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 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,

Fast & Fully Automated Analytical Next Generation HPLC System all should be fully Software controlled

The HPLC System should be a true plug & play method compatibility system for HPLC/UHPLC separation. The hardware design must have next generation features so that it can reduce the risk of common errors and improve the reliability of analytical measurements. It must reduce reagents and consumables waste and automate system checks to help & meet critical error reductions. It must increase in operational efficiency and productivity for saving time and money and boost the capacity of the lab. It must also identify potential errors earlier by reducing the number of retests and failure investigations so that the results achieved must be first time right.

1. **HPLC Quaternary Solvent Manager:**

- In built Quaternary Gradient pump for delivery and blending of up to four solvent systems or higher.
- Integrated four channel or better vacuum degasser chambers with automated piston seal wash. The Degasser must become disabled when the mobile phase flow rate is 0.0mL/min for more than 60 minutes.
- It must be capable of delivering aqueous and organic solvents at operating pressures minimum of 12,000 PSI or higher. The pump must be capable of reaching a maximum operating pressure of 12,000 PSI for at least upto 5 ml/min or higher.

- The Quaternary pump module must have a flow rate delivery as low as 0.001mL/min and as high as 10.000 ml/min or better with 0.001mL increments.
- There must be an easy to use, advanced Bi-directional touch screen with artificial intelligence features which must be integrated with the fully 21 CFR Part 11 compliant Software and must provide easy to follow steps for any users. Pre- run checks for common errors such as missing vials, incorrect column and preventative maintenance requirements must be present to catch these mistakes before the result in a sample analysis failure or preventing re-runs.
- The system must reduce common mistakes during analysis to more than 40% & must provide error free results in every first-time analysis by any first-time users with its technology. The vendor must provide declaration & give white paper in support of their technology.
- Delay Volume: The separation of compound must be done with Fast Resolution and with minimum gradient delay volume $<$ 1100 ul for the system to get sharper and better chromatograms with higher peak heights.
- There must be a provision of the instrument status lighting which must provide with a clear visual indication of the system status as in use, in idle condition or in state of error etc & there must be color-coded solvent tubing clips which must ensure the tubing remains organized to enable tracing from instrument to the solvent bottle flags.
- The pump must be able to program both isocratic and gradient methods, able to 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.
- The instrument must be able to create instrument method directly from different HPLC systems of same or different manufacturers of basic chromatographic conditions and must be automatically transferred into the system & must be reported providing traceability to the original method for compliance.
- Flow rate accuracy of $\pm$1% or better, Flow Precision of $<$0.01 % RSD or better & compositional precision of 0.04% RSD or better having pH range between 1 to 13 or better.
- Compressibility compensation must be Automatic and continuous for the solvents & requiring no user intervention.
- For Method development & Gradient profiling there must be a provision of 10 or more gradient curves including Linear, Step, Concave and Convex etc.
- The system must support fully integrated diagnostics with data preserved. The instrument must provide system guided start-up, pre-run checks to minimize sample analysis failures due to human error, Tool Free Fittings, Bi- directional touch screen interface, Intelligent method transfer & the system must provided with information about what needs attention & there must be guided workflows provided step-by-step guidance on how to resolve the common issues.

2. HPLC Sample Manager or Auto sampler:

- The system must be integrated with Auto sampler or Sample Manager having Flow through needle technology.
- The system must have QR code reader allowing for vial trays and consumables which must tell the system of what proper tray and /or plate is being used having its proper format.
- For Auto sampler or Sample Manager Injection volume range must be 0.1 to 100.0μl.
- Injection needle wash: Must be Integral, active and programmable along with Temperature control from 4^0C to 40^0 C.

- The injector precision must be equal to or less than 0.25% RSD or lesser.
- The injector linearity shall be equal to or better than 0.999 correlation coefficient over its entire injection range.
- Sample carryover must be as low as: ≤0.002% or lesser.
- The sample compartment temperature must be settable from 4^0C to 40^0C.
- The injector must have the ability to automatically dilute samples, to automatically withdraw from several sample vials and dispense into a single vial.
- The sample compartment must be able to accommodate both HPLC Vials and / or well plates having minimum 170 (2 ml) vials or 1000 well plates or better.

3. HPLC Thermal Column Management

- The column compartment must be able to support columns up to 300 mm in length & as wide as 4.6 mm ID or better.
- The column compartment temperature must have heating & cooling facility from 4 Degree C upto 90 Degrees C or better with Peltier control.
- The column compartment must have temperature accuracy of +/- 0.5 Degree C.
- 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.
- There must be complete column traceability and facilitate for post-run troubleshooting with HPLC Columns, Ready- to-use from the box, the columns must be secured with RFID or near field communications technology enabled device tag ensuring that they are always automatically identified, verified, and tracked by the system. The Column manager & Columns must be integrated with the Gradient methods & the Softwares so that if any wrong columns are attached, the system must quickly identify the same & gives warning messages or should alert the user immediately.

4. UV/Visible Detector:

- The UV/Visible Detector must be integrated with the entire instrument for making it fully compact design & having less footprint. There must be provision of adding any additional detector in the future also. The design must be shared in the bid.
- The UV/Visible wavelength range must be from 190-700 nm or better.
- The optical bandwidth must be < 5nm or lesser.
- The wavelength accuracy must be ±1.0nm or better & repeatability ±0.1 nm or better.
- The detector must have linearity and dynamic range of ≥0.999 from 0.0001 to 2 AU, ≤5% deviation up to 2.5 AU or better.
- The Detector must have a sampling rate of 1,2,5,10,40,80,160 Hz.
- The UV/Visible Detector must contain a Deuterium lamp as its light source with minimum warranty 2000 hours per lamp.
- The Flow Cell must come with Taper / Tapered Slit design or better to avoid Total Internal Reflection.

5. Original (OEM) HPLC Manufacturer's Licensed Software

- Chromatography software should come integrated with secured & relational database Oracle 19.0 or higher. Oracle database for easy tracking and trending, Instrument Method, Processing Method, Report Method, etc. should be present. The instrument manufacturer must be the manufacturer of the software also. 3rd party software must be avoided.
- It must come with minimum Five (5) named users license along with base license having separate username & passwords along with System Suitability option.
- Custom field / Custom calculations, Pre-made templates, customizable data reports, online help and answer Wizards should be included to help maximize the lab's productivity.
- Each injection is time and date stamped for easy archiving, retrieval of data along with Drag and Drop, look and feel of Windows must be present. Report publisher facility for customized reports. Custom reporting with view filters for easy retrieval.
- Software should offer multiple levels of password, security to ensure the integrity of all your raw data and results and extensive audit trail.
- Security of data, custom reporting with view filters for easy retrieval.
- The software should be able to show the capability of the system to operate in at least 10 or more various gradient curve mode including Linear, Step, concave, convex. exponential etc.
- It must be compliant ready with GLP/GMP & 21 CFR PART **11** & documents must be submitted related to same.
- Control, Data Processing & Single point control of HPLC, Detector and Mass spectrometer in the future must happen with the quoted Software.
- The System must capture; a) Column history and tracking with columns; b) Column matches the method; c) Records maximum temperature and pressure; d) Injection count; e) date of first and last injection; f) System audit trail; d) hardware and software modifications.
- Oracle database should come inbuilt with the software to manage the data properly.
- Software should have automatic built-in diagnostic facilities, programmability to run experiments and data processing including routine qualitative & quantitative analysis. It should be upgradable for automated method development Software.

6. INSTRUMENT & SOFTWARE QUALIFICATION SERVICE (IQ/OQ/PQ) & CERTIFICATION:

The instrument must be Qualified (IQ/OQ/PQ must be performed) along with the Software and European CE (4 Digit notified body) /BIS/CDSCO Certification from the competent authority. Necessary reagents along with Documents must 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. / Cas No / Product ID etc.

- Vendors must declare the availability of the spares for 10 years from the obsolescence date of the model from the Market. The Quoted model must be very latest & should not be more than 2-3 years old introduced / launched in the market. The Bidder / OEM must declare & must be authentic documents related to the same.

7. COLUMN:

The Instrument must come with C18 column having End-Capped for high efficiency and chemical stability with a wider usable pH range [pH 1-12] having dimensions of 4.6 x 250mm, 5um & must be RFID tagged for getting all digital information.

8. **Warranty**: 3-years comprehensive Warranty must come with the instrument except consumables.

A thorough Demonstration, Commissioning & Detailed training on Instrument & Application must be provided by the vendors on site.