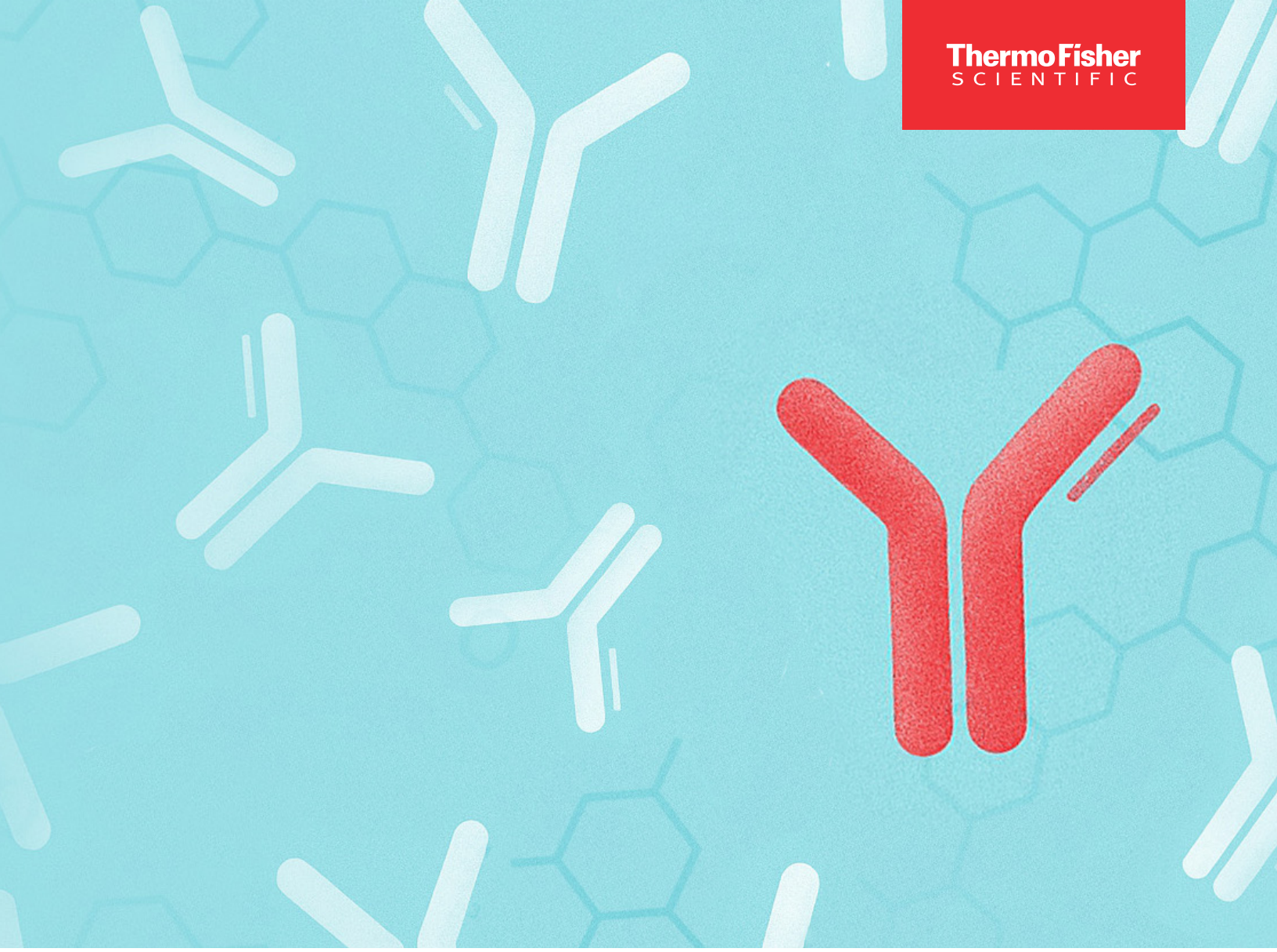


mAb purification

Chemical and resin compatibility for downstream processing

Helping enhance yield and purity of mAb capture and polish resins

Amplify your mAb downstream processes with the right resin and buffer combinations

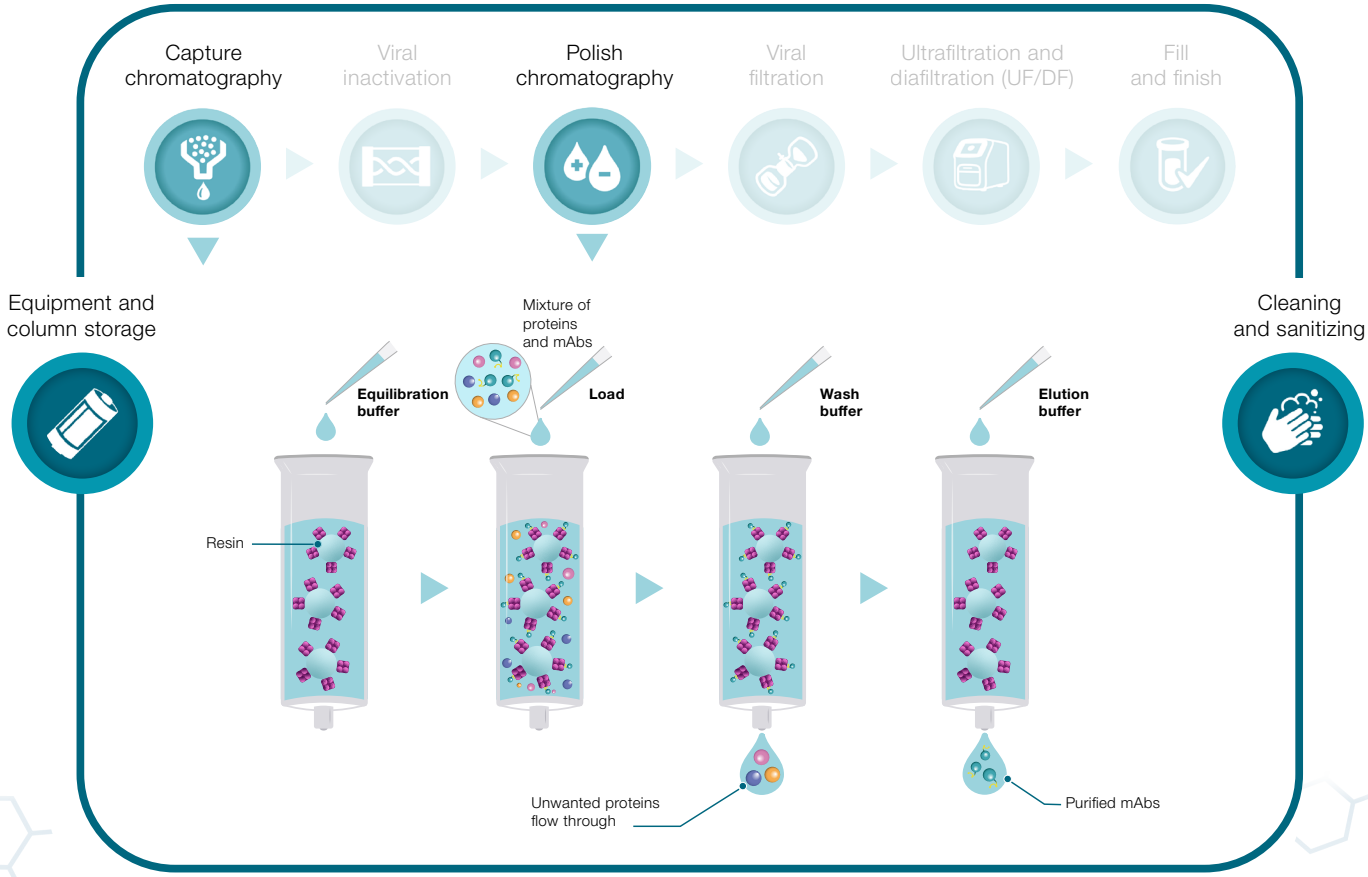
Monoclonal antibodies (mAbs) are critical components in modern therapeutics, providing targeted treatments for various diseases. Achieving high purity and yield in mAb manufacturing is essential to bring these life-changing medicines to market. High-quality resins and buffers play a pivotal role in optimizing the purification process, helping ensure that the final product meets stringent quality standards.

Thermo Fisher Scientific offers a comprehensive range of manufactured and sourced products that work synergistically to enhance downstream process performance and product quality. Our chromatography resins and chemicals support mAb purification as a comprehensive toolkit with a variety of chemistries for high yield, selectivity, and purity. Our ongoing supply chain support can help processes run smoothly so you can stay focused on developing lifesaving therapies.

mAb chromatography process needs

Purification of mAbs by chromatography involves equilibration, binding, washing, elution and cleaning steps. Equilibration conditions the column with a buffer to promote optimal binding. The crude sample is applied during the binding step under consistent buffer conditions. Washing removes nonspecifically bound impurities, often using buffers with added salts and detergents.

Elution releases the target molecule by altering buffer conditions, such as pH or salt concentration. The cleaning step often applies a stronger solution to remove tightly bound residual molecules from resin after purification. The proper selection of buffers enables efficient and effective mAb purification.



Thermo Fisher resin characteristics

		Thermo Scientific™ resin matrix	Purpose
Capture	Affinity	MabCaptureC™ Affinity Matrix	• Engineered protein A with affinity for the Fc region with cross-binding to VH3 domain • Purification of mAbs, recombinant 9 Fc-fusion proteins, and VH3 antibody fragments (i.e., Fabs, scFvs)
		CaptureSelect™ CH1-XL Affinity Matrix	• Affinity for the CH1 domain • Purification of mAbs, bispecific antibodies (bsAbs), and Fabs irrespective of light chains
		CaptureSelect™ FcXP Affinity Matrix	• Affinity for the CH3 domain • Purification mAbs (including multispecifics) and Fc-fusion proteins
		CaptureSelect™ KappaXP Affinity Matrix	• Affinity for the CL-kappa or CL-lambda domain • Purification of Fab fragments and bispecific antibodies
		CaptureSelect™ LambdaXP Affinity Matrix	
Polish	Hydrophobic interaction chromatography (HIC)	POROS™ Benzyl Ultra HIC Resin	Flow-through mode in lower salt to bind impurities such as HCPs, aggregates, and other high molecular weight (HMW) impurities
		POROS™ Benzyl HIC Resin	Bind-elute or flow-through mode depending on target molecule; purification of a wide range of biomolecules such as mAbs, enzymes, and antibody-drug conjugates (ADCs); can be used to separate product-related impurities (e.g., aggregates) and process-related impurities
		POROS™ Ethyl HIC Resin	Bind-elute mode of moderately to considerably hydrophobic molecules, including product-related impurities and aggregates
	Anion exchange (AEX)	POROS™ XQ	Strong, fully quaternized AEX resin for polish of a variety of biomolecules to remove negatively charged impurities and contaminants such as DNA, viruses, host-cell proteins (HCPs), aggregates, endotoxins, and empty or partial viral vectors
		POROS™ HQ	AEX resin with partially quaternized polyethyleneimine functional groups for the polish of a variety of biomolecules to remove negatively charged impurities and contaminants such as DNA, viruses, HCPs, aggregates, and endotoxins
		POROS™ 50 PI	Weak AEX resin with polyethyleneimine chemistry for the polish of a variety of biomolecules to remove negatively charged impurities and contaminants such as DNA, viruses, HCPs, aggregates, and endotoxins
		POROS™ 50 D	Weak AEX resin with dimethylaminopropyl chemistry for the polish of a variety of biomolecules to remove negatively charged impurities and contaminants such as DNA, viruses, HCPs, aggregates, and endotoxins
	Cation exchange (CEX)	POROS™ XS	High-binding capacity CEX resin typically operated in bind and elute mode, binding positively charged target molecule and allowing for the separation of impurities such as HMW and LMW species, HCPs, DNA, or product variants
		POROS™ HS	High-binding capacity CEX resin typically operated in bind and elute mode, binding positively charged target molecule and allowing for the separation of impurities such as HMW and LMW species, HCPs, DNA, or product variants
	Mix-mode (MMCEX)	POROS™ Caprylate Mixed-Mode Chromatography Resin	Hydrophobic and CEX chemistry for the flow-through removal of high levels of aggregates and other HMW species, as well as other process-related impurities

To request a sample of any of the following resins, please visit thermofisher.com/resinsample

Quality raw materials to complement your resins

Using high-quality chemicals in chromatography purification is essential for maintaining resin performance, enhancing efficiency for higher yields and purity, minimizing contamination risks, and preserving the integrity and longevity of the resin—all of which can contribute to reducing production costs.

Chemicals produced under Current Good Manufacturing Practice (cGMP) principles offer additional benefits critical for high-stakes applications such as large-molecule drug development, research, clinical trials, and production. These benefits include consistency and reliability through stringent quality standards, enhanced safety by minimizing contamination risks, and supporting compliance with regulatory requirements essential for these applications.

Benefits of adopting cGMP materials

Streamlined regulatory compliance
Facilitates early alignment with regulatory expectations

Tech transfer and scale-up
Materials aligned with commercial production standards, minimizing later adjustments

Cost and time efficiency
Minimizes comparability studies and delays, accelerating time-to-market

Recommended chemicals, process liquids, and buffers for resins

	Affinity	HIC	AEX	CEX	MMCEX
Acetic acid (CAS 64-19-7)	CIP	CIP	CIP	EQ, W, EL	EQ, W, EL, CIP
Ammonium sulfate (CAS 7783-20-2)		EQ, W, EL			
Benzyl alcohol (CAS 100-51-6)	Stor, CIP				
Citric acid (CAS 77-92-9)	EL	EQ, W, EL		EQ, W, EL	EQ, W, EL
Ethanol (CAS 64-17-5)	Stor	Stor, CIP	Stor	Stor	
Ethylene glycol (CAS 107-21-1)	Add	Add	Add	Add	Add
Glycine (CAS 56-40-6)	EL				
Guanidine hydrochloride (CAS 50-01-1)	CIP	CIP	CIP	CIP	CIP
HEPES (CAS 7365-45-9)	EQ, W	EQ, W	EQ, W	EQ, W, EL	EQ, W, EL
Isopropyl alcohol (CAS 67-63-0)		CIP	CIP	CIP	CIP
Phosphate buffered saline (PBS) (CAS 2439-54-5)	EQ, W	EQ, W	EQ, W	EQ, W	EQ, W
Phosphoric acid (CAS 7664-38-2)	CIP	CIP	CIP		
Sodium acetate (CAS 127-09-3)	EL	EQ, EL, CIP	CIP	EQ, W, EL	EQ, W, EL
Sodium chloride (CAS 7647-14-5)	EQ, W	EQ, W, EL	EQ, W, EL, CIP	EQ, W, EL, CIP	EQ, W, EL, CIP
Sodium citrate anhydrous (CAS 68-04-2)	EL	EQ, W, EL		EQ, W, EL	EQ, W, EL
Sodium hydroxide (CAS 1310-73-2)	CIP	CIP	CIP, Stor	CIP, Stor	CIP, Stor
Sodium phosphate dibasic dihydrate (CAS 10028-24-7)	EQ, W	EQ, W	EQ, W	EQ, W	EQ, W, EL
Sodium phosphate monobasic dihydrate (CAS 13472-35-0)	EQ, W	EQ, W	EQ, W	EQ, W	EQ, W, EL
Sodium sulfate anhydrous (CAS 7757-82-6)	EQ, W	EQ, W, EL	EQ, W	EQ, W, EL	EQ, W, EL
Tromethamine (Tris, Tris Base) (CAS 77-86-1)	EQ, W	EQ, W	EQ, W, EL		
Urea (CAS 57-13-6)	W, CIP	CIP	CIP	CIP	CIP

Note: Please consult the product information sheet or a technical specialist for additional details on ideal buffer use, concentrations, etc. for each resin.

Key

EQ: Equilibration
W: Wash
EL: Elution
CIP: Clean-in-place
Stor: Storage
Add: Buffer additive

Our chemical network

Thermo Fisher offers a broad portfolio of multicompendial chemicals, process liquids, and buffers both through our global network of trusted manufacturers and suppliers, as well as our in-house manufacturing of Gibco™ Process Liquids and Buffers. We deliver chemicals in dry and liquid formats, with quantities starting at 1 kg and 100 mL. Our comprehensive quality documentation for sourced chemicals, process liquids, and buffers enables easy integration into your workflows.

Manufacturers and suppliers

- **Ajinomoto Group**
- **Avantor**
- **BASF**
- **BioSpectra**
- BIOVECTRA
- **Cytiva**
- DFE Pharma
- **Dr. Paul Lohmann**
- Gibco™ feeds and supplements
- **Gibco Process Liquids and Buffers**
- **Greenfield Global**
- **Hawkins**
- **Macco Organiques**
- **Quality Chemicals**
- **Spectrum Chemical**
- STERIS
- Veltek

Categories

- **Acid solutions**
- **Amino acids**
- **Base solutions**
- **Biological buffers**
- Biological reagents
- Carbohydrates
- Cleaning agents and disinfectants
- Denaturants
- Minerals and vitamins
- **Salts**
- **Solvents**
- Supplements
- Surfactants and emulsifiers
- Water

Grades

- American Chemical Society (ACS)
- **GMP**
- **Pharma**
- Reagent
- Technical

Compendia

- British Pharmacopoeia (BP)
- Chinese Pharmacopoeia (ChP)
- European Pharmacopoeia (Ph. Eur.)
- Food Chemicals Codex (FCC)
- Japanese Pharmacopoeia (JP)
- National Forumulary (NF)
- United States Pharmacopoeia (USP)

Documentation

- Certificate of Analysis (CoA)
- Certification of Origin (CoO)
- Drug Master File (DMF)*
- Regulatory certificates
- Safety Data Sheet (SDS)
- Technical Data Sheet (TDS)

The blue bolded font denotes suppliers, categories, and grades most applicable to downstream purification processes.

* Drug Master Files are available for select products.

Advanced chemical supply chain support

We provide a suite of chemical services and supply chain support to complement your downstream operations, including storage, supply assurance, sampling, recycling, and more. Our facilities meet ISO 9001, cGMP, and Good Distribution Practice (GDP) standards, minimizing risks of order nonconformances and contamination. We offer robust support for quality agreements and vendor questionnaires, helping ensure that all regulatory and compliance requirements are met efficiently and effectively. Our team of technical specialists in cGMP-compliant chemical supply chain management helps you achieve quality compliance and prevent process interruptions or delays.

We strive to work as an extension of your team to create a reliable chemical supply chain, supporting your business continuity and accelerating your speed-to-market.

Storage

Sourcing & procurement

Vendor managed inventory

Container recycling, reuse & disposal

Raw material sampling

Why source chemicals through Thermo Fisher?

Streamline operations

Access chemical products backed by redundant processes and supported by cGMP- and GDP-compliant supply chain infrastructure

Trusted collaborations

Build a reliable supply of available, consistently manufactured chemicals through our global network of chemical manufacturers and suppliers

Comprehensive support

Receive extensive technical support and customer service for raw material forecasting and product usage advice

Experience

Leverage the combined experience of Thermo Fisher and other chemical manufacturer and supplier teams to stay ahead in your processes

Learn more at **thermofisher.com/downstreamchemicals**