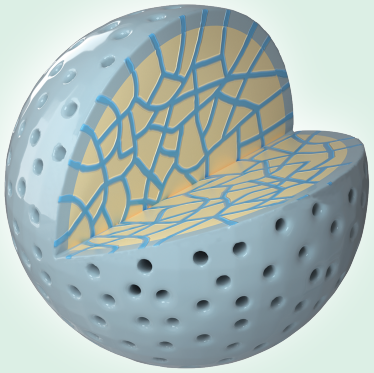
Monomix Core Series

A Polymeric Porous Chromatographic Medium with a Core–Shell Structure

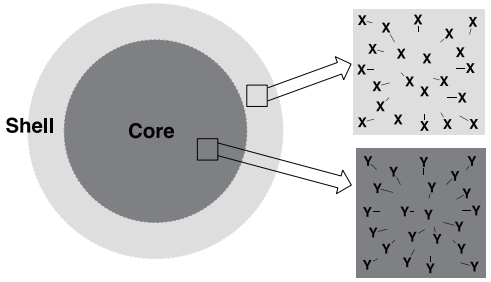
Sepax Technologies, Inc.

Monomix Core chromatographic media, designed and developed by Sepax Technologies, Inc., 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, Sepax Monomix Core Series , is comprised of mono–size beads with an average bead size in 60 μm.



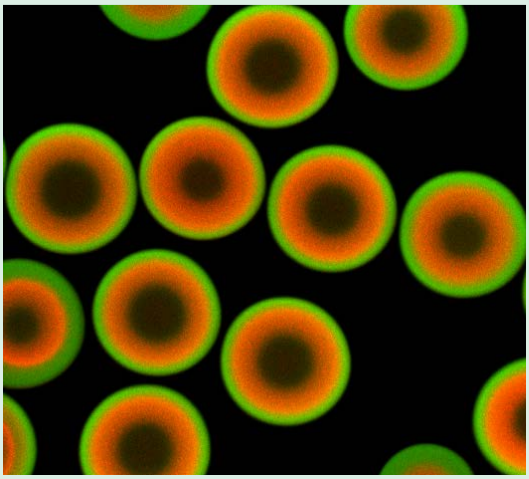
- **Monomix Core Series is broadly applicable to separation and purification of various types of biomolecules, such as proteins, antibody, VLPs, vaccines, viral vectors or viruses, liposomes, LNP (lipid nanoparticles), Plasmid, DNA, RNA, etc.**



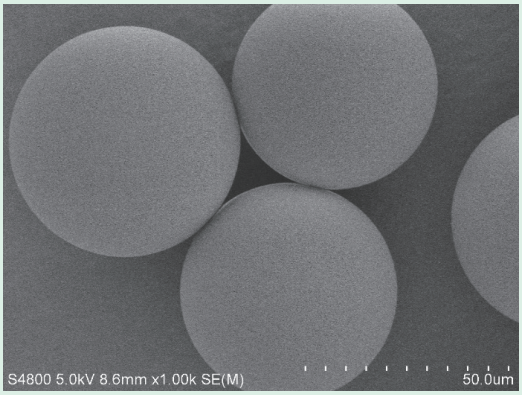
X and Y can be cationic, anionic, hydrophobic, hydrophilic, affinity, or mixed–mode functional groups.

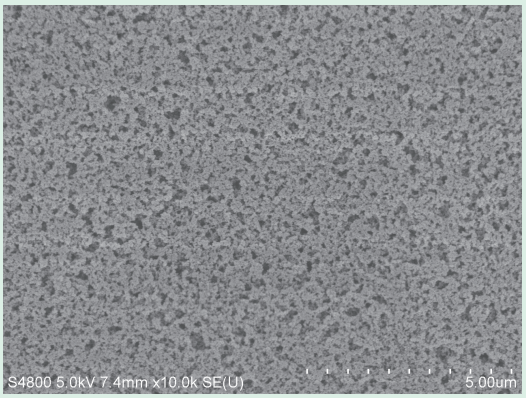
X and Y can be either chemically distinct, or the same functional group with different density.

Schematic diagram of core–shell hierarchical layer structure: Monomix Core with core–shell two–layer structure.



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.





SEM of Monomix Core Series: mono–sized porous beads with core–shell structure (D_{50} = 59.1 μm)

Key Features of Monomix Core Series

- 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
- A systematic platform solution for 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
- Can withstand higher flow rates when compared with traditional agarose-based multimodal chromatographic media
- 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

Comparison of Technical Parameters

Medium Brand	Capto™ Core , COA(measured value)	Monomix Core
Matrix	Agarose based	Polymeric based
Volume average particle diameter D_{50} (μm)	NA (88.3)	60 ± 10, tunable upon request
Particle size distribution D_{90}/ D_{10}	NA (2.22), polydispersed	≤1.5, mono-sized
Average pore size, protein cut off MW	Capto Core 700: 700 kD Capto Core 400: 400 kD	Monomix Core 1000: 1000 Å, 700 kD Monomix Core 500: 500 Å, 400 kD
Shell thickness uniformity	Not good	Good
Variation in volume ratio of core/shell distribution among resins	Large. Polydispersed beads, hard to precisely control	Small. Monodispersed beads, easy to precisely control
Surface chemistry of shell layer	-OH	Hydrophilic functional groups
Surface chemistry of core layer	Octylamine	Amine
Ion exchange capacity of core layer (μmol Cl^-/mL medium)	40-85 (45)	80-300
Maximum linear flow rate	500 cm/h	1000 cm/h
Operation temperature	4-30 ℃	≤ 40 ℃
pH stability	3-13	2-13
Operation pressure limit	≤ 0.5 Mpa (5 bar)	≤ 1 Mpa (10 bar)
Mobile phase compatibility	All commonly used aqueous buffers, such as 1 M NaOH, 6 M guanidine hydrochloride, 30% IPA and 70% EtOH	All commonly used aqueous buffers, such as 1 M NaOH, 6 M guanidine hydrochloride, 30% IPA and 70% EtOH
Long-term storing condition	20% EtOH	20% EtOH
CIP conditions	1 M NaOH in 30% IPA aqueous solution	1 M NaOH in aqueous solution, or 1 M NaOH in 30% IPA aqueous solution

Ordering Information

Brand	Particle size Pore size	PN	Quantity (L)	Prepacked columns (mL)
Monomix Core 1000	60 μm / 1000 Å	290160950	5, 10, 50	1 , 4.2 ,5
Monomix Core 500	60 μm / 500 Å	290160500	5, 10, 50	1 , 4.2 ,5

- Innovative technology, Sepax Technologies Inc. own intellectual properties (IP)
- With PCT international patent application submitted

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