**TFF System specification**

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| **HSK No.** | **Item No.** | **Description** | **Units** | **Quantity** |
|  | 1 | Semi-automatic laboratory scale tangential flow filtration (TFF) system | SYS | 1 |

1. **End-user’s Uses**
   1. Laboratory scale tangential flow filtration (TFF) system wherein multiple operation should be possible such as concentration, diafiltration, single pass TFF, Hollow fiber operation capabilities.
   2. TFF system should be able to handle a cassette size in a range of 0.1 to 1 m2 of surface area.
   3. System should be equipped with HMI and software to control and automate the macrosteps such as concentration, diafiltration, recirculation, flushing, tank emptying and tank filling.
   4. The control software should indicate P&ID and live trends / historical trend of the data. The P&ID should be interactive with schematic of the flow path with icons of actuators, sensors, and virtual sensors
   5. The TFF system should be equipped with flowmeters, pressure sensors, UV, pH / conductivity sensors in feed, retentate and permeate line wherever is required as per process.
   6. Tank should be equipped with weighing capability which eventually integrated in control software.
   7. Software should be equipped to custom program various TFF unit operations (concentration, diafiltration, washing, flushing, recovery, cleaning) and possibility to automate them.
   8. The cassette holder should be universal wherein different vendor TFF cassettes could be fixed.
   9. TFF system should support and help to generate linear scalable parameters for higher scale-up studies.
2. **Configuration of goods**
   1. TFF system with full package
3. **Performance and specification**
   1. Filtration Area: 0.1 m2 to 1.14 m2
   2. Tank Volume: up to 5000 mL and minimum working volume of 300 mL
   3. Supported Devices: cassettes 0.1/0.11 m2 up to 5 Nos; cassettes 0.5/0.57 m2 up to 2 Nos
   4. Cassette holder: SS 316L with capability to hold different vendor TFF cassettes
   5. Pump Flow Rate: Feed pump range at 1 bar - 100–12000 mL/min
   6. Process Temperature Range: 5–40 °C
   7. Connection to holder: Micro clamp (25 mm ferrule)
   8. Maximum Operating Pressure: 5 bars
   9. Weight (nominal): Bench top model with gross weight less then 75 Kg
   10. Power Supply: 100 – 240 V~, 50 – 60 Hz with protective earth
   11. Materials of Construction for All Wetted Parts: SS-316L and polymer- PP, PVDF, PPSU, PEEK, PC, HDPE, PTFE, EPDM, Santoprene, Silicone platinum cured
   12. Permeate line: Filtrate pH/conductivity enables monitoring of flush or buffer exchange efficiency and Filtrate UV allows to detect and prevent protein loss
   13. Retentate/feed/permeate line:Low range pressure sensors provide the level of accuracy needed in microfiltration
   14. Temperature control unit maintains product temperature or warms up a cleaning solution
   15. Flow meters: on retentate and feed line
   16. Pressure control valve: On feed and retentate valve
   17. Tank weighing scale with magnetic stirring system.
   18. Holder: For 0,1 m2 and cassettes 0,11 m2
   19. Control software and HMI: P&ID displays the complete process flow path and provides a snapshot of the system’s current state. From the P&ID, a user can directly interact, control, and monitor system components. The P&ID schematic shows icons of actuators, sensors, and virtual sensors together with information on tags, control mode (manual or automatic), and additional system settings and key parameter values such as setpoints or current speed. The HMI should have sufficient space in gigabyte (GB) to archive historical data and trend.
   20. Software: Control Software provides real-time monitoring and control of all TFF System processes. With an intuitive user interface, you can operate the system with minimal training. The home screen provides: • Persistent left navigation bar for easy access to P&ID, trends, recipes, alarms, and settings • Top banner with alarms and system information • Customizable pinned sensors bar with actuator and sensor parameters of interest • Status bar with current state of the process • Interactive P&ID schematic of the flow path with icons of actuators, sensors, and virtual sensors • Update Utility allows you to upload and install the latest version of the Control Software for TFF system. In addition, the Control Software offers the following features to support users in their application runs, from recipe creation and starting a run to monitoring and reporting.
4. **Accessories**
   1. All applicable as per full package
5. **Remarks**
   1. Installation and Operational Qualification (IQ/OQ) service
   2. Regulatory requirements: All plastic and elastomer parts in contact with the product comply with USP Class VI or USP or FDA title 21 CFR, paragraph 177 or ISO 10993-5. All stainless-steel parts manufactured from 316L stainless-steel or equivalent in contact with the product complies with material certificate 3.1 following EN 10204.
   3. Language support: English and Korean
   4. On site installation by certified engineer
   5. Two year warranty service shall be provided
6. **‘위 규격서에서 명시한 제품과 동등 이상의 다른 제품 납품이 가능한 업체는 입찰에 참가할 수 있음’.**