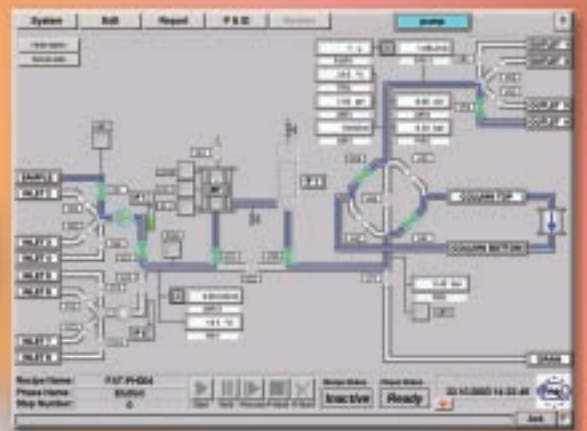
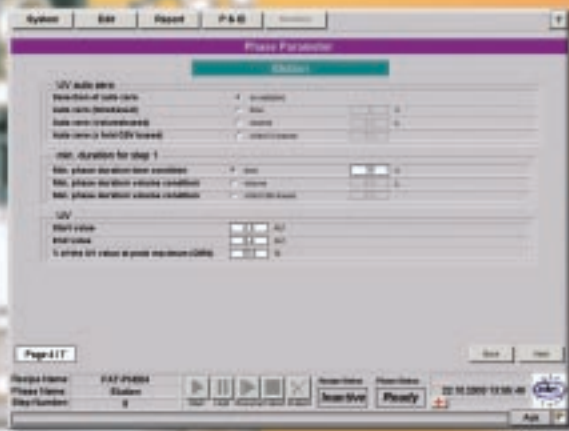


Chromatography Systems for the Biopharmaceutical Industry

Improving choice, flexibility and operating costs for purification processes





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Pall's chromatography systems cover a full range of applications with the highest consistency in design principles and operating protocols.

We meet our customers needs with both standardized and fully customized products, and offer comprehensive local support wherever the location.

Features of Pall's Chromatography Systems

Each Pall system is designed to provide:

- Conformance to critical industry standards
- Reduction in time spent in process development and manufacturing applications
- Optimum flexibility for changing process demands
- Run-to-run reproducibility
- Efficiency of installation and ease of use

• Process performance

Precision gradient with two pumps

Broad system flow range for ion exchange, affinity, hydrophobic interaction and gel permeation applications

Consistent system layout allows true linear process scale up

Forward/reverse and column by-pass control

Low system hold-up volumes

• High quality materials and components

Stainless steel (316L) pipe work and internal surface finish to 0.4µm (16µ-inch) + electro-polish ensures system cleanability

In-line sanitary grade instrumentation

Full material certification package

• GAMP compliance

Design in accordance with GAMP guidelines, to ensure that process and regulatory requirements are met

Documentation and protocols include DQ, IQ/OQ and FAT to verify compliance to requirements

Designed for full CFR21 pt 11 compliance

• Flexible and proven, user-friendly software

Operation by selection of pre-configured protocols

Automation using convenient and flexible recipes

Password controls to set different user levels

Override of automatic functions where required

Simple but comprehensive intuitive screen display with touch screen and keyboard operation

• Real-time data viewing, data storage and analysis

High quality instrumentation and signal generation

Clear visual display of process conditions, set point and alarms

Data point acquisition and recording

• Simple system integration

Industry standard platform running on 'Microsoft' 'Windows' 2000

Optional interfaces to allow master control or data acquisition

Segmented system control and operator interface hardware

• Safety and ease of operation

Orientation friendly layout with easy component access and industry standard terminations

IP/ NEMA rated

Easily transportable systems with locking adjustable castors

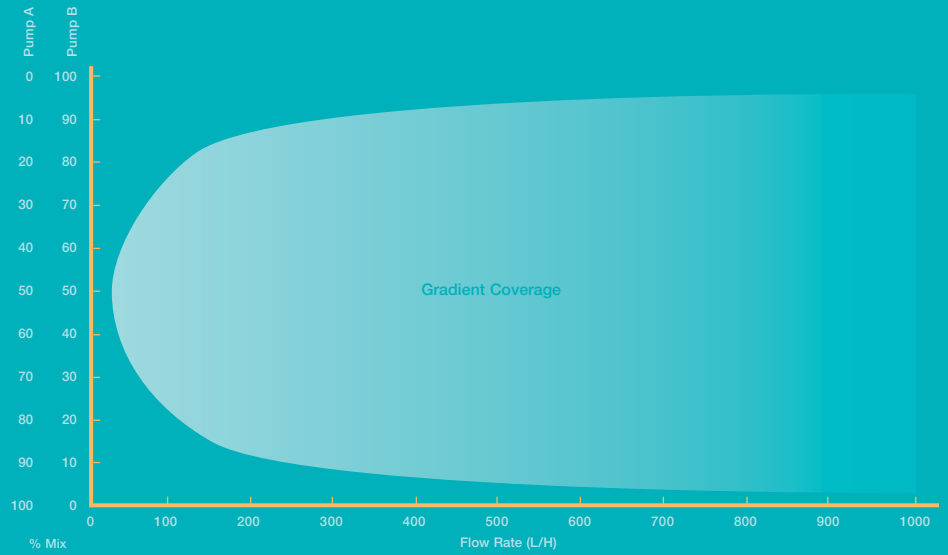
Complete pre-column air detection

Hard-wired back-up features

Internal UPS included for safe shut-down and restore of automation

Gradient capability

The turn down ratio (maximum flow divided by minimum flow) of the pump determines system gradient and in-line dilution capabilities. The diagram shows the coverage for the PK50 system within the flow range of the system pumps. Due to the large turn down the pumps are capable of 5 – 95% mixing over a wide flow range. The gradient is feedback controlled using the pre-column conductivity transmitter.



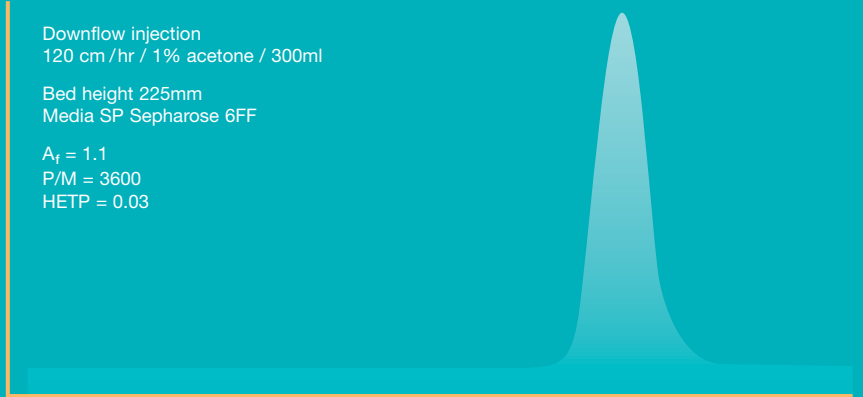
Pall Chromatography System with a Euroflow Resolute 280 column

Downflow injection
120 cm/hr / 1% acetone / 300ml

Bed height 225mm
Media SP Sepharose 6FF

$A_r = 1.1$
 $P/M = 3600$
 $HETP = 0.03$

UV (AU)



Time (S)

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Hardware Features	Benefit
Sanitary multi-port valve technology	Reduces dead-legs to a minimum. Compacts flow path.
316L stainless steel wetted flow path	Robust chemically resistant flow path. Valves fabricated in-line reducing clamp connections.
Two-pump gradient / In-line dilution	Precise in-line mixing- fast accurate step and gradient formation.
Designed for CIP	Turbulent flow velocities achievable in pipe work. Extended temperatures possible.
Flow through instrumentation	Instrumentation flow cell in-line, eliminating dead-legs and minimizing hold-up volume.
Industry standard instrumentation	Reliable monitoring and control of process conditions.
Conformance to ASME BPE	Major components designed for conformance to BPE for inherent sanitary design.
FDA conforming non metallic parts	Validation and compatibility with pharmaceutical manufacturing requirements.
System drain	Post-pump system fully drainable for storage.
4 - Piston diaphragm pump	Pump head design gives virtually pulsation free flow.
No manual pump-stroke adjustment	Fully automated control - repeatable setting with reduced operator intervention.
System validation	Testing protocols including DQ, IQ/OQ and FAT support, for fast track validation and system start-up.
Documentation	Comprehensive support documentation in accordance with GAMP guidelines.
Easily accessible parts	Easy maintenance and replacement.
Standard skid range uses consistent layout philosophy and components	Consistent Scale-Up.

System flow range performance - volumetric flow rate L/H

Column Diameter (mm)	Linear Flow Rate cm/H								
	10	50	100	200	300	400	500	1000	2000
180		13	25	51	76	102	127	254	509
280	6	31	62	123	185	246	308	616	1232
400	13	63	126	251	377	503	628	1257	2513
600	28	141	283	565	848	1131	1414	2827	5655
800	50	251	503	1005	1508	2011	2513	5027	10053
1000	79	393	785	1571	2356	3142	3927	7854	15708
1200	113	565	1131	2262	3393	4524	5655	11310	22619
1400	154	770	1539	3079	4618	6158	7697	15394	30788
1600	201	1005	2011	4021	6032	8042	10053	20106	40212
2000	314	1571	3142	6283	9425	12566	15708	31416	62832

System Size	Maximum Flow L/H
PK10	100
PK50	1000
PK300	4000
PKX	Customized Solution

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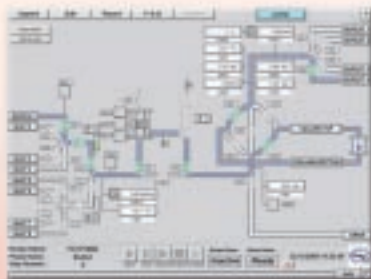
Improving choice, flexibility and operating costs for purification processes

System Sizes

System	PK10	PK50	PK300
Flow range (L/H)	10-100	50-1000	300-4000
Piping id (mm)	4.6 (0.18")	15.7 (0.62")	34.8 (1.4")
Pipe connections	¼" Tri-clamp	¾" Tri-clamp	1½" Tri-clamp
Dimensions (mm)	900 x 1300 x 1400 (35" x 51" x 55")	950 x 1300 x 1400 (37" x 51" x 55")	TBA
Uncrated weight (kg)	250 (550 lbs)	300 (660 lbs)	TBA

System Ratings (applicable to all)

Working pressure	6 barg (87 psig)
Working temperature	2–60°C (36-140°F)
Surface finish - internal	0.4 µm (16 µ-inch) Ra + Electro-polish
Operating environment	Temperature and Humidity 30°C (86°F) max, 95% humidity
Electrical ratings	IP54/NEMA 13
Electrical and safety approvals	CE and UL
Quality systems	ISO9000
Design standards	ASME BPE, GAMP
CFR21 part 11 compliance	Yes



General Specifications

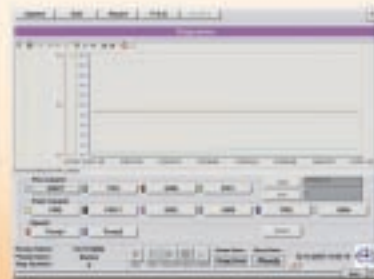
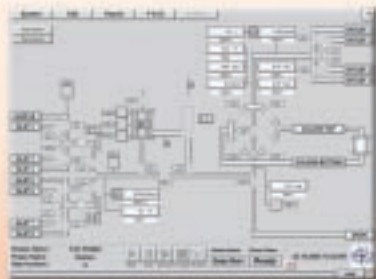
Pumps	Two x Four - Piston Diaphragm Pumps
Gradient/In-line dilution capability	5 to 95% typical (see chart)
Inlets including product sample	8
Outlets including waste	4
Column flow control	Forward, Reverse, By-pass
Bubble trap	Automated Vent Control, with By-pass
Filter	Pre-column, 0.2µm Pall standard, with By-pass
Air sensor	Sample Feed, Pre-column

Instrumentation

Item	Position	Range	Accuracy
Flow meter	Post-column	0-1500 L/H (dependent on system)	±1% (of reading)
Pressure transmitter	Pre and Post-column	0-6 barg (0-87 psig)	±0.5%
Conductivity	Pre and Post-column	0-200 mS	±2%
Temperature	Pre-column with Post-column option	0-100°C (0-212°F)	±0.5°C (±1°F)
pH	Post-column with Pre column option	0-14 pH	±1%
UV	Post-column	0-5 AU, 280nm	±2% (±1% typical)

Wetted Material List

Item	Material
Pipework	Stainless Steel 316L
Pumps	Stainless Steel 316L, EPDM, Santoprene, Polypropylene
Valves	Stainless Steel 316L, EPDM
Bubble trap	Acrylic, Stainless Steel 316L, EPDM
Filter	Polyethersulfone, PVDF or as specified
Instrumentation	Stainless Steel 316L, Titanium, EPDM, PVDF, Quartz, Glass.
Elastomeric seals	EPDM or silicone





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