Notice Inviting e-Tender

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Procurement, supply and installation of Hi Tech Analytical Instruments for State Drugs Control & Research Laboratory (SDCRL) of the Government of West Bengal

(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT-279 /2025 **Dated-08.04.2025**

The following amendment have been made in the tender document,

Amendment –I (Revision of Technical Specification)

The revised technical specifications for the item is given below,

Highly Sensitive Triple Quadrupole LCMS / MS System

Specifications	Requirement
LC-MSMS (Triple Quadrupole)	A Bench Top Highly Sensitive Triple/Tandem Quadrupole LCMS/MS System with facility to either use as standalone or connect to a Fast Liquid Chromatography system using lesser than 2μm particle size columns for high sensitivity for both qualitative and quantitative analysis along with research purpose for small molecules research, Drugs analysis, Impurity profiling, Nitrosamines along with software to meet global regulations like USFDA & 21 CFR Part II compliance. Both MS, Software and LC should be from same manufacturer.
Mass Range	5 to 2000 m/z or better
Scan speed	Should have the scan speed of 18,000 amu/sec or more in Triple Quadrupole mode
Mass stability	Less than $\pm$0.1 Da over a 24-hour period
Interface	Dual orthogonal off axis or equivalent source technology capable of avoiding

	interferences from solvents and other extraneous matter, handling large batches of complex sample matrix over a long period of time without performance degradation.
Ionization source	1. Combined / Dual ionization ESI and APCI sources to be provided as standard, with facility of interchanging easily by the user, and auto-detection of installed source by the instrument and software. The ionization must be done both in a positive & negative mode. 2. The combined ionization (ESI & APCI) source must operate along with reference spray to facilitate automated accurate mass measurements within single LCMS experiment. The instrument should be capable of internal reference mass correction for MS and MS/MS operation without losing sensitivity. 3. Sample introduction must be done by direct infusion integrated with system fluidics without any external syringe pump in addition of using Liquid Chromatography. The Sample Introduction Technology must be associated with automated system parameter checking along with alert generation. It must provide calibrant delivery system with programmable divert valve & Automated Mass Calibration. 4. An atmospheric pressure solids analysis probe (ASAP) for the direct sampling and introduction of solids and liquids should be available as an additional source for research purpose. 5. Switching between positive & negative mode should be ≤ 25 ms or better. 6. The source shall have a flow rate compatibility from 50μL/min to 2000 μL/min, without flow splitting in both ESI and APCI modes. 7. Switching between MS & MS/MS mode must be less than equal to 3 ms. 8. Desolvation Temperature: The upper limit of the desolvation temperature must be more than 400 degree C, which should be programmable and used in all the different probe usages including combined / dual ESI & APCI for every Solvents & Compounds. 9. All source parameters to be adjustable through software automatically including mass calibration, sample tuning & MRM method development must be done fully automatically.
Source cleaning	The cleaning of the source should be done without venting the system and facility to Vacuum Interlock should be provided. The Vacuum must remain intact during the cleaning, Source interchange or Servicing of the system. Vendors must assure the same in writing.
Infusion Device	Infusion device must be integral to the instrument for direct sample introduction and must be controllable from the instrument software. At least 3 user-changeable sample vials should be built into the system to allow tuning and calibration solutions to be infused into the probe via a selection valve. A fourth vial or equivalent should also be available containing the wash solution to ensure the system is ready to analyse the next tuning or calibration solution.
Vacuum system	A robust high efficiency Oil less vacuum system with minimum/zero maintenance and utility with low noise level and automatic vacuum lock system
Triple Quadrupole	Quadrupoles having high standards of mechanical tolerances and minimum coefficient of Thermal expansion to ensure highest mass stability with pre-aligned pre filters to ensure excellent focusing of Ions into all the Quadrupoles for high sensitivity and resolution in both Q1 and Q3.
Instrument Detection limit	Should be 0.4 femtogram or less from minimum ten replicate injection of Reserpine (Proof of Statement must be provided)
Mass Resolution	Must be automatically adjusted to desired resolution (0.50 Da, 0.75 Da or 1.00 Da FWHM)

Sensitivity	1. MRM ESI +ve 1pg On column reserpine and –ve chloramphenicol should give chromatographic S/N greater than 50,00,000:1(Fifty Lakhs is to One) without smoothening MRM transition 609-195 at unit resolution (Proof of Statement must be provided) 2. Documentary evidence to be submitted along with quotation. For ten injections, %RSD should be < 5%. Chromatograms to be provided, with details of mobile phase, column, and injection volume. Statistical treatment used to determine S/N ratio is to be specified along with raw data.
Collision cell	Should be specially designed collision cell to allow use of very low Dwell times (1 milliseconds or less) without sacrificing sensitivity and eliminate Crosstalk to enable Multiple MRM Transition Studies within a single run.
MRM Acquisition Rate	Should be capable of minimum 500 MRM or more data points [sec in a single time period with no loss in sensitivity for co-eluting components at anyone point of time.
Operating Modes	Tandem mass spectrometry should have following scan options a. Full scan b. Selected ion monitoring/recording (SIM/SIR) c. Product ion scanning. d. Precursor ion scanning. e. Neutral loss/gain scanning. f. Multiple reaction monitoring. g. Simultaneous full scan and MRM along with matrix monitoring to be performed in a single run. h. +ve / - ve polarity switching time between alternate MRM scans of minimum 25ms. i. Fully Automatic tuning & Mass Calibration. j. Information dependent acquisition system scan mode of MRM to high sensitivity product ion scan for library confirmation.
Dynamic range	6 orders of magnitude or better
Detector	1. Must have very long life, low noise, highly efficient photomultiplier, or electron multiplier detector. 2. The detector should last for the lifetime of the instrument, not require regular gain adjustment, and operate in both positive and negative ion modes capable of switching rapidly between the two modes (≤15 ms).
UUPLC	**A. Pump:** 1. Quaternary / Binary operating pump(s) with an operating pressure of minimum 15000 psi or better. 2. The flow rate range should be 0.010 to 2.000 ml/min or better, in 0.001mL increments. 3. Flow rate accuracy must be ±0.1 % & Flow Rate Precision should be ≤0.075% Relative Standard Deviation or better with Compressibility Compensation fully Automatic & Continuous. 4. Solvent Blending must be Fully Automatic & can program gradient methods directly in terms of pH and percent organic, pH and salt concentration. It must also Program gradients directly in terms of pH and ionic strength to minimize manual mobile phase preparation and reduce potential for human error in routine analysis. 5. The system must produce different gradient curves / profiles (>10 different curves including linear, Step, Convex, Concave etc.) **B. Degasser:** The instrument should have in-built Vacuum degasser facility with minimum four

	lines and should be efficient to remove dissolved air online. C. **System Delay Volume:** Should be less than 400 micro litre, independent of system backpressure along with Gradient Delay Volume of Less than 300 micro litre. The Total Band spread should be less than12 micro litre. D. **Auto sampler:** Auto sampler should be available with a capacity of approx. 90 vials or more of 1.5 ml or better capacity & sufficient no. of spare sample vials must be provided. The auto sampler should have cooling facility upto 4 degrees or better and heating upto 40 degrees or better. 1. Programmable injection volume from 0.1ul to10ul or better must be available with Flow through needle with a carryover of the auto sampler must be less than 0.002% or Lesser. 2. It must have advanced features like Auto- Dilution, Auto-Addition & Load Ahead capabilities. 3. It must have the latest needle wash capabilities like Integral, Active & Programmable. 4. Auto sampler vials universal to UHPLC / HPLC with 2 ml capacity must be provided at least 1000 no.'s with septa & cap. E. **Column Oven**: Column Temperature Control should be from ambient to ≥90 deg. C or better with a Temperature control from ambient to maximum operating temperature. Temperature control precision should be 0.1°C. **F. Columns & Standards:** 1. Sub 2 microns (1.7um / 1.6um) C18 UHPLC/UPLC Columns should be Quoted with Smaller Dimensions with a pH level of 2 - 12. 2. Sub 2 microns (1.7um / 1.6um) HILIC UHPLC/UPLC Columns should be Quoted with Smaller Dimensions with a pH level of 2 - 12. 3. Column usage history tracking technology must be associated with the column so that all the information related to number of injections, solvent consumption, Temperature, Pressure etc. Should be available electronically & archives all of them so that the data can be acquired as when required & must help to create a paperless laboratory.
Software	1. Application software for quantitative applications must be compatible with LC/MS and LC/MS/MS data. Data can be full scan, SIR/SIM or MRM. 2. Data Acquisition, Peak Integration, Calibration, Quantification must be fully automated. 3. Quantification parameters must be stored for each compound and individually selected and loaded into new methods. The quantification method editor must be viewable in page view or as a spreadsheet. 4. The software must allow the monitoring of the molecular ion up to 4 confirmatory ions. 5. Technology for system optimization and status monitoring, technology should monitor and perform the following parameter: - System parameters checking and alerts - Integrated sample/calibrant delivery system and programmable divert valve - Automated mass calibration - Automated sample tuning - Automated SIR and MRM method development - LC/MS system checks-automated on-column performance test. 6. The application software must flag samples in the browser report when: - the ion ratios fall out-with the user-defined values the maximum blank acceptance level (user input) has been exceeded - the maximum concentration limit (user input) has been exceeded - the concentration is below the reporting concentration limit (user input)

	- the concentration falls below the minimum recovery % level (user input) - the concentration falls above the maximum recovery % level (user input) - the coefficient of determination for a calibration curve falls below a user-set level - the peak of the compound of interest falls below a user defined S/N ratio 7. Software should have the latest library database of around 1500 compounds viz. (Antibiotic residues, drugs residue, Mycotoxins, Vitamins etc.) 8. The database should contain Molecular formula, Mono isotopic mass, Parent ion, Cone voltage (V), Production 1, Collision energy (eV) Production 2, RT and sensitivity. 9. The Software must be secured & must be compliant ready with 21 CFR Part 11 guidelines. Bidders must provide the same in Writing.
Workstation & Accessories:	A Workstation should be provided for controlling the mass spectrometer, the LC and the auto-sampler with data acquisition & for data processing and analysis with minimum following specification: - Memory / RAM: Minimum 60 GB or higher - Hard disk: 10 TB or better - CPU: Dual-Processor, 3.5 GHz or better - Operating system: Windows 10, 64 - bit or better. - LCD monitor. - 1 Laser jet printer. All hardware and software including drivers, monitor, device interfaces cards / network must be preinstalled and preconfigured on the computer provided.
Instrument and Software Qualification Service & Certification:	1. The instrument must be "Qualified" along with the Software. Necessary reagents along with Documents must be Quoted with valid Cat/Cas no.'s & should be provided for valid "Instrument Qualification, Operational & Performance Qualification" of the instrument along with Specification check during the installation. 2. The vendors must quote the Qualification kits with defined list of items along with valid Cat. No./Product ID etc. 3. During installation and qualification, Instrument should perform as per submitted specification in presence of user. 4. Equipment should be European CE (4 Digit notified body) /BIS/CDSCO Certification from the competent authority.
Nitrogen Generator with in- built compressor	A suitable imported noise free nitrogen gas generator with in-built compressor, filters, or any other accessory required for functioning of system, should be supplied to take care gas requirements for ionization source. The generator must have a minimum 100 psi pressure with a flow rate more than required for functioning of system, should be supplied to take care gas requirements for 30L/min or higher.
System Performance Certificate	1. The requirements in this section pertain to the working requirements of the system. Any claims made in the compliance statement should be substantiated by giving suitable detailed outputs from the quoted model of the instrument generated at the applications lab of the supplier, in the form of reports for easy reference. 2. Proof of Performance documents must be provided with the Compliance sheet. 3. The reports should necessarily include the instrument output data, graphs and chromatograms using the quoted model of the instrument at the applications lab of the supplier / manufacturer. 4. The model offered by the vendor should have capability to demonstrate the above-mentioned parameter in presence of user.
Warranty	Warranty of the instrument along with Nitrogen generator must be 3 (Three) Years comprehensive warranty from the installation except consumables &

	perishable items.
Others:	1. The other auxiliary gases along with regulator should also be supplied along with the system. 2. Solvent required for successful installation must be quoted. 3. Installation must be done at user's site with no extra costs involved. A one week (at least) general entry-level training-cum-workshop and advanced-level training-cum-workshop must be arranged at the user's site by the vendor on experimental and data analysis part, with no extra cost involved. 4. Proof of Performance documents must be provided with the Compliance sheet. 5. The Vendor / OEM must submit at least 5 or more customer details / PO copies / references of the Quoted LCMS/MS model (equivalent or higher) supplied in India. The recent user details of the same Quoted model must be provided & must be present in major pharmaceutical companies of India in R&D & QC sections. The bidder must mention all the details in their bids.