

KrosFlo[®]

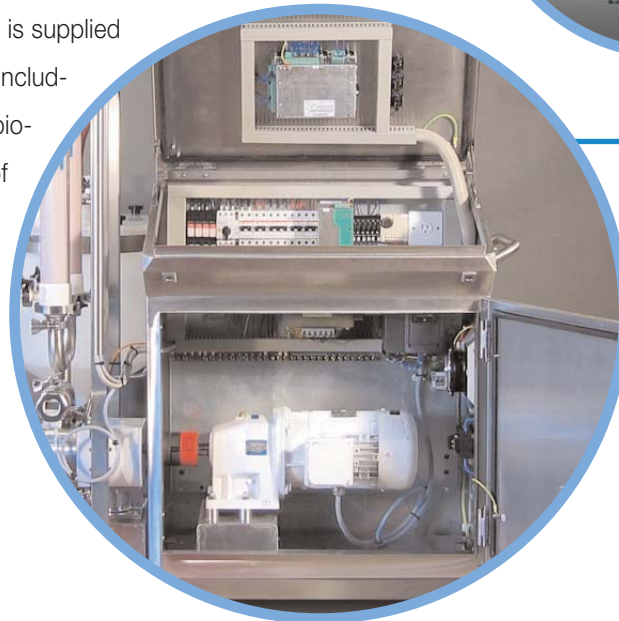
Pharma Production System

Tangential Flow Filtration System for
Production Volumes of 50 to 5,000 L



KrosFlo® Pharma Production System

Finally, an “OFF-THE-SHELF”, cGMP tangential flow filtration system designed for the pharmaceutical and diagnostic industries featuring automatic pressure and flow controls for processing up to 5,000 liters. Instead of contracting expensive outside services and engineering firms to consult, design, engineer, manufacture and install a custom, mid-range production system that could take up to a year of your valuable time, Spectrum introduces the KrosFlo® Pharma System that is available in JUST 6 WEEKS! The cGMP system complies with FDA regulations and is supplied with a complete cGMP documentation package, including test protocols for processing therapeutic biopharmaceuticals. Ideal for production volumes of 50 to 5,000 liters, the KrosFlo® Pharma System features a single standard design with the flexibility for a variety of build options. The various combinations of these standard options, allows Spectrum to offer 12 different system models that are readily available “OFF-THE-SHELF”.



OPERATOR TERMINAL

The System is controlled via a programmable PLC, Siemens C7-613 Controller. Since the PLC has 5 input/output accesses, the system can be operated under manual or semi-automatic control. The system can also interface with a data acquisition network.

14 HF MODULE SIZES

All 12 KrosFlo® Pharma System designs feature a “slide-lock” manifold to accommodate HF filters ranging from 1-5 ft in length, including 14 sizes & types of Spectrum HF modules:

- KrosFlo® Plus (3 sizes) CellFlo® Plus (3 sizes)
- KrosFlo® MAX (3 sizes) CellFlo® MAX (3 sizes)
- KrosFlo® SIP (2 sizes)

6 ROTARY LOBE PUMP TYPES

The process is driven by one of three capacity pumps with optional pump head flush system for diagnostic applications. The Flush System consists of pump head with double mechanical seals, SS manifold for flushing and override flow sensor to prevent dry operation of lobe pump.

- 50 LPM with or w/o Flushing
- 100 LPM with or w/o Flushing
- 200 LPM with or w/o Flushing

3 SYSTEM CAPACITY DESIGNS

The KrosFlo® Pharma System is available in three capacity designs depending on the process volume:

- Single KrosFlo® Plus 50 - 1,000 L
- Dual KrosFlo® Plus 100 - 2,000 L
- Single KrosFlo® MAX 200 - 5,000 L

2 FLOW-PATH TYPES

Each capacity design can be combined with one of two Flow-path types for use with either disposable HF modules or re-use (SIP) HF modules:

- Clean-in-Place (CIP)
- Steam-in-Place (SIP)



STANDARD SYSTEM DESIGN & FEATURES

The 12 standard KrosFlo Pharma Systems are specifically designed for complete FDA compliance and to meet the needs of the various process applications:

- Standard AC pump drive motor (460VAC, 3 phase, 60HZ)
- Reducer between drive & pump for increased torque at low RPM's w/ high pressure
- Standard frequency converter for stabilizing pump speed
- Sanitary Rotary lobe pump (50, 100 or 200 LPM)
- Standard CIP or optional SIP flow-path with height adjustment
- Sanitary 316 SS manifolds for 3 system capacities:
 - Single KrosFlo Plus
 - Dual KrosFlo Plus
 - Single KrosFlo MAX
- 3.1B certified & foreseen piping & welds
- Carting design w/ locking swivel wheels
- Inlet & outlet electronic pressure transducers
- High/Low pressure alarm w/ auto shut-off
- Sanitary back-pressure membrane-valve (manual)
- Sanitary “zero-deadleg” drain-valve (manual)
- Automated Operator Interface Terminal (OT) w/ PLC
- Complete cGMP Documentation & Validation Package

OPERATION & CONTROL

All 12 standard systems offer semi-automatic process, ideal for validated processes:

- Operator Terminal (OT) w/ 3 operating modes
 - Manual Control
 - Automatic Pressure Control
 - Automatic Flow Control
- Programmable PLC (Siemens C7-613 Controller) with 5 input/output accesses
 - 3 accesses for standard system:
 - Inlet pressure
 - Outlet pressure
 - Pump drive control.
 - 2 accesses can be used for system options:
 - Flow transmitter
 - Permeate pressure
- pH meter
- Conductivity meter
- Temperature
- Permeate IR Detection
- Data Acquisition
- Software and PLC complies w/ 21-CFR, part 11 Regulations

STANDARD cGMP DOCUMENTATION & VALIDATION PACKAGE

The KrosFlo® Pharma System comes with a complete cGMP Documentation Package. Combined with Spectrum's disposable hollow fiber membrane modules, process validation has never been easier. The Documentation Package includes:

- “As Built” Process Flow Diagram (PFD) & Lay-out Drawing
- cGMP Piping Weld Logs
- Listing & hardcopy of the PLC software
- “As Built” Electrical Diagram and Cabling List
- Complete documentation of implemented components & Calibration Certificates
- 3.1B Certificates for INOX materials
- Completed Factory Acceptance Test (FAT) Protocol
- Operating Manual & Service Manual

PRODUCTION SCALE APPLICATIONS

- Cell Washing
- Protein Purification
- Virus Purification
- Lysate Clarification
- Macromolecule Isolation
- Microparticle Diafiltration
- Viral Vector Concentration
- Fermentation Harvesting
- Antibody Production
- Viral Clarification
- E. coli Concentration
- Desalt & Buffer Exchange

WHICH SYSTEM MODEL IS RIGHT FOR YOU?

SELECTION IS AS EASY AS... A B C!

Since not all process applications are alike, Spectrum has designed 12 different models of the KrosFlo® Pharma Systems ready to be installed and operated in 6 weeks. Select the system that's right for your application based on:

Volume Capacity?

- A. 50 - 1,000 liters
- B. 100 - 2,000 liters
- C. 500 - 5,000 liters

Flow-Path Type?

- D. Standard flow-path
- E. SIP flow-path

Process Application?

- F. Pharmaceutical & Bioprocessing
- G. Diagnostic & Microparticle



KrosFlo Pharma System Selection Guide

Selection Key	Product Number	Flow-Path Type	Pump Capacity	Pump Head Type
A D F	SYPH-100-01N	Single KrosFlo® Plus/CellFlo® Plus	50 LPM	Standard
A D G	SYPH-100-F1N	Single KrosFlo® Plus/CellFlo® Plus	50 LPM	Flushing
A E F	SYPS-100-01N	Single KrosFlo® Plus/CellFlo® Plus-SIP	50 LPM	Standard
A E G	SYPS-100-F1N	Single KrosFlo® Plus/CellFlo® Plus-SIP	50 LPM	Flushing
B D F	SYPH-200-01N	Dual KrosFlo® Plus/CellFlo® Plus	100 LPM	Standard
B D G	SYPH-200-F1N	Dual KrosFlo® Plus/CellFlo® Plus	100 LPM	Flushing
B E F	SYPS-200-01N	Dual KrosFlo® Plus/CellFlo® Plus-SIP	100 LPM	Standard
B E G	SYPS-200-F1N	Dual KrosFlo Plus/CellFlo Plus-SIP	100 LPM	Flushing
C D F	SYPH-400-01N	Single KrosFlo MAX/CellFlo MAX	200 LPM	Standard
C D G	SYPH-400-F1N	Single KrosFlo MAX/CellFlo MAX	200 LPM	Flushing
C E F	SYPS-400-01N	Single KrosFlo MAX/CellFlo MAX-SIP	200 LPM	Standard
C E G	SYPS-400-F1N	Single KrosFlo MAX/CellFlo MAX-SIP	200 LPM	Flushing

CUSTOMIZE YOUR STANDARD SYSTEM WITH OPTIONS & ACCESSORIES:

Select the following features you would like to incorporate into your KrosFlo® Pharma System.

System Options

Product Number	Description
ACPU-021-01N	Peristaltic Pump, 2 LPM, 110 V
ACPU-022-01N	Peristaltic Pump, 2 LPM, 220 V
ACFM-100-01N	Flow Meter for 50/100 LPM pump
ACFM-200-01N	Flow Meter for 200 LPM pump
ACCM-10P-01N	Conductivity Meter, Permeate
ACCM-10R-01N	Conductivity Meter, Retentate
ACPH-10P-01N	pH Meter, Permeate
ACPH-10R-01N	pH Meter, Retentate

Process Reservoirs

Product Number	Description
ACTO-005-C1N	Process Reservoir, 50 L conical bottom w/ 1.5" san. conn., SS dolly w/ lock wheels
ACTO-020-C1N	Process Reservoir, 200 L conical bottom w/ 1.5" san. conn., SS dolly w/ lock wheels
ACTO-050-C1N	Process Reservoir, 500 L conical bottom w/ 1.5" san. conn., SS dolly w/ lock wheels
ACTO-100-C1N	Process Reservoir, 1000 L conical bottom w/ 1.5" san. conn., SS dolly w/ lock wheels



MAINTENANCE & SERVICE CONTRACTS

Unplanned process downtime due to system repairs and maintenance is one of the biggest costs in production. Annual contracts are available to provide quick on-site servicing to keep the filtration system in top operating condition. Contracts can be customized for your particular system and operation needs to include:

- Expedient repairs by expert service engineers
- Calibration of all electronic measuring equipment
- Replacement of all gaskets and seals
- System Software check
- Scheduled and timely maintenance
- Motor & pump check & tune-up
- Electronics & wiring check
- Repair & maintenance documentation for GMP files

The best way to prevent costly production downtime, equipment damage and potential batch loss due to a system failure is by implementing a Maintenance & Service Contract with Spectrum.



800-634-3300 (toll-free in U.S. and Canada)
310-885-4600 (worldwide)

18617 Broadwick Street • Rancho Dominguez, CA 90220 USA