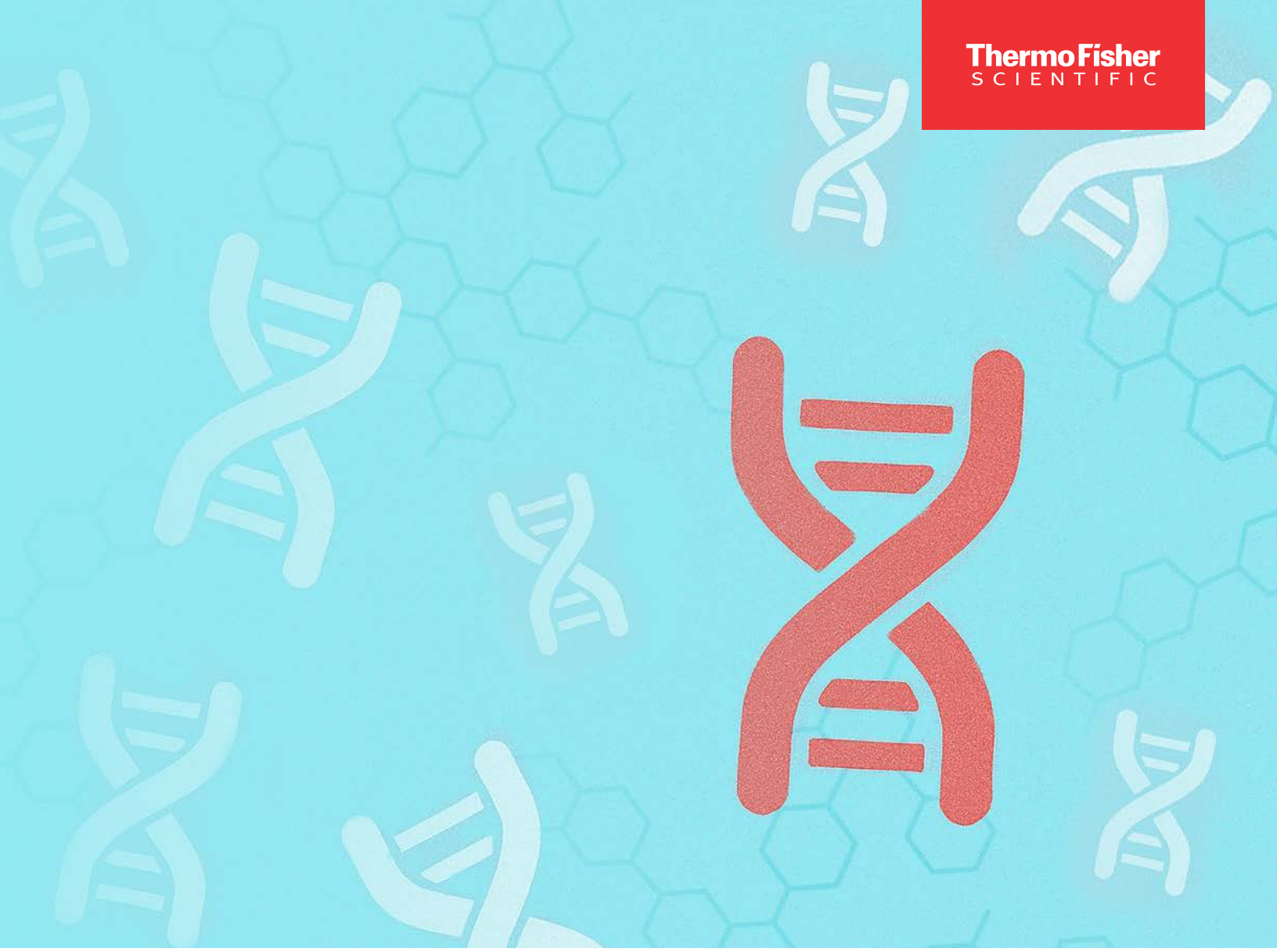


Viral vector purification

Chemical and resin compatibility for downstream purification

Helping enhance yield and purity of gene therapy capture and polish resins

Amplify your viral vector downstream processes with the right resin and buffer combinations

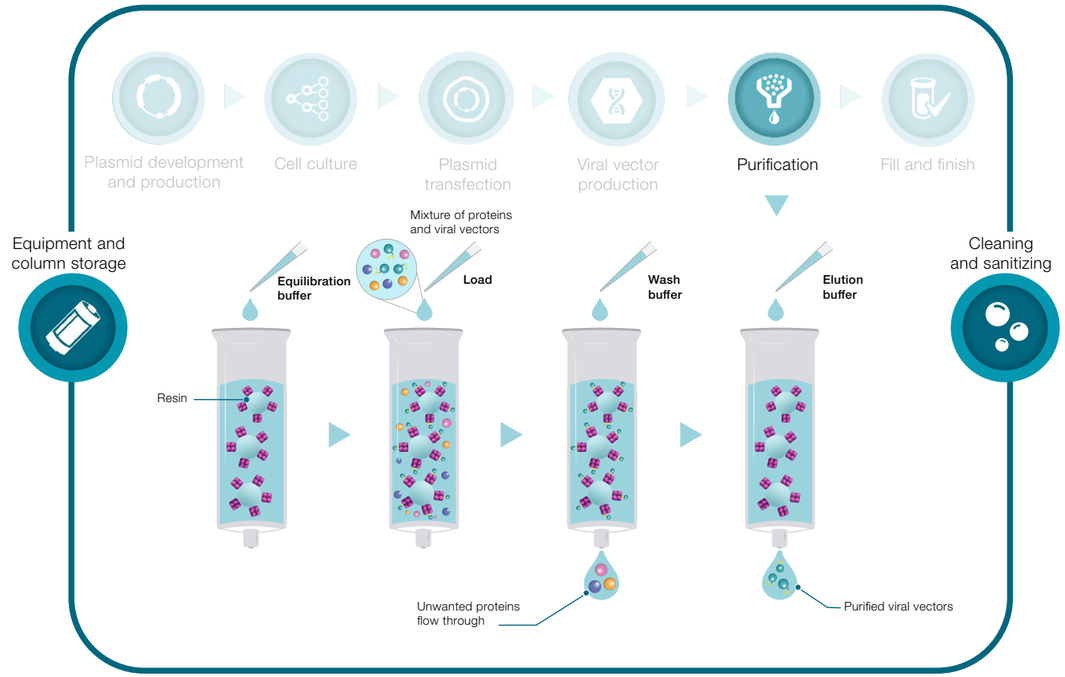
Viral vectors, such as lentivirus and adeno-associated virus (AAV), are critical in developing modern gene therapy that provides targeted treatment for various genetic disorders and diseases. Achieving high purity and yield in the manufacturing of these viral vectors is essential for therapeutic efficacy and patient safety. High-quality resins and buffers play a pivotal role in optimizing the purification process, helping to 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 help ensure maximum purification and yield. Our chromatography resins and chemicals support viral vector purification as a vast purification toolkit with a variety of chemistries for high yield, selectivity, and purity. Ongoing supply chain support can help processes run smoothly so you can stay focused on developing lifesaving therapies.

Viral vector chromatography process needs

Viral vector purification by chromatography has evolved to follow a traditional process scheme of capture and polish, similar to monoclonal antibodies (mAbs). Each chromatography unit operation involves equilibration, bind, wash, elute, and strip steps. Equilibration conditions the column with a buffer to promote optimal binding. The crude sample is applied during the bind step under consistent buffer conditions. Washing helps remove nonspecifically bound impurities, often using buffers with added salts or detergents. Elution releases the viral vectors by altering buffer conditions, such as pH or salt concentration. The strip step applies a strong buffer or solution to clean and regenerate the column.

The proper selection of resins and buffers can help ensure efficient and effective viral vector purification.



Affinity resins

Affinity chromatography separates biomolecules using their interaction with a specific affinity ligand on a chromatography matrix, resulting in higher yield and purity in a single step. This technique enhances the efficiency of downstream processes.

Thermo Scientific™ POROS™ CaptureSelect™ AAV affinity resins help to:

- Reduce the number of steps, and increase purity and yield in a single capture step
- Increase productivity and provide flexibility in the AAV purification process
- Efficiently scale and establish a single purification platform for multiple AAV serotypes, including engineered capsids

Polish resins

Post affinity capture, the removal of empty or partially filled capsids is critical. Anion exchange chromatography is commonly used as a scalable and robust method for use at the development and manufacturing scales.

The use of Thermo Scientific™ POROS™ HQ or XQ anion exchange resins helps to:

- Separate full capsids from empty and partially filled capsids due to slight differences in their isoelectric point
- Enable high purity and recovery of the desired form of the therapeutic AAV product
- Efficiently scale up the AAV manufacturing process run at high flow rates

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 often 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

	Equilibration	Wash	Elution	Strip	Clean-in-place	Buffer additive
Acetic acid (CAS 64-19-7)			●	●	●	
Argenine (CAS 74-79-3)						●
Citric acid (CAS 77-92-9)			●	●	●	
Ethanol (CAS 64-17-5)					●	
Ethylene glycol (CAS 107-21-1)						●
Glycine (CAS 56-40-6)			●			
Guanidine hydrochloride (CAS 50-01-1)					●	●
Hydrochloric acid (CAS 7647-01-0)					●	●
Isopropyl alcohol (CAS 67-63-0)					●	
Magnesium chloride (CAS 7786-30-3)			●			
Phosphate buffered saline (PBS) (CAS 2439-54-5)	●	●	●			
Phosphoric acid (CAS 7664-38-2)				●	●	
Poloxamer (CAS 9003-11-6)	●					●
Potassium chloride (CAS 7447-40-7)	●	●				
Propylene glycol (CAS 57-55-6)			●			
Sodium acetate (CAS 127-09-3)			●			
Sodium chloride (CAS 7647-14-5)	●	●	●	●	●	●
Sodium hydroxide (CAS 1310-73-2)					●	
Sodium phosphate dibasic dihydrate (CAS 10028-24-7)	●	●				
Sodium phosphate monobasic dihydrate (CAS 13472-35-0)	●	●				
Tromethamine (Tris, Tris Base) (CAS 77-86-1)	●	●	●			
Urea (CAS 57-13-6)					●	

Our chemical network

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

Manufacturers and suppliers

- **Ajinomoto Group**
- **Avantor**
- **BASF**
- **BioSpectra**
- BIOVECTRA
- DFE Pharma
- **Dr. Paul Lohmann**
- **Gibco™ feeds and supplements**
- **Gibco Process Liquids and Buffers**
- **Greenfield Global**
- **Hawkins**
- **Macco Organiques**
- **Quality Chemicals**
- **Spectrum**
- 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 Formulary (NF)
- United States Pharmacopeia (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.
* DMFs are available for selected products.

Advanced chemical supply chain support

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

We strive to help your team create chemical supply chain, supporting your business continuity and helping to accelerate 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 as well as other chemical manufacturer and supplier teams to help advance your processes

Ordering information

Description	Volume	Cat. No.
POROS CaptureSelect AAVX Affinity Resin	250 mL	**A36742**
	1 L	**A36743**
	5 L	**A36744**
	10 L	**A36745**
POROS CaptureSelect AAV8 Affinity Resin	250 mL	**A30792**
	1 L	**A30793**
	5 L	**A30794**
	10 L	**A30795**
POROS CaptureSelect AAV9 Affinity Resin	250 mL	**A27355**
	1 L	**A27359**
	5 L	**A27358**
	10 L	**A27357**
POROS XQ strong AEX resin	250 mL	**4467820**
	1 L	**4467818**
	5 L	**4467817**
	10 L	**4467816**
POROS 50 HQ strong AEX resin	250 mL	**1255911**
	1 L	**1255907**
	5 L	**1255909**
	10 L	**1255908**

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

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