

Item Description: HPLC systems with suitable Detector System

Reference No: NIPER- G/178/EQP/HPLC/2020-21 dated:04.03.2021

With reference to the tender enquiry No: NIPER- G/178/EQP/HPLC/2020-21 dated:04.03.2021 NIPER-G has been invited open tender enquiry for the procurement of HPLC with Detectors. The following point has been discussed during the pre-bid meeting held on 09.03.2021 and the necessary amendment has been made in the tender document. Bidders are here by requested to quote the bids accordingly.

Total Requirement HPLC and Detectors of all NIPERs

Institute	HPLC	PDA	FLD	ELSD	RI
NIPER Guwahati	1	1	1	-	1
NIPER Hyderabad	1	1	-	1	-
NIPER Kolkata	2	2	1	1	1
NIPER Hajipur	3	3	1	1	1
Total No. units	7	7	3	3	3

HPLC systems with suitable Detector system

HPLC WITH PDA, RI AND FLD		Amended specifications
Solvent Management System:	<ul style="list-style-type: none"> Quaternary Pump The system should have pump which has two independent pistons with independent motors and pressure transducers, which must help in reducing the baseline ripples and provides the smooth base line in detecting and quantifying the smallest peaks. 	<ul style="list-style-type: none"> No change No change
	<ul style="list-style-type: none"> Continuous and Automatic compressibility compensation provided in the pumping mechanism helps in greater accuracy of flow rate when working with gradient analysis and help in reproducibility of retention time in results. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Integrated Vacuum Degasser: Integrated high efficiency vacuum degassing (with 500 μL to 2.0 mL internal volume per chamber) of minimum 4 channels must be provided. 	<ul style="list-style-type: none"> Less than or equal to 500 μL-700 μL internal volume per chamber
	<ul style="list-style-type: none"> Flow rate from 0.01 ml/min to 10 ml / min or higher. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Flow precision of < 0.075% RSD or better. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Dry prime and wet prime should be Automatic and controlled from front panel 	<ul style="list-style-type: none"> Purging (Dry prime and wet prime, equivalent or better) should be Automatic and controlled from front

		panel
	<ul style="list-style-type: none"> Effective delay volume of < 650 μl strictly, independent of system backpressure or better. 	<ul style="list-style-type: none"> Effective delay volume of less than or equal 650 μl strictly, independent of system backpressure or better.
	<ul style="list-style-type: none"> Facility for Automated Solvent Blending/mixing, online pH, ionic strength & organic modifier blending from solvents must be present to attain a perfect pH without human intervention. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> 5000 psi or higher operating pressure for both Solvent and Sample Management functions 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Ten (10 or more) different programmable gradient profiles including linear, step, concave and convex. 	<ul style="list-style-type: none"> Omitted
	<ul style="list-style-type: none"> Integrated active, programmable and continuous plunger seal-wash 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Tool-free, simple access to plungers, plunger seals, plunger wash seals. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Column oven: Should be present integrated there with the system at a Temperature range ambient (25⁰C) to 60⁰ C or better with accuracy of $\pm 2^{\circ}$C 	<ul style="list-style-type: none"> No change
In-Built / Integrated Auto Sampler:	<ul style="list-style-type: none"> The flow through needle design with active and continuous needle wash help in reducing the carry over effect of the previous sample. 	<ul style="list-style-type: none"> Modular autosampler
	<ul style="list-style-type: none"> Number of sample vials/wells: More than 110 no. with five trays 	<ul style="list-style-type: none"> Number of sample vials/wells: More than 100 no. or above with minimum number of trays
	<ul style="list-style-type: none"> Volume of sample: Up to 2ml 	<ul style="list-style-type: none"> Volume of sample: 1.5 to 2mL No change
	<ul style="list-style-type: none"> Sample carryover must be $\leq 0.0025\%$ or better. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Sample delivery precision: 0.3% RSD 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Injection Needle wash: Integral, active and programmable. 	<ul style="list-style-type: none"> The Autosampler must be fully integrated/Modular/ integral part of the entire system.
	<ul style="list-style-type: none"> The Autosampler must be fully integrated / integral part of the entire system. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Sample temperature: 4^oC to 40^oC or better 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Injection volume: 0.1 to 100 μl 	<ul style="list-style-type: none"> No change
Photo Diode Array Detector:	<ul style="list-style-type: none"> Wavelength range: 190-800 nm or better. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Wavelength repeatability: ± 0.1 nm or better. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Wavelength Accuracy: ± 1 nm or better. 	<ul style="list-style-type: none"> No change

	<ul style="list-style-type: none"> Data Acquisition: Up to 80 points / sec or higher. Light Source: Preferably dual lamp <i>i.e.</i> Deuterium lamp and tungsten lamps covering entire range; Lamp should be of 2000 hrs warranty without drop in the energy level with appropriate backup from software and hardware. It should be associated with Lamp optimization software to ensure consistent high sensitivity applications & reproducibility. Flow cell Design: Suitable flow cell design for avoiding total internal reflection with a Cell Volume must be less than 10 μl. 	<ul style="list-style-type: none"> No change No change Flow cell Design: Suitable flow cell 1 design for avoiding total internal reflection with a Cell Volume in the range of 8-13 μl.
	<ul style="list-style-type: none"> Spectral Resolution/Optical Band pass: 1.2nm per photodiode with a total of 1024 photodiodes, digital and optical (3D mode) 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Operating mode: Both 2D and 3D 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Linearity Range: $\leq 5\%$ at 2.0 AU 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Noise: $\leq 10 \times 10^{-6}$ AU 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Drift : $\leq 1 \times 10^{-3}$ AU/hour 	<ul style="list-style-type: none"> No change
Fluorescence Detector	<ul style="list-style-type: none"> Wavelength Range: 200 to 880 nm or better 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Emission Wavelength Range: 210 to 900 nm 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Bandwidth: 20 nm 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Wavelength Accuracy: in the range of ± 3nm 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Wavelength Repeatability: ± 0.25 nm 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Sensitivity: S/N, Raman peak of Water ≥ 1000 	<ul style="list-style-type: none"> Omitted
	<ul style="list-style-type: none"> Measurement Range: 0.001 to 100,000.000 emission units. 	<ul style="list-style-type: none"> Omitted
	<ul style="list-style-type: none"> Data Channels: Up to Four 2D channels or One 3D channels. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Sampling Rate: Upto 20 points / s. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Light Source: Xenon Lamp, should have 2000 hrs warranty. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Flow cell design: Axially Illuminated. 	<ul style="list-style-type: none"> Omitted
<ul style="list-style-type: none"> Flow Cell Volume: up to 13 μl 	<ul style="list-style-type: none"> No change 	
Refractive Index Detector	<ul style="list-style-type: none"> RI Units: 1.00 to 1.75 with measuring range of 5×10^{-3} to 7.0×10^{-9} RIU. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Flow cell should be temperature controlled or with heat exchangers to have minimum noise of 2.5×10^{-9} RIU with 2s time constant. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Cell should have minimum volume of 8-10microliter or less to be compatible with flow rates upto 10ml/min. 	<ul style="list-style-type: none"> Cell should have minimum volume of 8-10microliter or less to be compatible with flow rates upto 5ml/min.

	<ul style="list-style-type: none"> Flow Cell: Fused Quartz. 	<ul style="list-style-type: none"> Omitted
	<ul style="list-style-type: none"> Flow cell volume: 10 µl. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Light source: LED or equivalent 	<ul style="list-style-type: none"> No change
Evaporative Light Scattering Detector (ELSD)	<ul style="list-style-type: none"> ELSD shall be from the same vendor 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> High-sensitivity ELSD with operation up to 120°C 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Detector: Photomultiplier Tube Digital Signal Processing 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Temperature range: Evaporator 25-120 °C (in 1°C increments) 	<ul style="list-style-type: none"> Omitted
	<ul style="list-style-type: none"> Temperature range: Nebulizer: 25-90 °C (in 1°C increments) 	<ul style="list-style-type: none"> Omitted
	<ul style="list-style-type: none"> Eluent Flow Rate: 0.2-5 mL/min 	<ul style="list-style-type: none"> Eluent Flow Rate: 0.2-2.0 mL/min
	<ul style="list-style-type: none"> Digital output: 80Hz 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Should have safety features such as gas shutoff valve and vapor and leak detection 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Gas used should be Nitrogen or other inert gas, to be supplied with the gas cylinder and regulator 	<ul style="list-style-type: none"> No change
Instrument along with Detectors and Software Qualification Service & Certification	<ul style="list-style-type: none"> System Qualification (as per GLP Compliance) along with all detectors and Software (IQ/OQ) must be quoted. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Vendors must quote the Qualification kits with defined list of items along with valid Cat. No./Product ID etc. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> During installation and qualification, Instrument should perform as per submitted specification in presence of user. 	<ul style="list-style-type: none"> No change
Columns & Accessories: (Supplied with each unit of HPLC separately)	<ul style="list-style-type: none"> Suitable analytical C18 column (preferably workable in the pH range of 1-12 with end capping) (2 No.), Chiral column preferably (ODH or ADH) (01), phenyl hexyl column (01), amino column, Luna amide column (01), Cyano column (1) & Normal phase column (1 No.) should be quoted with the system with the dimension of 4.6×250 mm, with 5µm particle size 	<ul style="list-style-type: none"> Suitable analytical C18 column (preferably workable in the pH range of 1-12 with end capping) (2 No.), Chiral column preferably (ODH or ADH) (01), phenyl hexyl column (01), amino column, amide column (01), Cyano column (1) & Normal phase column (1 No.) should be quoted with the system with the dimension of 4.6×250 mm, with 5µm particle size
	<ul style="list-style-type: none"> 2ml Vial with Cap and Pre-slit PTFE/Silicone Septa – 1000 nos 	<ul style="list-style-type: none"> 1.5 -2ml Vial with Cap and Pre-slit PTFE/Silicone Septa – 1000 nos
	<ul style="list-style-type: none"> Total recovery Vial with Cap and Pre-slit PTFE/Silicone Septa – 200 nos 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> 150µl Glass insert with bottom spring– 2000 nos 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Nylon Syringe Filter for sample (0.2µm particle size) – 2000 nos 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> PVDF Syringe Filter for sample (0.2µm particle size) – 2000 nos 	<ul style="list-style-type: none"> No change

	<ul style="list-style-type: none"> Membrane Filters (nylon) for solvent (0.45 µm pore size and 47mm diameter) - 1000 nos. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Membrane Filters (PVDF) for solvent (0.45 µm pore size and 47 mm diameter) - 500 nos. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Solvent reservoir bottles of 250 mL – 10Nos, 500mL – 10Nos and 1000mL-10Nos 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Universal Ferules – 20 Nos 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Inlet filters – 10 Nos 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> 1 Spare lamp for each detector 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Suitable Peek Tube Cutter – 1 no. Suitable Stainless-Steel Tubing Cutter with Blades – 1 no. 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Suitable Solvent Inlet Filter – 10nos 	<ul style="list-style-type: none"> No change
	<ul style="list-style-type: none"> Suitable Stainless-steel Union – 1 no. 	<ul style="list-style-type: none"> No change
HPLC waste reservoir	<ul style="list-style-type: none"> 4 numbers: Capacity up to 8-10 liters, compatible for storage of polar and non-polar solvents. Should be supplied with 50 meters connecting tube 	<ul style="list-style-type: none"> No change
Server based Chromatography Network Software		
Original Server based Network Chromatography Data Software (Should quote in optional item)	<ul style="list-style-type: none"> Network based Chromatography Data Software must contain a structurally validated and ORACLE or suitable/equivalent relational database management system which should allow searching and filtering of information using multiple search parameters. Network based Chromatography data software can connect 10 nos Chromatography systems. Oracle database or suitable/equivalent must be present for easy tracking and trending, Instrument Method, Processing Method, Report Method, etc. The software must come with System Suitability facility for checking Detector noise and drift, USP Resolution, Signal to Noise ratio, USP Peak Tailing, Plate count etc. Vendor should quote 2 nos LC control Licenses (with catalogue no.) to connect above HPLC systems & 5 numbers of user's licenses for the creation of separate user names& passwords. Software should have extensive custom calculation capabilities, eliminating the need for external applications to meet the laboratory needs. For example, these might include calculations for multi-component assay, impurities and system suitability. software must be able to store each analytical method including instrument set 	<ul style="list-style-type: none"> No change

	<p>points, data acquisition, data evaluation and reporting parameters as one analytical specification.</p> <ul style="list-style-type: none"> • Apex peak integration algorithm should be available. • Software must allow the system to run unattended, and it must be capable of monitoring the instrument during acquisition and recording both instrument performance parameters: temperature, pressure and including ambient temperature and any unusual or unexpected events that would affect the integrity or quality of the results. A log to record each functional step the software executes. A log to record when and who modified the methods. The software must allow programmed shutdown of the instrument, including the lamps in the detector. • Pre-made templates, customizable data reports, online help and answer Wizards must be included to help maximize your lab's productivity. • Each injection is time and date stamped for easy archiving, retrieval of data. • Report publisher facility for customized reports. • Software should offer multiple levels of password, security to ensure the integrity of all your raw data and results. • The Software must be associated with Audit Trail. • It must be complied with GLP/GMP & 21 CFR PART 11 & documents must be submitted related to same along with Audit trial and content management. 	
QbD software (Should quote as optional item)	<ul style="list-style-type: none"> • QbD software (perpetual license) must be provided which can be integrated with the supplied HPLC. The supplied software must meet all regulatory requirements of ICH 	<ul style="list-style-type: none"> • QbD software (perpetual license)/smart method scouting or equivalent software must be provided which can be integrated with the supplied HPLC. The supplied software must meet all regulatory requirements of ICH
Server for Network Chromatography Data Software	<ul style="list-style-type: none"> • Intel® Xeon® E5 series Single Quad Core 2.1 GHz or more • 16 GB RAM • Dual RAID Controller Card • HDD – 300 GB SAS 15K - 6 nos. • DVD ROM Drive • LAN card 1GBPS - 2 no's (Including on board) • Windows 2016 Server Standard edition (64bit OS) • SVGA Monitor (27 inch), keyboard and Mouse • DLT Tape backup systems and DLT Tapes 	<ul style="list-style-type: none"> • No change



राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान गुवाहाटी

NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH GUWAHATI

(Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Govt. of India)

	for Backups.	
Computer (7 nos) for connecting HPLC Systems with inbuilt wifi	<ul style="list-style-type: none">• Intel i7 processor (latest generation) 2.4 Ghz or More• 12 GB RAM• 300 GB Hard Disk• DVD ROM Drive• LAN card 1GBPS - 2 no's (Including on board)• Windows 10 Professional (64 bit – OS)• 27 inch Monitor, keyboard and Mouse.	<ul style="list-style-type: none">• No change
Printer (7Nos)	<ul style="list-style-type: none">• Laser Jet Printer (3 in one)	<ul style="list-style-type: none">• No change

Note:

There is no change in general terms and conditions mentioned earlier.

System should have 3 years comprehensive warranty.

Vendor should also quote for 2 years AMC once warranty period is completed as optional.

Optional items or accessories mentioned above should be supplied with each HPLC unit.

Sd/-

Stores and Purchase Officer

Sd/-

Registrar Incharge