

Equipment Description: Liquid Chromatograph - Single Quadrupole Mass Spectrometer – Diode Array Detector System (LC-MS-DAD)

Location: Pharmaceutical Laboratory

Quantity: 1 unit

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.

Introduction

This tender includes the specifications for the procurement of one unit of liquid chromatograph - single quadrupole mass spectrometer - diode array detector (LC/MS/DAD) system. The Authority shall reserve all rights to award as a whole or partially for this tender

Requirement & Specifications	Compliances Checklist (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 • 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> - Provide a high pressure binary pump system with at least 4 solvent lines to enable at least 2 individual solvent lines to be utilized concurrently. - Integrated diagnostic functions that pre-empts system malfunction. - Integrated degassing unit at least for 4 solvent lines. - Maximum operating pressure of 1000 bar or higher. - Shall enable settable flow range set points from 0.001 – 2 mL/min or better. - Flow precision of $\leq 0.07\%$ Relative Standard Deviation (RSD) or ≤ 0.01 min Standard Deviation (SD), whichever is greater. - Flow accuracy of $\pm 1.0\%$ or better. - User selectable compressibility compensation, based on mobile phase compressibility.	YES/ NO

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i) Support and function in the pH range of 1.0 – 12.5 or better. j) Shall permit high pressure binary mixing for gradient formation. k) Shall include active seal wash kit for improved seal life if buffer solvent is used. l) User-settable mobile phase composition range from 0 – 100% m) Mobile phase composition precision of $\leq 0.2\%$ RSD or better. n) Software and local control functions. o) Enable communications via controller-area network. Remote: ready, start, stop and shut-down signals with optional LAN. p) 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) Able to notify the lab when the maintenance is due, early maintenance feedback to be provided for continuous tracking of system 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) Able to handle a minimum of 100 pieces of 2 mL HPLC vials. b) Come with thermostat with settable temperature from 4 °C – 40 °C in 1 °C increments or better. c) Capable of automated injection of sample volumes of 0.1 – 100 µL in 0.1 µL increments or better. d) Carryover of ≤ 10 ppm with needle wash. e) Come with a flush port. f) Compatible to withstand high pressure of at least 1000 Bar. g) Injection precision of $\leq 0.25\%$ RSD. h) Injection cycle time of ≤ 20 s for draw speed of 200 µL/min or better.	YES/ NO
3. <u>Column Compartment</u> a) Temperature range of at least 10°C below ambient to 90 °C. b) Temperature precision of ± 0.05 °C or better. c) Temperature accuracy of ± 0.5 °C or better. d) Minimum column capacity of two columns of 30 cm.	YES/ NO
4. <u>Diode Array Detector (DAD)</u> a) Detection must be via 1024-element diode array. b) Slit width must be programmable at 1, 2, 4, 8 nm.	YES/ NO

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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 – 400 nm. 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 100 Hz or higher.	
5. <u>Single Quadrupole Mass Spectrometer System with ESI Source</u> a) The system must be a bench top model with a maximum scan speed of 10,000 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 up to at least 3000 m/z. d) Dynamic range must be $\geq 4 \times 10^6$. 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 absolute value of ± 0.1 Da of measured mass over a 12 hour period. 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 or better. h) Mass measurement accuracy must be less than ± 0.15 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 200:1.	YES/ NO

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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) m) All systems must be able to provide proper isotope ratios for a halogen containing test compound up to the maximum specified scan speed. n) System must be controlled using industry standard TCP/IP LAN protocols. o) Systems must not require any plumbing changes to perform calibration and tuning for easy operation. p) 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. q) System must be capable of displaying, acquiring, storing and manipulating mass spectral information and diode array spectral information simultaneously.	
6. <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 - 24" LED monitor or larger - Keyboard - Mouse and mouse pad - Pre-installed with Windows 10, Microsoft office and antivirus software which is compatible with the data management software system of the system <u>Printer specifications:</u> - Monthly duty cycle: 80,000 pages per month	YES/ NO

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- Memory: 256MB - Processor Speed: 1200 MHz - Speed: at least 35 pages per minute - Size: A4 - Auto Duplex: Yes - Paper Tray: 2 x 500 sheets - Print Technology: Monochrome Laser - Print resolution: 1200dpi - Network printer: Yes	
7. <u>Data Management Software System</u> a) Shall be a flexible Windows-based data system that provides instrument control and data analysis. b) Shall work seamlessly with application-specific software modules. c) Have the ability to run in a fully automated manner, while also providing for sophisticated manual data evaluation. d) Able to perform background subtraction in the same chromatogram at any time-point. e) Able to generate multiple wavelengths library search results in one report for a single injection. f) Easy to use for library matching i.e. matching on screen to be done within 1-2 steps. g) Have the feature to protect testing methods from being tampered. h) Shall be mutually compatible with the lab existing in-house library developed using Agilent Chemstation software. i) Shall provide an original copy of application software. j) Shall provide free update of the PC operation system software during the warranty period.	YES/ NO
8. <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 2 years' 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 system. These shall include the operator's manuals/software manual and system manuals.	YES/ NO

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d) The Contractor must be able to perform risk assessment for the LC/MS/DAD system that is located in the designated air-conditioned laboratory. A risk assessment report in 5x5 matrix must be submitted prior to the delivery of the system. e) During the installation of the system, the Contractor must make sure the system 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 systems. 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 system must be fully commissioned within 1 month upon delivery.	
9. <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, system 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
10. <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	YES/ NO

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method developments and on-site training by factory-trained engineer. 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 (at least 1 track record must be submitted) for the sale and provision of maintenance support services for the model proposed in this tender in Annex D.	
11. <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 including repair wear & tear parts. (iv) Provision of all necessary kits, consumables (inclusive of all related tuning solutions with certified validity for the entire duration of the maintenance contract). (v) Update/upgrade of software revisions.	YES/ NO
12. <u>Replacement of Components</u> 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 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 System in Good Working Order.	YES/ NO
13. <u>Guarantee</u> a) The Contractor hereby warrants that all the System 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 at least three (3) months from the date of acceptance of the Services	YES/ NO

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by the Authority (hereinafter referred to as “the System 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 at least three (3) months from the date of acceptance of the materials by the Authority (hereinafter referred to as “the Materials Guarantee Period”). The System 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 System 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 13 (a) above, the Contractor shall at the written request of the Authority replace the same at the expense of the Contractor or if the Authority so agrees make good or repair the same at the expense within a Guarantee Turn-Around-Time of 7 days . The System 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.	

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

Reference To	Remarks