GLOBAL LEADER IN ANALYTICAL
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Sepax Technologies, Inc.

Process Media Product Catalog

Sepax Technologies, Inc.

Innovative Chromatography Technology

Sepax Technologies, Inc

Since 2002, Sepax Technologies, a Delaware US-based company, has been providing innovative liquid chromatography products and services and has emerged as a leader in the biological separation and purification industry. Sepax specializes in the development and manufacture of HPLC analytical columns, preparative and process media, and medical diagnostics products in a wide range of modalities, such as SEC, IEX, HIC, Affinity, Mixed Mode and RP. Sepax also provides LC services, including analytical testing, method development and optimization, purification, custom resin development, and ligand immobilization.

Certified to the ISO 9001-2015 standards, Sepax focuses on customer & market needs, and is continuing to expand its presence and supply chain around the globe in three business platforms: Analytical Chromatography, Industrial Purification and Medical Diagnostics.

A SPECIALIZED AND INNOVATIVE

CHROMATOGRAPHY EXPERT

Three
Global Locations

Annual Manufacturing Capacity
100,000L

Global Customers
5,000+

Patents
60+

Innovative Technology
Superior

Publication Reference
1000+

Affinity

Multimodal

IEX

HIC

SEC

RP

Generik FPLC

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Sepax Technologies, Inc.

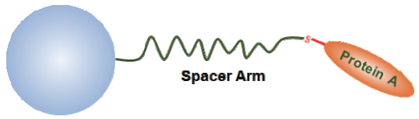
MabPurix P45
Polymer-Based Protein A Affinity Resins

Introduction

MabPurix P45 affinity resins are made from monodispersed porous polymethacrylate based beads with average particle size of 45 µm. The base beads are treated with proprietary coating technology to provide hydrophilicity and bio-inertness to avoid non-specific binding, and then are covalently bonded with a base resistant recombinant Protein A through a proprietary method. MabPurix P45 affinity resins are specifically designed for purification of biomolecules such as monoclonal antibodies, bispecific antibodies and Fc fusion proteins.

Resin Structure

Figure 1. MabPurix P45 affinity resin structure



Features

- High binding capacity
- High alkaline resistance (0.5 M NaOH)
- Low level of Protein A leaching and residual HCP
- Fast binding affinity with less residence time and lower pressure
- Hydrophilic, biocompatible, negligible non-specific binding
- Pass FDA DMF filing for direct FDA application regulatory reference
- Supply Capacity: >200 L/Batch

Technical Specifications

Type	MabPurix P45
Matrix	PMA
Particle Size	45 µm
Ligand	rProtein A (alkaline resistant)
DBC	50 mg hIgG/mL resin (4 min residence time)
Maximum back pressure	1 MPa
pH stability	3-12
0.5 M NaOH Stability	Soaking 25 h, DBC > 80%
CIP	Up to 0.5 M NaOH
Storage	20% EtOH or 2% Benzyl alcohol 2-8℃

Figure 2. MabPurix P45 Scanning electron microscope image

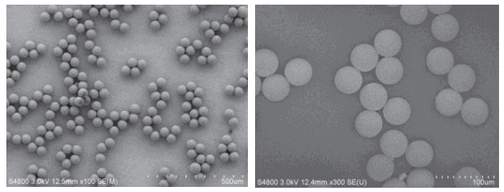
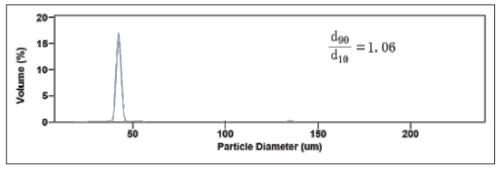


Figure 3. MabPurix P45 Particle Size Distribution



Performance Characteristics

(1) Monodispersed size distribution: particle sizes are 45 µm, which are monodispersely distributed, D90/D10 ≤ 1.3.

(2) Faster protein mass transfer: the variation of DBC is small within the 1.5-6.0 min residence time. MabPurix P45 affinity resins improves downstream purification process for biologic targets and increases productivity under the same conditions of the column dimensions and the resin bed volume.

(3) Faster flow rate: Compared to conventional agarose beads, polymethacrylate base beads have improved the pressure resistance, which enables the more productive purification run at a higher flow rate with reduced total run time, as well as the possibility of packing a longer column and processing more cycles and batches of biological samples). For some less stable biologics, which require faster purification, MabPurix P45 affinity resins can not only increase production throughput but also improve yield and product quality.

Figure 4 .MabPurix P45 Pressure - Linear Flow Rate

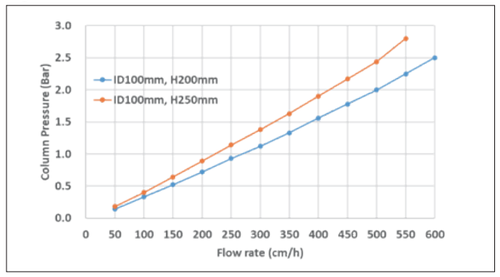
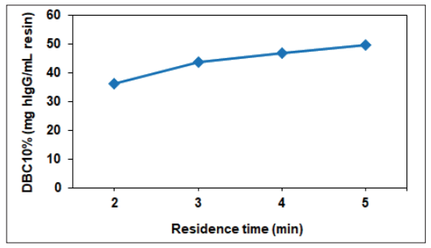
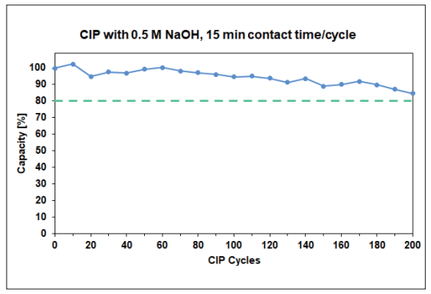


Figure 5 MabPurix P45 DBC vs. Residence Time



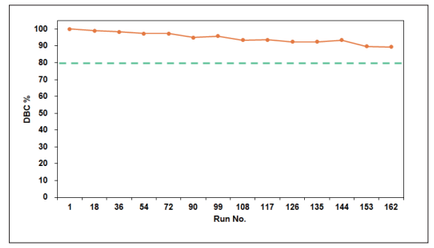
MabPurix P45 DBC = 50 mg/mL @ 5 min residence time

Figure 6 MabPurix P45 CIP with 0.5M NaOH



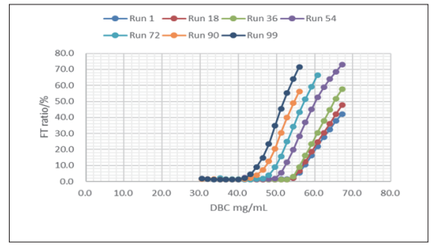
MabPurix P45 used 0.5 M NaOH for CIP, and the DBC remained above 80% of the initial DBC after 200 cycles.

Figure 7 MabPurix P45 Lifetime Test of Monoclonal Antibody Purification



MabPurix P45 used 0.1 M and 0.5 M NaOH CIP alternatively in the alkali resistance test, and the DBC remained above 80% of the initial DBC after 160 cycles.

Figure 8 MabPurix P45 Lifetime Test of Monoclonal Antibody Purification



No early flowthroughs were observed during the monoclonal antibody purification on MabPurix P45.

FDA DMF filing

FDA U.S. FOOD & DRUG ADMINISTRATION

MASTER FILE ACKNOWLEDGEMENT
Februarv 10. 2022

MF #: 28059

MF Holder: Sepax Technologies, Inc.

MF Title: Master File Type II – "Affinity Chromatographic Resins (MabPurix™) "

Submission Date: January 26, 2022

On February 10, 2022, Sepax Technologies independently developed and patented MabPurix A/P series protein A affinity resins passed the FDA DMF filing (MF #: 28059). Customers who use Sepax Technologies-related products can directly refer to the DMF filing materials in the regulatory filing documents submitted to FDA for new drug registration without providing specific information about raw materials and excipients.

Ordering Information

Product Name	Particle Size (µm)	Part Number
MabPurix P45	45	270845990

Cartridge Size:1,4.2 ,5 mL, Pack Size: 5 L and under,10 L,50 L

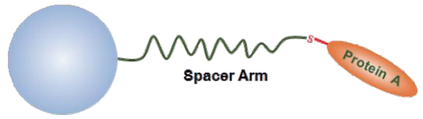
MabPurix A45&A65
Agarose Based Protein A Affinity Resins

Introduction

MabPurix A45 and A65 affinity resins use spherical, narrow dispersed, highly cross-linked agarose gel as the base matrix. Through the unique proprietary linker and coating technology, the agarose matrix is bonded to the alkaline resistant recombinant Protein A ligand, which is specifically designed for purification of biomolecules such as mono-clonal antibodies, bispecific antibodies and Fc fusion proteins. MabPurix A affinity resins have higher pressure resistance than regular agarose gel based resins.

Resin Structure

Figure 1 MabPurix A45 and A65 affinity resin structure



Features

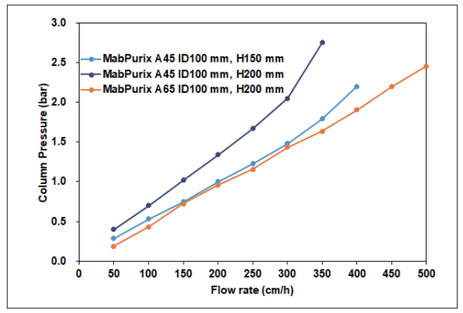
- High DBC Capacity
- Low level of Protein A Leaching and residual HCP
- Fast binding affinity with less residence time
- Hydrophilic, biocompatible, negligible non-specific binding
- High pH resistance (0.5 M NaOH)
- Low pressure
- Small volume change under standard packing condition
- High pressure resistance

Technical Specifications

Type	MabPurix A45	MabPurix A65
Matrix	Agarose	
Particle Size	45 μm	65 μm
Ligand	rProtein A (alkaline resistant)	
DBC	70 mg hIgG/mL resin	53 mg hIgG/mL resin
Maximum back pressure	0.3 MPa	
pH stability	3-12	
0.5 M NaOH Stability	Soaking 25 h, DBC > 70%	
CIP	Up to 0.5 M NaOH	
Storage	20% EtOH or 2% Benzyl alcohol 2-8℃	

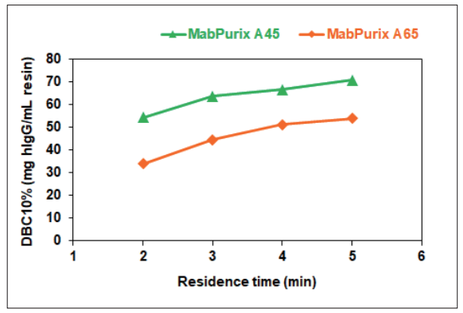
Performance Characteristics

Figure 2 MabPurix A45/A65 Pressure - Linear Flow Rate



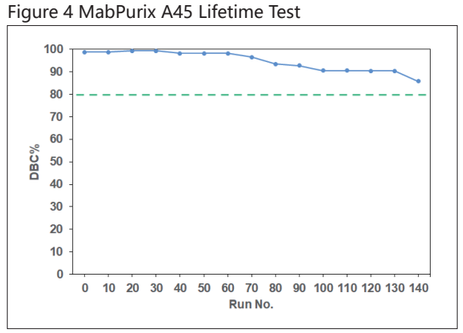
Mobile Phase: 1 M NaCl

Figure 3 MabPurix A45/A65 DBC vs. Residence Time



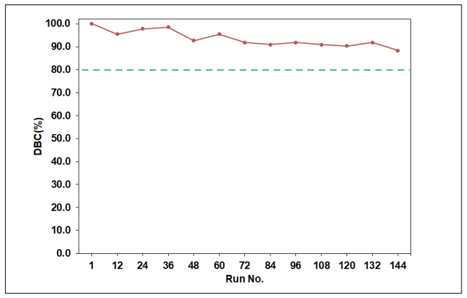
MabPurix A45 DBC is 70 mg/mL and MabPurix A65 DBC is 53 mg/mL @ 5 min residence time

Figure 4 MabPurix A45 Lifetime Test



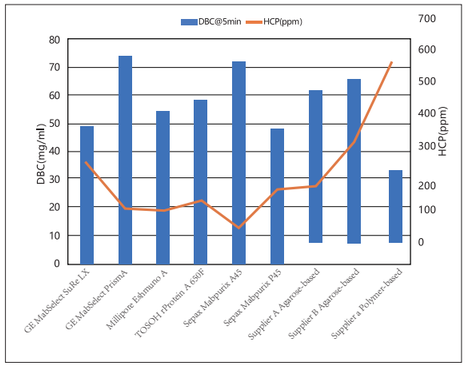
MabPurix A45 used 0.1 M NaOH and 0.5 M NaOH alternatively for CIP in the lifetime test of monoclonal antibody purification, and the DBC remained above 80% of the initial DBC after 150 cycles.

Figure 5 MabPurix A45 Lifetime Test



MabPurix A45 used 0.1 M NaOH and 0.5 M NaOH alternatively for CIP monoclonal antibody purification, and the DBC remained above 80% of the initial DBC after 150 cycles.

Figure 7 Affinity Resins Competition
Comparison - DBC and HCP: MabPurix vs. Other Brands



Scalability

MabPurix Affinity Resins have been successfully used in various manufacturing and clinical III GMP production stage of monoclonal antibody projects

Column Picture(800 mm ID x 18.5 cm, < 1 bar column pressure)

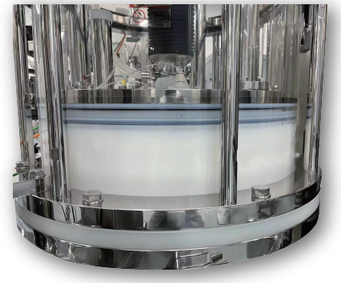
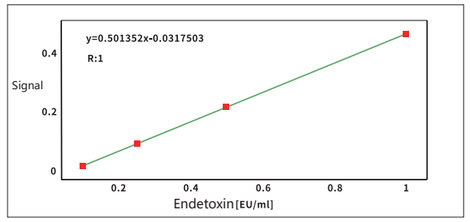


Figure 6 MabPurix Affinity Resin - Control of Endotoxin Level

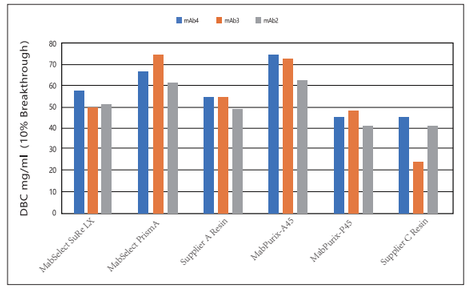


Sample	OD	Endotoxin (EU/mL)
MabPurix A45	0.2235	0.5091

As shown in Figure 6, the endotoxin level of MabPurix A45 is 0.51 EU/mL.

Figure 8 Affinity Resins Competition

Comparison - DBC @ 5 min Residence Time: MabPurix vs. Other Brands



Ordering Information

Product Name	Particle Size (μm)	Part Number
MabPurix A45	45	270745990
MabPurix A65	65	270765990

Cartridge Size: 1,4.2 ,5 mL, Pack Size: 5 L and under,10 L,50 L

Monomix dT20 mRNA Affinity Resin

Introduction

Sepax Monomix dT20 Affinity Resin is based on 30 μm narrowly dispersed polymethacrylate rigid beads functionalized with a polyhydroxylated surface coating layer that provides a bio-inert surface and shows low non-specific binding. Oligo dT20-mer is conjugated to the bead surface through a proprietary technology. The resulting affinity resin is specifically designed and highly optimized for the isolation of messenger RNA (mRNA).

Most mRNA molecules contain a tail of poly(adenylic acid) (polyA tail). The Monomix dT20 Affinity Resin surface allows capture of mRNA through base pairing between oligo dT20-mer and the mRNA polyA tail using a simple and convenient chromatography process.

Features

- Provide efficient capture and release under standard mRNA purification conditions, simplify subsequent purification steps, and maximize overall production efficiency.
- Decreases process development time and enhances productivity.
- Allows reduction in plasmid DNA and other transcription mix components.
- Stable at elevated temperatures for the breakdown of undesired higher order structures, if needed.
- Excellent scalability. Provide prepacked columns, semi-prep column, prep column and bulk resin.
- Non-animal derived

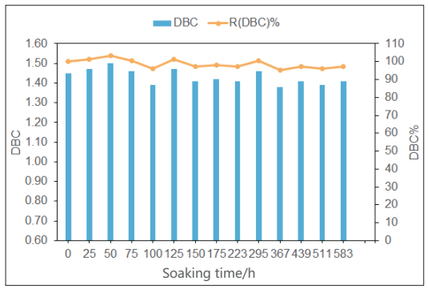
Technical Specifications

Resin Type	Monomix dT(20)
Base Matrix	Hydrophilic polymethacrylate
Particle Size D50	30 μm
Average Pore Size	1000 Å
Functional Group	Oligo dT20-mer
dT20 ligand density	≥2.0 mg/mL resin
Dynamic Binding Capacity Based on Oligo A40	≥0.75 mg/mL resin
Operating Temperature	4-65 °C
pH Stability	2-12
Operating Pressure (Process FPLC Condition)	≤10 bar (1 MPa)
Operating Pressure (Analytical HPLC Column)	≤100 bar (10 MPa)
Long-term Storage	Store in 20% ethanol aqueous solution, 2-8℃. Do not freeze resin or column.
CIP	0.1-0.5M NaOH. Recommend starting with 0.1M NaOH to prolong resin life

DBC test used 1000 nt mRNA sample under condition: 10 mM Tris-HCl, 1 mM EDTA, 5 mM DTT, 1.0 M NaCl, pH 7.0

Performance Characteristics

Figure 1 Monomix dT20 Affinity Resin 0.5 M NaOH Soaking Test



Monomix dT20 resin was soaked for 583h, DBC remained above 90% of the initial value, which demonstrates its good alkaline resistance.

Applications

Figure 2: mRNA sample purification - sample loading 2 mg/mL

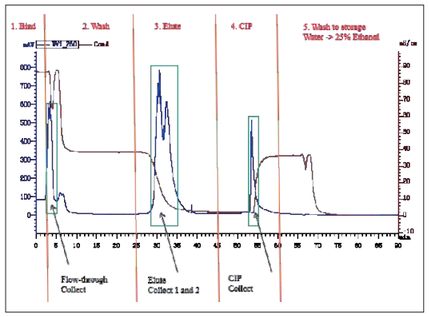
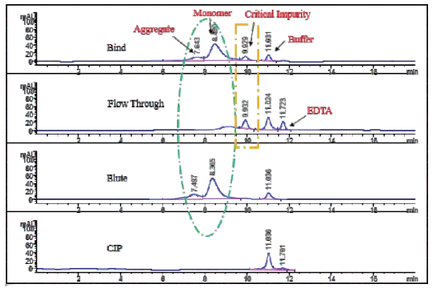


Figure 3: mRNA sample purification - purity of the target in the elution fraction is > 95%



Ordering Information

Product Name	Particle Size	Part Number
Monomix dT20	30 μm	283030950

Cartridge Size:1,4.2 ,5 mL,
Pack Size: 5 L and under,10 L,50 L

Proteomix POR50-dT20 mRNA Affinity Resin

Introduction

Sepax Technologies Proteomix POR50-dT20 mRNA Affinity Resin is based on 50 μm hydrophilic polymethacrylate beads with a perfusive porous structure with large through pores, and has good physical and chemical stability as well as good pressure resistance. The base beads are treated with proprietary coating technology to provide hydrophilicity and bio-inertness to avoid non-specific binding. The Oligo dT20-mer was then bonded to the surface through the proprietary surface modification technology. The resulting affinity resin is specially designed and highly optimized for the isolation of messenger RNA (mRNA).

Most mRNA molecules contain a tail of poly(adenylic acid) (polyA tail), up to 250 bases in length. The Proteomix POR50-dT20 Affinity Resin surface allows capture of mRNA though base pairing between oligo dT20-mer and the mRNA polyA tail using a simple and convenient chromatography procedure.

Features

- Provide efficient capture and release under standard mRNA purification conditions, simplify subsequent purification steps, and maximize overall production efficiency.
- The ultra-large pore sizes enable high loading capacity of long-chain large size mRNAs, easier to elute with a higher recovery.
- Decreases process development time and enhances productivity.
- Allows reduction in plasmid DNA and other transcription mix components.
- Stable at elevated temperatures for the breakdown of undesired higher order structures, if needed.
- Excellent scalability. Provide prepacked columns, semi-prep column, prep column and bulk resin.
- Non-animal derived

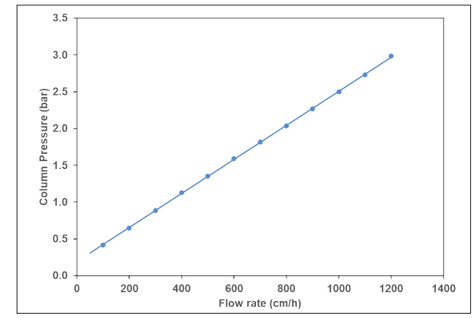
Technical Specifications

Resin Type	Proteomix POR50-dT20
Base Matrix	Hydrophilic polymethacrylate
Functional Group	Oligo dT20
Particle Size	50 μm
DBC (based on Oligo A40)	≥0.75 mg/mL resin
mRNA Binding Capacity *	≥2.0 mg/mL resin
Operating Pressure	≤1 MPa (10 bar)
pH Stability	2-12
Operating Temperature	4-65 °C
Long-term Storage	2-8ºC, Store in 20% ethanol aqueous solution
CIP	0.1 M NaOH

* mRNA binding capacity test is based on 1000 nt mRNA samples, Binding condition is 10 mM Tris-HCl, 1 mM EDTA, 5 mM DTT, 1.0 M NaCl, pH 7.5.

Performance Characteristics

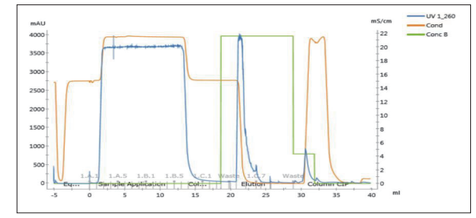
Figure 1. Proteomix POR50-dT20 Affinity Resin Pressure - Linear Flow Rate



Proteomix POR50-dT20 has low back pressure, e.g. pressure is at 0.75 bar at ~200 cm/h normal linear flow rate.

Applications

Figure 2. Purification of mRNA Sample (2.6 mg/mL)



Ordering Information

Product Name	Particle Size	Part Number
Proteomix POR50-dT20	50 μm	2221509D0

Cartridge Size:1,4.2 ,5 mL,
Pack Size: 5 L and under,10 L,50 L

Monomix MC-Boronate Affinity Resins

Introduction

Sepax Monomix MC-Boronate affinity resins are designed to purify and analyze cis-diol containing compounds, such as glycoproteins, nucleic acids and sugars. The base beads are monosized, composed of hydrophilic polymethacrylate (PMA) of high physical and chemical stability, with m-Aminophenyl boronate covalently linked using a proprietary hydrophilic linker. This highly hydrophilic resin surface allows for minimized non-specific bindings with biological samples. The resin is currently offered with particle sizes of 30 and 60 µm and pore size of 1000 Å. The exclusion limit of dextran is approximately 2 x 106, and the exclusion limit of globular proteins is approximately 1 x 10^7, suitable for industrial purification

Resin Structure

Figure 1. MC-Boronate affinity resin structure

Technical Specifications

Resin	Monomix MC30-Boronate	Monomix MC60-Boronate
Base Bead Material	Monosized Hydrophilic Polymethacrylate	
Particle Size (µm)	30 µm	60 µm
Pore Size (Å)	1000 Å	
Boronate Loading (µmol/mL resin)	30-80	
Max Linear Flow Rate (cm/h)	1800 cm/h	
Operation Temperature (°C)	≤40℃	
pH Stability Range	2-12	
Operation Pressure	≤1 Mpa(10 bar)	
Mobile Phase Compatibility	1. Compatible with aqueous solution, water mixed with acetonitrile, acetone or methanol. Typical buffers: phosphate, acetate and HEPES, MES, primary amine-free salt buffer system. 2. The use of buffers pH<6.5 or cis-diol-containing reagents may affect adsorption.	
Long-term Storage	Store in 20% ethanol aqueous solution, 50% (v/v)	
Regeneration	Use 2.0–3.0 M NaCl	
CIP	Use 3-10 column volume of 0.1-0.5 M NaOH under 2-10 °C	

Ordering Information

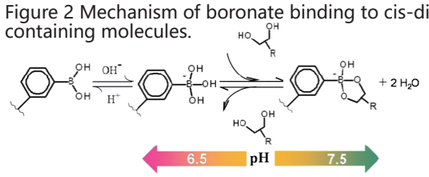
Product Name	Particle Size(µm)	Part Number
Monomix MC30-Boronate	30	283430950
Monomix MC60-Boronate	60	283460950

Cartridge Size:1,4.2,5 mL, Pack Size: 5 L and under,10 L,50 L

Purification Mechanism

Boronate binds to molecules with a cis-diol functional group in a pH dependent way. The mechanism has been suggested that under mild basic conditions, coplanar cis-diol containing molecules bind to boronate to reversibly form a thermodynamically favored five-member ring. The binding is more stable at pH>7.5, while dissociation occurs at pH while dissociation occurs at pH<6.5. The binding can be enhanced in the presence of Mg2+. The diol containing molecules in the boronate complex can also be removed or eluted with other cis-diol reagents, such as sorbitol and mannitol.

Figure 2 Mechanism of boronate binding to cis-diol containing molecules.



Resin Characteristics

- High binding capacity and excellent biocompatibility
- Capable of withstanding high pressure and high flow rate due to rigid base bead material
- High separation resolution, efficiency and recovery
- High lot-to-lot consistency
- Easy to scale up
- Highly hydrophilic surface with minimal non-specific binding
- Small volume change under normal packing conditions

Monomix MC-NTA IMAC Affinity Resins

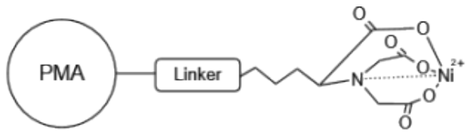
Introduction

Monomix MC-NTA IMAC resin is a metal affinity chromatography (IMAC) suitable for purification of recombinant proteins with a histidine (His) tag, which are widely used in the biotech industry. It is based on hydrophilic polymethacrylate beads with the particle size of 60 µ m and pore size of 1000 Å, and has high physical and chemical stability. The base beads are treated with proprietary coating technology to provide hydrophilicity and bio-inertness to avoid non-specific binding. On the hydrophilic surface, carboxylic acid groups that can chelate polyvalent metal ions are attached with a proprietary linker optimized for bioseparations.

Monomix MC-NTA IMAC resins have two types: free acid type (Monomix MC-NTA CA) and chelated nickel ion type (Monomix MC-NTA Ni). Free acid type can be used for removal of metal ions, and other metal ion types of packing can also be customized according to the customers' requirements and can be reused. These two types of IMAC resin have the following structures shown in Figure 1.

Figure. 1 Resin structure of Monomix MC60-NTA

Monomix MC60-NTA CA



Monomix MC60-NTA Ni

The resin has high chemical stability and can tolerate 0.1-0.5 M NaOH solution for CIP. It is not strongly resistant to EDTA and DTT. Recharge metal ions may be needed after certain cycles of use.

Technical Specification

Resin type	Monomix MC60-NTA Ni	Monomix MC60-NTA CA
Base Matrix	Hydrophilic polymethacrylate	
Particle size	60 µm	
Pore size	1000 Å	
His-tag protein loading	≥30 mg/mL	>100 µeq./mL
Maximum linear flow rate(cm/h)	≤1800 cm/h	
Operating temperature	≤40°C	
pH Range	1-13	
Maximum pressure	≤1 MPa (10 bar)	
Compatible Mobile Phases	Compatible with aqueous solution, a mixture of water and acetonitrile, ethanol, etc. Typical buffers: Tris, phosphate, and acetate; Also compatible with 6 M guanidine hydrochloride and 8 M urea	
Storage	50% (v/v) in 20% ethanol	
Regeneration	0.1-0.5 M NaCl	
CIP	0.1-0.5 M NaOH	

Ordering Information

Product Name	Particle Size	Part Number
Monomix MC60-NTA CA	60 µm	285560950
Monomix MC60-NTA Ni	60 µm	285460950

Cartridge Size:1,4.2 ,5 mL,
Pack Size: 5 L and under,10 L,50 L

Polar MC IMAC Affinity Resins

Introduction

Sepax Polar MC-IMAC Excel resins are metal affinity chromatography (IMAC), suitable for the purification of recombinant proteins with a histidine (His) tag, which are widely used in the biotech industry. The resins are composed of hydrophilic polymethacrylate (PMA) base beads with high physical and chemical stability. The resins have particle sizes of 30 µm or 60 µm and a pore size of 800 Å. The surface of the resins is highly hydrophilic, which minimizes non-specific adsorption with biological samples. On the hydrophilic surface, carboxylic acid groups that can chelate polyvalent metal ions are attached with a proprietary linker optimized for bioseparations.

Polar MC-IMAC resins have two types: free acid type (Polar MC30-CA Excel or Polar MC60-CA Excel, carboxylic acid) and chelated nickel ion type (Polar MC30-Ni Excel or Polar MC60-Ni Excel). Free acid type can be used for metal ion removal, and other metal ion type resins can also be customized according to customer requirements. The structure of these two types of IMAC resins is shown in Figure 1.

Figure 1a. S Polar MC30/60-CA Excel resin structure

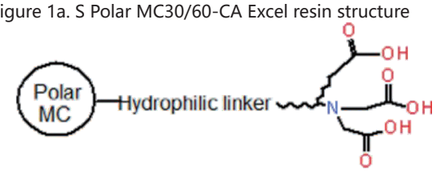
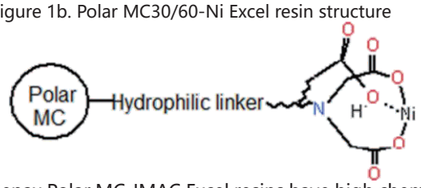


Figure 1b. Polar MC30/60-Ni Excel resin structure



Sepax Polar MC-IMAC Excel resins have high chemical stability and can withstand 100 cleaning cycles using 0.5M NaOH solution. The metal ion chelated resins can be washed with 0.1 M ethylenediaminetetraacetic acid (EDTA) without loss of metal ions. Thus, no recharge of metal ion is necessary after each use. Both products can be offered as bulk resins, FPLC columns, or conventional HPLC columns.

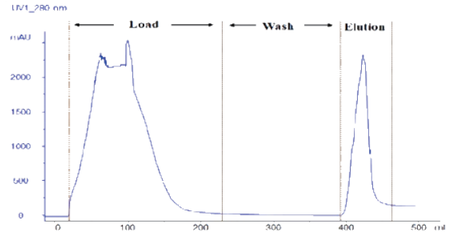
Technical Specifications

Product	Polar MC30-CA Excel, Polar MC30-Ni Excel, Polar MC60-CA Excel,Polar MC60-Ni Excel
Matrix	Hydrophilic polymethacrylate
Particle Size	20 - 45 µm (average 30 µm) 45 - 90 µm (average 60 µm)
Pore Size	800Å
pH Stability	Polar MC-CA Excel: 1-13 Polar MC-Ni Excel: 1-13
Loading Capacity	Polar MC30-CA Excel: >120 µeq. carboxylic group /mL Polar MC30-Ni Excel: 40-60 µeq. Ni2+ /mL Polar MC60-CA Excel: >100 µeq. carboxylic group /mL Polar MC60-Ni Excel: 40-60 µeq. Ni2+ /mL
HIS-Protein Loading	Polar MC30-Ni Excel, ~20 mg/mL Polar MC60-Ni Excel, ~15 mg/mL
Linear Flow Rate	≤ 1800 cm/hour
Operation Temperature	≤ 40 °C
Maximum Pressure	≤ 3 MPa (30 bar)
Compatible Mobile Phase	Aqueous solutions, or a mixture of water and acetonitrile, acetone or methanol. Commonly used buffers: phosphate, Tris and acetate, also compatible with 6M guanidine hydrochloride, 8M urea, 0.1M EDTA, 10mM DTT
Packing	50% (v/v) in 20% ethanol aqueous solution

Application

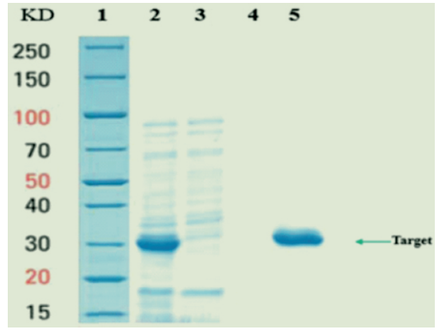
The resins can be used as batch mode or column mode as shown in Figure 2. A crude His-tagged protein 300 mL was loaded to 15 x 220 mm Sepax Generik FPLC column (PN# 202000-1525-AF) packed with Polar MC60-Ni Excel resin. After washing with a loading buffer, the targeted protein was eluted at a flow rate of 7.5 mL/min with 500 mM imidazole in 25 mM sodium phosphate pH 8 buffer. The collected fractions were confirmed with 10% tris-glycine SDS-Pages.

Figure 2. Purification of an exemplary His-tagged protein on Polar MC60-Ni Excel.



Load: Crude His-tagged protein in 25 mM sodium phosphate pH 8, 0.5 M NaCl was loaded onto Polar MC60-Ni Excel resin at a flow rate of 5.0 mL/min.
Wash: The column was washed with 25 mM sodium phosphate pH 8, 0.5 M NaCl.
Elute: The target His-tagged protein was eluted with 25 mM sodium phosphate pH 8, 0.5 M NaCl, 0.5 M Imidazole. Each fraction was collected.

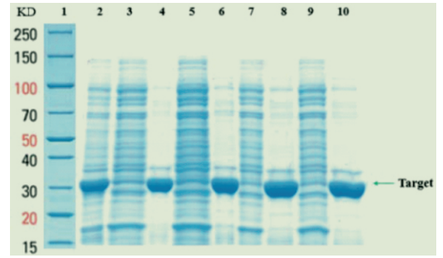
Figure 3. 10% Tris-Glycine SDS-Page analysis of fractions collected from the above purification .



Lane 1: Molecular weight ladder
Lane 2: Crude His-tagged protein sample
Lane 3: Flowthrough collected as the sample was loaded onto the column
Lane 4: washing fraction after the sample loaded
Lane 5: Elution of the target with 500 mM imidazole

Caustic stability and reusability of the IMAC Excel resin are demonstrated as the resin can tolerate 90 column volume wash with 0.5 M NaOH (Figure 4). After each 30 cycle wash with 0.5 M NaOH at flow rate of 0.25 column volume/min with a total contact time of 2 hrs, the resin was repeatedly used for the purification of the same His-tagged protein. The result showed the resin binding character remained the same.

Figure 4. 10% Tris-Glycine SDS-Page analysis of fractions collected from the above purification



Lane 1: Molecular weight ladder
Lane 2: Crude His-tagged protein sample
Lane 3: Flowthrough collected as sample the was loaded on the fresh column
Lane 4: Elution of the target with from fresh Ni column
Lane 5: Flowthrough collected after column was cleaned with 30 column volumes of 0.5 M NaOH at a flow rate of 0.25 column volume/min with a total 2 hrs contact time
Lane 6: Elution of the target from Ni column cleaned with 30 column volumes of 0.5 M NaOH
Lane 7: Flowthrough collected after column was cleaned with another 30 column volumes of 0.5 M NaOH at a flow rate of 0.25 column volume/min with a total 2 hrs contact time
Lane 8: Elution of the target from Ni column cleaned with another 30 column volumes of 0.5 M NaOH
Lane 9: Flowthrough collected after column was cleaned with a third 30 column volumes of 0.5 M NaOH at a flow rate of 0.25 column volume/min with a total 2 hrs contact time
Lane 10: Elution of the target from Ni column cleaned with a third 30 column volumes of 0.5 M NaOH

Ordering Information

Product Name	Particle Size(µm)	Part Number
Polar MC30-CA Excel	30	270530800
Polar MC30-Ni Excel	30	270630800
Polar MC60-CA Excel	60	270560800
Polar MC60-Ni Excel	60	270660800

Cartridge Size:1,4.2,5 mL, Pack Size: 5 L and under,10 L,50 L

Monomix Core
Core-Shell Structured Multimodal Resin

Introduction

Monomix Core series core-shell structured multimodal resin is specifically designed for the separation and purification of biological macromolecules. It is a novel polymeric chromatographic medium with a core-shell(s) hierarchical layer structure, a narrow size distribution, and desired porous structure, which combines a size exclusion separation and various binding chemistries. The shell layer of Monomix Core is modified with hydrophilic groups, which effectively enhances the hydrophilicity of the separation medium, and then minimizes the nonspecific binding (NSB) of biomolecules.

Through surface modification technologies developed by Sepax Technologies, Inc., the core and shell layers of Monomix Core chromatographic media can be modified upon specific separation requests, with functional groups of choice and precise control over the desired density of coverage. Hence, the key chromatographic features of Monomix Core chromatographic media such as bead size, bead size uniformity, shell thickness and its uniformity, porous structure, functional group density in both shell layer and core layer, etc. can be consistently controlled and optimized to enhance certain properties.

The first commercial product of this family is composed of mono-size beads with an average bead size in 60 µm with the pore sizes of 1000 Å and 500 Å. The monodisperse particles provide good physical and chemical stability. And the resin can be broadly applicable to separation and purification of various types of biomolecules, such as proteins, antibodies, viruses, viral vectors, vaccines, DNA, RNA, Plasmid, LNP (lipid nanoparticles), etc.

Resin Structure

Figure 1. 3D Schematic Diagram of Monomix Core Resin

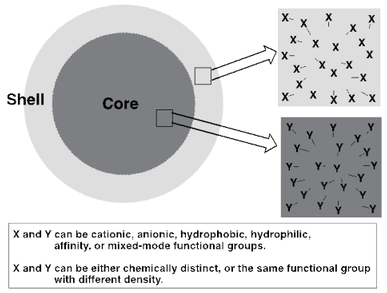


Figure 2. SEM of Monomix Core Resin Mono-sized porous beads with core-shell structure (D50 = 59.1 µm)

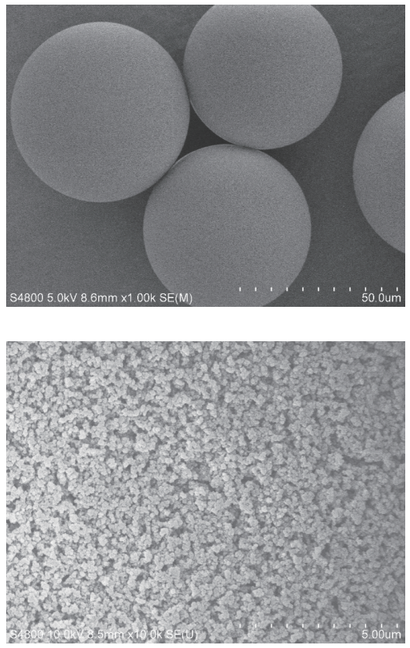


Figure 3. Visualization of core-shell hierarchical structure: CLSM studies of Monomix Core Series labeled with Congo Red in the intermediate layer and EDANS in the outer layer.

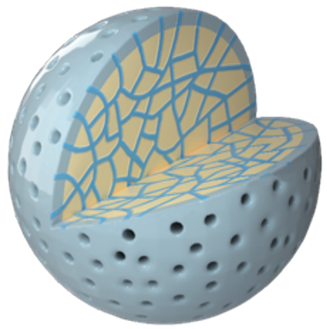
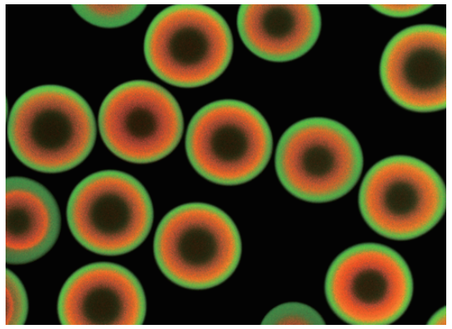


Figure 4. Schematic diagram of core-shell hierarchical layer structure. Monomix Core with core-shell two-layer structure.



Features

- Sepax Technologies Inc. owns the intellectual properties (IP) of this innovative technology
- Key chromatographic features such as bead size, bead size uniformity, shell thickness and its uniformity, porous structure, functional group density in both shell layer and core layer, etc. can be consistently controlled and optimized to meet separation and purification challenges of various biomolecules. Customization of chromatographic media with new features, such as mild CIP condition, etc. is feasible.
- Provide a systematic platform solution to new biologics in any stage from analytical characterization to production, and from small scale to full scale production.
- High capture capacity using flow-through mode.
- Excellent bead surface hydrophilicity, negligible nonspecific binding (NSB) to biomolecules, and excellent biocompatibility.
- Robust mechanical stability, excellent tolerance to high pressure and high flow rate.
- High resolution, high column efficiency, and high recovery.
- Excellent batch to batch repeatability & reproducibility.
- Scalable
- Minor bed volume change under common column packing conditions
- Customization is available upon request
- Secure supply chain of raw materials

Technical Specifications

Table 1. Monomix Core Series Technical Specifications

Medium	Monomix Core 1000	Monomix Core 500
Matrix	Polymeric based	
Average Particle Diameter D50 (µm)	60 ± 10	
Particle Size Distribution D_{90}/ D_{10}	≤1.5, mono-sized	
Average Pore Size	~1000 Å	~500 Å
Protein Cut Off MW	700 KDa	400 kDa
Surface chemistry of core layer	Amine	
Surface chemistry of shell layer	Hydrophilic functional groups	
DBC BSA (mg/mL)	> 15	> 12
Ion exchange capacity of core layer (µmol Cl-/mL medium)	80-200	100-300
Maximum linear flow rate	1000 cm/h	
pH stability	2-13	
Operation pressure limit	≤1Mpa (10 bar)	
CIP conditions	1 M NaOH in aqueous solution, or 1 M NaOH in 30% IPA aqueous solution	

Protein Cut-off MW (Capto™ Core VS Monomix Core)

Protein	MW (KD)	pI	Capto™ Core 700 measured value	Monomix Core 1000 measured value
Thyroglobulin	669	5.1	3.9%	1.2%
Apoferritin	450	4.2	2.8%	2.4%
hIgG	150	7.4-8.6	0%	0%
BSA	66	5.1	7.7%	6.7%
Ovalbumin	44.5	4.6	5.0%	5.0%

Ordering Information

Product series	Product Name	Particle/Pore	Part Number
Monomix Core	Monomix Core 1000	60 µm / 1000Å	290160950
	Monomix Core 500	60 µm / 500 Å	290160500

Cartridge Size:1,4.2,5 mL, Pack Size: 5 L and under,10 L,50 L

Multimodal

Monomix Series Ion Exchange Resins

Introduction

Monomix series ion exchange resins are specifically designed for the separation and purification of biological molecules. The resins are composed of hydrophilic polymethacrylate base beads with highly uniformly dispersed (D90/D10<1.3) particle sizes of 15, 30, 45 and 60 µm. Within the Monomix IEX series, Monomix MC resin has a pore size of 500 Å, which is a medium loading ion exchange resin, while Monomix HC has a pore size of 1000 Å and is a high loading capacity ion exchange resin with DBC greater than 80 mg/mL.

The Monomix resin surface is highly hydrophilic, which minimizes non-specific binding with biological samples. On the hydrophilic surface, different functional groups are linked with a proprietary linker and coating technology, which include strong cation exchange group (sulfonic acid), strong anion exchange group (trimethyl quaternary amine) and weak anion exchange group (diethylamine).

Monomix series ion exchange resins can be widely used for the separation and purification of biological samples such as antibody, vaccine, insulin, protein, nucleic acid, heparin, etc.

Resin Structure

Figure 1. Resin structure of Monomix series SP and S cation exchange media

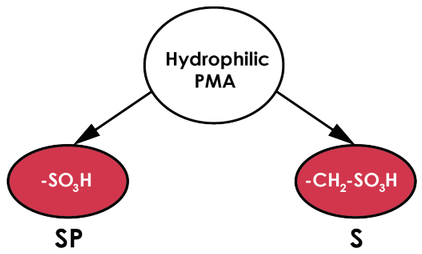
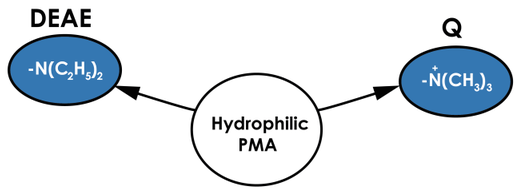


Figure 2. Resin structure of Monomix series Q, DEAE and MAX anion exchange media



Features:

- High binding capacity and excellent biocompatibility
- Rigid beads can be operated at high pressure and fast flow rate
- High resolution, efficiency, and recovery
- Easy to scale up
- Highly hydrophilic surface with minimal non-specific binding
- Small volume change under standard packing condition

Figure 3. SEM of Monomix MC30 (particle size 30 µm). Highly uniformly dispersed medium with very narrow particle distribution (D90/D10 < 1.3)

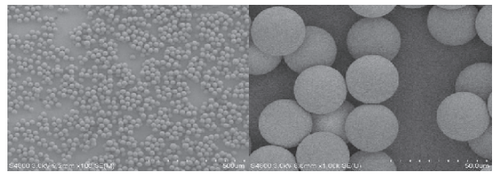
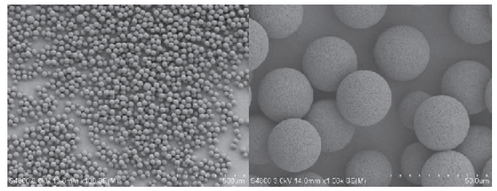


Figure 4. SEM of Monomix HC30 (particle size 30 µm)



Technical Specifications

Table 1.Monomix CEX Technical Specifications

Resin Type	Monomix HC-SP			Monomix Mab60-SP
Matrix	Hydrophilic polymethacrylate			Hydrophilic polymethacrylate
Functional Group	$-SO_3H$			$-SO_3H$
Particle Size	30 µm	45 µm	60 µm	30
Pore Size	1000 Å			1000 Å
DBC (per mL resin)	≥ 90 mg Lysozyme	≥ 85 mg Lysozyme	≥ 90 mg Lysozyme	≥ 60 mg Lysozyme
Maximum Linear Flow Rate	1000 cm/h			
Operation Temperature	≤ 40℃			
pH Range	2-12			
Maximum Pressure	≤ 1 MPa (10 bar)			
Mobile Phase Compatibility	Compatible with aqueous solution (eg. Tris, phosphate, and acetate), a mixture of water and acetonitrile, ethanol, etc.			
Storage	50% (v/v) in 20% ethanol			
Regeneration	1-2 M NaCl			
CIP	0.5 M HCl or 0.5-1.0 M NaOH. Impurities with strong hydrophobic binding can be cleaned with 0.1-1% Tween or Triton X-100			

Table 2.Monomix AEX Technical Specifications

Resin Type	Monomix Mab60-Q	Monomix HC60-Q Excel	Monomix HC60-DEAE Excel
Matrix	Hydrophilic polymethacrylate		
Functional Group	$-N+(CH_3)_3$	$-N^+(CH_3)_3$	$-N(CH_2CH_3)_2$
Particle Size	60 µm	60 µm	60 µm
Pore Size	1000 Å	1000 Å	1000 Å
DBC (per mL resin)	≥ 80 mg BSA	≥ 100 mg BSA	≥ 80 mg BSA
Maximum Linear Flow Rate	1000 cm/h		
Operation Temperature	≤ 40℃		
pH Range	2-14		
Maximum Pressure	≤ 1 MPa (10 bar)		
Mobile Phase Compatibility	Compatible with aqueous solution (eg. Tris, phosphate, and acetate), a mixture of water and acetonitrile, ethanol, etc.		
Storage	50% (v/v) in 20% ethanol		
Regeneration	1-2 M NaCl		
CIP	0.5 M HCl or 0.5-1.0 M NaOH. Impurities with strong hydrophobic binding can be cleaned with 0.1-1% Tween or Triton X-100		

*Dynamic Binding Capacity Test Method:

Monomix HC-SP: linear flow rate at 360 cm/h; Sample solution is 50 mM phosphate buffer with 1 mg/mL lysozyme (pH=6.0).

Monomix HC-Q: linear flow rate at 180 cm/h; Sample solution is 50 mM Tris buffer with 2 mg/mL BSA (pH=8.5).

Monomix HC-DEAE: linear flow rate at 180 cm/h; Sample solution is 20 mM Tris buffer with 2 mg/mL bovine serum protein (pH=8.0).

High DBC Capacity

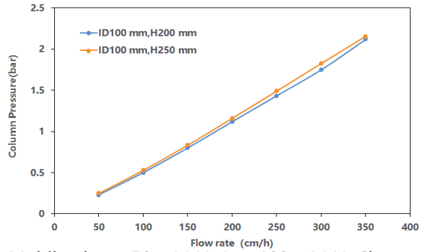
Monomix IEX chromatography resins are composed of hydrophilic polymethacrylate base beads and provide high dynamic binding capacity even at short residence time conditions. Monomix IEX can reduce the downstream purification time and improve the productivity, under the same column size and resin volume for biological sample production; Within the same downstream purification time, Monomix IEX can be operated with longer length columns (larger packing volume), and can process more biological samples in batches, thus improving production efficiency.

Faster operating flow rate

Compared with the traditional agarose matrix, the use of polymethacrylate matrix can improve the pressure resistance of the resin, achieve sample purification at a faster flow rate, thus saving valuable time and improving the production efficiency. For unstable biological samples, the yield and quality control of the product can be improved while improving the production efficiency.

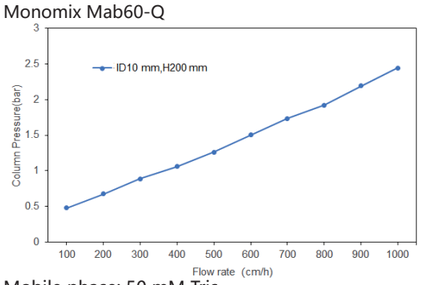
Figure 5. Pressure vs Linear Flow Rate of Monomix IEX resins

Monomix Mab60-SP



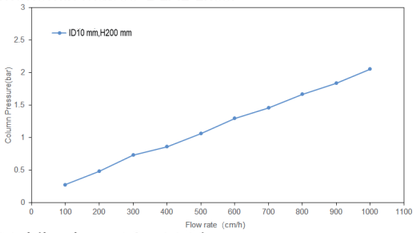
Mobile phase: 50 mM NaAc, 100 mM NaCl

Monomix Mab60-Q



Mobile phase: 50 mM Tris

Monomix Mab60-DEAE Excel

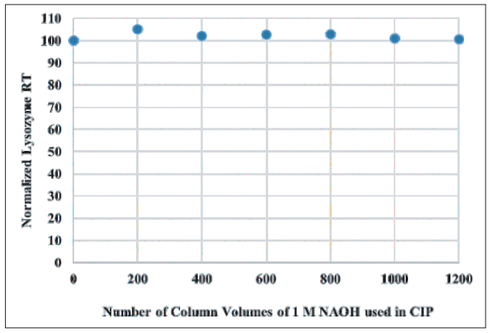


Mobile phase: 50 mM Tris

Ultra-high Alkaline Resistance

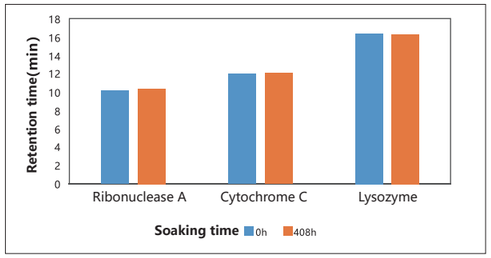
Monomix IEX resin can be used between pH 2-12, and it also shows good alkaline resistance at 1.0 M NaOH CIP cleaning. As shown in Figure 6, the change in the retention time of Lysozyme is negligible when the 1200 column volume of 1.0 M NaOH is applied for CIP cleaning.

Figure 6. Monomix IEX resin resistance to 1.0 M NaOH CIP



Resin: Monomix HC30-SP (30 μm, 1000 Å)
Sample: lysozyme (1 mg/mL)

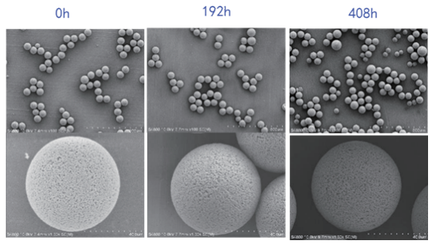
Figure 7. Monomix HC60-SP resin resistance to 0.5 M NaOH - QC



Resin: Monomix HC60-SP (60 μm, 1000 Å)
Sample: Ribonuclease A & Cytochrome C & Lysozyme (5 mg/mL)

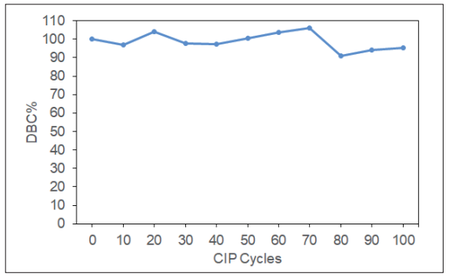
After 408h soaking in 0.5 M NaOH, the RSD% OF QC retention time remains within 2%.

Figure 8. Monomix HC60-SP resin resistance to 0.5 M NaOH



After 408h soaking in 0.5 M NaOH, the spherical shape and pore structure of the resin observed by SEM remain unchanged.

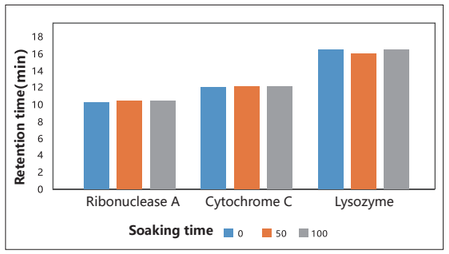
Figure 9. Monomix HC60-SP resin resistance to 1M NaOH CIP (DBC)



Resin: Monomix HC60-SP (60 μm, 1000 Å)
Sample: Lysozyme

The DBC after 1 M NaOH CIP 100 cycles is basically unchanged, and the RSD% of the test result is 3.3%.

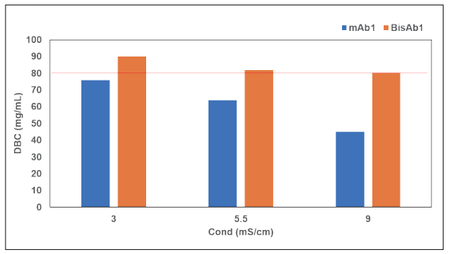
Figure 10. Monomix HC60-SP resin resistance to 1 M NaOH CIP (QC)



Resin: Monomix HC60-SP (60 μm, 1000 Å)
Sample: Ribonuclease A & Cytochrome C & Lysozyme (5 mg/mL)

The QC retention time after 1 M NaOH CIP 100 cycles remains unchanged, and the RSD% of the test result is within 1%.

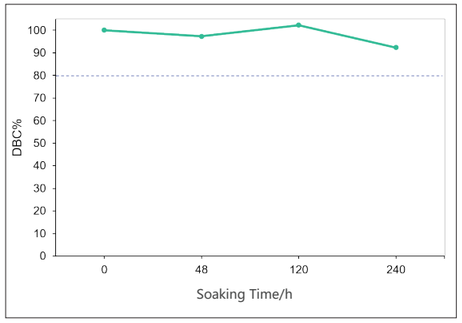
Figure 11. Monomix Mab60-SP Antibody DBC test



Resin: Column: Monomix Mab60-SP (10 × 200 mm)
Sample: Monoclonal Antibody & Bispecific Antibody

Monomix Mab60-SP showed good salt tolerance in the bispecific antibody project.

Figure 12. Monomix Mab60-Q resin resistance to 1 M NaOH Soak



Resin: Monomix Mab60-Q (60 μm, 1000 Å)
Sample: BSA (1 mg/mL)

The DBC remains at more than 80% of the initial value after 240 h of soaking in 1M NaOH solution

Negligible non-specific binding

The surface of Monomix IEX contains multiple hydrophilic domains, which can minimize its non-specific binding when used for biological analysis. As shown in Figure 13, both Monomix Mab60-Q and SP showed the minimum nonspecific binding on samples (lysozyme and bovine serum protein).

Figure 13. 18 consecutive injections of BSA samples on Monomix Mab60-Q resin

Resin: Monomix Mab60-Q (60 μm, 1000 Å)
Sample: 0.5 mg/mL BSA

Ordering Information

Product Name	Functional Group Type	Particle Size / Pore Size	Part Number
Monomix HC30-SP	strong cation exchange group	30 μm, 1000 Å	280630950
Monomix HC45-SP	strong cation exchange group	45 μm, 1000 Å	280645950
Monomix HC60-SP	strong cation exchange group	60 μm, 1000 Å	280660950
Monomix Mab60-SP	strong cation exchange group	60 μm, 1000 Å	284760950
Monomix Mab60-Q	strong anion exchange group	60 μm, 1000 Å	285060950
Monomix HC60-Q Excel	strong anion exchange group	60 μm, 1000 Å	285660950
Monomix HC60-DEAE Excel	weak anion exchange group	60 μm, 1000 Å	285160950

Cartridge Size:1,4.2,5 mL, Pack Size: 5 L and under,10 L,50 L

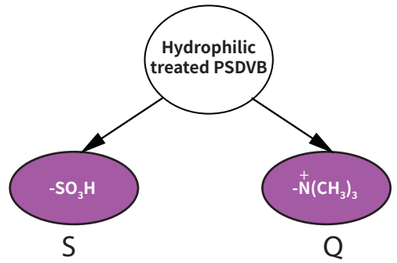
Proteomix POR Ion Exchange Resin

Introduction

Proteomix POR ion exchange resin is specifically designed for the separation and purification of biological samples. Proteomix POR-S/Q is based on the uniform PS/DVB beads with particle size of 15/30 μm. It has good physical and chemical stability with better pressure resistance. The Proteomix POR-S/Q resin surface is modified with a unique coating technology, which is highly hydrophilic and minimizes non-specific binding with biological samples. Through proprietary surface modification technology, different spacer arms and ion exchange functional groups are bonded on the surface of hydrophilic matrix to obtain strong cation exchange (S), strong anion exchange (Q) and other chromatographic media, and ensure the high density and uniformity of the surface ion exchange layer. Proteomix POR-S/Q ion exchange resin can be widely used for the separation and purification of biological samples such as vaccines, insulin, protein, nucleic acid, etc.

Resin Structure

Figure 1. Proteomix POR15-S/Q Resin Strucure



Features

- High binding capacity and excellent biocompatibility
- Rigid beads can be operated under high pressure and fast flow rate
- High resolution, efficiency, and recovery
- High batch-to-batch reproducibility
- Easy to scale up
- Highly hydrophilic surface, negligible non-specific binding
- Small volume change under standard packing condition

Technical Specifications

Table1. Proteomix POR Technical Specifications

Resin Type	Proteomix POR15-S	Proteomix POR15-Q	Proteomix POR30-S	Proteomix POR30-Q
Matrix	Hydrophilic modified polystyrene/divinylbenzene (PS/DVB)		Hydrophilic modified polystyrene /divinylbenzene(PS/DVB)	
Functional Group	$-SO_3H$	$-N^+(CH_3)_3$	$-SO_3H$	$-N^+(CH_3)_3$
Particle Size	15 μm	15 μm	30 μm	30 μm
DBC (per mL resin)	≥ 40 mg Lysozyme	≥ 40 mg BSA	≥ 40 mg Lysozyme	≥ 40 mg BSA
Maximum Linear Flow Rate	1800 cm/h		2000 cm/h	
Recommended Linear Flow Rate for Optimal Result	150-900 cm/h		300-1000 cm/h	
Operation Temperature	4-40℃		4-40℃	
pH Range	2-13	2-12	2-13	2-12
Maximum Pressure	≤ 15 MPa (150 bar)			
Compatible Mobile Phases	Compatible with aqueous solution, a mixture of water and acetonitrile, ethanol, etc. Typical buffers: Tris, phosphate, and acetate.			
Storage	20% ethanol or 2% benzyl alcohol			
Regeneration	1-2 M NaCl,or 0.5-1.0 M NaOH			
CIP	0.5 M HCl or 0.5-1.0 M NaOH. Impurities with strong hydrophobic binding can be cleaned with 0.1-1% Tween			

* Dynamic Binding Capacity Test Method:
Proteomix POR15/30-S: linear flow rate at 360 cm/h; Sample solution is 50 mM phosphate buffer with 1 mg/mL lysozyme (pH=6.0).
Proteomix POR15/30-Q: The linear flow rate at 180 cm/h; Sample solution is 50 mM Tris buffer with 2 mg/mL BSA (pH=8.5).

Ordering Information

Product Name	Functional Group Type	Particle Size (μm)	Part Number
Proteomix POR15-S	strong cation exchange group	15 μm	221115950
Proteomix POR15-Q	strong anion exchange group	15 μm	221415950
Proteomix POR30-S	strong cation exchange group	30 μm	221130950
Proteomix POR30-Q	strong anion exchange group	30 μm	221430950

Cartridge Size:1,4.2,5 mL, Pack Size: 5 L and under,10 L,50 L

IEX

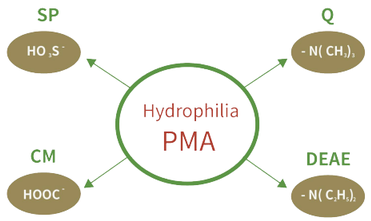
Polar MC
Ion Exchange Resins

Introduction

Polar MC ion exchange resin is specially designed for the separation and purification of biological samples. Polar MC resin has uniform particles in 30 and 60 μm size with 800 Å pore size. It has good physical and chemical stability. The Polar MC ion exchange resin surface is treated with special hydrophilic coating technology, which is highly hydrophilic and minimizes non-specific binding with biological samples. Through the proprietary surface modification technology, four types of functional groups were bonded to the matrix to make the ion exchange resins, which include strong cation exchange (SP), strong anion exchange (Q), weak cation exchange (CM) and weak anion exchange (DEAE). Polar MC ion exchange resin can be widely used for the separation and purification of biological samples such as insulin, antibody, protein, nucleic acid, vaccine, heparin, etc.

Resin Structure

Figure 1. Polar MC-SP, Q, CM and DEAE resin structure



Features

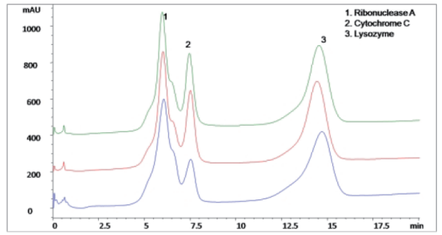
- High binding capacity and excellent biocompatibility
- Rigid beads can be operated under high pressure and fast flow rate
- High resolution, efficiency, and recovery
- High inter-batch reproducibility
- Easy to scale up
- Highly hydrophilic surface, negligible non-specific binding
- Small volume change under standard packing condition

Technical Specifications

Resin Type	Polar MC-Q		Polar MC-DEAE		Polar MC-SP		Polar MC-CM	
Matrix	Hydrophilic polymethacrylate							
Functional Group	$-N^+(CH_3)_3$		$-N(C_2H_5)_2$		$-SO_3H$		$-CH_2COOH$	
Particle Size	30	60	30	60	30	60	30	60
Pore Size	800							
DBC (per mL resin)	46 mg BSA	43 mg BSA	37 mg BSA	35 mg BSA	51 mg Lysozyme	46 mg Lysozyme	45 mg Lysozyme	37 mg Lysozyme
Maximum Linear Flow Rate	3800							
Operation Temperature	≤40℃							
pH Range	2-12							
Maximum Pressure	≤3 M Pa (30 bar)							
Compatible Mobile Phases	Compatible with aqueous solution, a mixture of water and acetonitrile, ethanol, etc. Typical buffers: Tris, phosphate, and acetate.							
Storage	50% (v/v) in 20% ethanol							
Regeneration	1-2 M NaCl							
CIP	0.5 M HCl or 0.5M NaOH							

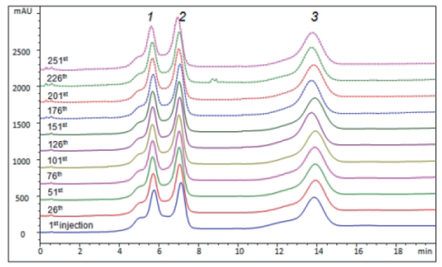
*Dynamic load measurement method:
Polar MC-Q, DEAE: flow rate at 180 cm/h; Sample solution is 50 mM Tris (pH8.5) with 2.0 mg/mL BSA.
Poalr MC-SP, CM: flow rate at 360 cm/h; Sample solution is 50 mM sodium phosphate buffer with 1.0 mg/mL lysozyme (pH6.0).

Figure 6: Polar MC 30-SP Lot to Lot Consistency



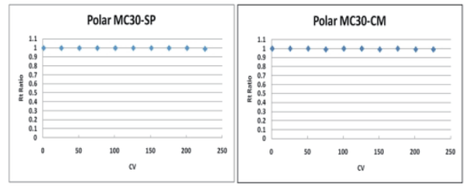
Column: Polar MC 30-SP (30 μm, 800Å, 4.6 x 50 mm)
Sample: Ribonuclease A, Cytochrome C, Lysozyme (5 mg/mL)

Figure 7: Polar MC 30-SP Lifetime Test



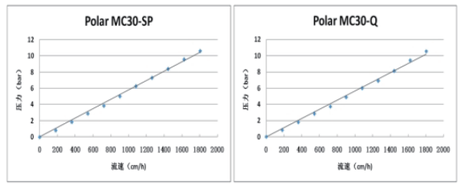
Column: Polar MC 30-SP (30 μm, 800Å, 4.6 x 50 mm)
Sample: Ribonuclease A, Cytochrome C, Lysozyme (5 mg/mL)

Figure 8: Polar MC 30-SP/CM CIP Test



Column: Polar MC 30-SP/CM (30 μm, 800Å, 4.6 x 50 mm)
Sample: Lysozyme

Figure 9: Polar MC 30-SP/CM - Pressure vs Linear Flow Rate



Column: Polar MC 30-SP/CM (30 μm, 800Å, 4.6 x 50 mm)
Mobile Phase: 100 mM NaCl

Ordering Information

Product Name	Particle Size (μm)	Part Number
Polar MC30-SP	30	190230800
Polar MC30-Q	30	190430800
Polar MC30-DEAE	30	190530800
Polar MC30-CM	30	190330800
Polar MC60-SP	60	190260800
Polar MC60-Q	60	190460800
Polar MC60-DEAE	60	190560800
Polar MC60-CM	60	190360800

Cartridge Size:1,4.2 ,5 mL, Pack Size: 5 L and under,10 L,50 L

Monomix MC-HIC Resins
Generik MC-HIC Resins

Introduction

Hydrophobic (HIC) resins can be used in various stages of protein purification, such as capture, medium purification, and fine purification. Sepax Technologies provides two types of HIC process media: Monomix MC-HIC and Generik MC-HIC. These two resins are based on polymethacrylate beads with the particle sizes in 30 and 60 µm. Generik MC-HIC is polydisperse with a pore size of 800 Å and is more hydrophobic. While Monomix MC-HIC has a more uniform particle size distribution with larger pore size of 1000 Å, which is more suitable for protein with larger molecular weight.

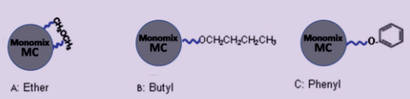
HIC resins have high physical and chemical stability. The surface has been specially modified, which has better hydrophilicity to avoid non-specific adsorption with biological samples to the greatest extent.

Resin Structure:

The resin surface of HIC is covered with a hydrophilic nanometer thin layer, bonded with different functional groups through chemical modification, such as Ether, Butyl and phenyl, as shown in figure 1. Different groups provide different hydrophobic properties, the hydrophobicity ranges from weak to strong: Ether, Butyl and Phenyl

Generik MC-HIC is the most hydrophobic resin as it directly bonds different functional groups, such as Butyl, Ether and Phenyl, on the surface of the base beads through modification.

Figure 1 HIC Ether(A), Butyl(B) and Phenyl(C) Structure



Features

Monomix MC-HIC Resins have high mechanical stability thus the resins can be operated under pressure up to 10 bar. This enables the development of the industrial purification process with shorter operating time and higher flow rate. High chemical stability ensures that the media can withstand cleaning operations at pH 14. These excellent media properties would meet the needs of separation and purification at all stages from the laboratory development process, and scale-up to production stage.

Technical Specifications

Table1. Monomix MC-HIC Technical Specifications

Media Type	Monomix MC-HIC Ether		Monomix MC-HIC Butyl		Monomix MC-HIC Phenyl	
Particle size (µm)	30	60	30	60	30	60
pore size (Å)	1000 Å					
Dynamic Binding Capacity* (mg lysozyme/mL resins)	> 20	> 10	> 40	> 20	> 45	> 30
Operation pH	2-13					
Operating Temperature	40℃					
Resin Pressure Limit	1 MPa (10 bar)					
Mobile Phase Compatibility	Compatible with an aqueous solution, a mixture of water and acetonitrile. acetone, or methanol. Typical buffers: phosphate, Tris, and acetate.					
Liner Flow Rate	1800 cm/h					
Storage	50%(v/v) Suspension in 20% of ethanol					

*DBC Test method：1 mg/mL lysozyme solution in 25 mM sodium phosphate buffer (pH 7) + 2 M (NH4)2SO4, Liner Flow Rate 360 cm/h. Detection: 280 nm. The DBC is based on 10% break through.

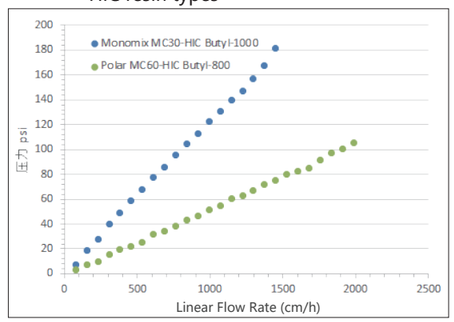
Table2. Generik MC-HIC Technical Specifications

Media Type	Generik MC-HIC Butyl		Generik MC-HIC Phenyl	
Particle size (µm)	30 µm	60 µm	30 µm	60 µm
pore size (Å)	800 Å			
Dynamic Binding Capacity* (mg lysozyme/mL resins)	> 40	> 30	> 45	> 40
Operation pH	2-13			
Operating Temperature	40℃			
Resin Pressure Limit	3 MPa (30 bar)			
Mobile Phase Compatibility	Compatible with an aqueous solution, a mixture of water and acetonitrile. acetone, or methanol. Typical buffers: phosphate, Tris, and acetate.			
Liner Flow Rate	1800 cm/h			
Storage	50%(v/v) Suspension in 20% of ethanol			

Faster operating flow rate

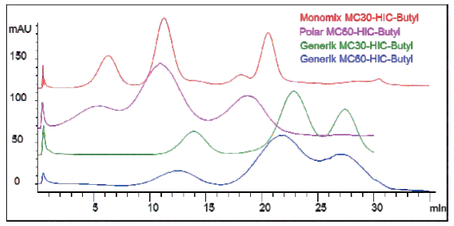
Compared with the traditional agarose matrix, the use of polymethacrylate matrix can improve the pressure resistance of the resin, thus can achieve purification at faster flow rates (or can pack longer columns, or can process more biological samples), can save valuable time and improve production efficiency. For unstable biological samples (requiring rapid separation and purification of crude sample), the yield and quality control of products can be also improved while improving productivity.

Figure 2 .Pressure - Linear Flow Rate of two HIC resin types



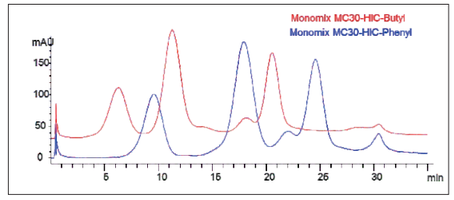
Comparison of Different HIC Resin Phases

Figure 3. Performance Comparison of Different HIC resins



Samples: ribonuclease A, lysozyme, chymotrypsinogen (2 mg/mL)

Figure 4. Performance Comparison of Different Phases of Monomix MC-HIC



Samples: ribonuclease A, lysozyme, chymotrypsinogen (2 mg/mL)

Ordering Information

Product Name	Particle size/Pore size	Part Number
Monomix MC30-HIC Ether	30 µm，1000 Å	281730950
Monomix MC30- HIC Butyl		281630950
Monomix MC30- HIC Phenyl		281930950
Monomix MC60-HIC Ether	60 µm，1000 Å	281760950
Monomix MC60- HIC Butyl		281660950
Monomix MC60- HIC Phenyl		281960950
Generik MC30- HIC Butyl	30 µm，800 Å	181430800
Generik MC30- HIC Phenyl		181630800
Generik MC60- HIC Butyl	60 µm，800 Å	181460800
Generik MC60- HIC Phenyl		181660800

Cartridge Size:1，4．2，5 mL， Pack Size: 5 L and under,10 L,50 L

Monomix MC SEC

Introduction

Monomix MC SEC resins are highly crosslinked spherical resins made of polymethylacrylate. These rigid resins are narrowly dispersed particles with particle size selection of 10, 15, 30 and 60 µm and pore size selection of 500 and 1000 Å. These resins have proprietary hydrophilic surface functional groups that minimize non-specific binding. Monomix MC SEC resins possess several key benefits: a broad pH tolerant range (1-14), elevated operating temperature (up to 80°C), high operating pressure (up to 20 bar), monosized particle (D90/D10 < 1.3, low column back pressure, high theoretical plate number), smooth surface and highly spherical (for easy column packing).

Monomix MC SEC resins are highly stable over a variety of operational conditions and are compatible with many commonly used organic solvents and aqueous buffers. Compared to agarose bulk media, they have more rigid backbones so they can resist higher column back pressure and thus be operated at a higher flow rate. Additionally cleaning and CIP are user friendly and effective and thus elongate resin life. Overall they can increase purification productivity and save purification cost. They have demonstrated SEC mechanism based applications in proteins, polysaccharides, VLP, and other biomacromolecules.

Features

- Monomix SEC resins are narrowly dispersed particles
- Well controlled pore structure
- Rigid beads can be operated at higher flow rates and higher pressure
- High dynamic capacity and high loading capacity
- High separation efficiency and resolution
- Wide pH range
- Negligible non-specific binding for high recovery of biological samples

Technical Specifications

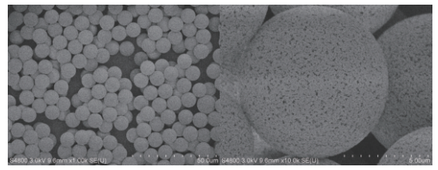
Product Name	Monomix MC-10 SEC	Monomix MC-15 SEC	Monomix MC-30 SEC	Monomix MC-60 SEC
Matrix	Polymethacrylate, rigid, porous microspheres			
Average Particle Size (µm)	10.0±1.0	15.0±1.5	30.0±5.0	60.0±10.0
Particle Size DistributionD_{90}/D_{10})	≤1.3			
Average Pore Size (Å)	500，1000	500，1000	1000	1000
Specific Pore Volume (mL/g)	≥1.0			
Max Pressure	2 MPa（20 bar）	2 MPa（20 bar）	2 MPa（20 bar）	2 MPa（20 bar）
Operation Temperature（℃）	≤80℃			
pH Working Range	2-12			
pH Cleaning Range (CIP)	1-14			
Storage Conditions	2-30℃，20% ethanol			
Compatible Solyent	Compatible with many commonly used organic solvents and aqueous solution.			
CIP and Regeneration	0.1-1.0 M NaOH, 20% cthanol, 30% isopropanol, 30% acetonitrile, 2% sodium laurovl sarcosinate,20% isopropanol/0.01 M HCl, 1 M acetic acid, 8 M urea, 6 M guanidine hydrochloride			

Performance Test

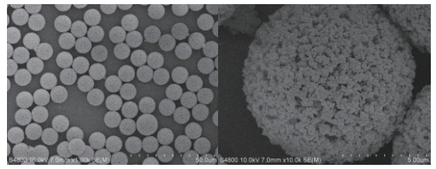
1.Resin performance

Figure 1. SEM images of Monomix MC SEC

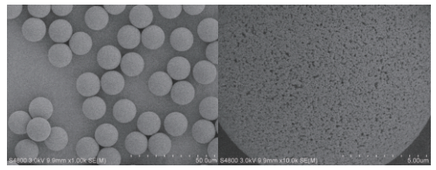
1）Monomix MC-10 SEC500



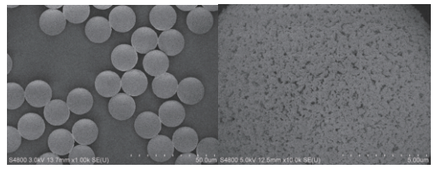
2）Monomix MC-10 SEC1000



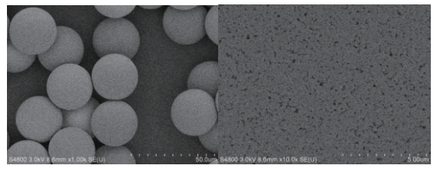
3）Monomix MC-15 SEC500



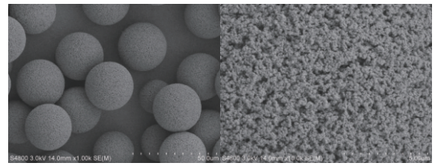
4）Monomix MC-15 SEC1000



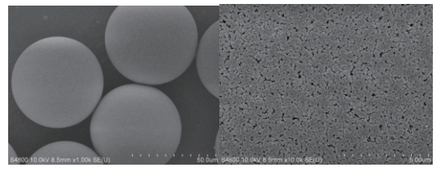
5）Monomix MC-30 SEC500



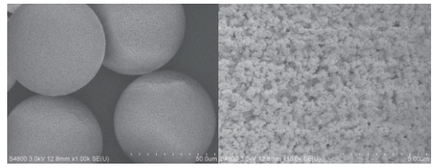
6）Monomix MC-30 SEC1000



7）Monomix MC-60 SEC500

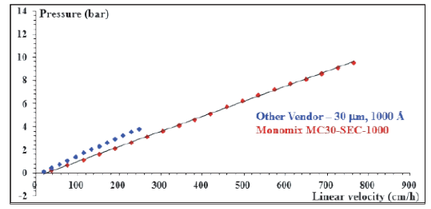


8）Monomix MC-60 SEC1000



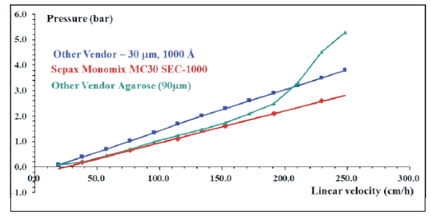
2. Linear Flow Rate-Pressure

Figure 2. Linear Flow Rate-Pressure Test



The back pressure of Monomix MC30-SEC was under 10 bar at 760 cm/hour when tested in a 10 x 450 mm FPLC column. Monomix MC30 SEC-1000 can be operated at a higher flow rate and lower back pressure when compared with 30 µm, 1000 Å, polymethacrylate resin from other vendors.

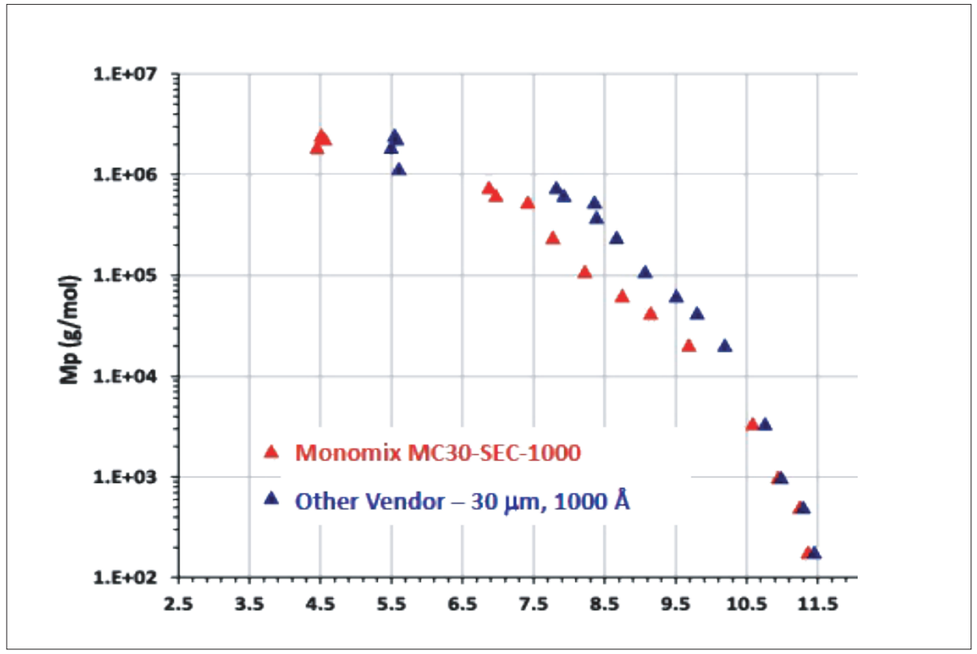
Figure 3. Linear Flow Rate-Pressure Test - Monomix MC30-SEC vs Other Brands



Monomix MC30 SEC-1000 has lower pressure than the 30 µm, 1000 Å, polymethacrylate resin from other vendor. Monomix MC30 SEC-1000 was close to Agarose (90 µm) resin from other vendor resin at low linear flow rate by using a 10 x 450 FPLC column. At high linear flow rate, the pressure of the Agarose (90 µm) resin from other vendor would increase significantly, while the back pressure of Monomix MC SEC 30-1000 increased linearly at the flow rate up to 760 cm/hour.

3.Calibration Curve with Dextran

Figure 4. Calibration Curve with Dextran



Monomix MC30 SEC-1000 exhibits a similar dextran exclusion molecular weight (indication of pore size) as the 30 µm, 1000 Å, polymethacrylate resin from another vendor.

Ordering Information

Product Name	Particle Size (µm)	Pore Size (Å)	Part Number
MonomixMC-10 SEC500	10	500	280110300
MonomixMC-10 SEC1000	10	1000	280110950
MonomixMC-15 SEC500	15	500	280115500
MonomixMC-15 SEC1000	15	1000	280115950
MonomixMC-30 SEC500	30	500	280130500
MonomixMC-30 SEC1000	30	1000	280130950
MonomixMC-60 SEC1000	60	1000	280160950

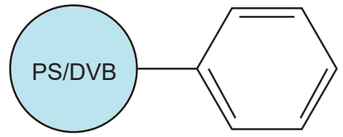
Cartridge Size:1,4.2,5 mL, Pack Size: 5 L and under,10 L,50 L

Poly RP Resins

Introduction

Sepax PolyRP process media are highly crosslinked spherical resins made of styrene and divinylbenzene. These highly rigid beads are narrowly dispersed particles containing abundant phenyl surface functional groups that enable hydrophobic interaction which is useful in reversed phase separation. Compared with conventional silica based reverse phase reins, it has more uniform particle size distribution and well controlled particle size, and is more stable over a variety of operational conditions: wider pH range pH (1- 14), and high temperatures resistance up to 200°C (operating temperature up to 80°C). They are compatible with many commonly used organic solvents and aqueous buffers.

Resin Structure



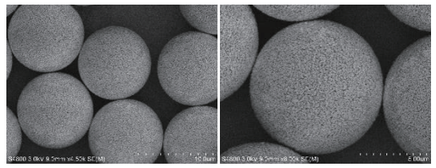
Features

- High cross-linked PS/DVB matrix
- Can be operated under high pressure
- High operating temperature up to 80 °C
- Wide pH range (1-14)

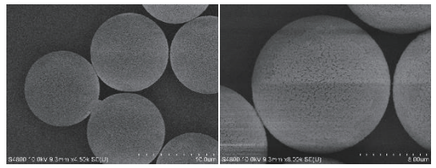
1. Resin Performance

Figure1.PolyRP10 (10 µm) SEM

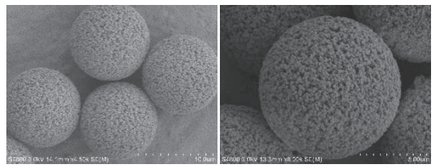
1) Pore size 100 Å



2) Pore size 300 Å



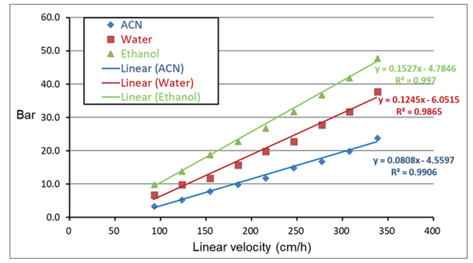
3) Pore size 1000 Å



Performance Test

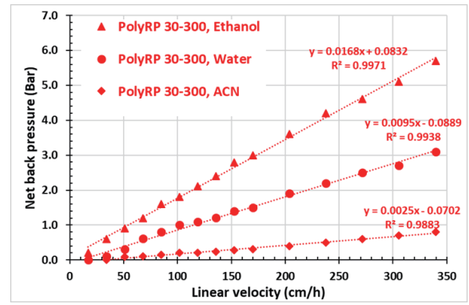
1. Pressure – Linear Flow Rate

Figure 1. Pressure vs Linear Flow Rate - Different Buffers



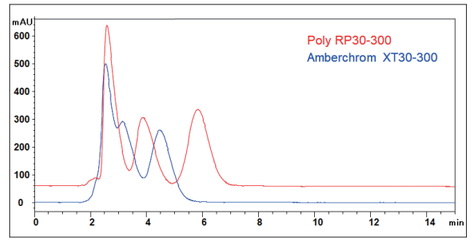
Column: PolyRP10-300 (10 µm, 300Å, 50 x 250 mm)
On the 50 ID mm column, it still has a good linear relationship at high flow rate.

Figure 2. Pressure vs Linear Flow Rate - Different Buffers



Column: PolyRP 30-300 (30 µm, 300 Å, 15 × 410 mm)
PolyRP 10-300 Common RP Buffers – Back Pressure Order: Ethanol>Water>ACN

Figure 3. PolyRP Resin QC Test



Column: PolyRP 30-300 (30 µ m, 300 Å, 15 × 410 mm)
Sample: 1. P-aminobenzoic acid (0.2 mg/mL);
2. p-cyanophenol (0.04 mg/mL);
3. p-nitroaniline (0.2 mg/mL)

The superior porous structure enables PolyRP 30-300 to better separate three QC molecules.

Technical Specifications

Resin Type	PolyRP				
Particle distribution	10.0±1.0μm	15.0±1.5 μm	30.0±3.0 μm	50-100 μm	85-155 μm
Average particle size (μm)	10 μm	15 μm	30 μm	75 μm	125 μm
Average pore size (Å)	100，300，500，1000 Å			300，500 Å	300，500 Å
Packing density (g/mL)	0.29±0.03	0.29±0.03 (100 Å) 0.26±0.03 (> 100 Å)	0.29±0.03 (100 Å) 0.26±0.03 (> 100 Å)	0.20±0.04	0.20±0.04
Surface area (m^2/g)	200-1000	200-1000	200-1000	> 600	> 600
Pore volume (mL/g)	0.9-1.4	0.85-1.3 (100 Å) 1.5-2.4 (> 100 Å)	0.85-1.3 (100 Å) 1.5-2.4 (> 100 Å)	1.5-2.4	1.5-2.4
Swelling in Methanol	≤3%	≤3%	≤3%	≤30%	≤30%
pH working range	1-13	1-13	1-13	1-13	1-13
pH cleaning range (CIP)	1-14	1-14	1-14	1-14	1-14
Maximum operating pressure	10	10	10	4	4
Storage Condition	2-30°C,20% ethanol				
Chemistry stability	Compatible with many commonly used organic solvents and aqueous solution such as a mixture of water and acetonitrile, acetone, methanol, ethanol, n-propanol, THF; 1.0 M HCl, 1 M NaOH, 1 M HCl/ 90% methanol, 90% HAc, 0.45 M NaOH/40% isopropanol, 6 M guanidine.				
Autoclavable	20 min at 121℃				

Ordering Information

Product Name	Particle Size (μm)	Pore Size (Å)	Part Number
PolyRP-10	10	100	260110100
	10	300	260110300
	10	500	260110500
	10	1000	260110950
PolyRP -15	15	100	260115100
	15	300	260115300
	15	500	260115500
	15	1000	260115950
PolyRP -30	30	100	260130100
	30	300	260130300
	30	500	260130500
	30	1000	260130950
PolyRP -75	75	300	260175300
	75	500	260175500
PolyRP -125	125	300	260195300
	125	500	260195500

Cartridge Size:1,4.2 ,5 mL， Pack Size: 5 L and under,10 L,50 L

Generik FPLC Empty Column

Introduction:

Sepax Generik FPLC glass empty columns are applicable to the analysis and purification of medium and low pressure liquid chromatography use, with the pressure limit up to 900 psi (60 bar). The inner diameters of the glass column Sepax offers range from 6.6 mm to 50 mm, with the maximum length up to 500 mm. There are three types of column choices: both ends are adjustable (AA type); one end is adjustable while the other end is fixed (AF type); and both ends are fixed and not adjustable (FF type). The maximum adjustable height of an adjustable end is 80 mm. The design makes the adjustment of the column bed height more convenient for customers to use.

1) Standard LC system: The columns are made of a glass tube of the required dimensions pre-assembled with 25μm PTEF or PE frits with a wide range of use.

2) Chemical solvent system:

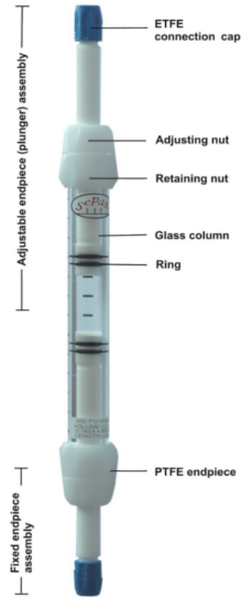
By replacing the PE filter to the PTFE filter, it would change the column to be suitable for chemical solvent applications

3) Selection of column tube and connector:

All columns are equipped with a set of connectors (two 1/4 "- 28UNF fitting) as standard to connect both ends of the column and the tubing. We can also provide M6 connectors to facilitate some users to connect other fittings with M6 threads in the system.

4) Replacement parts and related accessories

We provide paid service to replace glass column tubes, column tube end pieces, filters, and O-ring seals, frits, tubings, connectors, and other accessories



Technical Specifications:

Operating Parameters	
Operating temperature	4-20℃
pH stability	1-14
Chemical stability	Resistant to aqueous solutions and most solvents used in liquid chromatography. Not resistant to acetone, ketones, chlorinated hydrocarbons, aliphatic esters, phenol, >10% NaOH, > 10% HCl, > 5% acetic acid, or strong mineral acid.

Materials	
Glass column	Borosilicate glass
Endpiece	PTFE
Frit (bed support)	PE
O-Ring	FKM/FPM
Adjusting nut and retaining cap	Acetal
Connection cap and fitting nuts	Glass-filled polypropylene

Operating pressure	
ID-6.6mm	900 psi (60 bar)
ID-10mm	600 psi (40 bar)
ID-15mm	300 psi (20 bar)
ID-25mm	150 psi (10 bar)
ID-35mm	150 psi (10 bar)
ID-50mm	100 psi (6.7 bar)

Ordering Information

Column	Size	AF		AA		FF	
Part Number	I.D. x Length (mm)	Bed Height (cm)	Volume (mL)	Bed Height (cm)	Volume (mL)	Bed Height (cm)	Volume (mL)
202000-0605-AF/AA/FF	6.6x50	0.24-2	0.1-0.7	0.24-0.2	0.1-0.7	2	0.7
202000-0610-AF/AA/FF	6.6x100	0.24-7	0.1-2.4	0.24-7	0.1-2.4	7	2.4
202000-0615-AF/AA/FF	6.6x150	4-12	1.4-4.1	0.24-12	0.1-4.1	12	4.1
202000-0625-AF/AA/FF	6.6x250	14-22	4.8-7.5	6-22	2.1-7.5	22	7.5
202000-0640-AF/AA/FF	6.6x400	29-37	9.9-12.7	21-37	7.2-12.7	37	12.7
202000-1010-AF/AA/FF	10x100	0.24-7	0.2-5.5	0.24-7	0.2-5.5	7	5.5
202000-1015-AF/AA/FF	10x150	4-12	3.1-9.4	0.24-12	0.2-9.4	12	9.4
202000-1025-AF/AA/FF	10x250	14-22	11-17.3	6-22	3.1-17.3	22	17.3
202000-1040-AF/AA/FF	10x400	29-37	22.8-29.1	21-37	16.5-29.1	37	29.1
202000-1050-AF/AA/FF	10x500	39-47	30.6-36.9	31-47	24.3-36.9	47	36.9
202000-1510-AF/AA/FF	15x100	0.24-7	0.4-12.4	0.24-7	0.4-12.4	7	12.4
202000-1515-AF/AA/FF	15x150	4-12	7.1-21.2	0.24-12	0.4-21.2	12	21.2
202000-1525-AF/AA/FF	15x250	14-22	24.7-38.9	6-22	10.6-38.9	22	38.9
202000-1540-AF/AA/FF	15x400	29-37	51.2-65.4	21-37	37.1-65.4	37	65.4
202000-1550-AF/AA/FF	15x500	39-47	68.9-83.0	31-47	54.8-83.0	47	83
202000-2510-AF/AA/FF	25x100	0.24-7	1.2-34.4	0.24-7	1.2-34.4	7	34.4
202000-2515-AF/AA/FF	25x150	4-12	19.6-58.9	0.24-12	1.2-58.9	12	58.9
202000-2525-AF/AA/FF	25x250	14-22	68.7-108.0	6-22	29.4-108.0	22	108
202000-2540-AF/AA/FF	25x400	29-37	142.3-181.6	21-37	103.1-181.6	37	181.6
202000-2550-AF/AA/FF	25x500	39-47	191.4-230.7	31-47	152.1-230.7	47	230.7
202000-3515-AF/AA/FF	35x150	4-12	38.5-115.4	0.24-12	2.3-115.4	12	115.4
202000-3525-AF/AA/FF	35x250	14-22	134.7-211.6	6-22	57.7-211.6	22	211.6
202000-3540-AF/AA/FF	35x400	29-37	279.0-355.9	21-37	202.0-355.9	37	355.9
202000-5025-AF/AA/FF	50x250	14-22	280.4-440.6	6-22	120.2-440.6	22	440.6
202000-5040-AF/AA/FF	50x400	29-37	580.7-741.0	21-37	420.5-741.0	37	741
202000-5050-AF/AA/FF	50x500	39-47	781.0-941.2	31-47	620.8-941.2	47	941.2

AF: One fixed endpiece and one adjustable endpiece
AA: Two adjustable endpieces
FF: Non-adjustable with two fixed endpieces

Process Chromatography Media Recommendation for Corresponding Sepax Brand

Separation Mode	Type	Sepax	Cytiva (GE)	Merck EMD	Tosoh	Thermo Fisher Scientific
Affinity	Agarose Based Protein A	**MabPurix A45** **MabPurix A65**	MabSelect SuRe MabSelect SuRe LX MabSelect PrismA	ProSep Ultra Plus resin ProSep-vA Ultra resin ProSep-vA High Capacity		
	PMA Based Protein A	**MabPurix P45**		Eshmuno A	Toyopearl AF-rprotein A HC-650F Toyopearl AF-rProtein A-650F	POROS MabCapture A
	dT Affinity (mRNA)	**Monomix dT20** **Proteomix POR50-dT20 (Macroporous)**				POROS Oligo(dT)25
	IMAC Ni Affinity	**PMA Based** **Polar MC-Ni Excel (EDTA Tolerance)**	Ni Sepharose HP Ni Sepharose 6 FF Capto Chelating Ni Sepharose Excel	Fractogel Metal Chelate resin	Toyopearl AF-Chelate-650M	Ni-NTA Agarose
	Boronate Affinity	**Monomix MC-Boronate**				
Multimodal	Core Bead	**Monomix Core 500** **Monomix Core 1000**	Capto Core 400 Capto Core 700			
AEX	PS/DVB Based High Resolution	**Proteomix POR15-Q** **Proteomix POR30-Q**	Source 15Q Source 30Q			
	Q	**PMA Based** **Monomix Mab60-Q**	Q Sepharose FF Q Sepharose XL Q Sepharose HP Q Sepharose big beads Capto Q XP Capto Q ImpRes Capto Q	ESHMUNO Q	TSKgel SuperQ-5PW ToyoPearl super Q GigaCap Q ToyoPearl QAE	POROS HQ POROS XQ
	DEAE	**PMA Based** **Monomix HC60-DEAE Excel**	Capto DEAE ANX Sepharose 4 FF DEAE Sepharose FF	Fractogel EMD TMAE Fractogel EMD DEAE	TSKgel DEAE-5PW ToyoPearl DEAE ToyoPearl NH2	POROS PI50 POROS D50
CEX	PS/DVB Based High Resolution	**Proteomix POR15-S** **Proteomix POR30-S**	Source 15S Source 30S			
	SP/S	**PMA Based** **Monomix Mab60-SP** **Monomix HC-SP** **Monomix HC45-S**	Capto S ImpRes Capto S ImpAct SP Sepharose Big Beads SP Sepharose FF SP Sepharose XL SP Sepharose HP	Fractogel EMD SO_3^- Eshmuno S Eshmuno CPS Eshmuno CPX Eshmuno CP-FT	ToyoPearl SP ToyoPearl GigaCap S ToyoPearl Sulfate ToyoPearl MegaCap II SP TSKgel SP-3PW TSKgel SP-5PW	POROS XS POROS HS50
	CM	**PMA Based** **Polar MC-CM**	CM Sepharose	Fractogel EMD COO-	ToyoPearl CM ToyoPearl GigaCap CM	
SEC	PMA Based SEC	**Monomix MC-SEC**		Fractogel EMD BioSEC	ToyoPearl HW	
HIC	PMA Based HIC	**Monomix MC-HIC** **Polar MC-HIC** **Generik MC-HIC**	Source 15ISO Source 15PHE Sepharose 4 FF HIC Sepharose 6 FF HIC Capto HIC Capto ImpRes HIC	Fractogel EMD	ToyoPearl HIC TSKgel Phenyl-5PW TSKgel Ether-5PW	POROS Ethyl POROS Benzyl POROS Benzyl Ultra
RP	PS/DVB Based RP	**PolyRP**	Source 15 RPC Source 30 RPC			Oligo R3 Media
	Silica Based RP	**GP, HP, BR, Sapphire, Amethyst, Bio**		PharmPrep LiChroprep		