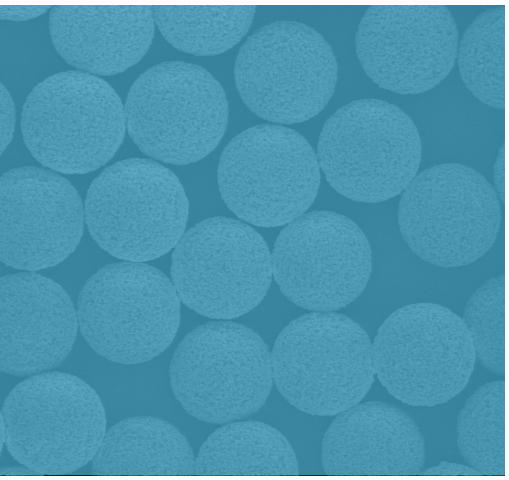
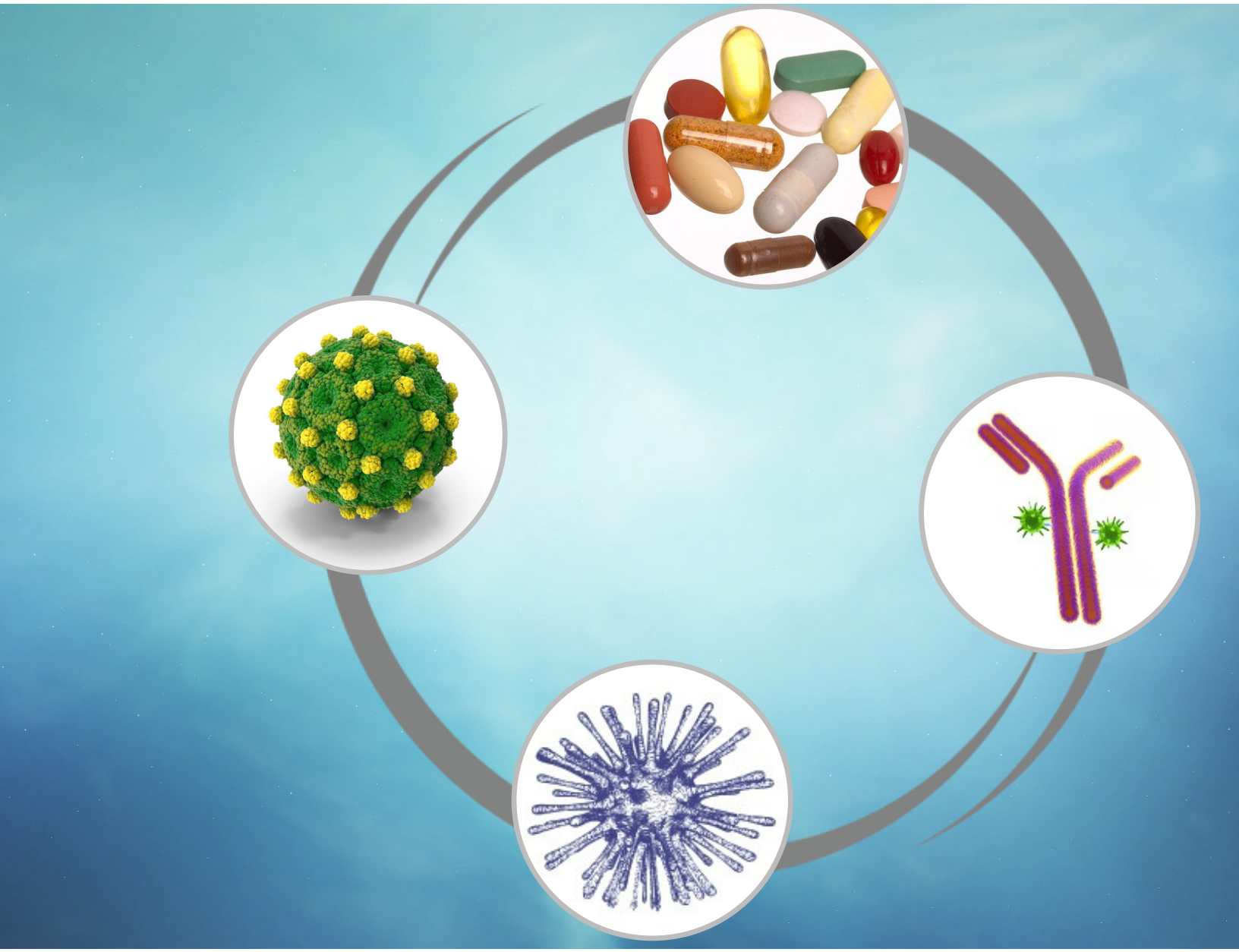
Sepax Technologies



Monomix™ MC SEC

SIZE EXCLUSION CHROMATOGRAPHY

POLYMERIC PROCESS MEDIA FOR
BIOMOLECULE SEPARATIONS



Our Specialty

Sepax Technologies, a Delaware US-based company, provides cutting edge products and services for liquid chromatography (LC). Sepax specializes in the development and manufacture of LC analytical, preparative and process separation & purification columns, bulk resins and systems in a wide range of modalities, such as SEC, IEX, HIC, Affinity, and RP.

Sepax also provides LC services, including analytical testing, method 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.

Our Commitment

At Sepax, we create value through serving customers' needs and solving their chromatographic separation and purification challenges. Through innovative technologies and solution-based approaches, Sepax delivers products and services that build lasting relationships with customers, achieving a strong leadership role in the industry. At Sepax, we firmly believe that there is nothing too complicated or challenging for us to consider.

Our Strategy

Whether you are conducting analytical research, in need of customized resins, or scale-up purification, Sepax Services offers unmatched technical capabilities and expertise. Working in tandem with our technical team and our customers, Sepax offers highly individualized services to meet your specific requirements, achieving project goals in an efficient and cost-effective manner.

Monomix™ MC SEC

Introduction

Monomix MC SEC bulk media 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. **Figure 1.** shows SEM images of 10, 15, and 60 µm Monomix MC SEC beads with 1000 Å pore size. 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 (D_{90}/D_{10} < 1.3, low column back pressure, high theoretical plate number), smooth surface and highly spherical (for easy column packing).

Monomix MC SEC bulk media are highly stable over a variety of operational conditions. They are compatible with many commonly used organic solvents and aqueous buffers. Compared to silica based SEC bulk media, they are more stable at extreme pH (1- 14) condition. Compared to agarose bulk media, they have more rigid backbones so they can resist high column back pressure and thus be operated at high 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.

SEM Analysis on Particle Morphology

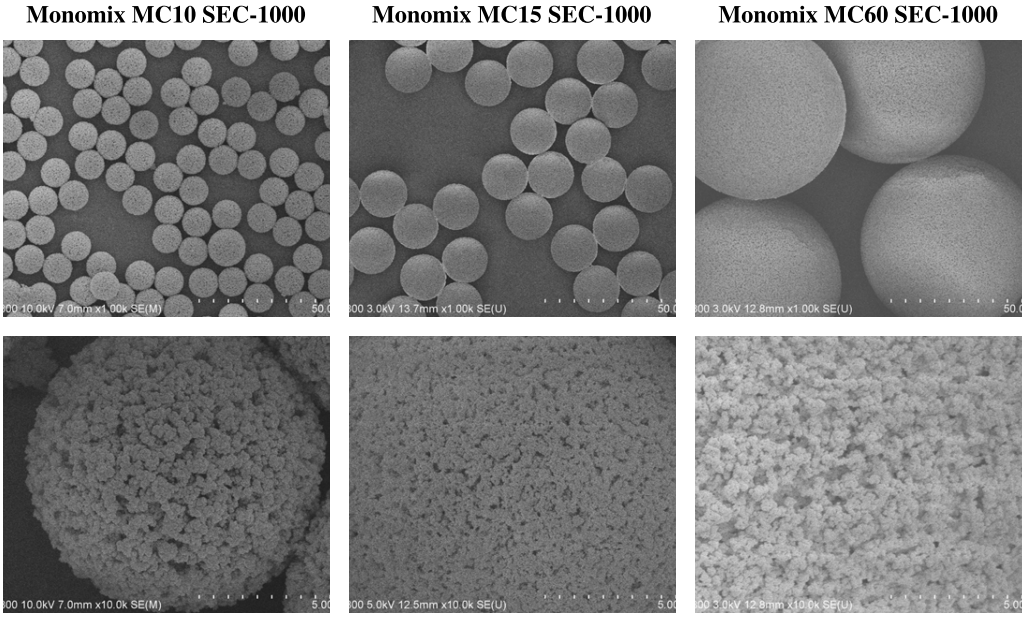


Figure 1. Rigid, spherical, mono-dispersed, porous microspheres. Precise control on particle morphology: bead size, pore size, surface area, pore volume.

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

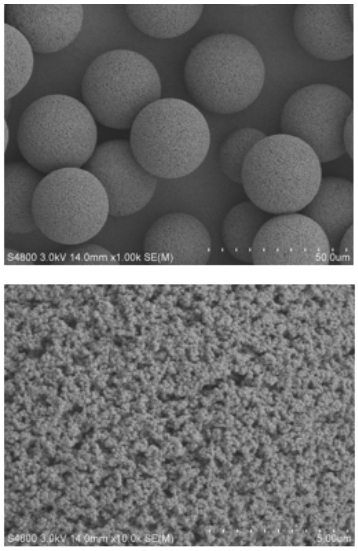
Resin Technical Specifications

Resin product	Monomix MC10 SEC	Monomix MC15 SEC	Monomix MC30 SEC	Monomix MC60 SEC
Matrix	Polymethacrylate, rigid, porous microspheres			
Average Particle Size (μm)	10.0±1.0	15.0±1.5	30.0±3.0	60.0±6.0
Particle Size Distribution (D_{90}/D_{10})	≤ 1.3			
Average Pore Size (Å)	500, 1000	500, 1000	500, 1000	500, 1000
Specific Pore Volume (mL/g)	≥ 1.0			
Max Pressure	2 MPa (20 bar)	2 MPa (20 bar)	1 MPa (10 bar)	1 MPa (10 bar)
Operation Temperature (℃)	≤ 80			
pH Working Range	2-12			
pH Cleaning Range (CIP)	1-14			
Storage Conditions	2-30 ℃, 20% ethanol			
Compatible Solvent	Compatible with many commonly used organic solvents and aqueous solution.			
CIP and Regeneration	0.1-1.0 M NaOH, 20% ethanol, 30% isopropanol, 30% acetonitrile, 2% sodium lauroyl sarcosinate, 20% isopropanol/0.01 M HCl, 1 M acetic acid, 8 M urea, 6 M guanidine hydrochloride			

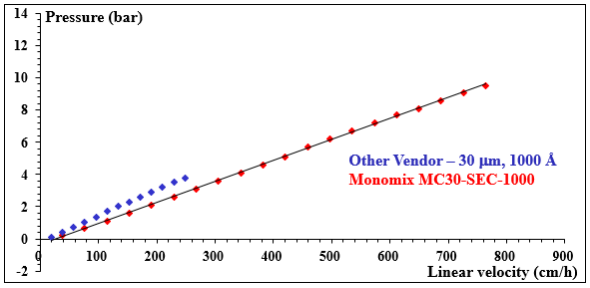
Characteristics of Sepax Monomix MC SEC-1000

Product Name	Monomix MC60 SEC-1000 Monomix MC30 SEC-1000 Monomix MC15 SEC-1000 Monomix MC10 SEC-1000
Matrix	Surface hydrophilized polymethacrylate
Color	White
Physical Form	Narrowly dispersed, porous spheres
Average Particle Size (µm)	60 ± 6.0 30 ± 3.0 15 ± 1.5 10 ± 1.0
Particle Size Distribution	$D_{90}/D_{10} \leq 1.3$
Average Pore Size (Å)	1000
PEO or PEG MW Separation (Dalton/mol)	500 - 1 x 10^6
Dextran MW Separation (Dalton/mol)	1 x 10^4 - 1 x 10^6
Globular Protein MW Separation (Dalton/mol)	4 x 10^4 – 5 x 10^6
Maximum Operating Pressure (Bar)	10 10 20 20
Operation Temperature (°C)	≤ 80
pH Working Range	2 – 12
pH Cleaning Range (CIP)	1 – 14
Storage Conditions	2 - 30°C, 20% Ethanol
Compatible Solvent	Compatible with many commonly used organic solvents and aqueous solution
CIP and Regeneration	0.1 – 1.0 M NaOH, 20% ethanol, 30% isopropanol, 30% acetonitrile, 2% sodium lauroyl sarcosinate, 20% isopropanol/0.01 M HCl, 1 M acetic acid, 8 M urea, 6 M guanidine hydrochloride
Change in Bed Volume	Minor change due to change(s) of pH or ion strength

Monomix MC30 SEC-1000

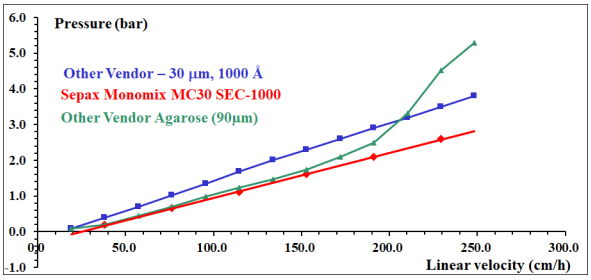


Flow Rate-Back Pressure Test



Resin: Monomix MC30 SEC-1000 (30 µm, 1000 Å)
Column: FPLC 10 x 500 mm, AA
Instrument: Sepax FPLC Generik HP36
Mobile Phase: 150 mM Sodium Phosphate, pH 7.0
Column Temperature: 25°C

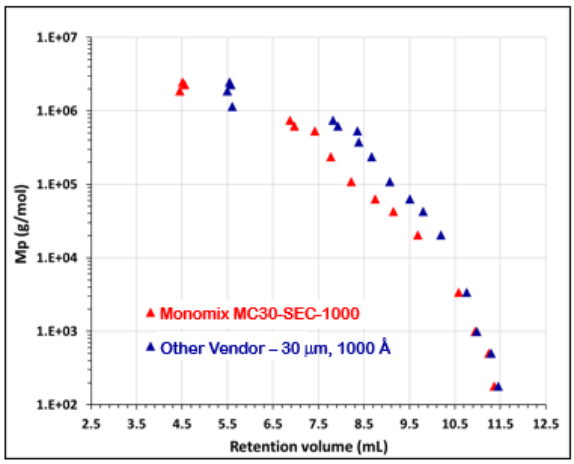
Figure 2. Monomix MC30 SEC-1000 shows a linear relationship. The back pressure was under 10 bar at 760 cm/hour when tested in a 10 x 450 FPLC column. Monomix MC30 SEC-1000 can operate at a higher flow rate and lower back pressure when compared with Other Vendor – 30 µm, 1000 Å, polymethacrylate resin.



Resin: Monomix MC30 SEC-1000 (30 µm, 1000 Å)
Column: FPLC 10 x 500 mm, AA
Instrument: Sepax FPLC Generik HP36
Mobile Phase: 150 mM Sodium Phosphate, pH 7.0
Column Temperature: 25°C

Figure 3. The back pressure of Monomix MC30 SEC-1000 was lower than the Other Vendor – 30 µm, 1000 Å, polymethacrylate resin. Monomix MC30 SEC-1000 was close to the Other Vendor Agarose (90 µm) resin at low linear velocity, when tested in a 10 x 450 FPLC column. At high linear back pressure of velocity the Other Vendor Agarose (90 µm) suddenly increased, but the back pressure of Monomix MC SEC 30-1000 increased linearly, with respect to the flow rate of up to 760 cm/hour.

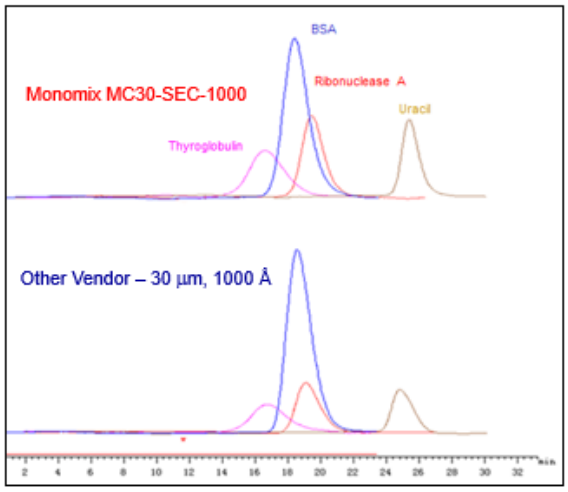
Calibration Curve with Dextran



Resin: Monomix MC30 SEC-1000 (30 µm, 1000 Å)
Column: 7.8 x 300 mm (Stainless Steel)
Instrument: Agilent 1260
Mobile Phase: 150 mM Sodium Phosphate, pH 7.0
Flow Rate: 1.0 mL/min (125 cm/h)
Detector: RI
Column Temperature: 25°C
Sample: 10 mg/mL
Injection Volume: 10 µL

Figure 4. Monomix MC30 SEC-1000 exhibits a similar dextran exclusion molecular weight (indication of pore size) as the Other Vendor – 30 µm, 1000 Å, polymethacrylate resin.

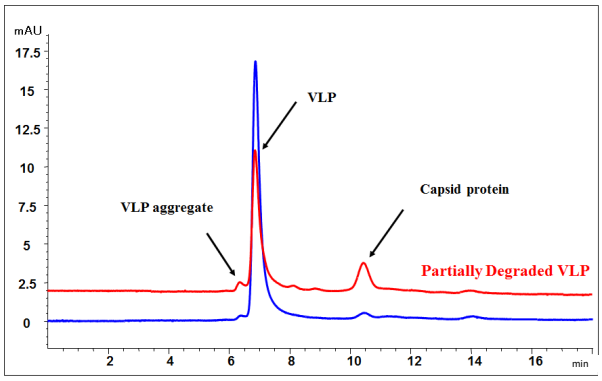
Separation of Four Protein Standards



Resin: Monomix MC30 SEC-1000 (30 µm, 1000 Å)
Column: FPLC 10 x 500 mm, AA
Instrument: Agilent 1260
Mobile Phase: 150 mM Sodium Phosphate, pH 7.0
Flow Rate: 1.5 mL/min (115 cm/h)
Detector: UV 214 nm
Column Temperature: RT
Samples: 1) Thyroglobulin (1.0 mg/mL) 2) BSA (1.0 mg/mL) 3) Ribonuclease A (1.0 mg/mL) 4) Uracil (0.25 mg/mL)
Injection Volume: 200 µL

Figure 5. The Monomix MC30 SEC-1000 column better separated four proteins than the Other Vendor – 30 µm, 1000 Å column.

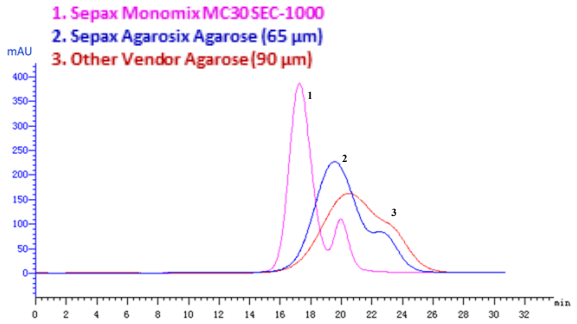
Crude VLP Separation



Resin: Monomix MC10 SEC-500 (10 µm, 500 Å)
Column: 7.8 x 300 mm (Stainless Steel)
Instrument: Agilent 1260
Mobile Phase: 20 mM Sodium Phosphate + 150 mM NaCl (pH 7.0)
Flow Rate: 0.81 mL/min (100 cm/h)
Detector: UV 280 nm
Column Temperature: 25 ℃
Sample: Crude VLP, ~80 nm
Injection Volume: 100 µL

Figure 6. Monomix MC10 SEC-500 column shows good separation of VLP, VLP aggregate and capsid protein. In partially degraded VLP sample intensity of VLP decreases while intensity of VLP aggregate and capsid protein increase. Capsid protein elutes at 10.43 min/ 8.45 mL, so its molecular weight is between BSA (8.24 mL) and Ribonuclease A (8.83 mL) [data not shown].

VLP Capsid Protein and Aggregation Analysis



Resin: Monomix MC30 SEC-1000 (30 µm, 1000 Å)
Column: FPLC 10 x 500 mm, AA
Instrument: Agilent 1260
Mobile Phase: 20 mM Sodium Phosphate (pH 7.0) + 0.15 M NaCl
Flow Rate: 1.5 mL/min (115 cm/h)
Detector: UV 214 nm
Column Temperature: RT
Sample: Crude Lentivirus (~20 MDa)
Injection Volume: 1.0 mL

Figure 7. Monomix MC30 SEC-1000 showed higher resolution and efficiency compared to two agarose based resins in Lentivirus purification.

Ordering Information

Resin	Particle Size	Pore Size	Part Number
Monomix MC10 SEC-500	10 µm	500 Å	280110500
Monomix MC10 SEC-1000	10 µm	1000 Å	280110950
Monomix MC15 SEC-500	15 µm	500 Å	280115500
Monomix MC15 SEC-1000	15 µm	1000 Å	280115950
Monomix MC30 SEC-500	30 µm	500 Å	280130500
Monomix MC30 SEC-1000	30 µm	1000 Å	280130950
Monomix MC60 SEC-500	60 µm	500 Å	280160500
Monomix MC60 SEC-1000	60 µm	1000 Å	280160950

Standard packing size:
1L, 5L, 10L, 25L, 50L, 100L
Additional pack sizes are available

Additional particle and pore sizes are available. Pre-packed stainless-steel columns for sample preparation and separation process development/ scale-up are available.

Please contact your regional sales agent for more information.

Better Surface Chemistry For Better Separation

Sepax Technologies, Inc.

Delaware Technology Park
5 Innovation Way
Newark, Delaware 19711 USA
Tel: 302-366-1101
Fax: 302-366-1151
Toll Free: 1-877-SEPAX-US
www.sepax-tech.com