

The PAK System

Single-use platform to perform 4 continuous unit operations simultaneously

Areas

R&D - Pilot - Production - GMP

Applications

- Diafiltration
- Chromatography
- Viral Inactivation
- Inline Concentration
- Filtration
- Monoclonal antibodies and other biopharmaceuticals

Benefits

- Realize over 4-fold productivity improvement and 50% reduction in capital requirements when compared to batch processes.
- Reduce hold tank volumes over 100-fold by simultaneous operation of purification steps in series.
- Connect multiple skids in series to operate an entire downstream process continuously, with instrumentation and buffer management seamlessly integrated.
- Select any order of unit operations and update operating parameters in minutes with PurSync™ dynamic automation package.
- Simplify setup with our solid, single use flow kit that includes all tubing connections, static mixers, instrumentation ports and a break vessel in one ergonomic design.
- Ensure compliance with 21 CFR Part 11 automation and product contact materials that meet USP Class VI testing requirements.



The PAK system is designed for simultaneous operation of 4 sequential purification steps for monoclonal antibodies and other biopharmaceuticals:

- Diafiltration,
- Chromatography,
- Viral inactivation,
- Inline concentration & filtration.



The PAK System

Single-use platform to perform 4 continuous unit operations simultaneously

SPECIFICATIONS

Equipment & Instrumentation

- 36 valves
- 8 pumps : 4 buffer pumps + 4 product pumps
- 8 pH or conductivity sensors
- 8 pressure sensors
- 6 scales
- 2 dual wavelength UV meters
- 2 single use mass flow meters

Single Use Flow Kit

- 500 ml
 - Quick setup in the Pilot PAK™ continuous purification system
- Solid flow kit includes:**
- Connections for two pH and/or conductivity meters
 - Connection for one UV meter
 - Two static mixers for inline pH adjustment or inline dilution
 - One mixing vessel with one vent, two hose barb inlet/outlet ports and one 3/4" sanitary port
 - **Materials of construction:** Nylon 12 and fused silica
 - Materials meet USP Class VI and/or ISO 10993 specifications
 - Gamma compatible

GENERAL SPECIFICATIONS

Dimensions W x D x H

53" x 31" x 33" (65" height with cart)

Flow Rate Range

- Option 1: 0.3 ml/min to 240 ml/min (low flow pump)
- Option 2: 1.3 ml/min to 1.7 L/min (high flow pump)

Tubing Diameters Accepted

1/16", 1/8", 3/16", 1/4"

Pressure Limit

4 bar (58 psi)

Equipment

1 buffer pump, 1 product pump, 5 pinch valves, and 5 buffer inlet valves per stage (4 stages)

PurSync™ Automation Control Package

Synchronous operation of four sequential purification stages per system, and up to four systems in series.

- Control schemes for low pH viral inactivation, TFF for single pass concentration and diafiltration, viral and other filtration, and chromatography.
- Inline buffer adjustment based on pH, conductivity, or volumetric ratio on inlet and outlet of purification stages. Pressure control for each purification stage.
- Automated startup and shutdown, including priming, sanitization, equilibration, and storage.

Materials of Construction

Flow Kit: Nylon 12 with fused silica windows
Product contact materials meet USP Class VI and/or ISO 10993.



The PAK System

SPECIFICATIONS

INSTRUMENTATION

Pressure Sensors

60 psi max
Quantity : 8

UV Meters

Any two specified wavelengths from 185nm to 2600nm
Quantity : 2

pH Meters

0 à 14
Quantity : 8 max

Conductivity Meters

0.02 mS/cm to 500 mS/cm
Quantity : 8 max

Mass Flow Meters

20 g/min à 1500 g/min with density reading
quantity : 1

Scales

- Floor scales with 450kg capacity
Quantity 0-2
- Bench scales with 10kg capacity
Quantity 4-6

OTHER SPECIFICATIONS

Electrical Requirements

120 VAC, 20 A

Required Air Supply

90 psi

PLC

Rockwell CompactLogix™ 5380





The PAK System

SYSTEM SIZING

► **One Automated System | Multiple Disposable Flow Kits**

Purification of 50 L Cell Culture per Day¹ (250 g mAb / day)

	Low pH VI	Filtration	Polish Chrom	UF/DF
Product Flow Rate	~10 ml/min	~10 ml/min	~10 ml/min	~10 ml/min
Buffer Flow Rate	1 to 2 ml/min	1 to 2 ml/min	~50 ml/min	~10 ml/min
Product Tubing Diameter	1/8"	1/8"	1/8"	1/8"
Buffer Tubing Diameter	1/16"	1/16"	1/8"	1/8"
Flow Kit Vessel Volume	0.2 L	0.2 L	5 L	0.2 L

Purification of 500 L Cell Culture per Day¹ (2,500 g mAb / day)

	pH bas IV	Filtration	Chromato ²	UF/DF
Product Flow Rate	~100 ml/min	~100 ml/min	~100 ml/min	~100 ml/min
Buffer Flow Rate	10 to 20 ml/min	10 to 20 ml/min	~500 ml/min	~100 ml/min
Product Tubing Diameter	1/4"	1/4"	1/4"	1/4"
Buffer Tubing Diameter	1/8"	1/8"	1/4"	1/4"
Flow Kit Vessel Volume	2 L	2 L	50 L	2 L

¹ Assumes 5 g/L cell culture media with 3.5X concentration factor over first capture step.

² Requires optional high flow pump and floor scale.



The PAK System

SYSTEM SIZING

Purification of 5,000 L Cell Culture per Day¹ (25,000 g mAb / day) | Process Scale System

	pH bas IV	Filtration	Chromato	UF/DF
Product Flow Rate	~1 L/min	~1 L/min	~1 L/min	~1 L/min
Buffer Flow Rate	100 to 200 ml/min	100 to 200 ml/min	~5 L/min	~1 L/min
Product Tubing Diameter	1/2"	1/2"	1/2"	1/2"
Buffer Tubing Diameter	1/4"	1/4"	1/2"	1/2"
Flow Kit Vessel Volume	20 L	20 L	500 L	20 L

¹ Assumes 5 g/L cell culture media with 3.5X concentration factor over first capture step.

PAK
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