Notice Inviting e-Tender

West Bengal Medical Services Corporation Limited
Swasthya Sathi
GN-29, Salt Lake, Sector-V
Kolkata-700091
Phone No (033) 40340307/320
E mail: procurement@wbmsc.gov.in

Procurement, supply and installation of different medical equipment for Rare Diseases at IPGME&R SSKM Hospital of the Government of West Bengal
(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT-496 /2025	Dated-12.06.2025

The following amendment have been made in the tender document,

Amendment –IV (Revision of Technical Specification)

The revised technical specifications for the item is given below,

High Sensitive Triple Quadrupole LCMSMS System for Neonatal Applications

Specification	Requirement
LC-MSMS (Triple Quadrupole)	A Bench Top High 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 2 μm particle size columns for high sensitivity for both qualitative and quantitative analysis
Mass Range	2 to 2000 amu or better
Scan speed	Should have the scan speed of 18,000 amu/sec or higher in Triple Quadrupole mode
Mass stability	Less than 0.1Da over a 24 hour period or better.
Interface	Dual orthogonal or off axis 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	• Combined ESI and APCI sources to be provided with auto-detection of installed source by the instrument and software. The ionization must be done both in a positive & negative mode.

Specification	Requirement
	• The combined ionization (ESI & APCI) source must operate along with reference spray to facilitate automated accurate mass measurements within single LCMS experiment. • Switching between ESI and APCI should be ≤25 millisecond or better. The MS to MS/MS switching must be present. • The source should be easily removable from the system to facilitate user cleaning without venting the vacuum, with automatic standby of system while the source / probe is being removed. • The source shall have a flow rate compatibility from 50μL/min to 2000 μL/min. without flow splitting in both ESI and APCI modes • Desolvation temperature for sources should be more than 600^{0}C or higher • All source parameters to be adjustable through software.
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 system fluidics of the instrument for direct sample introduction and must be controllable from the instrument software. No external syringe pump should not be present outside the system for direct injection.
Vacuum system	A robust high efficiency 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 2.5 femtogram or less (Proof of Statement must be provided) from ten (10) replicate injections for both positive and negative modes.
Mass Resolution	Must be automatically adjusted to desired resolution (0.50 Da, 0.75 Da or 1.00 Da FWHM) or better.
Sensitivity	• MRM ESI +ve 1pg On column reserpine should give chromatographic S/N greater than or equal to 5,50,000:1 without smoothening MRM transition 609>195 at unit resolution (Proof of Statement must be provided) • MRM ESI -ve 1pg On column chloramphenicol should give chromatographic S /N greater than or equal to 2,00,000:1 without smoothening MRM transition 321>152 at unit resolution (Proof of Statement must be provided) • 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 of 0.8 milliseconds or less without sacrificing sensitivity and eliminate Cross-talk to enable Multiple MRM Transition Studies within a single run.
MRM Acquisition rate	Should be capable of minimum 550 MRM data points / Secor higher 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

Specification	Requirement
	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 is minimum 15ms. i. Automatic and manual tuning. j. Information dependent acquisition system or equivalent scan mode of MRM to high sensitivity product ion scan for library confirmation.
Dynamic range	6 orders of magnitude or better
Detector	• Long life highly efficient electron multiplier or photomultiplier detector • Must operate both +ve and -ve ion mode and back
UHPLC	**Pump:** • Quaternary operating pump(s) with an operating pressure of minimum 15000 psi or better. Purging of pumps must be automated through the software. • The flow rate range should be 0.010 to 2.000 mL/min or better, in 0.001mLincrements. • Flow rate accuracy: ±1% or better. • Flow Rate Precision: ≤0.075% Relative Standard Deviation or better. • 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. **Degasser:** • The instrument should have an in-built Vacuum degasser facility with minimum four lines and should be efficient to remove dissolved air online. **System Delay Volume:** • Should be less than <700 microlitre, independent of system backpressure along with Gradient Delay Volume facility. The Total Bandspread should be less than 12 microlitre. **Autosampler:** • Autosampler should be available with a capacity of anprox, 90 vials or more of 1.5 ml or greater capacity & sufficient no. of spare sample vials must be provided. The autosampler should have cooling facility upto 4 degrees or better and heating upto 40 degrees or better. • Programmable injection volume from 0.1ul to 10ul or better must be available with Integral, Active & Programmable needle wash. • It must have advanced features like Auto-Dilution, Auto-Addition & Load Ahead capabilities. • The carryover of the autosampler must be less than 0.002% or better. Compressibility Compensation of the Solvents should be Automatic& Continuous. **Column Oven:** • Column Temperature Control should be from ambient to ≥80 deg. C or better with a Temperature control from ambient to maximum operating temperature. Temperature control precision should be 0.1^{0}C

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	<u>Columns & Accessories:</u> • Reversed Phase / C18: 1.7/< 2 µm, 2.1 X 100 mm, pH level of 2 -12; Qty: 2 Nos. • Normal Phase / HILIC Column: less than 2µm, 2.1 X 100 mm; Qty: 2 Nos. • Guard column and inline filter must be included. • Necessary Autosampler LCMS certified Vials 1000 No's must be Quoted. • 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	• Application software for quantitative applications having the additional requirement of Quality Control (QC) checks to satisfy statutory or regulatory requirements must be available. • This application must compatible with LC/MS and LC/MS/MS data. Data can be full scan, SIR/SIM or MRM. • Data Acquisition. Peak Integration. Calibration, Quantification and QC calculations must be fully automated. • Quantification and QC 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 • This application software must allow the monitoring of the molecular ion plus up to 4 confirmatory ions. • 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. • 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 & 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. • Software for Neonatal/Newborn Screening to be supplied. • Software must be complied with GLP/GMP & 21CFR PART 11 & documents must be submitted related to same.
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 60GB or higher • Hard disk: 10 TB or better • CPU: Dual-Processor, 3.5 GHz or better

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	• Operating system: Windows 10, 64 - bit or better. • LCD monitor. • Colour printer (LaserJet)- Qty.-1 All hardware and software including drivers, monitor, device interfaces cards/network must be preinstalled and preconfigured on the computer provided. Or factory recommended PC with compatible software and hardware must be included.
Start-up Kit along with Newborn application IVD kits	LC-MS/MS installation kit should be supplied as standard along with regent & standards for NBS for at least 2000 samples.
Instrument and Software Qualification Service & Certification:	• 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. • The vendors must quote the Qualification kits with defined list of items along with valid Cat. No. / Product ID etc. • During installation and qualification, Instrument should perform as per submitted specification in presence of user. • Standard & safety certification: Certificate/ Registration/ License of the manufacturer- CDSCO/ 4 digit European CE from the notified body/ European CE/ CE (Declaration of Conformity)/USFDA.
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
Warranty	Warranty of the instrument along with Nitrogen generator must be 2 (Two) years comprehensive warranty from the installation.
Others:	• The other auxiliary gases along with regulator should also be supplied along with the system. • Standards/reagents and solvent required for successful installation must be quoted. • 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. • Proof of Performance documents must be provided with the Compliance sheet • The Vendor must submit at least 5 or more, latest customer details / PO copies / references of the same Quoted model supplied in India. • Satisfactory performance certificate for quoted model taken from government organization along with technical bid shall be submitted. • The model offered by the vendor should have capability to demonstrate the above-mentioned parameter in presence of the user. • Prior installation of the system must be present for neonatal metabolic screening and rare diseases at any govt teaching hospital (either state or central govt). • Hands on training of at least 2 persons must be provided for the Newborn Screening in hospital settings. • Technical hand holding support to the CoE for alteast 6 months to initiate and to

Specification	Requirement
	run the application for newborn screening.
Hardware	Both MS and LC should be from same manufacturer.