

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.

Specifications for a Gas Chromatograph - Single Quadrupole Mass Spectrometer and Flame Ionization Detector (Pharmaceutical Laboratory)

A. Introduction

This tender includes the specifications for the procurement of one unit of gas chromatograph tandem single quadrupole mass spectrometer and flame ionization detector.

B. General

A robust and sensitive bench top/stand-alone gas chromatograph - single quadrupole mass spectrometer and flame ionization detector shall offer configurations as follows:

- Gas Chromatograph (GC)
- Autosampler
- Column Oven
- Split/Splitless inlet
- Electronic Pneumatic Control (EPC)
- Mass Spectrometer with EI Source
- Flame Ionization Detector
- Computer Hardware and Software
- Data Management Software System
- Installation, Commissioning and Warranty
- Training
- Technical Support
- Accessories & Miscellaneous

The GC/MS-FID unit shall offer equivalent or superior functions as follows:

1. Gas Chromatograph

- (a) Must have two inlets and two detectors.
- (b) Full Electronic Pneumatic Control (EPC) must be available for all inlets and detectors.
- (c) EPC must provide four column flow control modes: constant pressure, ramped pressure (three ramps), constant flow, or ramped flow (three ramps).
- (d) Must have pre-programmed leak tests.
- (e) Must provide context sensitive on-line help.
- (f) GC display must be able to show GC and autosampler set points at the GC or data system in English characters.
- (g) Must provide set point control from the local user interface or via a networked data system.
- (h) Good to have clock-time programming that can be used to initiate events (on/off, method start, etc.) at a future date and time.
- (i) Must provide a run time deviation log created for each analysis
- (j) Must have chromatographic performance with retention time repeatability < 0.008 % and area repeatability < 1 % RSD.

- (k) Operating parameters can be entered through the operating software. Preferably, the parameters like leak checking, start/stop functions and etc can be controlled by touch screen interface.
- (l) The LAN interface must allow real-time monitoring of the GC, even during operation.
- (m) Must have graphic display of GC counters and provide a real-time notification via indicator/advisory when a counter limit is reached.
- (n) Must offer safety and maintenance features to support extensive diagnostics, error detection and leak detection.

2. Autosampler

- (a) Must provide an injection tower with an autosampler tray.
- (b) Autosampler tray must be able to handle at least 150 pcs of 2 ml sample vials, the control is random access using the data management software.
- (c) Must be able to auto-detect type and volume of the syringe used by the system.
- (d) Must have self-aligning injector and able to be installed or removed without the use of tools.
- (e) Must have sensors to detect that a vial has been grasped and the sample vial has been transferred to the injector.
- (f) Must have sensors to detect the injection port location for easy movement between front and rear inlet ports.
- (g) GC shall have the capacity to have two auto injectors mounted simultaneously on the GC so that injections can be made.
- (h) Must have fast injection time in less than 100 milliseconds.
- (i) Must allow installation and automation of syringes featuring volumes in the minimum range of 1 to 10 μ L.
- (j) Minimum sample injection: ≤ 10 nL (with 1 μ L syringe); ≤ 0.1 μ L (with 5 μ L syringe).
- (k) Must allow injection volume settings of 1% to 50% of syringe volume in increments of 1%.
- (l) Must have fully programmable syringe dispense rate, draw rate, and injection rate.
- (m) Must have adjustable sampling depth to access very small sample volume.
- (n) Must have the capability to rinse the syringes pre- and post-injection with 2 different solvents.
- (o) Must allow minimum setting range of 0 - 15 pre-washes of sample.
- (p) Must allow minimum setting range of 0 - 15 pre-injection sample pumps.
- (q) Must have a minimum programmable viscosity delay of 0 - 7 seconds.
- (r) Must have sufficient wash and waste vials for handling large numbers of samples over weekends. Total wash solvent volume (usable volume; or volume above the minimum fill line of the solvent wash vials) shall be at least 20 mL distributed in at least 4 solvent wash vials to ensure adequate washing of the syringes for a full sequence of 150 samples with the laboratory's current wash settings.
- (s) Must be capable of carrying out advanced function such as online-derivatization, bar-code reading etc.

- (t) Must be able to handle priority sample, which can be inserted into the sequence at any time.
- (u) Must be able to perform next sample overlap to decrease analysis time and increase throughput by performing pre-run rinses and picking up the next sample before the current run is completed.
- (v) Must be able to support standard 2 mL glass vials, and micro vial inserts.
- (w) Must have removable sample tray for easy checking of vials.
- (x) Must have adjustable plunger speed.
- (y) Must have user-changeable syringe carriage.

3. Column Oven

- (a) Must have a minimum operating temperature range of 10 °C above ambient to 450 °C.
- (b) Must have a temperature set point resolution of at least 0.1 °C.
- (c) Must have a maximum achievable temperature ramp rate of at least 120 °C/min.
- (d) Must have a fast cool down from 450 °C to 50 °C in no more than 4 minutes.
- (e) Must be able to accommodate at least two capillary columns (max. dimensions 100 m x 0.53 mm i.d.).
- (f) Must be able to support at least 20 oven ramps with 21 plateaus and allow negative ramps.
- (g) As a safety feature, it must turn off power automatically when the door is opened.

4. Split/Splitless Inlet – 2 sets

- (a) Must have electronic pneumatic control (EPC) of carrier, split and septum purge gases, including electronic ON/OFF.
- (b) Must support different modes of injection such as Split, Splitless, Pulsed-Split and Pulsed-Splitless mode.
- (c) Must be suitable for capillary columns in the range of 0.05 to 0.53 mm id.
- (d) Must allow split ratio set point up to at least 5000:1 and allow the split ratio to be set electronically.
- (e) Must have flow sensors for the control of split ratio.
- (f) Must have a maximum operating temperature up to 400 °C.
- (g) EPC must be available within the following pressure ranges:
 - 0 to 100 psig for columns $\geq$ 0.200 mm diameter
 - 0 to 150 psig for columns $<$ 0.200 mm diameter.
- (h) Must be able to set a minimum total flow range of 0 to 1250 mL/min for helium or hydrogen.
- (i) Must have a built-in inlet sealing system for quick, easy, inlet liner changes to minimize System downtime.
- (j) Must have gas saver mode to reduce gas consumption without compromising performance.
- (k) Must have electronic septum purge flow control to eliminate ghost peaks.

- (l) Must be able to change the split and septum purge flow without changing the column flow.
- (m) Chemical deactivated inert inlet must be available together with suitable inert consumable supplies (inert liner, inert gold seal, inert column etc.) to improve data/peak quality and reduce the system maintenance.

5. Electronic Pneumatics Control (EPC)

- (a) EPC must be compensated for atmospheric pressure and temperature variation.
- (b) Must have psig (gauge) and psia (absolute) pressure control to provide stability in pressure.
- (c) Pressure set points must be able to be adjusted by increments of 0.001 psi.
- (d) Must have automatic leak checking which can be enabled by user for every run so that the system alerts the user when a leak is detected.
- (e) Must be able to select pressure units as bar, psi or kPa.
- (f) Must be able to set up to a maximum of 3 pressure/flow ramps in addition to injecting at a different (pulsed) pressure.
- (g) Flow/pressure setpoints must be set via GC or data system software.
- (h) Constant flow mode must be available.
- (i) Must be able to select carrier and makeup gas types. Carrier types supported are helium, hydrogen, and nitrogen. Makeup gas types available are detector specific.
- (j) Must have a pressure sensor accuracy of $< \pm 2\%$ and repeatability of $< \pm 0.05\text{psi}$.
- (k) Must have a temperature coefficient of $< \pm 0.01 \text{ psi}/^\circ\text{C}$.
- (l) Must have a drift of $< \pm 0.1\text{psi}/6 \text{ months}$.
- (m) Must have a flow sensor accuracy of $< \pm 5\%$ and repeatability of $< \pm 0.35\%$ of setpoint.

6. Mass Spectrometer with EI Source

- (a) Mass spectrometer must utilize a Quadrupole Mass Filter consisting of a monolithic quartz structure. A quadrupole consisting of 4 separate rods is not acceptable. The rods must have a true hyperbolic shape in keeping with quadrupole theory. The quadrupole must be independently heated.
- (b) The quadrupole's coating shall be made of inert material such as gold that will not oxidize, thus keeping maintenance and cleaning to a minimum.
- (c) The metallic parts of the ion source shall be constructed entirely from inert material. Stainless steel is not acceptable as it is not suitable for analysis of trace reactive materials.
- (d) Must have the efficiency to support synchronous SIM/Scan, which enables collection of both SIM data and full scan data in the same acquisition cycle. The software must automatically configure the number of SIM groups, SIM cycles across the peak, and the ions added to each group.
- (e) The system must provide one click autotune for PFTBA, with the ability to print out auto-tune results automatically. It must also be able to perform and print out evaluation of auto-tune.
- (f) There shall be 2 filaments available in the ion source allowing automatic switching to another when one fails, to minimize downtime

- (g) Source: Electron Ionization (EI)
 - Ionization energy: 10 – 150 eV or better
 - Ionization current: 5 – 250 μ A or better
- (h) Transfer line temperature: 100 – 350 °C or better
- (i) Ion source temperature: 150 – 350 °C or better
- (j) Quadrupole temperature: 110 – 200 °C or better
- (k) Mass range: To at least 1000 a.m.u. with unit mass resolution over the entire mass range
- (l) Mass accuracy: 1 μ L injection of 100 pg/ μ L (Octafluoronaphthalene) OFN, scanning from 50 to 300 u, will give its monoisotope at m/z 271.987 $\pm$ 0.005.
- (m) Mass axis stability: Not more than 0.10 amu/48 hrs
- (n) Detector: Triple-Axis Detector with high energy dynode and long-life Electron Multiplier for increased sensitivity
- (o) Dynamic range: at least 10^6 .
- (p) Electronic scan rate: at least 12,500 amu/sec and scanning at increments of 0.1 amu or less for better mass resolution
- (q) EI Scan sensitivity (measured by Signal to noise ratio):
1 μ L injection of 1 pg/ μ L OFN standard solution must give at least 1200:1 S/N scanning from 50 to 300 u at nominal 272 u ion using Helium gas with a liquid autosampler.
- (r) EI SIM sensitivity (measured by Instrument Detection Limit):
8 sequential 1 μ L injections of 100 fg/ μ L OFN standard solution at nominal 272 u ion must give instrument detection limit of 10 fg or less.
- (s) Spectral Accuracy:
1 μ L injection of 100 pg/ μ L OFN, scanning from 50 to 300 u, will give at least 99.0% spectral accuracy.
- (t) SIM capability: at least 100 SIM ion groups, with up to minimum 60 ions per group.
- (u) Must utilize a high-vacuum performance turbo pump with a minimum pumping speed of 255 L/sec and a 2.5 m³/h mechanical pump to create high vacuum.
- (v) Must have an oil-free roughing pump for easy maintenance.
- (w) The system must offer retention time locking capability to provide the same retention time after column maintenance. It must also offer ways to transfer a method to another system and maintain the retention time.
- (x) The software module must provide the creation of custom compound databases as well as the utilization of vendor provided databases.
- (y) Must have automated Sleep/Wake mode for electrical power and gas saving.

7. Flame Ionization Detector

- (a) Minimum detectable level (for tridecane) must be < 1.2 pg C/s.

- (b) Must be able to set data rate up to 1000 Hz.
- (c) Automatic flame ignition. Must provide flame out detection and automatic re-ignition.
- (d) Full-range digital data path enables peaks to be quantified over the entire 10^7 concentration range in a single run, without the need to set a switch or software setting to obtain this full range of data.
- (e) Must be able to control the flow of hydrogen and makeup gas nitrogen or helium from 0 -100 mL/min.
- (f) Maximum operating temperature 450 °C.

8. Computer Hardware and Software

- (a) A data acquisition/processing computer and a laser printer shall be provided with equivalent or better configurations as follows:

PC specifications:

- Operating System: Microsoft Windows 10 (latest build version) and Microsoft Office software 365 which is compatible with the data management software.
- Processor: Intel® Core™ 9th Gen i7 Processor or better
- Monitor: Minimum 22" IPS LED Monitor with resolution 1280 x 1024 dpi
- Hard Disk: 1TB 7200 rpm SATA 6Gb/s HDD or better
- Memory: Minimum 16GB DDR4 RAM
- Available Network Interface Ports: Shall be built-in to the computer board or PCI card based with minimum 2 ports. (Depending on System requirements; 1 of the ports will be used for connecting to HSA Network)
- DVD-ROM drive
- 104 key Keyboard
- Optical mouse and mouse pad
- Must be able to support HSA supplied managed anti-virus software.

Printer specifications:

- Monthly duty cycle: 3000-5000 pages per month
- Memory: 128MB
- Speed: at least 40 pages per minute
- Size: A4
- Automatic Duplex: Yes
- Paper Tray: 500 sheets
- Print Technology: Monochrome Laser
- Print resolution: 1200 x 1200 dpi
- Network printer: yes

9. Data Management Software System

- (a) Must be a Windows-based data system that provides system control and data analysis and able to view system status, user information, and monitor runs.
- (b) The software shall be able to control the GC through local area network (LAN) technology. The internet protocol (IP) address used on the system shall be in accordance to the standards of HSA Network plan.
- (c) The Tenderer shall ensure that the PC/notebook provided with the system is network ready and be able to connect to the HSA's network for interfacing with HSA's LIMS (Laboratory Information Management Software) system, e.g. LISA, LabWare, etc.

- (d) The system software must be able to interface with HSA's LIMS for the following:
 - i. Raw Data Files archival & retrieval.
 - ii. System test result report output to PDF for archival.
 - iii. System test result report for result uploading.
 - iv. To accept work list upload from HSA's LIMS, if applicable.
- (e) System shall be able to import and run a sequence file generated by the LIMS. The sequence file generated shall be in csv or txt file format.
- (f) The Contractor shall work with HSA personnel for the following:
 - i. To define and assign a Hostname and/or PC name given by HSA IT infrastructure team to facilitate the system management on HSA network.
 - ii. To define the Raw Data file structure & directory assigned by HSA to facilitate the automation of electronic archival and retrieval of files.
 - iii. To perform SIT and UAT to ensure the integration to HSA's LIMS system is running fine.
- (g) For the system report printing and extraction, the Contractor shall work with Laboratory to ensure the seamless integration and interface with HSA's LIMS.
- (h) The Computer system supplied with Microsoft Windows Operating system shall support HSA Microsoft Active Directory Domain infrastructure.
- (i) The Computer system supplied shall use Active Directory based user accounts without the requirement of having Domain Administrator privileges.
- (j) The Computer system together with the operation of the required scientific shall not require the use of local system privilege's account or rights for its functional use.
- (k) Lab monitor and Diagnostic software to allow continuous monitoring of GC in real time to alert user maintenance needs and system problems.
- (l) The software must be able to fully control the system using pre-stored methods of all the operating parameters.
- (m) Must have the capability to lock/adjust retention time using user-specified columns and settings to achieve the same retention times for the compounds on every run of the same methods.
- (n) The system shall have the capability for simple method transfer between different GC models.
- (o) Must be mutually compatible with the current Agilent in-house mass spectral library in ".L" format either directly or through conversion.
 - i. Should conversion of library be required, it must be user friendly and can be done by user
 - ii. The conversion must not cause any loss in mass spectra information (no missing ions and comparable ion ratios)
- (p) Must be able to use and share libraries through network drive with or without additional software. If additional software is required for the above function, tenderer shall quote for the software and to specify in the Price Schedule.
- (q) Must provide the latest version of the NIST mass spectra library.
- (r) Must be able to do library search for minimum 3 libraries at the same time.
- (s) Must be able to load and read data from existing GC-MS systems (Agilent 7890A-5975C, 7890B-5977A, and Intuvo 9000-5977B) in the laboratory. Acquired data from proposed system shall also be accessible in all GC-MS systems with or without additional software. If additional software is required for the above function, Tenderer shall include the cost for the software to meet the minimum requirement.

- (t) Must provide free update of the PC operation system software during warranty period.
- (u) All systems proposed shall be compliant to Good Laboratory Practice (GLP) with system suitability, system and sequence logbook.
- (v) User-friendly, intuitive software to facilitate efficient data analysis. Selection of spectra and chromatogram, magnification of spectra and chromatogram, integration, spectra subtraction, library search shall be completed in a minimum number of clicks compared to the existing GC-MS software.
- (w) Must be able to automatically set up a SIM/scan method from an injected standard.
- (x) Must have the ability to run in a fully automated manner, while also providing for manual data evaluation.
- (y) Must be able to acquire data, integrate, review and report on an actively running sample.
- (z) Able to perform and print out peak overlay and peak stacking for multiple chromatograms.
- (aa) Contractor shall work with the laboratory for the writing of macros, which can be tagged to the laboratory's in-house GC-MS methods to allow automatic printing of results after analysis; or equivalent function without the need of macro.
- (bb) The software must allow the generation and printing of a magnified mass spectrum. When performing this function, the mass spectrum of the selected compound from the library must be magnified simultaneously to the same scale and be included and printed in the match report. Printing of the magnified mass spectrum must be easy and with minimum number of clicks, without the need of preconfiguring the printing template for magnified mass spectrum.
- (cc) Must have the feature to protect testing methods from being tampered.
- (dd) Must have a deconvolution and reporting software module that combines the data results with NIST or in-house library search for target compounds into a single report.
- (ee) Must have built-in trace ion detection capability which will help the detection of low-level compounds in complex matrices.

10. Installation, Commissioning and Warranty

- (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 three (3) years warranty upon successful commissioning, covering 1 preventive maintenance per year with PM kit & tuning solution (if applicable), defective parts replacement, repair consumables, and labour support service. Any software revisions shall also be provided free-of-charge.
- (c) The PC and its installed software must come with at least 3-year warranty and accompanied with their system recovery CDs or DVDs.
- (d) Unlimited breakdown calls and on-site support services must be provided during Operating Hours i.e. 8:30am to 6pm from Monday to Friday excluding Saturday, Sunday and Public Holidays.
- (e) All documentation is to be supplied along with the system. These shall include the operator's manuals/software manual.
- (f) The Contractor must be able to perform risk assessment for the GC/MS system that is located in the designated air-conditioned laboratory. A risk assessment report must be submitted before the delivery of the system.

- (g) During the installation of the system, the Contractor must make sure the system is properly connected to the gas pipeline in the laboratory using the necessary tubings, connectors and other necessities with no leaking.
- (h) During the commissioning of the system, the technical specialist/engineer must validate the GC/MS 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 GC/MS system.
- (i) 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 system. These accessories shall include syringes of appropriate sizes, as well as cleaning tissue and cleaning buds at no additional cost.
- (j) The GC/MS system must be fully commissioned within 1 month upon delivery.

11. Training

- (a) On-site training for all end-users in the Pharmaceutical Division that is approximately 30 pax shall be provided by trained personnel(s), and shall cover topics including simple MS theory, system overview, MS tuning, MS method optimization, data acquisition, and general maintenance. In addition, a proposed training schedule must be provided upon request.
- (b) Comprehensive classroom training which covers the basics, maintenance and troubleshooting for GC/MS, must be provided for a minimum of 3 officers.
- (c) The training shall be conducted by factory-trained engineer. A copy of certification shall be submitted for verification upon request.

12. Technical Support

- (a) The GC/MS 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 GC/MS 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.
- (d) The service engineers and product specialists must be qualified to provide the relevant services. A copy of certification shall be submitted for evaluation upon request.

13. Accessories & Miscellaneous

- (a) The price quoted shall minimally include the following:
- (b) One GC Starter Kit. It must include leak detection fluid, swage-type fittings, copper tubing, syringes, screw-drivers and wrenches.
- (c) One MS maintenance kit. It must include ion source assembly, filament assembly, ion source cleaning kit, alumina absorbent pellet for rough pump traps and others.
- (d) One autosampler supply kit. It must include 2 ml sample vials and crimp caps, 4 ml solvent and waste bottles, and 10 µl autosampler syringe.
- (e) One split/splitless injection port kit. It must include septa 11 mm, O-rings, gold seals, and glass wool-packed splitless, single taper liners.

- (f) All gas purifiers required for the GC/MS system. Must also include one big universal trap.
- (g) Oven exhaust deflector and ion-gauge controller to monitor the pressure in the high vacuum chamber.
- (h) Glass wool-packed splitless, single taper inert liners. Quantity: 100.
- (i) Septa, nonstick BTO inlet, 11 mm. Quantity: 50.
- (j) Polyethylene glycol (PEG) stationary phase column 30 m x 0.25 mm x 0.25 µm, including consumables like gold seals, ferrules, column nuts. Quantity: 1 set.

14. Option to Purchase: 2 years post warranty maintenance services

Tenderer shall quote for option to purchase 2 years post warranty maintenance services for the gas chromatograph - single quadrupole mass spectrometer and flame ionization detector system. The price quoted shall minimally include the following:

- Provision of yearly preventive maintenance (1PM/year) including PM kit, tuning solution (if applicable);
- Provision of unlimited breakdown calls and on-site support services during Operating Hours.

15. Performance of Services for warranty and post warranty maintenance services

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

i. Preventive Maintenance

The Preventive Maintenance shall consist of:

- a. Routine maintenance of the System, including but not limited to the testing of functions and inspecting of the condition of the System in order to keep the System safe for use and in working order; and adjustment and/or repair of any defect in or malfunction of the System discovered by the Contractor's representatives during the course of routine maintenance checks.
- b. The Preventive Maintenance performed shall be in compliance with the maintenance procedures and safety tests specified by the manufacturer.

ii. Corrective Maintenance

- 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 attend 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 4 hours of the beginning of the next Working Day.
- b. 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 15 (II)-(a)** unless the Authority had agreed in writing to have the time period extended.

16. Replacement and Purchase of Components

- (a) The Contractor shall inform the Authority of any part or component of the System that needs to be replaced.

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

Reference To	Remarks