## SPECIFICATIONS FOR FPLC SYSTEM WITH ACCESSORIES

- Size exclusion, affinity, ion exchange, hydrophobic interaction, and reverse phase chromatography must all be performed by the automated purification system, which must be inert and biocompatible.
- The system should be fully modular system that can be further expanded to increase system capability and productivity.
- The system must have IP21 protection code.
- The flow rate of the system should be at least 20 ml/min with accuracy of ± 2%, and system should be capable of going to a flow of 50 ml/min as packing flow rate for the system with pressure rating of 20 MPa without adding any additional modules on to the system. Pump Type must be: Piston pump, metering type.
- For enduring performance and compatibility with typical chromatographic buffers, the pump head piston of the system should be composed of hydrophobic material.
- The system should have a 2 mm flow cell and a 2  $\mu$ L cell volume as standard, with the option of a 5 mm optical path and a 6  $\mu$ L illuminated cell volume.
- System viscosity range must range between 0.4 to 9 cP (5 cP above 12.5 mL/min).
- Rotary type valve must be part of the system and must have options of using up to in range of 10-12 valves.
- A chamber with a magnetic stirrer should be the mixing principle.
- System must be capable of accurate, automatic gradient formation from 0 to 100% gradient over the entire flow range of 1 to 20 ml/min.
- To prevent heat generation in the flow cell, the UV-monitor should be able to detect a wavelength of 280 nm utilising LED technology. The lifetime should be more than 3500 hr and it should be off when not required to improve the life.
- System UV detector should have an absorbance range of -5000 to 5000 mAU with a resolution of 0.01 mAU crucial for sharp peaks and for samples in the negative spectra of the absorbance.
- System should be supplied with a conductive monitor for conductivity measurement between 0.01mS/cm up to 950 mS/cm, with automated temperature compensation and flow restrictor. System should have built temperature sensor to correct variation due to temperature.
- For more application flexibility, the system should be able to simultaneously incorporate third-party detectors and autosamplers via I/O boxes, either at the time of purchase or after.
- The system should be supplied with a fraction collector. It should be able to minimize spillage using drop sensor and allows the use of different volume tubes like 3, 8, 15 and 50 ml tubes. Fraction collector should also be capable to be used in time, volume or peak recognition mode.
- The system must come with a accessories box including but not limited to screw lids and cap membranes, tubing cutter, syringe (10 ml), 500  $\mu$ L sample loop, filter kit, tubing connector.
- System should be supplied with at least 3 port outlet valve for connecting to waste, fraction collector and one outlet position for main system.
- System must include 1 ml prepacked columns (minimum 5) with different ion exchange resin (Sepharose).
- System must be quoted along with a compatible 2KvA UPS for system backup.
- System must be quoted with branded compatible PC (minimum: i5, 8 GB RAM, 512 GB SSD) capable of running the machine software.
- The automated purification system must carry a warranty of minimum of 1 year.
- Installation and training: Vendor must take care of on-site installation, demonstration, and training by a welltrained engineer. Required training for smooth operation of the instrument should be provided free of charge during and after installation.
- A list of users of the quoted equipment within the country should be enclosed.
- Original catalogue from the manufacturer with technical specifications and relevant application notes must be enclosed.
- The vendor must provide a certificate saying that prompt after-sales service such as regular maintenance, troubleshooting and fixing will be carried out by company-trained engineers.
- The system must be supplied with a software of following capabilities :-
  - 1. License base software with 21 CFR complied
  - 2. Intuitive user interface with an interactive process picture and simplified evaluation modules
  - 3. Built in templates for all the existing columns with option to develop method for third party

- 4. Sharing of methods and results along with remote access capabilities to systems to save valuable time and resources.
- 5. Scouting of up to 90 runs with individual parameters in single method.
- 6. Method Queues for combining of different purification techniques.
- 7. 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
- 8. Automatic data recovery after the run is over should be possible.
- **9.** 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.