

TECHNIKROM®



TechniKrom Bioprocess UF/DF/VF

Ultrafiltration/Diafiltration/Viral Filtration cGMP Systems

TechniKrom® provides pilot to production scale automated membrane filtration units using the same sanitary cGMP platform and technology base our LC system skids utilize. Units are designed to accommodate manual to fully automated operation depending upon need. Filtration optimization services are also provided.

UF/DF/VF cGMP Systems

Our membrane filtration units accommodate the variety of customer specified membrane technologies which are available today.



Validated Process Control with IQ/OQ

Allen Bradley PLC systems with PanelView™ or external PC provide real time data logging and viewing, as well as method creation and error testing, 21 CFR Part 11 audit trails and batch reports. TechniKrom's GAMP-4 and 21 CFR Part 11 capable process control package, including IQ/OQ protocols, execution and documentation available.

I. Manual Filtration System Option:

- A sanitary cGMP design, portable skid mounted filtration unit with industrial construction and full 316L stainless steel frame.
- All system tubing, fittings and diaphragm valves are traceable 316L stainless steel and electropolished on the interior with documented orbital welding as applicable. All tubing is individually PIN-stamped for full traceability. Interior surface finish is $\leq 20 \mu\text{in } R_a$.
- Sanitary Pump: Sanitary tri-clamp connections included.
- Sanitary Pressure Sensors
- Sanitary Coriolis Mass flowmeters
- Sanitary UV Sensor
- Sanitary Conductivity and pH Sensors
- Utilities: 3 phase, 460V (optional 230V), 60Hz power, and 90psi instrument grade air.
- UL approved control panel includes all electrical starters, relays, drives, and wiring.
- Multi-Channel Chart Recorder for logging of analog signals.
- All TechniKrom® systems are built according to our SOPP's to ensure that the highest state of quality control is incorporated into each system.

II. Fully Automated Option:

- UL approved control panel includes PLC, electrical starters, relays, drives, and wiring.
- PLC: On-board industrial high speed PLC with IEC certified compliant PLC software.
- TechniKrom 21 CFR Part 11 Control Software.

TECHNIKROM®

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