INDIAN INSTITUTE OF TECHNOLOGY BOMBAY

MATERIALS MANAGEMENT DIVISION

Powai, Mumbai 400076.

Ref. PR No. 1000048429 Rfx. No. 6100002261

Item Description: Ion-Exchange Chromatography System – 1 No.

Sr. No.	Tender Specifications	Compliance (Yes/No)	Additional Information
1.	The Chromatography system should support all the following chromatography techniques: Affinity Chromatography, Ion-Exchange chromatography, Size-Exclusion Chromatography & Hydrophobic Interaction Chromatography.		
2.	The system should have an operating flow rate of 120 ml/min or more. The flow rate should not deviate outside of ±1.5%. The system must have a feature to adjust the flow rate automatically when a run is performed in a cold environment.		
3.	The system should be able to withstand operating pressure of 20 bar or above.		
4.	The system should have a feature to avoid fouling. A gradient mixer with gradient between 0-100%.		
5.	The system should be supplied with 3 or more inlet lines. The system should contain a mixer for mixing of buffers.		
6.	The system should also have 3 or more outlet lines. It should be supplied with a fraction collector for 3, 8, 15, and 50 mL tubes, and must be equipped with sensor to control spillage.		
7.	The System should also have a temperature integrated conductivity meter, with range of 0.01-999 mS/cm.		
8.	The system should have capability to automatically bypass column avoiding any replumbing requirement. And should come with a wavelength detection of at least 280 nm and 260 nm simultaneously. The UV detector read value should be between -3 to +3 AU.		

	The UV lamp should not heat the protein sample and does not have warmup time, and it should have a total operating life of 4000 hours or more.		
9.	The system should be supplied with all accessories like tubings, connectors, and ferrules for the smooth running of the system.		
10.	The system must include a sample loop with a capacity of 150 mL. It should be supplied with all the Regulatory documentation.		
11.	The system should allow remote monitoring and control using a touchscreen display or computer.		
12.	System software data backup features for backup and restore of data files. The system software must have an inbuilt feature to queue up various purification methods for attended purification, real time control and modification of pre-designed methods during the run to enable method optimization.		
13.	The Software must be 21CFR part 11 compliant.		
14.	It should have flexibility to be integrated with third party detectors like fluorescence detectors, RI and autosamplers simultaneously for increased application flexibility.		
15.	On-site training for the hardware and applications need to be provided.		
16.	The external surfaces of the chromatography system and other supporting accessories should be easily cleanable with 70 % IPA and other standard cleaning agents employed in cleaning in drug manufacturing environment.		
17.	At least 12 months warranty from the date of installation shall be provided and should include replacement of non-consumable parts in case of manufacturing defect.		
18.	The supplier shall provide IQ (Installation Qualification), OQ (Operational Qualification), and software validation protocols. The execution of these protocols shall be performed on-site by trained engineers from the supplier or manufacturer. The system shall be qualified by certified engineers using the approved qualification documentation.		
19.	Should include at least 5 quantities of 5ml Mustang Q XT column, 5 quantities 50ml mustang Q XT column and 1L of Capto Plasmid Select resin		