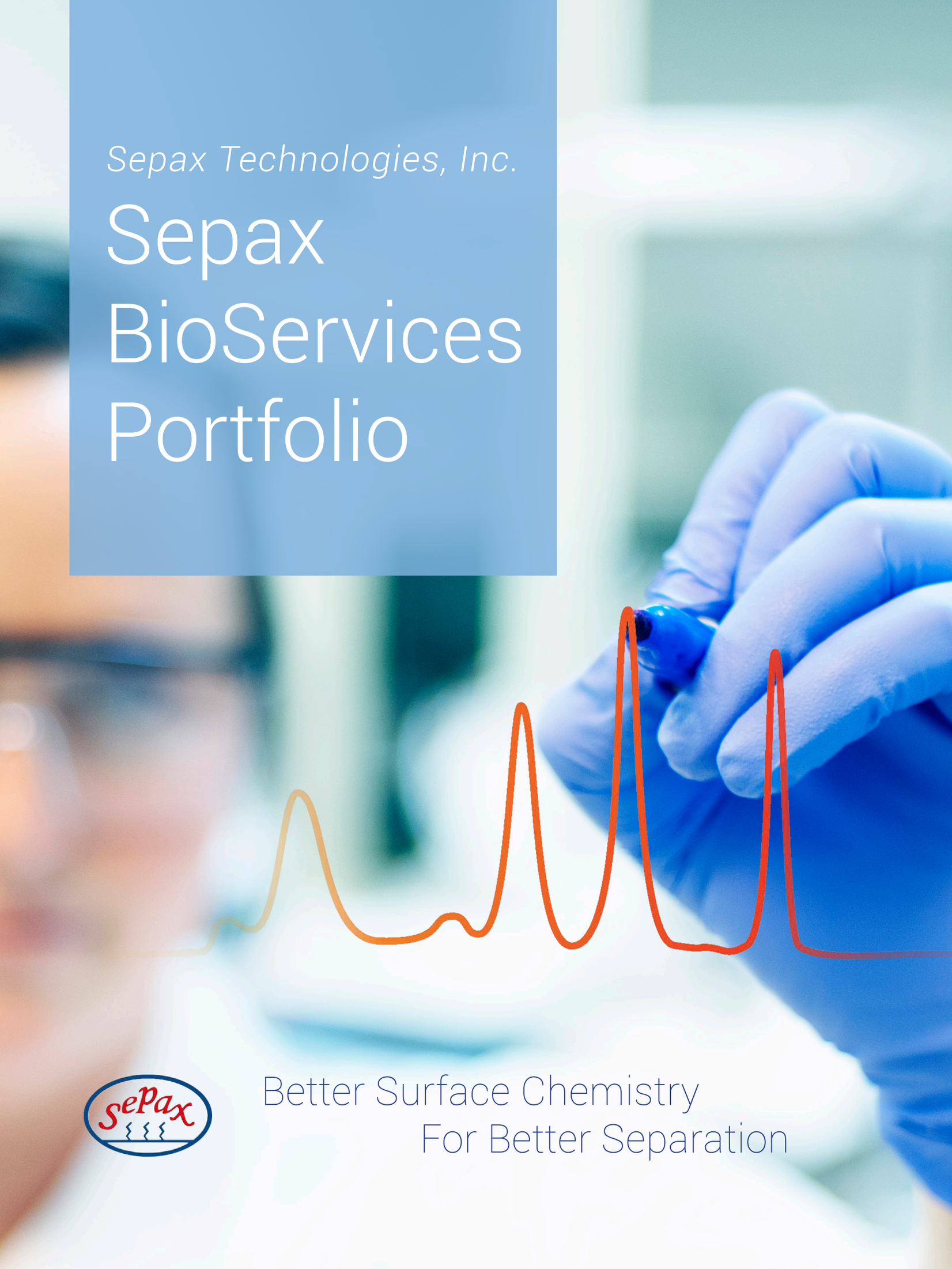
Sepax Technologies, Inc.

Sepax BioServices Portfolio



Better Surface Chemistry
For Better Separation

Our Specialty

Headquartered in Delaware, Sepax Technologies, Inc. has established itself as a leader in the biological separation industry since 2002.

Sepax focuses on our customers' needs and provides solutions to their challenges in chromatographic separation. Sepax specializes in the development and manufacturing of HPLC consumables, bulk media, and equipment for chemical and biological separations. Sepax has achieved innovative industry developments in the areas of particle synthesis and surface modification including a recent development and implementation of a unique process method for large scale bio-production of peptides. Sepax Quality Management System is ISO 9001:2008 certified.

Our Commitment

At Sepax, we believe that we create value through serving customers' needs and solving their challenges in the chromatography separation and purification industry.

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 offer unmatched technical capability and expertise. Working in tandem with our technical team and our customers, we offer highly individualized services to meet your specific requirements, helping you reach project goals in an efficient and cost-effective manner.

What We Offer

Analytical Chromatography

- Column and Sample Screening Method Development and Optimization
- Validation Services and On-Site Method Transfer
- Stability and Batch Releasing Test according to the client's specification
- In process sample quantitative method development
- USP Monograph Testing
- Biomolecule and Small Molecule Applications
- Affinity, IEX, HIC, SEC, RP and Others

Prep and Process Purification

- Analytical to Preparative Scale Up
- mg to g and to your Specified Purity
- Antibody and Recombinant Protein Purification
- Native Protein from Natural Sources Purification
- Method Development and Scouting Service
- Affinity, IEX, HIC, SEC, RP and Others

Custom Resin

- Resin Surface Modification (Silica, Polymer like PMA, PS/DVB and Agarose)
- Custom Affinity Resin Conjugation
- Custom Ligand Immobilization
- Pre-activated Resin for Ligand Immobilization
- Resin Matrix Development including Particle size, Pore Size, Degree of Cross-linkage, Ligand, Chemistry Spacer Arm, Linker and others
- Custom Column Packing

Surface Coating

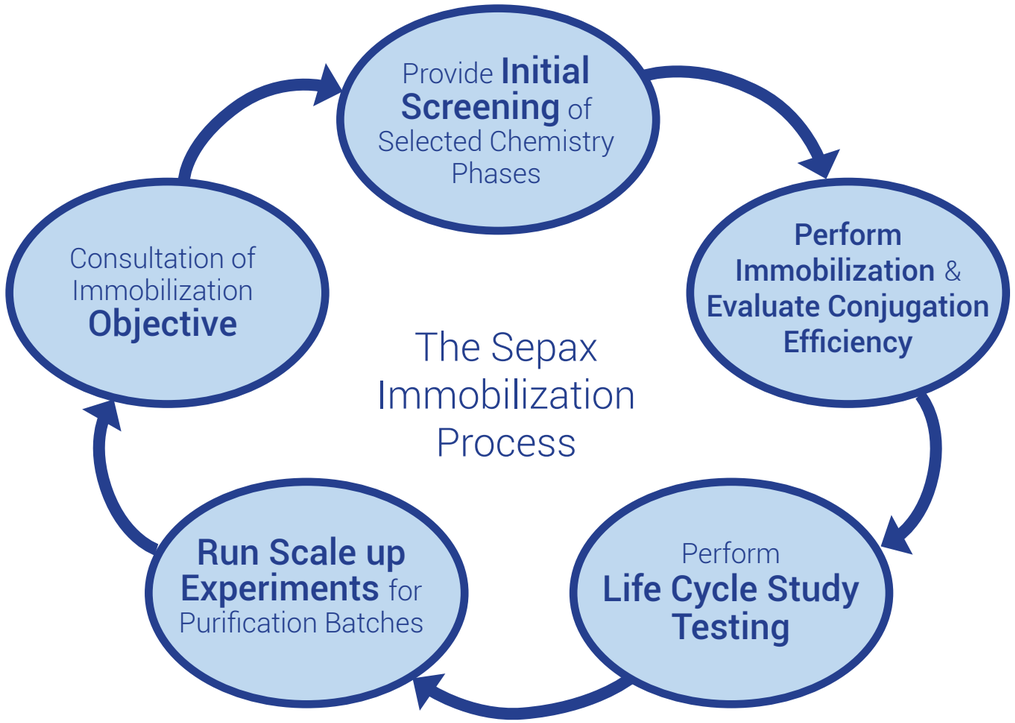
Custom-synthesis of surface coatings for capillary tubes, micro-channels, nano-particles or other device surfaces according to customer's specific needs

Our technologies on surface synthesis can make thin films from monolayers to polymer layers with the surface structure well defined and the thickness well controlled. The polarities and the functionalities of the coatings could be readily designed to meet various applications.

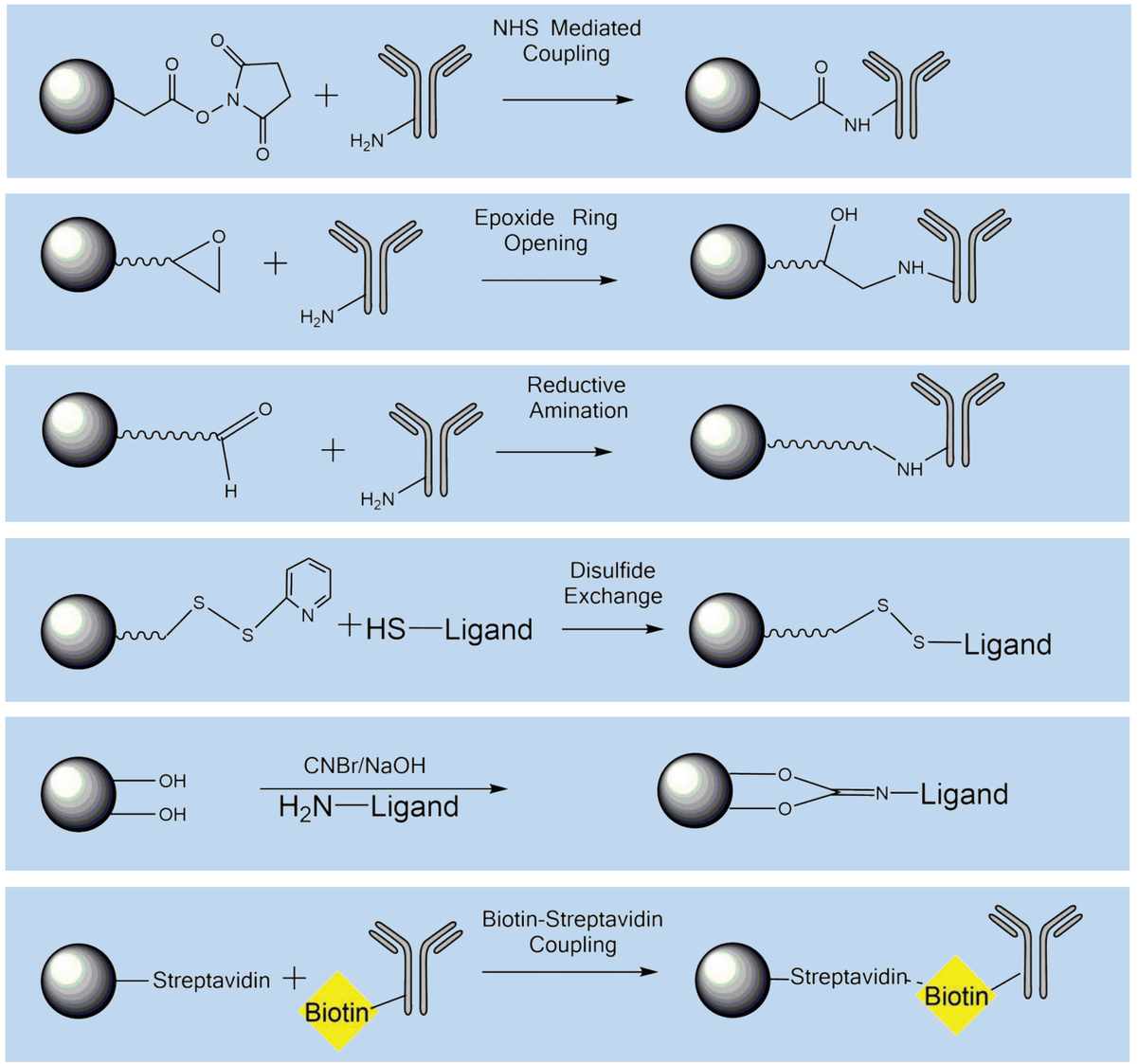
The Sepax à la Carte

Immobilization Menu

Ligand Type	Chemistry	Resin Matrix
▸ Antigen ▸ Antibody ▸ Enzyme ▸ Ligand ▸ DNA/RNA ▸ Other	▸ Extended Chain NHS ▸ Streptavidin-Biotin (non covalent attachment) ▸ Reductive Amination (reactive aldehyde) ▸ Extended Chain Epoxy ▸ Extended Chain CNBr ▸ Coupling Method of Customer's Choice	▸ Agarose ▸ PS-DVB ▸ Silica ▸ PMA ▸ Surface Modified PMA ▸ Surface Modified PS-DVB ▸ Surface Modified Silica (case by case basis) ▸ Customer Provided Matrix



PROTEIN/LIGAND IMMOBILIZATION METHODS



Showcase:

Immobilization

Showcase:

Analytical Screening and Method Development BioServices

Screening Parameters Leveraging various Sepax and other Vendor phases and Mobile Phase Flexibility:

- Separation Modes and Phases
- Surface Chemistry Selectivity
- Particle Size, Pore Size, Resin Matrix Support
- Running conditions: Mobile Phase, Modifier, Gradient, Temperature, Flow Rate and etc.

Phase	Product	Particle size (µm)	Pore Size	Support
Size Exclusion	Unix/Zenix/SRT (stand-up monolayer)	1.8, 3, 5	80-2000 Å	Silica
	Zenix-C/SRT-C (lay-down monolayer for hydrophobic samples)			
	SRT-10/10C (fast purification)	10	100-1000 Å	Silica
Ion Exchange	Proteomix SCX, WCX, SAX & WAX	1.7, 3, 5, 10	Non-Porous	PS/DVB
	Antibodix WCX			
Hydrophobic Interaction	Proteomix HIC Butyl, Phenyl, Propyl, Ethyl	1.7, 5, 10	Non-Porous	PS/DVB
Reversed /Normal /HILIC	Proteomix RP	5	100-1000 Å	PS/DVB
	C18, C8, C4, Phenyl, Cyano, Amino, Diol, Pyridine, Imidazole	1.8, 3, 5, 10	100-300 Å	Silica
	Mix mode: HP-SCX, HP-SAX		120 Å	
Specialty	Carbomix, H, Ca, Pb, Na, K (Sugar, Organic Acid)	5, 10	Non-Porous	PS/DVB

*We can also include other vendor's phases with Sepax BioService projects.
**Above parameters vary per sample difficulty and customer separation goal.

Sepax Analytical BioServices Process

1. Scientist-to-Scientist Discussion
Our scientists recommend an experimental approach based on experience with the sample type on phase chemistry, mobile phase, and all relevant parameters. The service project is designed using parameters outlined in the table to the left after gathering background information of your sample and learning about your separation goal.

2. Project Design
We deliver the experimental design with a detailed step by step outline and lead time for customer review

3. Experiment Implementation
Customer sends the sample to start experiment runs

4. Result Reporting
All data is organized into PPT format as a deliverable including HPLC running conditions. Scientist-to-Scientist meetings are scheduled to discuss the results and answer any questions.

Why Sepax BioServices?

Excellent product consistency
- Enhance client's ROI
- No risk pay per deliverable models
- Capital equipment purchase elimination - UHPLC/HPLC/PREP LC/FPLC/MALS
- Column or resin consumable purchase elimination
- Lower cost than temporary employee or FTE based projects
- Take advantage of our IP/industrial experience for over a decade with access to high level expertise

On time delivery
- U.S. Newark, Delaware-based operation for fast and reliable bio sample delivery

Timely support
- Fast turn-around
- Service designed with your final goal in mind
- Lower cost than traditional service competitors with added expertise in media synthesis
- Full analytical method development and on-site method transfer
- Scalable methods designed for preparative or process chromatography
- Confidentiality assurance (CDA/NDA) to protect our clients' intellectual property and information

Our laboratories support our clients through investment in quality
- HPLC, UHPLC, Prep LC, FPLC
- ÄKTA FPLCs for Chromatography
- Multi-Angle Light Scattering (MALS)
- CGMP
- Customized resin production up to 500 L
- Affinity
- Ion Exchange
- Hydrophobic Interaction
- Preparative and Analytical Size Exclusion
- PAGE, Western Blot

Showcase:

Size Exclusion Column Screening and Mobile Phase Optimization

Sample: Antibody Drug Conjugate (ADC)

Goal:

To screen out the most suitable size exclusion stationary phase and separation condition for high resolution separation between ADC monomer, aggregates, and fragments

Approach:

1. Screen different SEC column phases (Zenix SEC-300, Zenix-C SEC-300 and one other brand of SEC column from other major vendor in the market) to find most suitable column
2. Screen different mobile phases including with or without multiple types of modifiers to achieve best separation and sample recovery

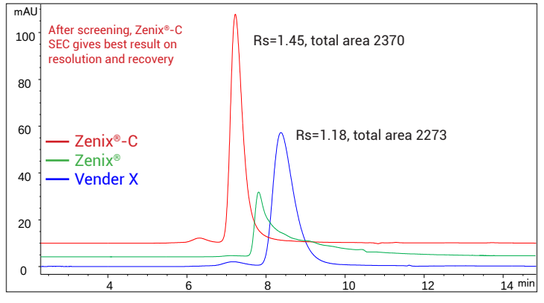
Conclusion:

1. Zenix-C SEC-300 (3 µm, 300 Å) column delivers best separation of this ADC sample.
2. 10% Acetonitrile and 200 mM NaClO4 gives the best result on the total protein recovery, resolution and tailing factor of monomer peak.

CHROMATOGRAMS

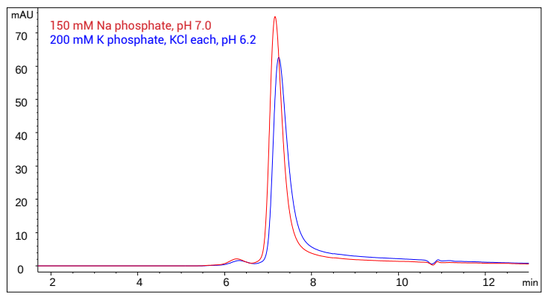
Antibody Drug Conjugate SEC Analysis - Zenix-C vs. Zenix vs. Vendor X

Columns: Zenix-C SEC-300 (3 µm, 300 Å, 7.8 x 300 mm), Zenix (3 µm, 300 Å, 7.8 x 300 mm) , Vendor X (5 µm, 250 Å, 7.8 x 300 mm)
Mobile phase: 150 mM phosphate buffer, pH 7.0
Flow rate: 1 mL/min; Detector: UV 280 nm; Column temperature: 25°C
Injection volume: 10 µL; Samples: Antibody drug conjugate 2 mg/mL



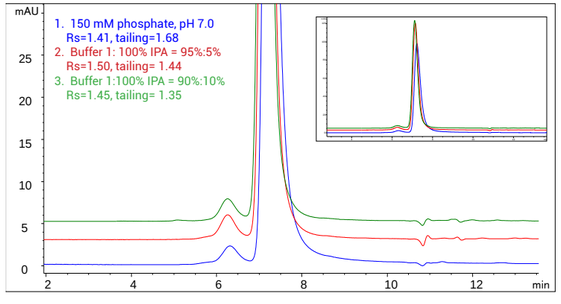
Antibody Drug Conjugate SEC Analysis - Salt difference

Column: Zenix-C SEC-300 (3 µm, 300 Å, 7.8 x 300 mm)
Mobile phase: as indicated
Flow rate: 1 mL/min; Detector: UV 214 nm; Column temperature: 25°C
Injection volume: 10 µL; Samples: ADC 2 mg/mL



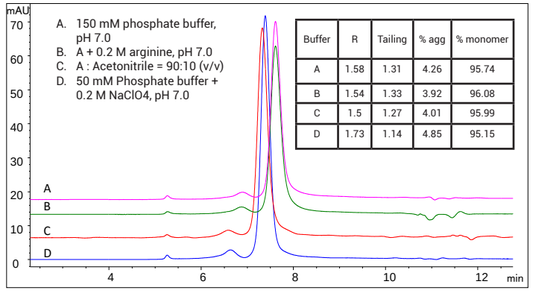
Antibody Drug Conjugate SEC Analysis - IPA modifier

Column: Zenix-C SEC-300 (3 µm, 300 Å, 7.8 x 300 mm)
Mobile phase: as indicated
Flow rate: 1 mL/min; Detector: UV 280 nm; Column temperature: 25°C
Injection volume: 10 µL; Samples: ADC 2 mg/mL



Antibody Drug Conjugate Analysis – Different organic modifiers

Column: Zenix-C SEC-300 (3 µm, 300 Å, 7.8 x 300 mm)
Mobile phase: As indicated
Flow rate: 1 mL/min; Detector: UV 280 nm; Column temperature: 25°C
Injection volume: 20 µL; Samples: ADC



Buffer	R	Tailing	% agg	% monomer
A	1.58	1.31	4.26	95.74
B	1.54	1.33	3.92	96.08
C	1.5	1.27	4.01	95.99
D	1.73	1.14	4.85	95.15

Showcase:

Ion Exchange Column Screening and Mobile Phase Screening

Sample: Antibody Q

Goal:

To screen out the most suitable ion exchange stationary phase and condition that provides high resolution separation of the charge variants of Antibody Q to perform Antibody Q lot to lot testing

Approach:

1. Screen five common buffer systems to find the best condition in order to achieve the highest separation and sample recovery
2. Screen Proteomix SCX and Antibodix WCX to find most suitable ion exchange column

Conclusion:

1. Tris buffer system provided a better separation, while pH/salt system exhibited similar pattern due to the common tris buffer component.
2. Antibodix WCX gives better resolution on the separation of charge variants in basic region on this specific antibody sample. Antibodix WCX was selected to perform Antibody Q lot to lot testing.

CHROMATOGRAMS

Mobile phase systems:

1. A: 20 mM NaAc, pH 5.15; B: A + 1 M LiCl, 20-29.4% from 10-35 min
2. A: 20 mM Phosphate buffer, pH 7.5; B: A + 1 M NaCl, 0-6% in 30 min
3. A: 2.4 mM Tris, 1.5 mM Imidazole, 11.6 mM Piperazine, pH 6.0; B:A + 0.5 M NaCl, pH 10.5, 5-19% from 5-25min
4. A: 20 mM Tris, pH 8.2, B: 20 mM Tris, 100 mM NaCl, pH 8.2, 2-62% from 2-32 min, 0.7 mL/min
5. A: 20 mM HEPES, pH 8.0, B: A + 1 M NaCl, 0-10% from 2-30 min

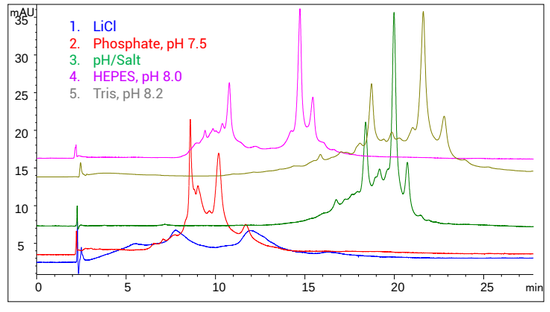
Columns

1. Proteomix SCX (5µm, 4.6 x 250 mm)
2. Antibodix WCX (5µm, 4.6 x 250 mm)

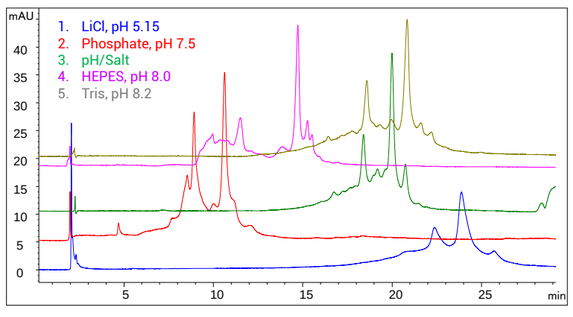
Column running conditions:

1. Flow rate: 0.8 mL/min or otherwise noted in the mobile phase section
2. Detector: UV 280 nm, Column temperature: 30°C
3. Injection volume: 20 µL, Sample: MAb Q 1 mg/mL

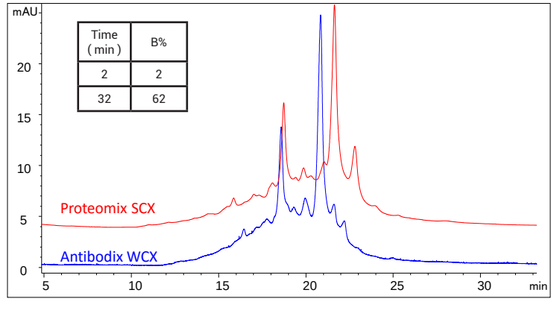
Proteomix SCX NP5, 4.6 x 250 mm



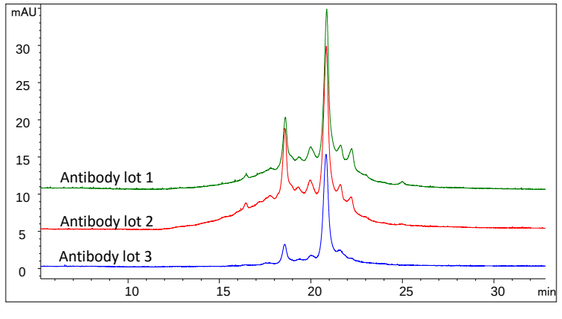
Antibodix NP5, 4.6 x 250 mm



Antibodix WCX vs. Proteomix SCX -Tris buffer



Antibody Q lot to lot test on Antibodix WCX



Contact Us

Additional resources on our website at: **www.sepax-tech.com**

Creation of a customer account will provide you with:

- Full access to application notes of your interested sample type
- Method development training webinars
- Up-to-date listing of where our columns have been cited in the scientific literature
- Easy way to view prices and request quotes

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Sepax BioServices solutions on various biological samples include:

- Monoclonal Antibody
- ADC
- Protein
- Insulin
- Peptide
- Vaccine/VLP
- Nanoparticle
- Oligonucleotide
- Carbohydrate
- Polymer
- Others