Annexure A

| | | | Annexure A |
|-----------|--|----------------------------------|------------|
| Sr no. | Technical specs for FPLC System with Cold Cabinet on Buyback Offer | Criteria Matching(Yes/No) | Remarks |
| 1 | FPLC System: The system should be of state-of-the-art Fast Protein Liquid Chromatography (FPLC) with an ability to support all the following chromatography techniques: Affinity Chromatography, Ion- Exchange chromatography, Size-Exclusion Chromatography & Hydrophobic Interaction Chromatography. Should have provision for attachment of column holders and accessories. Should be upgradable for microscale purification. Compatible with prepacked analytical and preparative columns from GE/Cytiva/BioRad or any other vendor. | | |
| 2 | The system should have an operating flow rate of 0.001 to 10 ml/min or more and should not deviate beyond $\pm 2\%$. The system should have feature to adjust the flow rate automatically when a run is being performed in a cold room or cold cabinet. | | |
| 3 | The system should have an automatic pump wash, prime and purge provision. | | |
| 4 | The system should be able to withstand operating pressure of 200 bar (or above). | | |
| 5 | System pump should be high-performance positive displacement bnary piston pump capable of delivering solutions/mixtures with viscosity up to 10.0 or higher cP and have mixer module with magnetic stirrer to generate gradient. | | |
| 6 | The system should have a gradient mixer and be capable of creating a gradient between 0-100%. | | |
| 7 | The system should be supplied with 4 inlet lines or more and allow selection between two A and two B positions in a single valve. Should have integrated air sensor(s) in the buffer line(s) to protect the columns. | | |
| 8 | System should allow automated sample loading of large volumes of samples through IMAC, affinity and ion-exchange columns, with pressure and air sensors to protect the column and allow complete sample application without the need to preprogram the sample volume. | | |
| 9 | The system should have a mixer for ensuring mixing of buffers. However, to avoid buffer dilution, the volume of the mixer should not exceed 1.5 mL. | | |
| 10 | The system should have space to keep the buffer containers at a height above the pump, to ensure positive hydrodynamic head. | | |
| 11 | The system should have safety feature to avoid buffer backmixing during standby state. | | |
| 12 | The system should have provision to pass protein sample into the column directly, bypassing the mixer. | | |

| | | 1 | |
|----|---|---|--|
| | System should support more than 3 loops at a time for multiple sample injections and must be capable of automated sample | | |
| 13 | injection with option of loop selection for different sample volumes. | | |
| | The system should be able to read the temperature in the flow | | |
| 14 | path with high accuracy. | | |
| | The system should come with column valves to allow connection of upto five columns and have an integrated bypass | | |
| | function, which enables washing of the system without | | |
| 15 | removing the column and allows reverse flow. | | |
| 16 | The system should enable automated up flow (reverse), down flow, and bypass of the columns. | | |
| 17 | The system should have pressure sensor pre and post columns for safety of the columns. | | |
| | The system should have a pH sensor which can be | | |
| | calibrated, controlled and operated automatically via system software. The pH sensor should allow 2-point or more | | |
| 18 | calibration. | | |
| 19 | The system should have at least 3 outlet ports. | | |
| | Fraction collector: The system should be supplied with a fraction collector which allows the use of 0.5, 1.5, 2 mL and | | |
| | 50 mL tubes. It should also allow usage of deep-well blocks | | |
| | and microplates, preferably 24, 48, and 96-well plates. | | |
| | Fraction collector should have an option to be used on "time, volume, or peak recognition" mode. It should have a | | |
| | technology/sensor to minimize spillage while collecting | | |
| 20 | fractions. | | |
| | The system should have a temperature integrated conductivity | | |
| 21 | meter with an accuracy of $\pm 2.0\%$, to verify/validate gradients. | | |
| | | | |
| | The system should come with a multi-wavelength detector which enables simultaneous monitoring of at least 3 or more | | |
| | different wavelengths (190 to 700 nm or above) with the | | |
| | following UV-Vis parameters: a UV range with noise of less | | |
| 22 | than 0.1 mAU and minimum UV linearity of $\pm 2.0\%$. | | |
| | The UV lamp should come with no or minimal warmup time | | |
| | and come with 2 to 5 mm analytical flow cell. The UV flow cell should have flow cell volume of less than 10 µL for higher | | |
| | sensitive detection of even smaller amount of target proteins | | |
| | such as from human fluids, and closely eluting impurities and | | |
| 23 | heterogenous samples. | | |
| | The software should be able to incorporate variable delay volume based on the position and length of the column and | | |
| 24 | tubing. | | |
| | The system should be supplied with all accessories like tubing, | | |
| 25 | connectors, ferrules for the smooth running of the system. | | |
| ۷3 | |] | |

| | | <u> </u> |
|----|---|----------|
| 26 | The system should come with in-built pressure sensor to regulate the flow rate and the system should be compatible for running in cold cabinet/ cold chamber/room. | |
| 27 | The system should be able to turn off UV lamp to save lamp capacity after a programmed run is over. | |
| 28 | The UV lamp should not heat the protein samples and the lamp should have the longest operating lifetime. Should mention the lifetime. | |
| 29 | System should be supplied with suitable computer, 27" FHD monitor and a latest color inkjet printer for software-based operations, data analysis and documentation. | |
| 30 | Software: The Software should have in-built library of column specifications from the vendor as well as third party vendors for ease of purification. Software should be freely upgradeable anytime and along with upgradation of system firmware to allow operations of system through upgraded software till the lifetime of the system. The software should have the feature of remote operation and visualizing the runs. Should have provision for multiple users and can be used in multiple systems with a site license. System software should have data backup features for backup and restore of data files. The software should have an inbuilt feature to queue up various purification methods for unattended purification, real time control and modification of pre-designed methods during the run to enable method optimization. GAMP and 21 CFR part 11 compliance desirable. | |
| 31 | Cold cabinet: Should come with a specifically designed cold cabinet to house the FPLC system and with accessories such as column holders to have up to 5 or more columns connected at a given time. | |
| 32 | Service and support: Should have more than a few installations of the same system in other parts of the country and have good local technical support; 27/7 online, and inperson in Delhi-NCR with a response time of 24-48 hrs. | |
| 33 | Company must provide a compliance statement supported by technical literature and website. | |
| 34 | An authorisation certificate from the OEM/manufacturer must be included in the technical bid | |
| 35 | User list must be enclosed for the quoted model supplied to any other institute/Organization in Delhi and NCR. | |
| 36 | Minimum 3 Customer satisfactory / performance certificate for specific quoted model from the end user should be included in the quote. | |
| 37 | Warranty 5 years including all spares, PM kit and calibrations of instrument on regular basis and as and when required. | |

| 38 | Consumables required during installation to setup the new instrument must be quoted along with the instrument. This includes loops (from 10 microliter to 10 ml and above upto 50ml), fittings, column holders and clamps. The consumables should be enough to attach five columns upon installation. | |
|----|---|--|
| 20 | Unpacking and shifting of the instrument including manpower, forklift/Crane if required during installation must | |
| 39 | be in the vendor scope. | |
| | AMC and CMC costs for next 5 years, after completion of 5 | |
| 40 | year warranty, should be quoted as optional. | |
| | Note: Price for Buyback equipment must be mentioned | |
| 41 | separately in the price bid. | |