INDIAN INSTITUTE OF TECHNOLOGY BOMBAY
MATERIALS MANAGEMENT DIVISION

PR NO.1000048548 **RFx No.6100002400**

Technical Specifications for Bioreactor

Sr. No.	Technical Specifications	Compliance (Yes/No)	Additional Information
1.	Bioreactor		
1.1	A small-scale, single-use, structured fixed-bed bioreactor or suspension platform, equipped with all the necessary components, tubing, and spare parts. A fully GMP compliant (21CFR part 11), single-use fixed-bed bioreactor proven for versatile applications.		
1.2	With Minimum working volume of 1-5 L and maximum working volume of 60 L		
1.3	The system with easy to clean stainless steel controller and power supply up to 110 V or 230 V, 50/60 Hz with safety cut-off switch.		
1.4	Power consumption to be maximum of 500 W		
1.5	Gas supply of 0.6-1.5 bar, and filtration with cut-off 0.22 µm)		
1.6	System with pressure sensor.		
1.7	Pt100 surface temperature sensor		
1.8	Allow in-line sampling of the fixed-bed and enable real-time monitoring of cell growth and metabolism without disrupting the culture environment.		
1.9	Compact Footprint		
2.	Basic unit: Control tower		
2.1	Stand-alone operation should have facility for data logging and export of data using USB without computer.		
2.2	Ethernet laptop connectivity to end user's laptop for control of process parameters through web interface.		
2.3	Controller with an integrated software interface for automated process execution and cell culture parameter monitoring and adjustment (pH, DO, temperature & agitation). The controller should perform the real-time detection, recording and control of pH, temperature, dissolved oxygen, and liquid/feed addition.		
2.4	At least two built-in Speed controlled peristaltic pump for addition of substrate/base (for substrate controller: totalizer, time-based setpoint profiles)		

2.5	Integrated temperature control system for maintaining temperatures up to 39°C and Integrated alarm system for process parameters and setpoints overshoots.		
2.6	Inbuilt audio-visual alarm system		
3.	DO, pH probes and DO control advanced		
3.1	One port each for pH probe, DO probe, T probe.		
3.2	pH Measurement range: 4.0 - 10.0 pH | 0.1 pH with Inline recalibration.		
4.	Gassing module additive flow- 3 Gas		
4.1	Flow rate range: 5-1000 mL/min		
5.	Software		
5.1	Software for bioprocess data acquisition, monitoring, control and automation		
5.2	The software should include below mentioned functions for easy navigation: - Overview for all system critical parameters. - User-friendly and intuitive graphical user interface - Alarm management according to the ANSI-18.2 standard - Common visualization of running and completed processes in one chart - Complies with the FDA requirements regarding 21 CFR Part 11 (Electronic Records and Signatures) and EudraLex Annex 11. - Easy and flexible data exporting as csv-file - Audit Trail function for batch related data and system configuration.		
6.	Documentation: IQ, OQ and PQ		
6.1	Documents as hardcopy or on CD. Including: a. Operating Manual b. CE Declaration of Conformity / NRTL certificate c. Quality Assurance Certificate d. Consumable list e. P&I diagram f. Wiring diagram g. Major component list h. Certificates of mass flow controllers i. Main documents: j. Functional Specification (FS) k. Verification Plan & Report (VPR) l. Product & Test Specification (PTS) m. Calibration Handbook n. Calibration list o. Deficiency List		
7.	Warranty		
7.1	5 Years warranty for the complete system should be offered.		
8.	Consumables		
8.1	Should provide consumables sufficient for atleast 10 batches		