support The LC/MS/DAD unit shall offer equivalent or superior functions as follows:	
1. <u>Liquid Chromatograph Mainframe</u> a) Must offer a high pressure binary pump system to enable at least 2 individual solvent lines to be utilized concurrently. b) Must offer integrated diagnostic functions that pre-empts instrument malfunction. c) Must offer an integrated degassing unit. d) Must offer a maximum operating pressure of 600 bar or higher. e) Must enable settable flow range set points from 0.001 – 5 mL/min. f) Must offer flow precision of $\leq 0.07\%$ Relative Standard Deviation (RSD) or ≤ 0.02 min Standard Deviation (SD), whichever is greater. g) Must offer flow accuracy of $\pm 1\%$ or better. h) Must offer user selectable compressibility compensation, based on mobile phase compressibility. i) Must support and function in the pH range of 1.0 – 12.5. j) Must permit high pressure binary mixing for gradient formation. k) Must include active seal wash kit for improved seal life if buffer solvent is used. l) Must offer user-settable mobile phase composition range from 0 – 100%. m) Must offer mobile phase composition precision of $\leq 0.2\%$ RSD or better. n) Must offer software and local control functions.	YES/ NO

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Equipment 2: Liquid Chromatograph – Single Quadrupole Mass Spectrometer – Diode Array Detector (LC/MS/DAD) System Location: Pharmaceutical Laboratory Quantity: 1 unit	Compliances (Yes/ No) <i>**If No, please indicate reason of non-compliances</i>
o) Must enable communications via controller-area network. Remote: ready, start, stop and shut-down signals with optional LAN. p) Must offer safety and maintenance features to support extensive diagnostics, error detection and display, leak detection, safe leak handling, leak output signal for shutdown of the pumping system. q) Must be able to notify the lab when the maintenance is due, early maintenance feedback to be provided 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. The system must also be able to provide electronic records of maintenance and errors.	
2. <u>Auto Sampler</u> a) Must be able to handle a minimum of 100 pieces of 2 mL HPLC vials. b) Must come with thermostat with settable temperature from 4 °C – 40 °C in 1°C increments. c) Must be capable of automated injection of sample volumes of 0.1 – 100 µL in 0.1 µL increments. d) Must have carryover of ≤ 0.004% (40 ppm) with needle wash. e) Must come with a flush port. f) Must be compatible to withstand high pressure of at least 600 bar. g) Must have the injection precision of ≤ 0.25% RSD. h) Must have injection cycle time of ≤ 20 s for draw speed 200 µL/min.	YES/ NO
3. <u>Column Compartment</u> a) Must have a temperature range of 5 °C above ambient to 80 °C. b) Must have a temperature stability of ± 0.1 °C or better. c) Must have a temperature accuracy of ± 0.5 °C or better. d) Must have a minimum column capacity of two columns of 30 cm.	YES/ NO
4. <u>Fraction Collector</u> a) Collection of fractions must be fully automated using pre-set experimental conditions and manual collection must also be allowed. b) Delay volume must be ≤ 50 µL. Automated delay volume calibration for optimum fraction collection must be available.	YES/ NO

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Equipment 2: Liquid Chromatograph – Single Quadrupole Mass Spectrometer – Diode Array Detector (LC/MS/DAD) System Location: Pharmaceutical Laboratory Quantity: 1 unit	Compliances (Yes/ No) <i>**If No, please indicate reason of non-compliances</i>
c) Must allow a maximum flow rate of 5 mL/min or higher for analytical scale purification. d) Fraction tray configuration must be available to hold at least 30 x 6 mL test tubes. e) Collector must have the capability to maintain temperature, range covering minimally from 4 °C – 40 °C, with ability to prevent condensation of water vapours when temperature set below room temperature. f) Trigger source for collection must be using either through pre-determined time set in the experimental procedures or through peak detection (UV- DAD detector) or mass detection (MS spectrometer). Manual trigger should also be an option available for manual collection. g) Maximum operating pressure of fractional collector of 6 bar or higher. h) Cooling capability must be available on the fraction collector. i) Fraction collector must be able to operate in the following mode : (i) Discrete fractions: default mode for all vessels. The flow is diverted to waste, while moving from one vessel position to the next vessel position. (ii) Continuous flow: optional, available only when using the deep well plates. It is possible to move from one well plate position to the next one without diverting the flow into the well plate to waste needle into location: Needle pushes into the vessel as deep as specified, for the use with capped vials and test tubes and well plates with closing mats. (iii) Droplet setup mode: The tip of the fraction collector needle will initially move down to the bottom of the well. Then it will slowly move upwards while the fraction is collected. The droplet setup mode enables the fraction collector to collect small fractions without bubbles.	
5. <u>Diode Array Detector (DAD)</u> a) Detection must be via 1024-element diode array. b) Diode width must be ≤ 1 nm. c) Linearity should be ≥ 2.0 AU (5%) at 265 nm or equivalent. d) Wavelength accuracy should not be more than ± 1 nm for self-calibration. e) Wavelength range must be at least 190 – 600 nm.	YES/ NO

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f) Flow cell must have path length of 10 mm and the ability to modify to switch or upgrade to different flow cells when required. g) Signal noise must be $\leq \pm 3 \times 10^{-6}$ AU at 230 nm. h) Wavelength drift must be $\leq 0.5 \times 10^{-3}$ AU/h after adequate warm up. i) Simultaneous acquisition of at least 6 specific wavelengths. j) Maximum sampling rate of 120 Hz or higher.	
6. <u>Single Quadrupole Mass Spectrometer System with ESI Source</u> a) The instrument must be a bench top model with a maximum scan speed of 10,400 Da/sec or higher. b) The mass analyser must be a single quadrupole MS system with ESI Source as standard. c) Mass range must be settable between 2 – 3000 m/z. d) Dynamic range must be $\geq 6 \times 10^6$. e) Detection of positive/negative ions must be user-selectable and the switching time between positive and negative polarity must be no more than 30 msec. f) Mass stability (drift) should not exceed the larger absolute value of ± 0.1 Da or ± 100 ppm of measured mass over a 12 hour period at constant temperature ± 3 °C. g) Resolution: The full width at half mass for the target peaks must be between 0.45 and 0.74 Da inclusive during auto-tuning. h) Mass measurement accuracy must be less than ± 0.13 Da during tuning. i) Auto-tuning must be standard with a syringe pump that delivers accurate calibrant injection under full workstation control in both positive and negative modes. Manual tuning must also be allowed. j) The system must have the possibility to install an additional software in future to determine accurate mass compound identification and elemental formula, which extends the capability and flexibility of LC/MS in future. k) Sensitivity requirement (positive ESI): The measured signal-to-noise ratio obtained from the chromatogram monitoring the quantification of m/z 609 ion on injection of 1 pg of reserpine must be more than 75:1, based on a 1-μL injection volume. l) The system must be able to install the following sources for future upgrade possibility: (i) Atmospheric pressure chemical ionization (APCI) (ii) Atmospheric pressure photoionization (APPI)	YES/ NO

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Equipment 2: Liquid Chromatograph – Single Quadrupole Mass Spectrometer – Diode Array Detector (LC/MS/DAD) System Location: Pharmaceutical Laboratory Quantity: 1 unit	Compliances (Yes/ No) <i>**If No, please indicate reason of non-compliances</i>
m) Instrument must be able to support active splitter for mass base purification which separate the main flow into two, one goes to the fraction collector and another one to the mass spectrometer. n) All systems must be able to provide proper isotope ratios for a halogen containing test compound up to the maximum specified scan speed. o) Mass spectrometer mainframe must be able to safely support HPLC modules to save space. p) System must be controlled using industry standard TCP/IP LAN protocols. q) All parameters that minimally include ion optics, calibration, and resolution must be established in less than 15 minutes and must be completed with greater than 90% reliability. r) Systems must not require any plumbing changes to perform calibration and tuning for easy operation. s) System must have the ability to cycle through four different acquisition modes on a scan by scan basis within a single run. At least 4 analysis modes can be viewed in the same software window. Switching time between modes will be 300 msec or less. These modes include: positive/negative polarity switching, variable fragmentor voltage selection, and concurrent SIM/scan. t) System must be capable of displaying, acquiring, storing and manipulating mass spectral information and diode array spectral information simultaneously.	
7. <u>Computer Hardware and Software</u> a) A data acquisition/processing computer and a laser jet printer shall be provided with equivalent or better configurations as follows: <u>PC specifications:</u> - 3 GHz processor with 8 GB RAM - DVD-ROM drive - Video card and monitor capable of 1280×1024 resolution (XGA) - 1 TB hard disk storage space - Operation system software with valid license - 20" LED monitor - Keyboard - Mouse and mouse pad - Pre-installed with Windows 7 (64-bit), Microsoft office and antivirus software which is compatible with the data management software system of the instrument <u>Printer specifications:</u> - Monthly duty cycle: 3000-5000 pages per month - Memory: 128MB - Speed: at least 20 pages per minute - Size: A4 - Duplex: Yes	YES/ NO

SECTION 3: REQUIREMENT SPECIFICATIONS
Equipment 2: LC/MS/DAD
Laboratory/ Location: Pharmaceutical Laboratory

HSA000ETT17000052
Quantity: 1 unit

Equipment 2: Liquid Chromatograph – Single Quadrupole Mass Spectrometer – Diode Array Detector (LC/MS/DAD) System Location: Pharmaceutical Laboratory Quantity: 1 unit	Compliances (Yes/ No) <i>**If No, please indicate reason of non-compliances</i>
- Paper Tray: 500 sheets - Print Technology: Monochrome Laser - Print resolution: 600dpi - Network printer: Yes	
8. <u>Data Management Software System</u> a) Must be a flexible Windows-based data system that provides instrument control and data analysis. b) Must work seamlessly with application-specific software modules. c) Must have the ability to run in a fully automated manner, while also providing for sophisticated manual data evaluation. d) Must be able to perform background subtraction in the same chromatogram at any time-point. e) Must be able to generate multiple wavelengths library search results in one report for a single injection. f) Must be easy to use for library matching i.e. matching on screen to be done within 1-2 steps. g) Must have the feature to protect testing methods from being tampered. h) Must be mutually compatible with the lab existing in-house library. i) Must be able to link up to OpenLAB Enterprise Content Manager which the Lab is currently using for data archival. j) Must provide an original copy of application software. k) Must provide free update of the PC operation system software during the warranty period.	YES/ NO
9. <u>Installation, Commissioning and Warranty</u> a) Prices quoted are to include delivery, installation, commission, calibration, Installation Qualification and Operation Qualification (IQ & OQ) and training of operators. b) System must come with at least two year warranty upon successful commissioning, covering 1 preventive maintenance per year, defective parts replacement, consumables, and labour support service. Any software revisions should also be provided free-of-charge during warranty period. c) All documentation is to be supplied along with the equipment. These shall include the operator's manuals/software manual and equipment manuals. d) The Contractor must be able to perform risk assessment for the LC/MS/DAD instrument that is located in the designated air-conditioned laboratory. A risk	YES/ NO

SECTION 3: REQUIREMENT SPECIFICATIONS
Equipment 2: LC/MS/DAD
Laboratory/ Location: Pharmaceutical Laboratory

HSA000ETT17000052
Quantity: 1 unit

Equipment 2: Liquid Chromatograph – Single Quadrupole Mass Spectrometer – Diode Array Detector (LC/MS/DAD) System Location: Pharmaceutical Laboratory Quantity: 1 unit	Compliances (Yes/ No) <i>**If No, please indicate reason of non-compliances</i>
assessment report in 5x5 matrix must be submitted prior to the delivery of the instrument. e) During the installation of the instrument, the Contractor must make sure the instrument is connected to the gas pipeline in the laboratory using the necessary tubings, connectors and other necessities with no leakage. f) During the commissioning of the instrument, the technical specialist/engineer must validate the LC/MS/DAD system based on the Contractor's performance specifications on-site. A copy of the validation report must be submitted to HSA - Pharmaceutical Laboratory after validation has been carried out on the LC/MS/DAD system. g) The Contractor must supply the calibration standards with their certificate of analysis attached, and all other accessories necessary to carry out validation checks and maintenance of the instruments. These accessories shall include syringes of appropriate sizes, as well as cleaning tissue and cleaning buds at no additional cost. h) The LC/MS/DAD instrument must be fully commissioned within 1 month upon delivery.	
10. <u>Training</u> a) On-site training for all end-users in the Pharmaceutical Division that is approximately 30 people shall be provided by trained personnel(s), and shall cover topics including simple MS theory, instrument overview, MS method optimization, data acquisition, and general maintenance. In addition, a proposed training schedule must be supplied together with the submission of tender document. b) 1 comprehensive classroom training which covers the basics, maintenance and troubleshooting for LC/MS/DAD, must be provided for a minimum of 2 officers. c) The training shall be conducted by factory-trained engineer. A copy of certification shall be submitted for evaluation upon request.	YES/ NO
11. <u>Technical Support</u> a) The LC/MS/DAD system must be guaranteed to have parts, comprehensive service and application support for at least 7 years after the date of purchase. b) Provision of familiarization tutorials featuring video clips on various operations and maintenance of the proposed LC/MS/DAD system must be available as a reference for new users. c) Tenderer must be able to provide application, technical and maintenance support locally throughout the warranty period. These shall include the provision of local technical specialist to assist in method developments and on-site training by factory-trained engineer.	YES/ NO

SECTION 3: REQUIREMENT SPECIFICATIONS
Equipment 2: LC/MS/DAD
Laboratory/ Location: Pharmaceutical Laboratory

HSA000ETT17000052
Quantity: 1 unit

Equipment 2: Liquid Chromatograph – Single Quadrupole Mass Spectrometer – Diode Array Detector (LC/MS/DAD) System Location: Pharmaceutical Laboratory Quantity: 1 unit	Compliances (Yes/ No) <i>**If No, please indicate reason of non-compliances</i>
d) The service engineers and product specialists must be qualified to provide the services. A copy of certification shall be submitted for evaluation upon request. e) Tenderer shall provide past 2 years track records for the sale and provision of maintenance support services for the similar products proposed in this tender in Annex D Performance Summary.	
12. <u>Option to purchase: Post-Warranty 2-year Comprehensive Maintenance Contract</u> a) Tenderer is required to quote for a 2-year comprehensive maintenance contract after the warranty period. The comprehensive maintenance contract shall cover the overall system including hardware and software. The price quoted shall minimally include the following: (i) Provision of unlimited breakdown calls and on-site services during operating hours i.e. Monday to Friday 8:30am to 6pm excluding public holidays. (ii) To provide 1 preventive maintenance per year. (iii) Provision of replacement parts at no additional cost. (iv) Provision of all necessary kits, consumables (inclusive of all related tuning solutions with certified validity for the entire duration of the maintenance contract) at no additional cost. (v) Any software revisions should also be provided at free-of-charge.	YES/ NO
13. <u>Replacement and Purchase of Components</u> a) The Contractor shall inform the Authority of any part or component of the Equipment 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 approach (which shall subsequently be confirmed in writing) obtained from an authorised officer at 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 Equipment in Good Working Order.	YES/ NO
14. <u>Guarantee</u> a) 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 one (1) month 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,	YES/ NO

SECTION 3: REQUIREMENT SPECIFICATIONS
Equipment 2: LC/MS/DAD
Laboratory/ Location: Pharmaceutical Laboratory

HSA000ETT17000052
Quantity: 1 unit

Equipment 2: Liquid Chromatograph – Single Quadrupole Mass Spectrometer – Diode Array Detector (LC/MS/DAD) System Location: Pharmaceutical Laboratory unit Quantity: 1	Compliances (Yes/ No) <i>**If No, please indicate reason of non-compliances</i>
workmanship or materials used or any failure or malfunction due to quality of material, workmanship, design, assembly, installation or integration for a period of one (1) month 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". b) 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 14 (a) 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 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 one (1) month 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.	

COMPLIANCE OF REQUIREMENT SPECIFICATIONS

I hereby confirm that I can meet all the specifications and requirements as stated in Section 3: Requirement Specifications.

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

Tenderer's official
Stamp:

Authorized Signature

Name:

Designation:

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

Reference To	Remarks

SECTION 3: REQUIREMENT SPECIFICATIONS
Equipment 3: HPLC
Laboratory/ Location: Pharmaceutical Laboratory

HSA000ETT17000052
Quantity: 1 unit

Equipment 3: High Performance Liquid Chromatograph (HPLC) System Location: Pharmaceutical Laboratory Quantity: 1 unit	Compliances Checklist (Yes/ No) <i>**If No, please indicate reason of non-compliances</i>
The HPLC unit should have an equivalent, if not better capabilities, than those stated below:	
A. <u>Quaternary Gradient Solvent Delivery Pump</u> - 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. - Must have a minimum settable flow range of 0.001 – 5 mL/min, in 0.001 mL/min increments - Flow precision must be ≤0.07 % RSD. - The flow accuracy shall not exceed ±1%. - The settable mobile-phase composition must be from 0-100%. - The precision of mobile phase composition must be ≤0.15 % RSD. - The delay volume must not be more than 350 µL. - 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 - Active seal wash kit must be included for improved seal life if buffer solvent is used. - 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.	YES/ NO
B. <u>On-line Degassing Unit</u> - Membrane degassing unit for at least four flow lines. - Maximum operating flow rate must be 5 ml/min per flow line or better. - Each channel has an internal capacity of not less than 12 mL 1.2ml that allows a better stabilization process. - It must have a leak sensor as a safety feature. - Low noise and other environmental friendly features preferred.	YES/ NO

C. <u>Auto-Injector</u> 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.	YES/ NO
D. <u>Thermostated Column Compartment</u> 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.	YES/ NO
E. <u>Diode Array Detector (DAD)</u> 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. 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	YES/ NO

SECTION 3: REQUIREMENT SPECIFICATIONS
Equipment 3: HPLC
Laboratory/ Location: Pharmaceutical Laboratory

HSA000ETT17000052
Quantity: 1 unit

9. Wavelength drift much be less than 0.9×10^{-3} AU/h.	
F. <u>Circular Dichroism Detector (CD)</u> 1. Wavelength accuracy: not more than +/- 5 nm. 2. Wavelength reproducibility: not more than +/- 0.5 nm. 3. Wavelength setting range: at least 200-460 nm or better 4. Measurement range: at least 200-460 nm or better 5. Noise level: not more than 0.04 mdeg 6. Drift: Not more than 0.1 mdeg/h 7. Data Output: at least 100 Hz	YES/ NO
G. <u>Data processing</u> 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 be 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. 5. The instrument must be able to acquire the signal of the detectors if they are from different brands. Vendor to be fully responsible to include additional software or communication module to be incorporated if needed for processing of data from the 2 detectors.	YES/ NO
H. <u>Others</u> 1. All modules in HPLC system must be able to communicate with each other. 2. Computer (networkable) and Printer: a) CPU with 3.2 GHz speed Intel Xeon processor, 4GB RAM and 500GB HDD. b) Graphics: Intel HD Graphics P4600 c) Lan I/O: Integrated Intel 82579LM Gigabit Network Connection d) Energy Star 5.0 enabled and qualified. e) Licensed windows operating system – Windows 7 professional or latest version pre-installed with installation CD/ recovery disk included. f) Microsoft Office – latest version pre-installed with installation CD included. g) Anti-virus software pre-installed. h) All necessary computer interfaces, cables, connectors and software drivers to be provided. i) At least 20-inch LCD monitor. j) USB optical scroll mouse and mouse pad k) USB keyboard	YES/ NO

SECTION 3: REQUIREMENT SPECIFICATIONS
Equipment 3: HPLC
Laboratory/ Location: Pharmaceutical Laboratory

HSA000ETT17000052
Quantity: 1 unit

l) Able to integrate (seamlessly) with software system and to provide necessary accessories required for this integration (e.g. network card and etc.). m) Network Colour Laser Jet printer with automatic duplex printing, at least 30ppm print speeds (letter/ A4), resolution of 1200 x 1200 dpi, 1.2GHz processor, 1G memory), allow network printing, , hi-speed USB 2.0 , or better. 3) 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. 4) At least 2 on-site training for operating the system and performing maintenance must be provided respectively. Tenderer shall provide comprehensive training for equipment at Tenderer's Training Centre. 5) The reporting format must be customisable by the laboratory. 6) The price quoted shall include Installation Qualification and Operation Qualification (IQ/OQ) to be performed for the HPLC system. 7) 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. 8) Original copy of application software must be provided. 9) Free update of the operation system software must be provided during warranty period. 10) The software must allow the setting of accessibility to folders and data for different user roles. 11) The Contractor must be able to perform risk assessment for the HPLC instrument that is located in the designated laboratory. A risk assessment report in 5x5 matrix must be submitted prior to the delivery of the instrument.	
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COMPLIANCE OF REQUIREMENT SPECIFICATIONS

I hereby confirm that I can meet all the specifications and requirements as stated in Section 3: Requirement Specifications.

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

Tenderer's official
Stamp:

Authorized Signature

Name:

Designation:

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

Reference To	Remarks

SECTION 3: REQUIREMENT SPECIFICATIONS
Equipment 3: HPLC
Laboratory/ Location: Pharmaceutical Laboratory

HSA000ETT17000052
Quantity: 1 unit
