Sepax Technologies, Inc.

BioServices Portfolio

Sepax Technologies, Inc.

5 Innovation Way
Newark, DE, 19711, USA
Phone: 302-366-1101
Email: info@sepax-tech.com
For Technical Consultation, Please Contact:
Techsupport@sepax-tech.com or (877) SEPAX-US, Press #3

Sepax Technologies, Inc.

BETTER SURFACE CHEMISTRY FOR BETTER SEPARATION

Sepax Technologies, Inc. is committed to creating products of value for our clients. We pride ourselves on chromatography tools and applications that can support various applications for R&D and quality-based assays. Sepax develops state of the art media and columns for analytical and process development scientists inspiring ingenuity and success.

Take advantage of our passion and expertise.

January 2023
5 Innovation Way
Newark, DE, 19711, USA

Contact Us

Phone: 302-366-1101
Tech Support: (877) SEPAX-US, Press #3
Email: info@sepax-tech.com

Connect with Us

Website: www.sepax-tech.com
LinkedIn: Sepax Technologies
Facebook: @Sepaxtech

Table of Contents

Sepax Technologies, Inc.

Headquartered in Delaware, USA, Sepax Technologies, Inc. has established itself as a leader in the biological separation industry since 2002. We have successfully and quickly expanded to become a global leading chromatography product manufacturer and service provider.

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.

In addition to our site in Delaware, we have two global facilities; a Resin Manufacturing site and Analytical Applications lab focusing on commercial support and medical diagnostics.

Resin Manufacturing Facility
Site Highlight

- 10-acre land
- 30,000 m2 building area
- Product lines include: Affinity, IEX, HIC, SEC, etc.
- Capacity: 100,000L/year
- Lot sizes: 100, 200, 500L

Our Specialty

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, 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 Unique methods and preparative purification platform for biomolecules of peptides. Sepax Quality Management System is ISO 9001:2015 certified.

Our Commitment

At Sepax, we believe that creating value through serving our customers' needs and solving their challenges in the analytical chromatography separation and preparative purification industry is just the beginning. Our dedicated team firmly believe that there is nothing too complicated or challenging for us to consider. We work, grow, and succeed together!

Our Strategy

Whether you are conducting analytical research, in need of customized resins, or preparative, 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 requirements, helping 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.

Regulatory Standards

Sepax uses requirements and guidelines to ensure product quality and prevent risks to public wellbeing. Regulatory Agencies： US (FDA), China (NMPA), Europe (EMA).

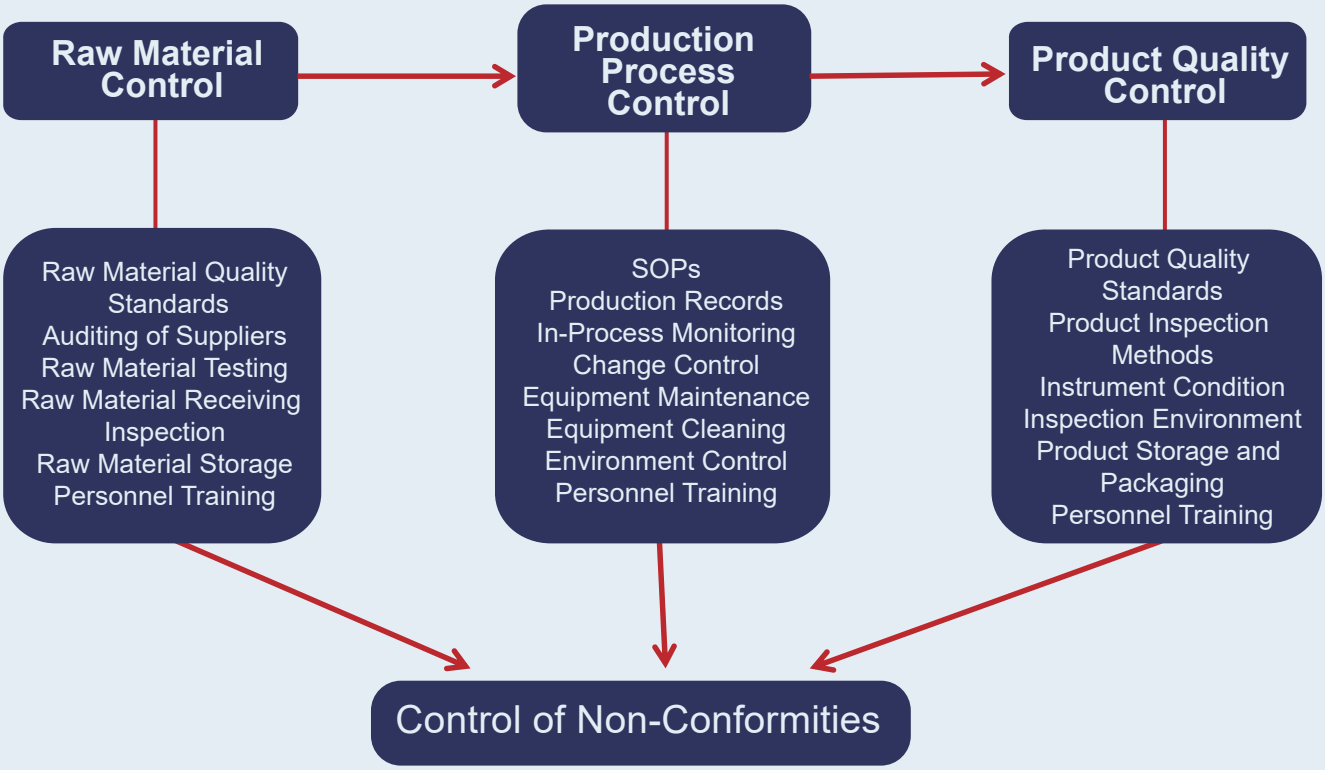
Compliance Focus

- Clean and hygienic production environment
- Prevention of cross contamination
- Clearly defined process parameters and control to ensure quality consistency
- Management of change
- All instructions and SOPs documented in clear, unambiguous wording
- Operator training
- Record keeping for quality and quantity verification
- Risk prevention in product transportation and distribution
- Ability and system to recall products from end-users/distributors
- Corrective and preventive actions resulting from customer complaints and product deficiencies

Sepax Packing Offerings Custom/ Standard

With over 17 years of extensive column packing experience, Sepax has developed technologies for packing a variety of LC columns, analytical with ID from 2.1 to 7.8 mm, semi-prep and preparative with ID of 10, 21.1, 30 and 50 mm, and industrial scale columns with ID from 50 to 800 mm. Sepax also packs FPLC columns with ID from 6.6 to 300 mm.

Sepax Quality Management – Input-to-Output Total Process Control



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, etc.

Phase	Product	Particle Size (μm)	Pore Size (Å)	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	Proteomix RP	5	100-1000 Å	PS/DVB
Mixed mode	Mix mode: HP-SCX, HP-SAX	1.8, 3, 5, 10	120 Å	Silica
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.

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. R&D Reports.

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
- Methods can be scaled from analytical to preparative 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)
- Customized resin production up to 500 L
- Affinity
- Ion Exchange
- Hydrophobic Interaction
- Customized resin for analytical/prep

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

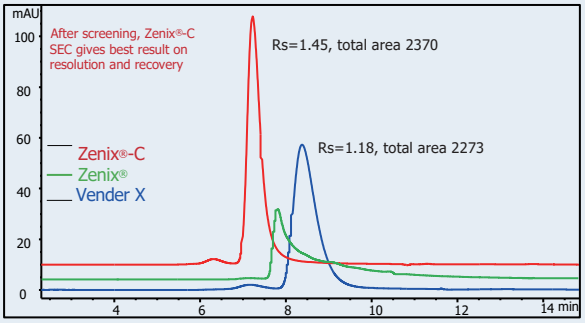
Conclusion:

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

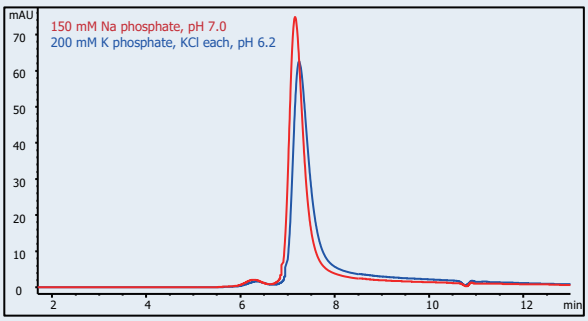
Antibody Drug Conjugate SEC Analysis Zenix-C vs. Zenix vs. Vendor X

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



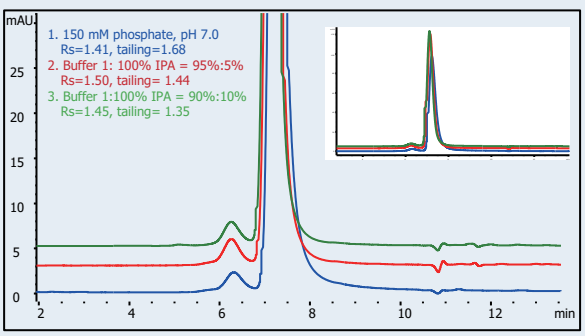
Antibody Drug Conjugate SEC Analysis Salt difference

Column: Zenix-C SEC-300, 3 µm, 300 Å, 7.8 x 300 mm; Flow Rate: 1 mL/min; Detector: UV 214 nm; Column Temperature: 25 °C Injection volume: 10 µL; Samples: ADC 2 mg/mL



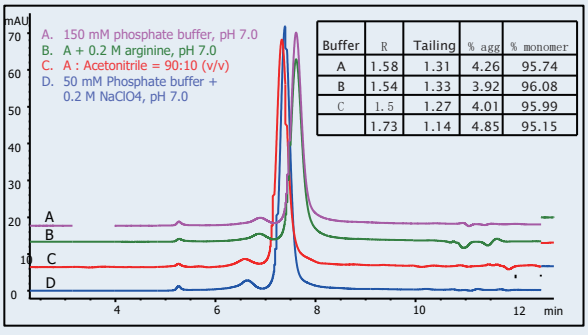
Antibody Drug Conjugate SEC Analysis IPA modifier

Column: Zenix-C SEC-300, 3 µm, 300 Å, 7.8 x 300 mm; 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; 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
	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

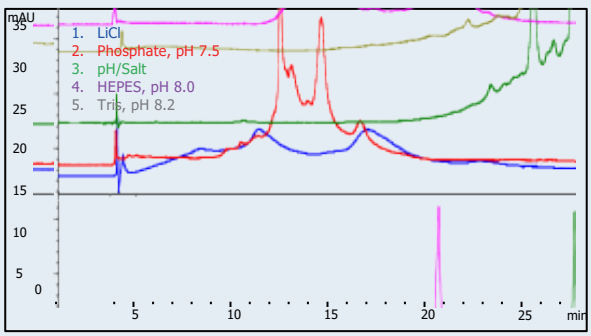
Columns

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

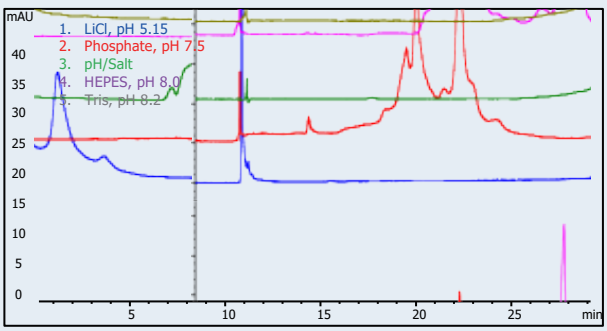
Column Running Conditions:

1. Flow Rate: 0.8 mL/min or otherwise noted in the mobile phase section
2. Detector: UV 280 nm
3. Column Temperature: 30 °C
4. Injection Volume: 20 µL
5. Sample: MAb Q 1 mg/mL

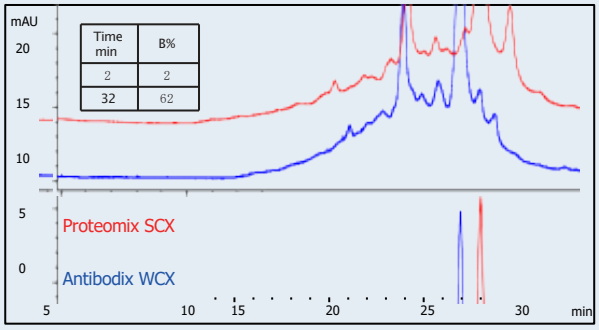
Proteomix SCX NP5, 4.6 x 250 mm



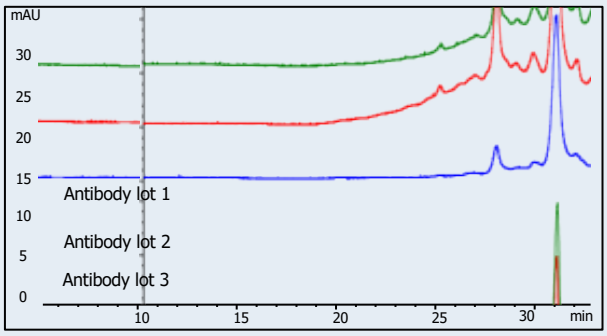
Antibodix NP5, 4.6 x 250 mm



Antibodix WCX vs. Proteomix SCX -Tris buffer



Antibody Q lot to lot test on Antibodix WCX



Showcase

Analytical Characterization of Monoclonal Antibody IgG2

INTRODUCTION

In this showcase we present the IgG2 Vectibix (panitumumab) characterization in a few different chromatographic areas. Vectibix is a fully human mAb IgG2 specific to the epidermal growth factor receptor (EGFR). First, we apply size exclusion chromatography with 1.8 µm particle size, 300 Å modified resin surface for Vectibix IgG2 aggregate, monomer and fragment analysis. With added MALS detector, molecular weight of different species can be determined in the same SEC separation. The second characterization method is the strong cation exchange chromatography. It provides the charge variants separation which may be due to IgG2's major disulfide-mediated structural isoforms. Fractions of the charge variants separation can be collected for further characterization. In the third chromatographic method, Proteomix HIC butyl provides an orthogonal analysis of Vectibix variants under the native running condition based upon the different species' hydrophobicity. Lastly Intact IgG2 and DTT reduced subunits can be analyzed with reversed phase chemistry. Polymer based Proteomix RP1000 provides excellent evaluation of IgG2 subunit heterogeneity. In conclusion, these four chromatographic methods provide a comprehensive characterization of IgG2 Vectibix heterogeneity.

EXPERIMENTAL CONDITIONS:

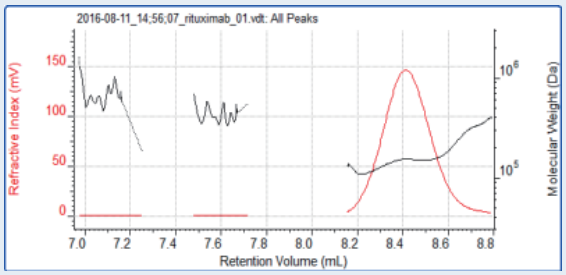
Columns: Zenix® - C SEC-300-LS (3 µm, 7.8 x 300 mm)
Unix® - C SEC-80 (1.8 µm, 4.6 x 300 mm)
Proteomix® SCX NP5 (5 µm, 2.1 x 250 mm)
Proteomix® HIC Butyl-NP5 (5 µm, 4.6 x 50 mm)
Proteomix® RP-1000 (5 µm, 1000 Å, 2.1 x 100 mm)
Samples: Monoclonal Antibody Vectibix IgG2 Erbitux IgG1 LC

CONCLUSION

Zenix-C SEC-300 SEC provides high resolution separation of Vectibix aggregates and monomers. With multi-angle light scattering detector, absolute molecular weight can be determined, aggregation behavior of the mAb can be monitored.
Zenix-C LS column exhibits extreme low shedding with high SEC resolution.
Sub 2µm Unix-C SEC offers higher resolution between aggregate, monomer and fragments of the biomolecule.
Proteomix SCX provides excellent charge variants separation, further fraction collection and peptide mapping can yield information on disulfide shuffling.
Two completely different charge variant profiles are generated with Proteomix SCX for IgG1 and IgG2 due to structure difference while targeting same EGFR.
Hydrophobicity of mAbs can be evaluated using native LC conditions with Proteomix HIC. IgG2 Vectibix and IgG1 Erbitux have different HIC profiles.
With large pore reversed phase chromatography, reduced Vectibix fragments can be separated with online mass spec analysis capability.
High resolution SEC, cationic exchange, native HIC and large pore reversed phase offer a wide range of orthogonal analysis for monoclonal antibody heterogeneity.

SIZE EXCLUSION CHROMATOGRAPHY (SEC-MALS)

Column: Zenix-C SEC-300, 3 µm, 300 Å, 7.8 x 300 mm; Mobile Phase: 150 mM phosphate buffer, pH 7.0; Flow Rate: 1.0 mL/min; Column Temperature: RT; Triple Detector: UV 280 nm, RI, MALS; Sample: Rituximab

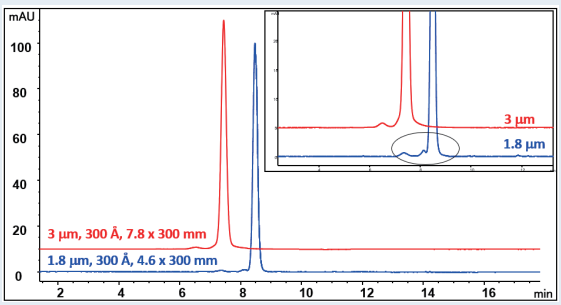


LIGHT SCATTERING RESULTS

Peak	1	2	3
Ret Vol (mL)	7.030	7.534	8.410
Mw (Da)	591,733	429,578	150,414
Mw/Mn	1.134	1.030	1.027
Rg(w) (nm)	24.74	19.08	10.22
Wt Fr (Peak)	0.0028	0.0031	0.9942
MALS Area (90°)	0.11	0.08	8.46

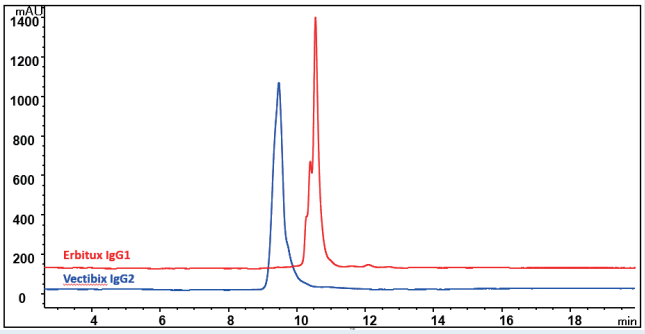
SUB 2 UM SIZE EXCLUSION CHROMATOGRAPHY (SEC)

Column: Unix-C SEC-300, 1.8 µm, 300 Å, 4.6 x 300 mm and Zenix-C SEC-300, 3 µm, 300 Å, 7.8 x 30 mm; Mobile phase: 150 mM phosphate buffer, pH 7.0; Flow Rate: 0.3 mL/min; Detector: UV 280 nm; Column Temperature: RT; Sample: Vectibix



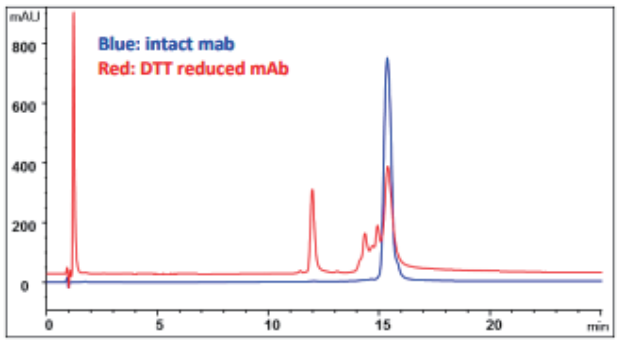
HYDROPHOBIC INTERACTION CHROMATOGRAPHY

Column: Proteomix HIC Butyl-NP5 4.6 × 50 mm; Mobile Phase A: 2 M Ammonium Sulfate + 100 mM Sodium Phosphate pH 7.0, B: 100 mM Sodium Phosphate pH 7.0; Flow Rate: 1.0 mL/min; Detection: UV 214 nm; Sample: Vectibix 20 mg/mL; Injection 1 µL



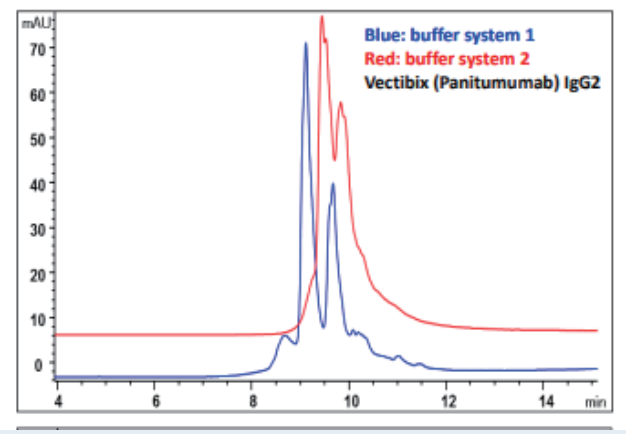
REVERSED PHASE PROTEOMIX RP-1000 SEPARATION AFTER IDES PROTEOLYSIS AND DTT REDUCTION

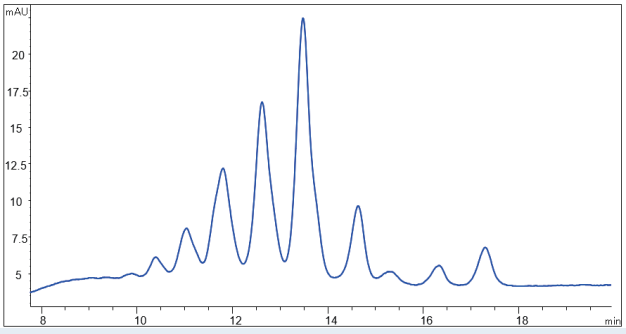
Column: Proteomix RP-1000, 5 µm, 1000 Å, 2.1 x 100 mm; Mobile Phase: A: 0.1% TFA in water, B: 0.1% TFA in 100% ACN; Flow Rate: 0.3 mL/min; Detector: UV 214 nm; Column Temperature: 78˚C; Gradient: 2-22 min 30% - 45% B; Injection: 5 µg intact and DTT reduced Vectibix



CHARGE VARIANTS SEPARATION WITH PROTEOMIX SCX

Column: Proteomix SCX NP5, 5 um, 2.1 x 250 mm, PEEK; Mobile Phase A: 16 mM MES, 10 mM MOPS, 12 mM TAPS, 10 mM CAPSO, 30 mM NaCl, pH 5.6, B: 10 mM MES, 12 mM MOPS, 14 mM TAPS, 16 mM CAPSO, 30 mM NaCl, pH 10.2, C: B+1 M NaCl; Flow Rate: 0.3 mL/min; Detector: UV 280 nm; Column Temperature: 25 ˚C; Injection volume: 3 µL; Sample: 2 mg/mL Erbitux





Sepax Affinity Services

Sepax Technologies has worked with a diverse variety of customer for over the last decade supporting multiple projects that involve resin and ligand chemistry selection for the best possible affinity performance. Some of the immobilization chemistries include, epoxy, NHS, Streptavidin Biotin, reductive amination, and disulfide exchange. We have successfully immobilized many ligands using our advanced chemistries and surface modifications.

As resin chemistry experts, we come equipped with over 12 polymer chemists with extensive experience in resin and ligand design. This coupled with our experience separates us from the rest. We have been successful in many applications and continue to expand our technical horizons.

Key Areas:

- Fusion Proteins
- Cross Reactivity
- RNA purification
- Glycosylated compound capture
- mAb separation and analysis
- BsMabs separation and analysis

Working in tandem with our scientists 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. In addition to these services, Sepax also provides OEM and ODM services.

Immobilization Chemistry

Ligand Type	Chemistry	Resin Matrix	Particle Size (µm)
➢ IgM ➢ Mab ➢ DNA ➢ RNA ➢ HSA ➢ Enzyme ➢ Boronate ➢ Protein A ➢ Heterodimer ➢ Heparin ➢ Custom Ligand	➢ Extended Chain NHS ➢ Streptavidin-Biotin (noncovalent 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	➢ Silica: 5, 10, 20, 40, 60 ➢ Agarose: 45, 65, 90 ➢ PS-DVB: 5, 10, 20, 30, 60 ➢ PMA: 10, 30, 60

Ligand Examples

DNA Immobilization——for microarrays and sensors

Heparin – protein purification, cation exchanger, and DNA purification-

Lectin – purification of glycoconjugates/ glycans/ glycoproteins

Boronate – simple ligand selectivity for glycated species

RNA – any dT useful for purification for RNA constructs

mAb – specific interaction with various proteins

Enzyme – clinical diagnostics, lab Assays, bio-catalysis

IgM –myoglobin analysis and other reactive species

IgG/HSA – cross interaction chromatography for drug ½ life studies and competition against other antigens

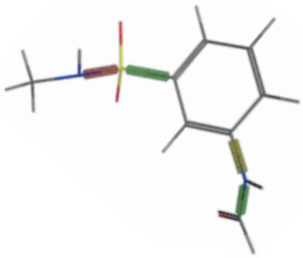
Heterodimer Affinity – separations of bispecifics in fermentation broths for 2-D analysis with SEC or in process monitoring

Custom Resins – immobilization of small molecule/protein for drug interaction/metabolism

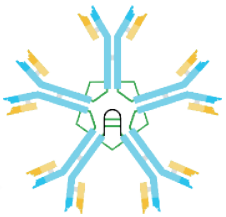
Ligand Types

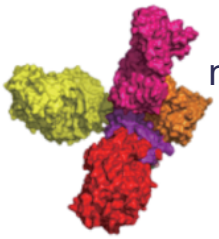
Sepax Immobilized Ligands

Custom Ligand

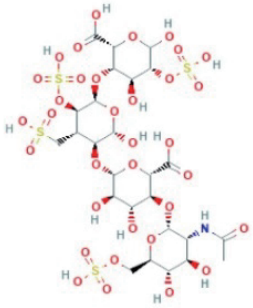


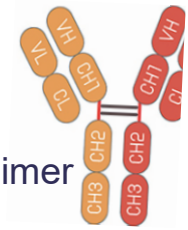
IgM



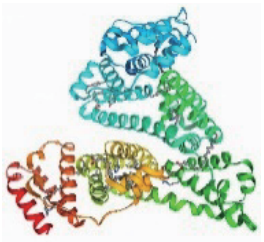


Heparin

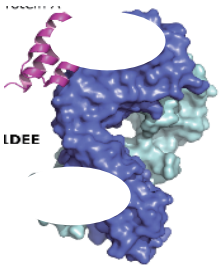




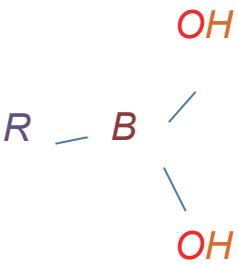
Heterodimer



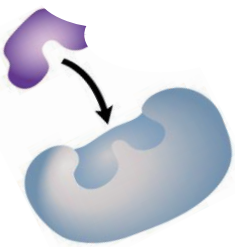
HSA



Protein A

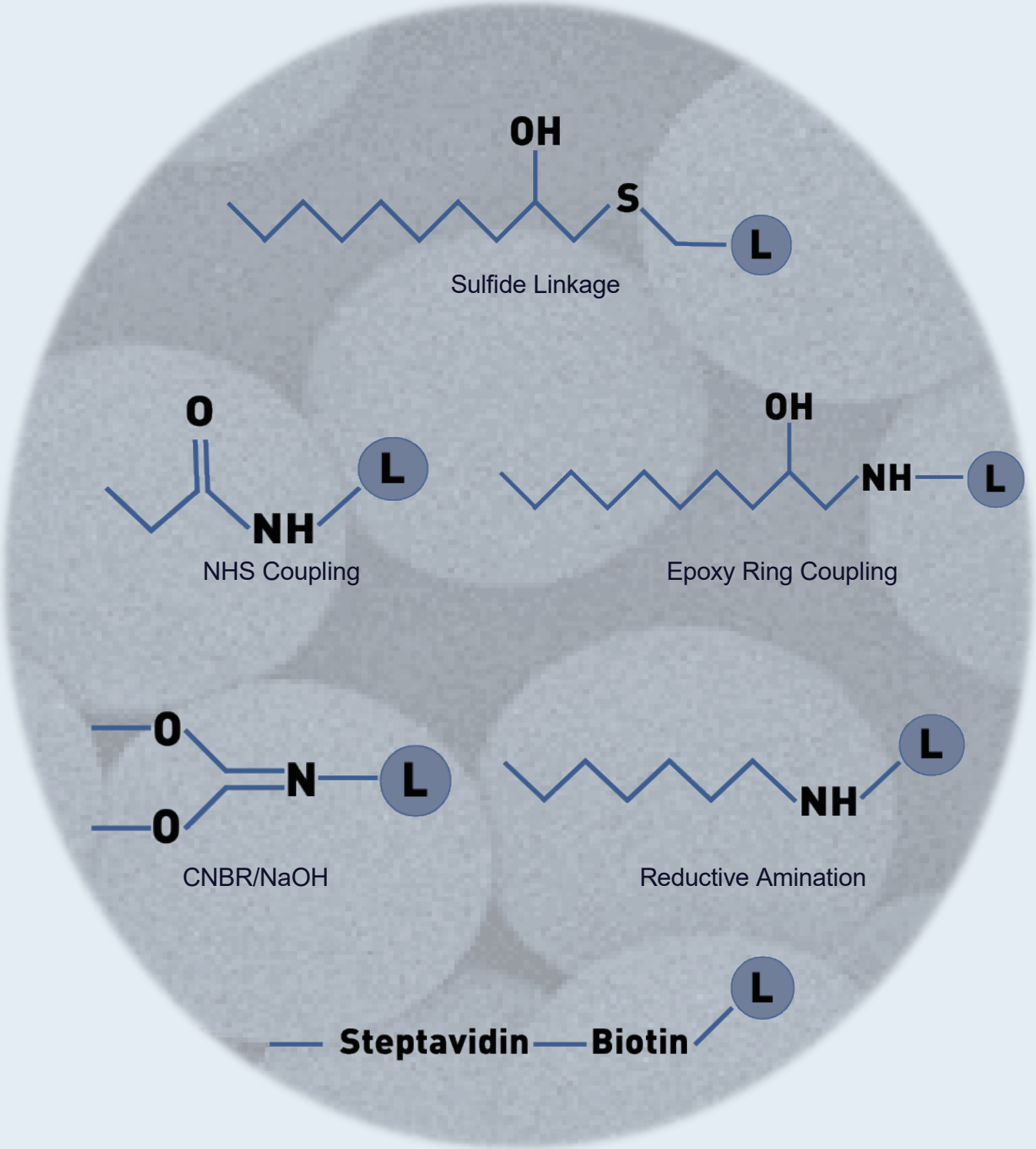


Boronate



Enzyme

Chemistry

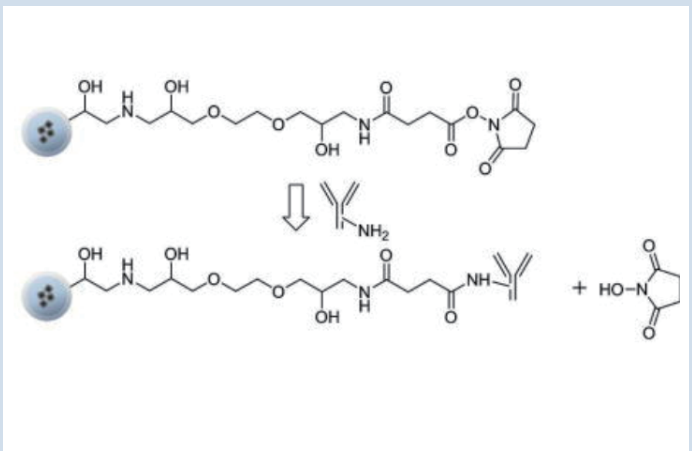

OH
S
L
Sulfide Linkage
O
L
NH
NHS Coupling
OH
NH
L
Epoxy Ring Coupling
O
N
L
O
CNBR/NaOH
L
NH
Reductive Amination
L
Steptavidin
Biotin

Affinity Process

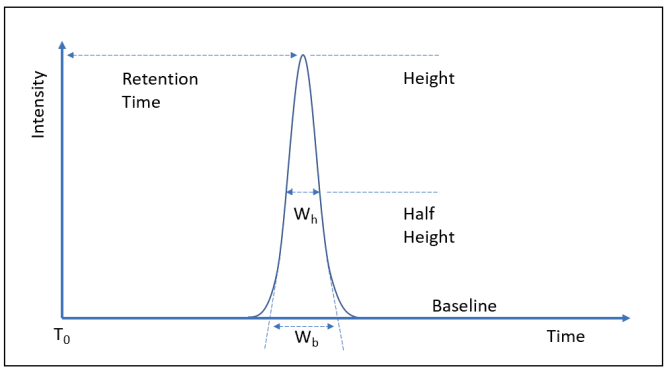
Sepax has developed an in-process method that measures the accuracy, conjugation efficiency, and reliability of ligand binding. Resin selection screening and linker chemistry reduces non-specific interaction and optimizes loading capacity. The covalent attachment of ligand to the linker bound to the matrix coupled with size exclusion chromatography quantitatively measures the binding efficiency.

1. Resin Selection

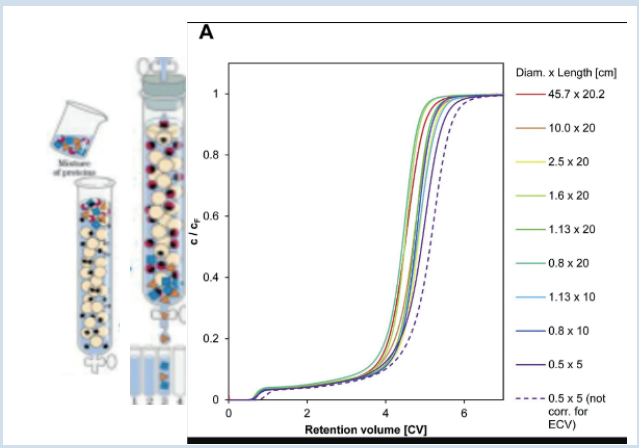
2. Determine Ligand/ Conjugation Type and Amount



5. Column Packing and Plate Count Measurement

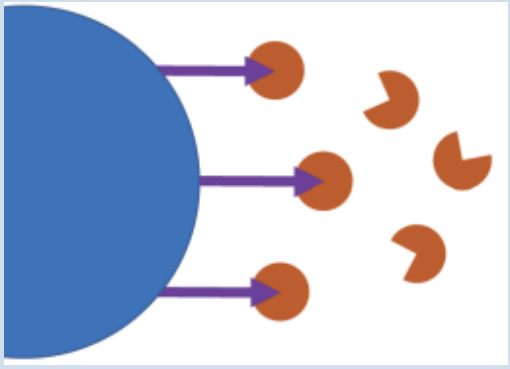


6. DBC Testing

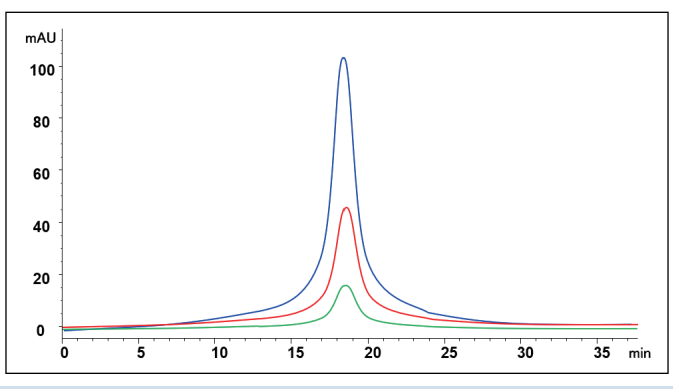


This allows for the optimal conjugation time and the highest possible ligand loading. From there, column packing efficiency is measured along with dynamic binding capacity (continuous feed to 10% breakthrough). Once capacity and packing is optimized, accuracy measurements are performed assessing linearity, LOD, LOQ, and spiked sample accuracy.

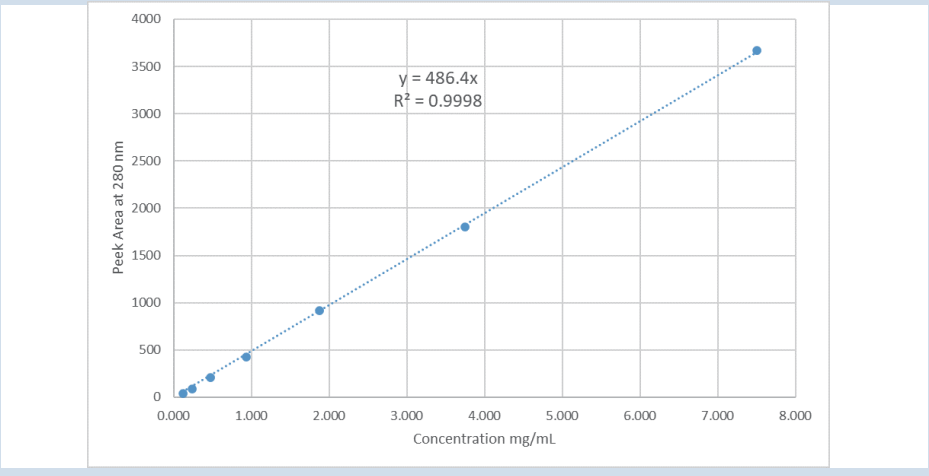
3. Immobilization



4. Conjugation Efficiency by SEC



7. Linearity/LOD/LOQ Qualification



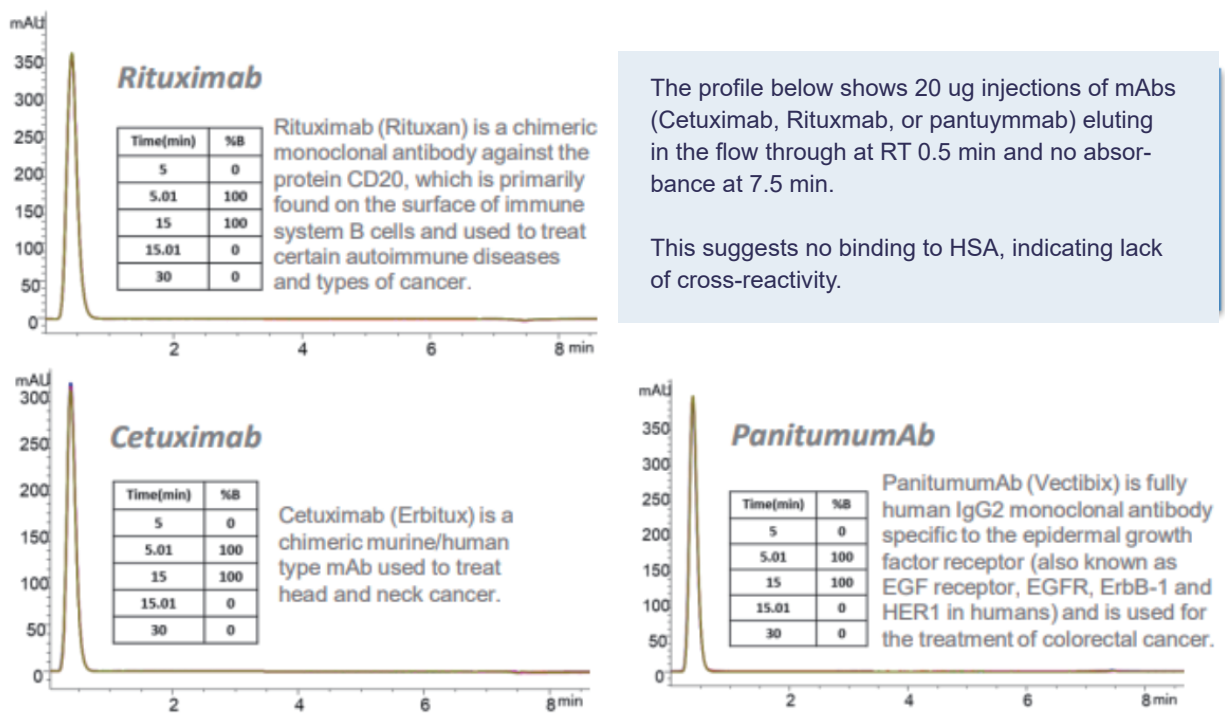
Immobilization Study – HSA

HSA is a ligand used to the cross-reactivity of a mAb with immobilized HSA may provide critical insight regarding mAb half-life, likelihood for adverse immune reactivity, and its potential efficacy. interaction with drugs including mAbs and can reveal stability (increased presence in blood stream) but also can limit bioavailability if tight to too.

Goal: To immobilize HSA and assay the linearity and access specificity and reactivity to commercially available mAbs.

CHROMATOGRAMS

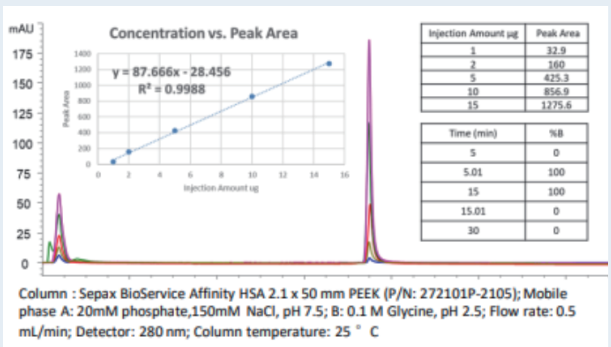
mAbs on Sepax BioService Affinity HSA Analytical Column



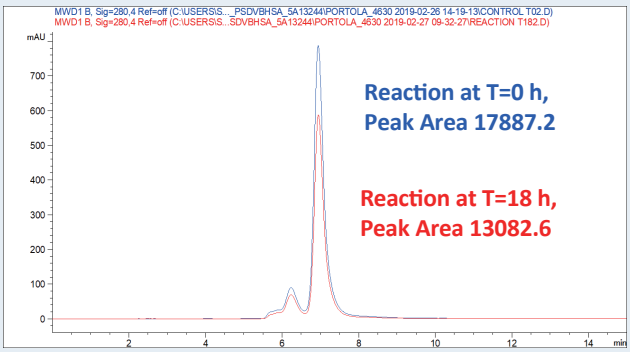
The profile below shows 20 ug injections of mAbs (Cetuximab, Rituxmab, or pantuymmab) eluting in the flow through at RT 0.5 min and no absorbance at 7.5 min.

This suggests no binding to HSA, indicating lack of cross-reactivity.

Column : Sepax BioService Affinity HSA 2.1 x 50 mm PEEK (P/N: 272101P-2105); Mobile phase A: 20mM phosphate,150mM NaCl, pH 7.5; B: 0.1 M Glycine, pH 2.5; Flow rate: 0.5 mL/min; Detector: 280 nm; Column temperature: 25 ° C; Sample: 2 mg/mL; Injection Amount: 10 µL



Column : Sepax BioService Affinity HSA 2.1 x 50 mm PEEK (P/N: 272101P-2105); Mobile phase A: 20mM phosphate,150mM NaCl, pH 7.5; B: 0.1 M Glycine, pH 2.5; Flow rate: 0.5 mL/min; Detector: 280 nm; Column temperature: 25 ° C



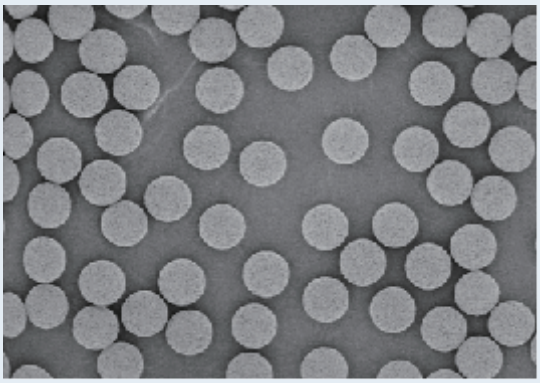
Linearity Assessment (Sample: Anti-HSA 1 mg/mL)

Showcase

Immobilization Study – AAV 9

The anti-aav9 antibody ligand was immobilized to a polymeric solid phase support and the conjugation efficiency was measured over time. Free antibody was measured at time zero and then at 18hrs, the area difference corresponding to the amount bound.

Goal: To immobilize AAV-9 and test conjugation efficiency via SEC method.

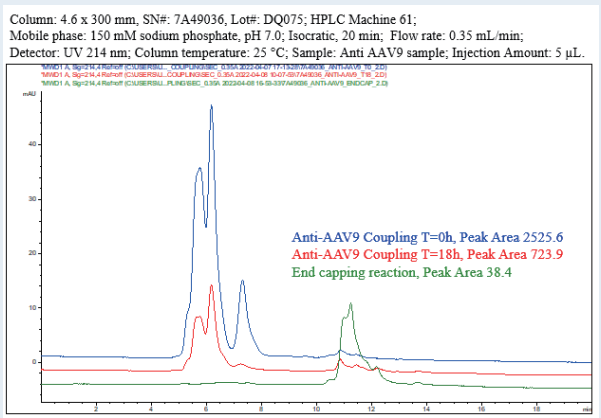


Sepax Monosized PS-DVB (20um) Resin- SEM

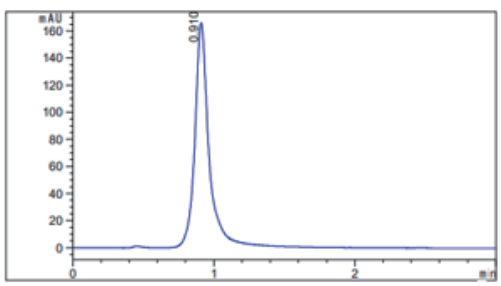
AAV Affinity Column	Details
Support Matrix (Particle size, Pore size)	Sepax Monosized PS-DVB (20 µm, 1000-2000 Å)
Immobilized Ligand	Anti-AAV9
Ligand Density	0.70 mg Anti-AAV9 /mL PSDVB resin
Column size ID x L	2.1 mm x 50 mm
Column Volume	0.17 mL
Column Format	PEEK
Pressure Limit	200 bar
PSDVB beads pH Range	1.2-13.0
Analytical Recommended Flow Rate	0.5-2 mL/min
For Purification Purpose: Recommended Flow Rate	≥3-minute residence time
Storage Temp	2-8 C, Do not freeze

CHROMATOGRAMS

Anti-AAV9 Coupling on PSDVB 20-2000 Beads Monitor



AAV Affinity Column QC



Compound Name	RT [min]	Height	Area	Plates	Tailing	Resolution
NaNO2	0.91	166	1180	554	1.30	

Sepax Service Partners

Looking for a team of subject matter experts who deliver valuable insights? Sepax's experienced team is here to help! Our partners offer a simpler way to connect scientists (like us) with the innovation, capabilities, and technologies you need.

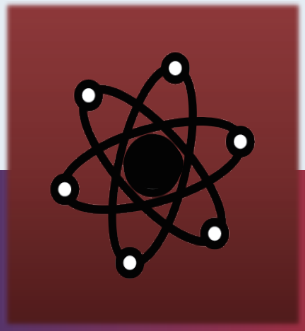
Science Exchange

scientist.com

- Secure Access
- Competitive Pricing
- Standardized and Custom Quoting
- Prequalified for a Variety of Services
- Payment Terms Defined
- CDA/NDA Execution

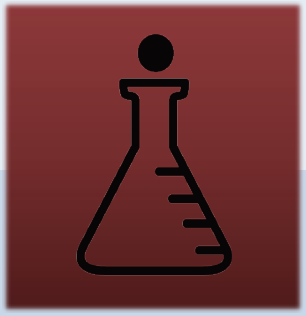
Efficiency Platform

Service Platform & Process



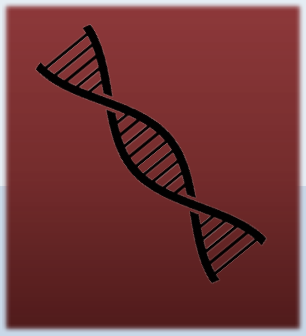
Target ID & Validation

- Characterize target ID
- Functional screening



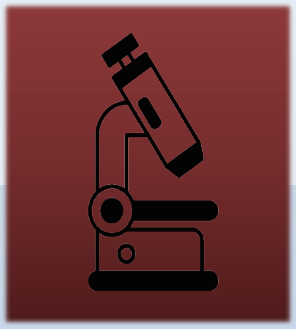
Lead ID & Optimization

- Identify and immobilize ligand
- Optimize chemistry
- Characterize resin, capacity, selectivity, and performance



Candidate Validation

- Scale up antibody Purification
- Biological structure characterization

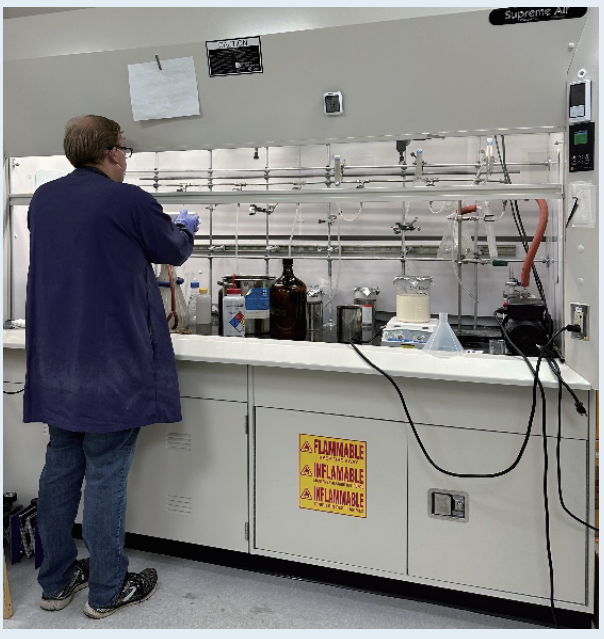


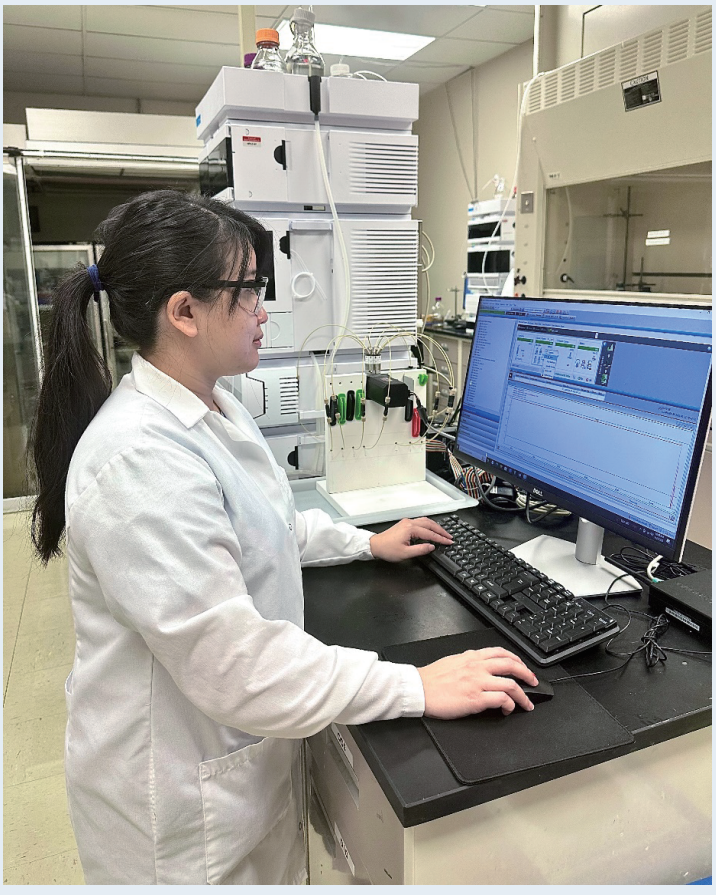
Enabling Studies

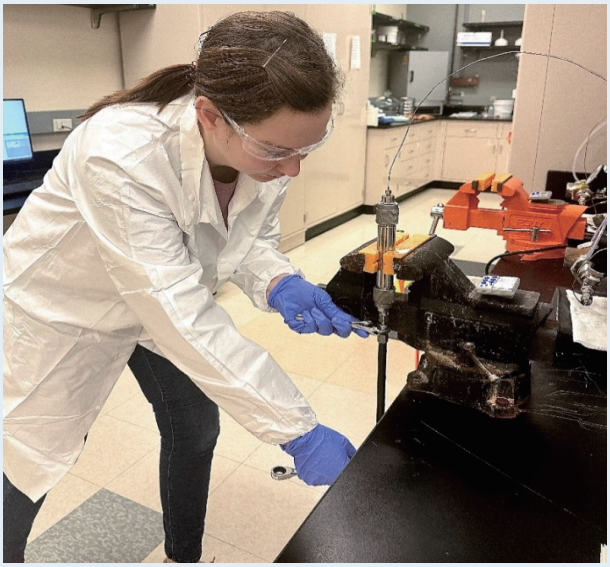
- Look into different ligands
- Optimize methods
- Process characterization and optimization

Sepax Labs

The Sepax Approach is simple. Our subject matter experts offer highly individualized services for each customer. We present the most cost-efficient method for analysis or purification after looking at all options available. We providing cutting edge products and services to our customers for analytical to preparative applications. As our capabilities continue to grow, so do our labs and equipment.







Area	Function/ Capability	Equipment/Software	Maker	Model
Bioinformatics	In silico design and engineering	PyMol, Coot, Snapgene		
Upstream	Molecular biology	PCR	Bio-Rad	T100
	Molecular biology	RT-PCR	Bio-Rad	C1000 Touch
	Fermentation	Bioreactor	Eppendorf	BioFlo 120
Downstream	Process development & Protein purification	Microfluidizer	Microfluidizer	Microfluidics
	Protein purification		Cytiva	Avant 150
	Protein purification		Cytiva	Avant Pure
Analytical	Protein analytics	Gel Staining	GenScript	eStain L1
	Protein analytics	Western Blotting	GenScript	eBlot
	Protein analytics	WB developer	GenScript	eZwest
	Protein analytics	Gel imager	Bio-Rad	ChemiDoc
	Protein analytics	HPLC	Agilent	1260 Infinity II
	protein analytics	Multi-Angle Light Scattering (MALS) Detector	Wyatt	DAWN
	Assays, ELISA	Plate Reader	Tecan	Infinite F200
	Assays, ELISA	Plate Reader	Tecan	HydroSpeed
	Particle/Resin	Surface Area		Pore volume, pore size: Mercury intrusion tester. Micromeritics,Autopore V
	Particle/Resin	Surface Area		Pore volume, pore size: Nitrogen adsorption BET. Micromeritics, Tristar II Plus
	Particle size analysis	Laser Scattering		Particle size analyzer. Bettersizer, 2600
General	General equipment	Thermo mixer	Eppendorf	Eppendorf ThermoMixer C
	General equipment	Shaker	Eppendorf	Eppendorf Innova 42/42R Incubated Shaker
	General equipment	Centrifuge (R)	Beckman	Avanti JXN-26
	General equipment	Benchtop centrifuge (R)	Eppendorf	Centrifuge 5804 R - Benchtop Centrifuge
	General equipment	Centrifuge (R)	Eppendorf	Centrifuge 5430 R, rotary knobs, refrigerated, with Rotor F-35-6-30 incl. rotor lid, 120 V/50-60 Hz (US)
	General equipment	Biosafety cabinet		