INDIAN INSTITUTE OF TECHNOLOGY BOMBAY

MATERIALS MANAGEMENT DIVISION

PR No. 1000053979 **RFx No.6100002793**

High Performance Chromatography including Thin Layer/HPLC/UHPLC/FPLC/HbHPLC/HPLC (coupled with Mass Spectrometry)

Sr. No	Technical Specifications	Technical Compliance (Yes / No)	Additional Information (if any)
1	**A. Purpose** I. The fast protein liquid chromatography (FPLC) is intended for fast purification of proteins, peptides, nucleic acids and viral vectors from microgram levels to tens of grams of target product. It is designed to work with various columns and chromatography resins to meet purification challenges.		
2	I. Inert biocompatible system for all purification and development work from microgram to gram scale. The system should be capable of performing all the chromatography techniques: Size exclusion, Affinity, Ion exchange, Hydrophobic interaction, and Reverse phase. II. Two pump system with 4 pump heads of Hydrophobic material can be used with high salt concentration buffers of up to 8 M urea and 6 M guanidinium hydrochloride. III. Should have manual provision to individually purge each of the four pump heads. IV. There should not be any siphoning effect due to gravity before the gradient formation. V. At least 4 buffer inlets for equilibration buffer, sample loading, wash buffer and elution buffer. VI. System should come along with a 2 mm flow cell (or the software should have the provision of normalizing the absorbance of 5 MM flow cell). VII. The system should deliver flow rate of 0.01 mL/min to 150 mL/min or more without need for changing pump-heads for the entire flow range and pressure limit of minimum 5 MPa.		

	VIII.	The system must have Conductivity Monitor of range 0.01 mS/cm to 999.99 mS/cm with an accuracy of ± 0.01 mS/cm. with built in temperature sensor to correct variation due to temperature. Conductivity monitor should be integrated with automated temperature and flow compensation system.		
	IX.	System should have piston pumps for high performance and long life and should have an accuracy of ± 1.2%.		
	X.	System should be capable of delivering flow rate up to 300 mL/min during column packing.		
	XI.	System should have the capability of running with automatic pressure -flow modulation option. System should have the capability of running with automatic option enabling to modulate the flow rate upon reaching the set pressure and continue the run without pausing the system without dropping the flow rate. (tolerance ~ 20 % of applied flow rate).		
	XII.	The system must have an in-line mixer equipped with magnetic stirrer to ensure accurate mixing of buffers. A mixer volume between 1.4 mL to 1.5 mL is mandatory.		
	XIII.	The UV flow cell must have a cell volume of not more than 2 µL for maximum sensitivity).		
	XIV.	The UV lamp should not require any start-up time or warmup time and should not heat the sample/protein. No warmup time must be there for the system detector to avoid sample degradation. Automatic switching off the lamp in stand-by mode. Capable of producing high signal to noise ratio.		
	XV.	The system must have two fixed wavelengths (280 nm and 260 nm) UV monitor.		
	XVI.	The UV lamp must have an operating life of more than 4000 hours.		
	XVII.	The UV module of the system must be able to read absorbance range from -6000 to +6000 mAU. , crucial for sharp peaks for samples in the negative spectra of the absorbance.		
	XVIII.	The system should have the option for monitoring pH through electrodes and there should be an option to bypass the pH monitor without re-plumbing.		
	XIX.	A flow restrictor should be present in the flow path to generate a back pressure that prevents the formation of air bubbles in the UV flow cell.		
	XX.	The system should be supplied with a round fraction collector having following properties:		

		- Minimize spillage using Drop Sync technique. - Allows collection of up to 175 fractions. - Allows use of 3, 8, 15 and 50 mL tubes. - Fraction volume 0.1 to 50 mL. - Automatic peak recognition using control software. - Fraction collector should be capable of being used in time, volume or peak recognition mode. - Allows using flammable liquids/solvents.		
	XXI.	The system should have the option to be integrated with third party Detectors like Fluorescence detectors, RI and Auto samplers simultaneously for increased application flexibility at the time of purchase or post-purchase.		
	XXII.	The system should have upgradable modular capability of having 2 UV monitors installed at the same time for giving flexibility and increased application capability for using small and large flow cells simultaneously to detect low concentration and high concentration proteins for increased application flexibility post-purchase.		
	XXIII.	All the accessories including PEEK Tubing, ferules and unions/connectors required to run the above should be supplied.		
	XXIV.	The system should have supplied with column control valve which allows connection of one column and has an integrated bypass function, which enables washing of the system without removing the column and allows reverse flow for increased application flexibility.		
	XXV.	The system must be supplied with one outlet valve having 3 outlet option.		
	XXVI.	The system should have pH valve and pH electrode for in-line pH monitoring during the run. pH monitor should be easily calibrated by injection of calibration buffer directly into the valve with the pH electrode mounted.		
	XXVII.	Multimodal chromatography resins should be provided for LV purification. It should be in pre-packed and loose resins format.		
	XVIII.	Empty columns should be provided which are designed for low to medium pressure, are user friendly, robust, and give reproducible packing (column volume 5-30 ml).		
	XXIX.	Prepacked columns should be provided which allows supercoiled covalently closed circular forms of plasmid DNA to be separated from open circular forms.		
	XXX.	System should have option to load the sample in fully automotive way.		

3	**B. System Control Software** I. The system must be provided with software that works on a single software platform with full networking capabilities and has capability to be controlled through an independent desktop or laptop computer. II. The software must have both users programmable and p re -defined application protocols and method templates. In addition, the software should have capability to be upgradable to different modules for multivariate analysis such as design of experiments functionality for method development and optimization. Software should be GMP and 21 CFR part 11 compliant. III. Built in templates for all the existing columns with option to develop method for third party. IV. Sharing of methods and results along with remote access capabilities to systems to save valuable time and resources V. Scouting of up to 99 runs with individual parameters in single method VI. Method Queues for combining of different purification techniques. VII. Software should perform real time control, data evaluation, watch commands, Scouting parameters, method queue, method wizard for easy programming, column library, with report generation option. VIII. Automatic data recovery after run is over should be possible. IX. Include WATCH functions (in addition to the alarms) in the control software to ensure that various parameters like pH, conductivity, pressure, etc. are in the acceptable range upon execution of an action by the operator. X. The system should be capable of being installed with Design of Experiment (DOE) software integrated with the System control software as a tool for experimental design for generating precise data in fewer experiments for time and cost-efficient method development. XI. The software must have a detailed evaluation segment for peak integration and evaluation, peak smoothening, peak offset adjustment, peak differentiation, peak addition and subtraction, peak overlay comparison of results and automated quantification of peak fractions.		
4	**C. Documents for regulatory compliance**		

	I. Test and calibration certificates traceable to national/international standards. II. Installation Qualification and Operational Qualification certificates II. Safety and compliance: Certified to ISO, cULus, and CE standards; floor bolting not mandatory, allowing flexibility in relocation.		
5	**D. After sales support/ service / Application support:** I. System should be supported by manufacturer or their authorized distributor with factory trained Service engineer.		
6	**E. Warranty** I. Standard 3 years		