Millipore®
Expert Pharm/BioPharm
Products & CTDMO Services

Data Sheet

CoPrime® Biochromatography Process-Scale Systems

Fully automated, configurable systems for biopharmaceutical manufacturing and cGMP process scale applications

The CoPrime® biochromatography systems are designed to achieve optimum separation and purification of monoclonal antibodies, vaccines, plasma, and therapeutic proteins. The systems support rapid scale-up and are ideally suited for pilot and process scale.

The CoPrime® systems are designed based on 50 years of process knowledge and engineering expertise to provide a configurable, intuitive process-scale purification solution. CoPrime® A, B, and C sizes have an extended flow rate span and optimized performance for greater gradient accuracy and purification reproduction. The CoPrime® C (40 L) covers higher scales and allows to scale-up directly from CoPrime® B (20 L). CoPrime® A (2,4 L) covers pre-clinical and clinical scales.

MilliporeSigma is the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany.

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Benefits

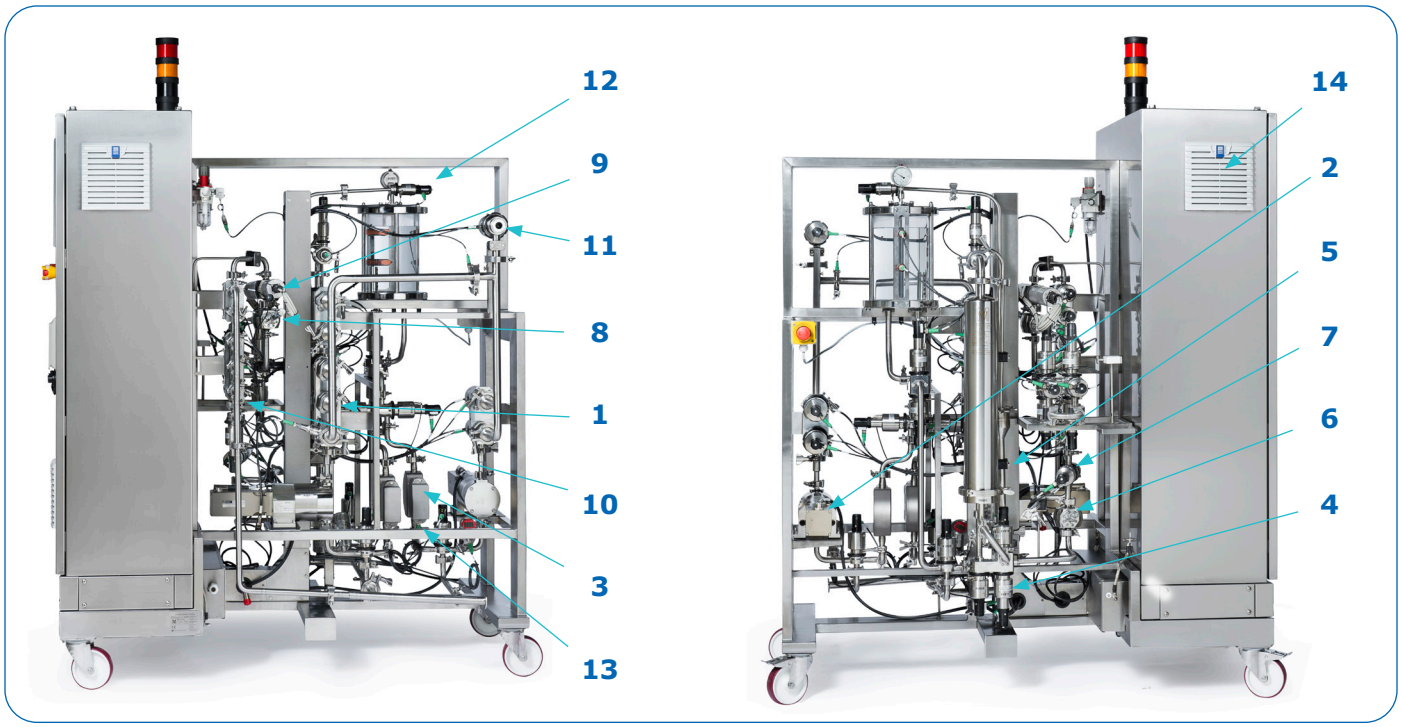
- Scalability with 3 flow rate ranges: CoPrime® Biochromatography System size A (2,4 L) up to 144 L/h
  CoPrime® Biochromatography System size B (20 L) up to 1,200 L/h
  CoPrime® Biochromatography System size C (40 L) up to 2,500 L/h
- Optimized design for very low hold-up volume
- Gradient precision across an extended flow rate window
- Consistent purified fractions over multiple cycles for optimum performance, reliability, and robustness

Configure to meet your purification requirements

Select from the options below to add to the CoPrime® Biochromatography System base platform to best meet your unique chromatography processing requirements. Some of the options have been included in the CoPrime® size A and C base system, see **Table 1** for details.

CoPrime® Biochromatography System size		CoPrime® A Biochromatography System 2,4 L	CoPrime® B Biochromatography System 20 L	CoPrime® C Biochromatography System 40 L
Total options		**5 options**	**14 options**	**8 options**
Option 1:	5 inlet ports	Included in base system	Yes	Included in base system
Option 2:	2nd feed pump		Yes	
Option 3:	mass flow meter		Yes	
Option 4:	valve block for pre-column filter	Inline filter only	Yes	Yes
Option 5:	valve block and pre-column filter	Not available	Yes	Yes
Option 6:	pre-column pH and conductivity sensor	Yes	Yes	Yes
Option 7:	HETP	Not available	Yes	Not available
Option 8:	post-column pH and conductivity sensor	Included in base system	Yes	Yes
Option 9:	post-column UV absorption sensor	Yes	Yes	Yes
Option 10:	5 outlet ports	Yes	Yes	Yes
Option 11:	CIP manifolds	Yes	Yes	Yes
Option 12:	valve position feedback-switch	Yes	Yes	Yes
Option 13:	magnetic flowmeter	Not available	Yes	Not available
Option 14:	system IPx5 rated	Included in base system	Yes	Included in base system

Table 1: Options for all CoPrime® Biochromatography System sizes.



Note: System displayed is CoPrime® Biochromatography System size B (20 L).

CoPrime® Biochrogmatography System size A (2,4 L)

The CoPrime® Biochrogmatography System size A base platform includes (in addition to size B base platform): 5 inlet manifold on first pump for multiple buffer processing, second pump with 2 inlets, mass flowmeters, post-column pH and conductivity sensors, and stainless steel filter hoods on the enclosure.

Option 6: Pre-column pH and conductivity

A conductivity sensor (with temperature compensation) and a pH sensor are fitted in the same flow cell, which is integrated in line between the filter and the column.

Option 9: Post-column UV sensor

With this option, a dual wavelength UV absorption sensor is proposed.

Option 10: Five outlets

Three additional ¼ in. outlet ports with valves are added downstream of the column to separate different fractions.

Option 11: CIP manifold

For cleaning the entire system (excluding the column) in CIP, from one single inlet to one single outlet

Option 12: Feedback switches on valve

With this option, every valve is mounted with an integrated position feedback switch. Closed position is physically detected.

Note: Valve block of pre-column filter option is not available for CoPrime® Biochromatography System size A, but an Opticap® XL 300 inline filter can be installed in place of the spool piece.

CoPrime® Biochromatography System size B (20 L)

The CoPrime® Biochromatography System size B base platform includes: air sensor on product inlet line, two inlets ports, one inlet pump, pressure transmitter and pressure switch on pump outlet, bubble trap with vent valve and air break, pre-column air sensor, pre-column pressure sensor and transmitter, column flow path valve block (forward, reverse or bypass), post column pressure transmitter sensor & transmitter, two outlets and drain ports, system drain line, electrical enclosure, and pressurized air supply block.

Option 1: 5 inlet manifold on 1 pump for multiple buffer processing

Option 2: Second pump with 2 inlets enabling:

- Mixing of two products with a regulated flow rate ratio (2% accuracy ofthe measured value from 180 L/h to 1,200 L/h)
- Linear gradient, from 10% to 90%, according to a rated slope basedon flow rate or conductivity (closed control loop: 2% accuracy ofthe measured value on volume or 2% accuracy of the full scale on conductivity)
- Step gradient, from 10% to 90%, according to set points onflow rate or conductivity (closed control loop: 2% accuracy ofthe measured value on flow or 2% accuracy of the full scale onconductivity)

Option 3: Mass flowmeter

One mass flowmeter is set up between the pump and the bubble trap for monitoring and regulation of the flow fed to the column.

Note: This option includes only one flowmeter. If option 2 (second pump) is selected, the flowmeter option is to be selected twice. The mass flowmeter option excludes the mag flowmeter option.

Option 4: Valve block of pre-column filter either disposable or in a housing

Note: Filter and housing not included.

Option 5: Valve block and pre-column filter housing

Note: Stainless steel 10 or 20 in housing.

Option 6: Pre-column pH and conductivity

A conductivity sensor (with temperature compensation) and a pH sensor are fitted in the same flow cell, which is integrated in line between the filter and the column.

Option 7: HETP inlet block valve

This option enables injection of the HETP sample as close as possible to the column inlet, through a divert valve.

Note: It is possible to perform an HETP sequence using an inlet port instead of the dedicated divert valve.

Option 8: Post-column pH conductivity

A conductivity sensor (with temperature compensation) and a pH sensor are fitted in the same flow cell, which is integrated in line between the column and outlet ports. Two ranges of conductivity are defined, one for the process and another for cleaning.

Option 9: Post-column UV sensor

With this option, a mono-wavelength UV absorption sensor or a dual-wavelength is proposed.

Option 10: Five outlets

Three additional ¾ in. outlet ports with valves are added downstream of the column to separate different fractions.

Option 11: CIP manifold

For cleaning the entire system (excluding the column) in CIP, from one single inlet to one single outlet

Option 12: Feedback switches on valve

With this option, every valve is mounted with an integrated position feedback switch. Closed position is physically detected.

Option 13: Electromagnetic flowmeter

The performance of the flowmeter is dependent on the conductivity of the product. Product conductivity must be greater than 5 µS/cm for liquids, in general, and greater than 10 µS/cm for demineralized water.

Option 14: Filter hoods

The addition of stainless steel filter hoods on the enclosure filters and fan allows an IP rating of IPx5.

CoPrime® Biochromatography System size C (40 L)

The CoPrime® Biochromatography System size C base platform includes (in addition to size B base platform): 5 inlet manifold on first pump for multiple buffer processing, Second pump with 2 inlets, Mass flowmeters and stainless steel filter hoods on the enclosure.

Option 4: Valve block of pre-column filter either disposable or in a housing

Note: Filter and housing not included.

Option 5: Valve block of pre-column filter either disposable or in a housing

Note: Filter and housing not included.

Option 6: Pre-column pH and conductivity

A conductivity sensor (with temperature compensation) and a pH sensor are fitted in the same flow cell, which is integrated in line between the filter and the column.

Option 8: Post-column pH conductivity

A conductivity sensor (with temperature compensation) and a pH sensor are fitted in the same flow cell, which is integrated in line between the column and outlet ports. Two ranges of conductivity are defined, one for the process and another for cleaning.

Option 9: Post-column UV sensor

With this option, a mono-wavelength UV absorption sensor or a dual-wavelength is proposed.

Option 10: Five outlets

Three additional 1 inch outlet ports with valves are added downstream of the column to separate different fractions.

Option 11: CIP manifold

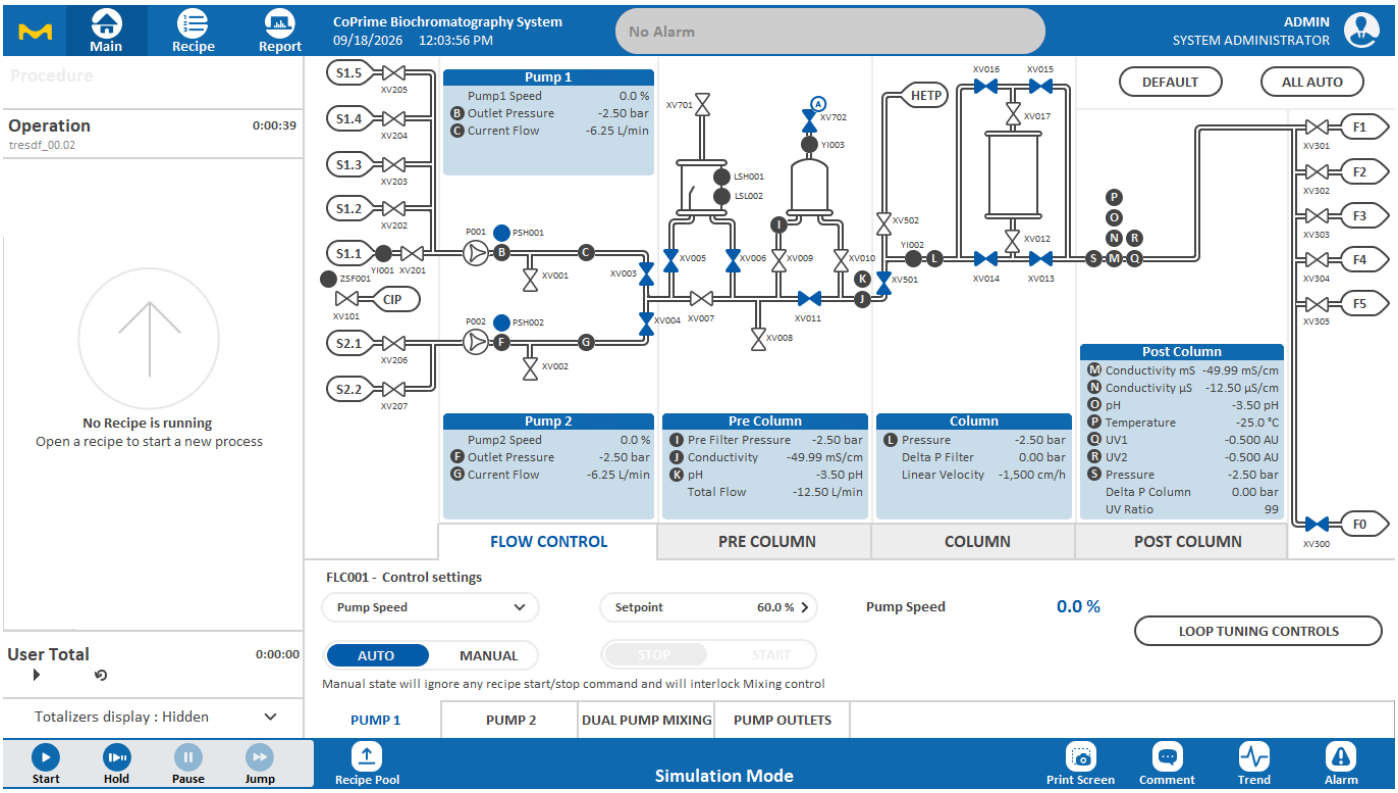
For cleaning the entire system (excluding the column) in CIP, from one single inlet to one single outlet

Option 12: Feedback switches on valve

With this option, every valve is mounted with an integrated position feedback switch. Closed position is physically detected.

Total Process Control and Connectivity

Common Control Platform® (CCP®) Software for Multiple Unit Operations



CCP® software provides a single control platform across our portfolio of automated systems at each step of your process that helps reduce training time for operators.

The software offers recipe driven processing that eliminates manual operation, reduces process variability, and minimizes risk of errors. Process operations are easily created and managed using the recipe editor, each aspect of your process is monitored from the HMI (Human Machine Interface), and the report generator allows you to create state-of-the-art batch reports.

The software is designed for GMP facilities, is in line with GAMP® 5 recommendations for automation software, and fulfills FDA guideline 21 CFR Part 11 requirements for electronic records and signatures and includes an accessible audit trail for verification.

CoPrime® Systems Service

The pharmaceutical and biotechnology industries are highly regulated and, to help you navigate this challenging environment, we offer a wide range of services. These services help you save time, lower costs, and comply with regulations. For your peace of mind, all our services are performed by our global experts who have an intimate knowledge of our equipment backed by decades of experience.

Qualification Services

Our qualification services are designed to make the integration of our system into your process as seamless as possible and ensure your equipment is properly installed and functioning per your pre-defined requirements.

- Factory acceptance test (FAT)
- Installation qualification/operational qualification (IQ/OQ)
- Full test package: this service is an alternative to standard IQ/OQ for customers who wish to have tests from FAT performed again at their site
- Performance qualification support (PQ)

Training Services

Appropriate training for users is not only a GMP requirement, but it also ensures your staff has the expertise to operate and manage the system as part of your manufacturing process. Our training offering has been designed to make your staff more autonomous in managing your system and your process while saving time and money.

Our training services cover system use and programming with interactive hands-on sessions and, depending on the training you select, may also include:

- Installing the Flexware® assemblies
- Interacting with the Human Machine Interface
- Manual and automatic system operation
- Troubleshooting issues
- Creating and managing your own recipes
- Process recommendations

These trainings can be delivered either at your site or in our M Lab™ Collaboration Centers. Please contact your local representative or email ilearn@milliporesigma.com to discuss our training offering.

System Service Reliance Plans

To help you ensure optimum equipment uptime while mitigating risks, we have developed a wide range of services and support that allow you to select a coverage level that best fits your needs. Our System Service Reliance Plans, a complete range of services for your systems, offer priority access to support while ensuring your equipment is properly maintained.

For additional details, please refer to the System Service Reliance Plans Data Sheet (MS_DS7881EN).

Specialized Services

Regular maintenance of your system is critical to avoid unnecessary downtime for repairs, minimize the risk of process deviations, and maintain optimum performance and compliance.

CCP® Software Recipe Design

Every process is unique and, to ensure that your system is optimized to deliver the best performance, our biomanufacturing engineers will configure your process into your own CCP® software recipe. This allows your system to run fully automatic, resulting in consistency and reduced operator error.

For catalogue numbers, please refer to the ordering information at the end of the document. For additional details, please refer to the illustrated spare parts list MS_SDS1687EN available at **SigmaAldrich.com**.

Repair Services and Spare Parts

Repair Services

In the event your system experiences a problem, our worldwide engineering organization will provide on-site or repair center technical support to get you back up and running as quickly as possible.

Spare Parts

Purchasing spare parts directly from us is the only way we can guarantee that you get the right parts every time, with the same level of performance as the original.

Services Catalogue Numbers

Cat. No.	Description
SSVFATCPB	CoPrime® Biochromatography System–FAT execution incl. protocol
SSVFATCPB2	CoPrime® Biochromatography System–FAT execution, qty = 2, incl. protocol
SSVQUACPB1	CoPrime® Biochromatography System–SAT & IQ/OQ execution incl. protocol & travel
SSVQUACPB2	CoPrime® Biochromatography System dummy skid configuration–SAT execution inclunded protocol & travel
SSVQUADOC	CoPrime® Biochromatography System documentation verification
SSVRPCCPB	CCP® Software recipe design qty 3
PTRCPBOP	CoPrime® Biochromatography System operator training, 1 day
PTRCPBCCP1	CoPrime® Biochromatography System–CCP® Software V.6 recipe writing, 1.5 day
PTRCPBCCP2	CoPrime® Biochromatography System–system use, troubleshooting and CCP® Software V.6 recipe writing, 3 days
PTRCPBCCP3	CoPrime® Biochromatography System–system use, process design, troubleshooting and CCP® Software V.6, recipe writing
SSVESPCPB	CoPrime® Biochromatography System–Essential Service Reliance Plan–execution, travel and protocol
SSVESPCPB + SSVADCCPB	CoPrime® Biochromatography System–Advanced Service Reliance Plan–execution, travel and protocol
SSVESPCPB + SSVTOCCPB	CoPrime® Biochromatography System–Total Reliance Plan–execution, travel and protocol

Available at **SigmaAldrich.com/services-plans**

Specifications

	CoPrime® A Biochromatography System 2,4 L	CoPrime® B Biochromatography System 20 L	CoPrime® C Biochromatography System 40 L
Mechanical Specifications			
System dimension L × W × H, in mm (Inches)	1,513* × 864 × 1,896 (59.6" × 34.1" × 74.7") * with keyboard support	1,680 × 9261 × 1,8142 (66.2" × 36.4" × 72.9") 1 with option 14, instead 851 2 without top flashlight	1,990 × 9261 × 2,0242 (78.4" × 36.4" × 79.5") 1 with option 14, instead 851 2 without top flashlight
Net Weight	280 kg (full options)	410 kg (full options)	800 kg (full options)
Materials of Construction	Piping: Stainless steel 316 L **Elastomer: EPDM in compliance with 21 CFR 177.2600**		
Connections			
Main line pre-pump	TC ¾" OD ⅜"	TC 1"½ OD 1"	TC 1"½ OD 1"½
Main line post-pump	TC ¾" OD ¼"	TC ¾" OD ¾"	TC 1"½ OD 1"
Fractions lines	TC ¾" OD ¼"	TC ¾" OD ¾"	TC 1"½ OD 1"
CIP inlet line	TC ¾" OD ⅜"	TC 1"½ OD 1"	TC 1"½ OD 1"½
Drain	TC ¾" OD ¾"	TC 1"½ OD 1"	TC 1"½ OD 1"½
Operating Specifications			
Max Fluid Viscosity	2 cP	2 cP	2 cP
Product Temperature Range	+4 to +30 °C	+4 to +30 °C	+4 to +30 °C
Maximum Pressure	4 barg	4 barg	6 barg
System Operating Temperature	+4 to +30 °C	+4 to +30 °C	+4 to +30 °C
Operating Humidity	15–60% (non-condensing)	15–60% (non-condensing)	15–60% (non-condensing)
Operating Specifications			
Valves			
Pneumatic Valves	Diaphragm valves	Diaphragm valves	Diaphragm valves
Pumps			
Feed Pump P001	**Diaphragm pump flow rate:** 0.05–3 L/min	**Diaphragm pump flow rate:** 0.3–20 L/min	**Diaphragm pump flow rate:** 0.83–40 L/min
Feed Pump P002	Same pump, included	Same pump, optional	Same pump, included
UV			
UV sensor	**Measurement range:** 0 to 3 AU +/–0.04	**Measurement range:** 0 to 2 AU +/–0.04	**Measurement range** 0–2 AU +/–0.04
OPL options	2 mm	2.5 mm 5 mm 10 mm	2.5 mm 5 mm 10 mm
Wavelengths options	**Dual wavelength:** 250–280 nm	**Single wavelength:** 254 nm 280 nm 300 nm 313 nm **Dual wavelength:** 254 nm, 280 nm 254 nm, 313 nm 254 nm, 300 nm 280 nm, 300 nm 280 nm, 313 nm 300 nm, 313 nm	**Single wavelength:** 254 nm 280 nm 300 nm 313 nm **Dual wavelength:** 254 nm, 280 nm 254 nm, 313 nm 254 nm, 300 nm 280 nm, 300 nm 280 nm, 313 nm 300 nm, 313 nm
Probes			
Flowmeters	Range: 0, 15–4 L/min +/–1% MV	Range: 1–25 L/min +/–1% MV	Range: 4–50 L/min +/–1% MV
Conductivity sensors	**Pre-column process range:** 1–100 mS/cm +/–3% MV – 100–200 mS/cm +/–5% MV **Post-column process range:** 1–100 mS/cm +/–3% MV – 100–200 mS/cm +/–5% MV **Post-column cleaning range:** 1–50 µS/cm +/–3% MV	**Pre-column process range:** 0–200 mS/cm +/–4 mS/cm **Post-column process range:** 0.1–200 mS/cm +/–4 mS/cm **Cleaning range:** 0.1–50 µS/cm +/–1 µS/cm	**Pre-column process range:** 0–200 mS/cm +/–4 mS/cm **Post-column process range:** 0.1–200 mS/cm +/–4 mS/cm **Cleaning range:** 0.1–50 µS/cm +/–1 µS/cm
pH sensor	**Range:** 0–14 pH +/–0.2	**Range:** 0–14 pH +/–0.1	**Range:** 0–14 pH +/–0.1

We offer an extensive portfolio of chromatography products to support your process from start to finish.

Affinity Media

Eshmuno® P Anti A/B
Eshmuno® A
Fractogel® EMD Chelate (M)

CEX Media

Eshmuno® S
Eshmuno® HCX
Eshmuno® CPX
Eshmuno® CP-FT
Eshmuno® CPS
Eshmuno® CMX
Fractogel® EMD SO_3^- (S)
Fractogel® EMD SE Hicap (M)
Fractogel® EMD COO^- (M)

AEX Media

Eshmuno® Q
Fractogel® EMD TMAE (S), (M)
Fractogel® EMD TMAE Hicap (M)
Fractogel® EMD TMAE Medicap (M)
Fractogel® EMD DEAE (M)
Fractogel® EMD DMAE (M)

Single-use Membrane Adsorber

Natrix® Q

Reversed Phase Media

LiChroprep® RP product range
PharmPrep™ P100 RP-18e
PharmPrep™ P100 RP-8e

Prepacked Columns

MiniChrom®
RoboColumn®
HiBar®
OPUS® 5 cm–80 cm (ID)

Chromatography Membrane

QuikScale®
IsoPak™
Vantage®

To place an order or receive technical assistance:
SigmaAldrich.com/support

For local contact information:
SigmaAldrich.com/offices

MilliporeSigma
400 Summit Drive
Burlington, MA 01803

SigmaAldrich.com

We have built a unique collection of life science brands with unrivalled experience in supporting your scientific advancements.

Millipore® Sigma-Aldrich® Supelco® Milli-Q® SAFC® BioReliance®

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