Revised Specification of UHPLC system for analysis of Pharmaceuticals, Chemical and biological products:

Qty: 2 (1 for NIPER-Hajipur & 1 for NIPER-Kolkata)

Description	Tender Specification
A. Pump	• The pump must mix from 4 solvent channels or higher • Flow rate range must be 0.001 - 2 mL/min or better • Operating pressures must be 15,000 psi or better • Flow rate accuracy must be ±0.1% or better. • Flow rate precision must be < 0.075% RSD or better. • The complete eluent flow path must be iron-free for the analysis of biomolecules atdemanding eluent conditions (pH 2-12, max. 1 mol/L chloride concentration, no buffer additive limitation). The system's biocompatible flow path must ensure robust and rugged operations in the most challenging biopharmaceutical applications such as ion exchange (IEX), size exclusion (SEC), hydrophilic interaction (HILIC), and reversed phase. • The pump must support automatic adjustment of the solvent compressibility over thecourse of a gradient, without manually setting software parameters. • The pump must have an adjustable purge function and automatic purging available throughan autosampler. • The pump must synchronize the injection with the auto sampler for best retention time precision. • Solvent blending must be Automated, on-line pH, ionic strength and organic modifier blending from pure solvents with automatic blending facility should be present. • Other specifications: • The operating principle of the pump must be serial dual piston. • Automatic compressibility compensation for any solvent or solvent mixture to providepulsation–free flow. • The pump must offer easy to operate fitting systems for tool-free maintenance of externallyaccessible tubing. • Pump pulsation must be < 1.0% or better • The default gradient delay volume must be 400uL or lesser. • The gradient/Composition accuracy must be better than ±0.5% or better • The gradient/Composition precision must be < 0.15% SD or better • The pump must provide 4 internal vacuum degassing channels. • The entire system should be suitable for Reverse Phase and Normal Phase Operation.
B. Automated Injector/Sampler	• The Auto sampler should operate at pressures in the range 15,000 psi or better & must be having Temperature operating from 4 – 40 degree C. • The linearity of the auto sampler must be r >0.99999 (caffeine in water).or better • The complete eluent flow path must be iron-free for the analysis of biomolecules at demanding eluent conditions (pH 2-12, max. 1 mol/L chloride concentration, no buffer additive limitation). Other specifications:

	• The injection principle of the auto sampler must be in-line split-loop (also called flow through needle) for high reproducibility injections with no sample loss. • The auto sampler must support system wellness counters for monitoring operating hours, total injections, needle counter, metering device, needle seat, injection valve. • The auto sampler must offer safety features, including leak sensor, automatic sample rack recognition, empty segment detection, and internal monitoring of all mechanical operations. • The auto sampler must allow customization of velocities for drawing and dispensing of sample to compensate for sample viscosity. • The auto sampler must support a sample capacity of four sample racks with any combination of the following types: 48×2 of1.5ml/2ml Vials or better. Injection needle wash must be Integral, active, programmable. • Advanced Autosampler features must include capabilities having Auto-dilution, auto-addition, and load-ahead. • The injection range of the auto sampler is 0.1–10 µL or higher. • The injection volume precision of the auto sampler < 0.25% RSD or better (caffeine in water), typically < 0.5% area RSD for 0.5 µL (caffeine in water). • The carryover of the auto sampler must be < 0.002% with caffeine or better. • The auto sampler must support injection cycle times down to 30 sec or lower.
C. PDA Detector:	• Source: D2 lamp or any better source • Wavelength range of: 190-800 nm or higher. • Flow Cell :10mm low dispersion flow cell having volume of 500 nano liter or less; high sensitivity 60mm flow cell with minimum reflection of lights and lowest possible dispersion. • Lamp temperature control facility should be available for better sensitivity & accuracy with Lamp Optimization and Life time monitoring facility. • Optical Bandwidth: 1.2 nm or better. • Number of Diodes : 512 or higher for better spectral resolution. • Data Acquisition : 80 Hz or better • Should be upgradable for pH and conductivity monitoring for Ion Exchange separation. • The detector should be capable to simultaneously acquire up to 10 channels of single-wavelength data along with 3D data. • The detector must be designed with a temperature-controlled optical bench. • Lamps and flow cells must be easily exchangeable from the front of the detector without the need for tools. • Identification chips monitor changes to flow cell and lamps automatically. Key life-spanparameters are automatically logged. The Lamp must be having minimum 2000 hrs of warranty. • The Detector must have a means to optimize lamp performance automatically and without user intervention. It must compensate for lamp degradation over time without the need to frequently replace the lamp. • Software tools must allow immediate on-line review of 3D data and software-supporteddiagnostic functions.

D. Column oven:	• Column compartment temperature range: 4–90 ˚C in 0.1 ˚C Increments or better. • Column number: minimum 2 number or higher for automated method scouting. • Column oven heating method: Forced air circulation for uniform heating. • Temperature Accuracy ±0.5 DEG C or better • Column Capacity : Two independent heat/cool zones per module. • 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. • Should support complete biocompatibility. Switching valves must come with Two nine-port, eight-position valves; must provide programmable, automatic, random access switching, waste and bypass positions for rapid solvent changeover.
E. Software and data collection:	• Graphical and user-friendly design of the software • Software capable of efficiently managing auto sampler, pump, detector and fraction collector • strictly validated/original licensed copy of the software • Free up gradation of software during the period of 5 years • Should be provided with desktop of suitable configuration and laser printer • Software should have integrated relational data base • Software should have gradient optimization feature with programming at least 1-11 different Gradient curves like (Linear, Convex, Concave etc.). Software should have Oracle or similar secured relational database integrated with the system. • Security features of software must comply fully with FDA 21 CFR Part 11. • System suitability, System security as well as System check functions must be provided which comply with Good Laboratory Practice (GLP) and Regulatory Conformity.
F. Accessories:	**Analytical Column:** • C18 UHPLC column (2.1 X 150 mm, 1.7µm) (1 nos) • C18 UHPLC column (2.1 X 100 mm, 1.7µm) (1 nos) • C8 UHPLC column (2.1 X 150 mm, 1.7µm) (1 nos) • C8 UHPLC column (2.1 X 100 mm, 1.7µm) (1 nos) • Phenyl UHPLC column (2.1X150 mm, 1.7µm) (1 nos) • Phenyl UHPLC column (2.1 X 100 mm, 1.7µm) (1 nos) • HILIC UHPLC column (2.1 X 150 mm, 1.7µm) (1 nos) • HILIC UHPLC column (2.1 X 100 mm, 1.7µm) (1 nos) • Appropriate guard columns for each type of columns should be provided Solid phase extraction C18 cartridges (2000 no) and Vacuum manifold (01) with vacuum pump (01) for solid phase extraction dedicatedly should be quoted along

	with the system (minimum 12 port) Syringe filters 0.22 micron 2000 should be quoted. PTFE for non-sterile (500 no) and 500 no. PVDF for non-sterile Sample and solvent filtration assembly kit with vacuum pump should be quoted along with the system.Filter papers for mobile phase filtration should be quoted as per filtration assembly (20 packets/total 2000 no. filter papers) Solvent bottles (10 no.=500 ml, 10 no.= 1L, 10 no.=250mL and 10no.=100mL) Sonicator/Ultrasonic Bath (3 L) should be quoted along with the system. Additional D2 Lamp (1 Nos) should be provided 5000 vials for Auto-sampler should be provided
G. Accessories : Suitable PC &Printer :	• **PC Suitable Desktop Configuration:** • Processor: Intel Core i7 • Memory 16GB DDR3RAM • Hard Disk Drive 1TB SATA HDD • Optical drive DVD read/Write • Ports- I/O (6) USB, 2.0 Ports, (1) serial port (1) PS/2 (1) RJ-45 (1) VGA (1) DVI-D (1) Line in (1) Line out (1) MIC ;SLOTS (2) full height PCI Slots (1) full height PCI-e× 1 Slot • full height PCI-e× 16 Slot Serial Port Card. • HD Graphics on Board ; Sound On Board. • HP 24" TFT Colour Monitor. • LAN : 1×10/100/1000 ; RS 232 Port ; KBD & Mouse HP • OS Original Win 10 Professional (License version) 64 Bit. • Microsoft Office Original (License version) 64 Bit. • Colour Laser Jet Printer with Scanner. • Suitable nitrogen generator with compressor for nebulizer based detector • All the imported components of HPLC should be available from a single Vendor. Warranty: Five year comprehensive warranty. • UPS capacity 2KVa (or higher) with 60 minutes Backup. • Branded Reputed Quality Battery Warranty Three years. • Spare parts for the regular maintenance including required tools, injection syringe, fittings, tubings etc.
H. Note :	• All the Tender Specification should be supported with online technical literatures. • The offered company should have minimum five installation with reputed institutes/Universities. • Performance certificate to be provided minimum three from Eastern India reputed organization. • All the required HPLC Components should be available from the same manufacturer. • System should be easily hyphenated with any existing Mass Spectrometer for Mass directed purification process. • Training: Vendor should provide comprehensive training for one week at the time of installation on operation and application of the equipment at NIPER Kolkata and NIPER Hajipur. • It is important for the vendors that they must supply appropriate

	documents specifying their users in higher academic institutions and industries in India. Appropriate certificates from the users for the last three years for the model quoted or similar model must be supplied justifying the stability, ease of operation and maintenance requirement such that we have the option to choose the best system in terms of performance and not mere specifications alone.

OPTIONAL Accessories :	**OPTIONAL DETECTORS:**
1. Multi channel Electrochemical detector :	• The detector should be a multichannel based ECD capable of analysis of sugars/carbohydrates by gradient. Analysis of amino acid without any form of derivatization. • Multi-array minimum four channel or higher electrochemical detection should produce qualitative and quantitative information for compound identification, • Should have unparalleled selectivity to femtomole levels • Operating Modes: Fix potential DC, Amperometry, Caulometry etc. • Potential Control: Up to four independently controlled channels • Integrated Column compartment: 30□-40 □or better. • Data Acquisition: Min 150Hz or higher. • Signal Range: 10pA to 100μA or better. • Potential Control Up to 8 channels • Suitable reference and working electrodes to be offered for neurotransmitters (dopamine, serotonin, Amino Acids and complex sugars analysis. • The detector should perform different modes DC, PAD and Caulometry etc. • The detector should be able to recognize any type or form of electrodes automatically. • Should support Plug-and-play electrochemical cells – eliminate noise and lengthy cable connections • Should provides automatic instrument configuration with optimized control of an attached electrochemical sensor • Should allow sensitive detection of amino acid
2. Universal nebulizer based Detector:	• The detector should be able to detect and deliver consistent response irrespective of the nature of the analytes suitable for both qualitative and quantitative analysis. • Should have Concentric nebulizer with Front mounted, snap-in design for minimum dispersion with high sensitivity. • It should be capable of analyzing non-volatiles, non-chromophores and semi-volatiles without derivatization. • The response of the detector should be sensitive towards analytes concentrations. • Optics must be Heated optics bench (constant 50 ˚C) • Light source should be Tungsten halogen polychromatic, front mounted, pre-

	aligned, user installable. • Lamp calibration: PMT calibration/normalization to compensate for lamp degradation over time. • Lamp normalization: On demand and at startup diagnostic corrects for lamp signal output decrease. • Detector must be Photomultiplier tube & with high Sensitivity. • Suitable flow design to assist better evaporation especially for the semi-volatiles. • Digital Data Collection Rate (max.): 80 Hz or better
Amino Acid analysis Kit:	**Amino acid derivatization accessories:** • AA UV-Vis based pre derivatization Kit, with required buffers, standards should be offered **Protein Hydrolyisis Accessories:** • Suitable Protein vacuum hydrolysis tube, Temperature regulated Protein hydrolysis heating bath to be offered. • Amino Acid standards, Solvents, Acids and Reagents to be offered. **Sample Preparation Accessories:** • Sample & Solvent filtration kit • SPE Cartridges with 16 port vacuum manifold with pump.
Manual Injector	Suitable analytical Injector with 20ul,100ul, 200ul Sample Loops and suitable HPLC Blunt End. syringes to be offered.50 uL –two,100uL -two, 200uL – Two.