

Eshmuno® AAV9 Chromatography Resin

High-capacity AAV9 capture with fast processing, gentle elution, and cost-saving reusability

Adeno-associated virus serotype 9 (AAV9) is a commonly used vector for viral gene therapy production. Robust, scalable production of AAV9 therapies relies on purification technologies that provide strong binding capacities, high flow rates, high virus recovery and caustic stability.

Eshmuno® AAV9 is an affinity capture resin designed for efficient purification of AAV9. This novel resin overcomes the limitations of traditional technologies and enables enhanced capture, which sets downstream purification up for success. By combining high flow rates and strong binding capacity, with high recovery and caustic stability, this resin technology accelerates production and helps reduce manufacturing costs.



Key Benefits

- **High binding capacity** for wild-type AAV9 and for a broad range of AAV9 capsid variants at short residence times (RT)
- **High recovery** $\geq 80\%$ when eluting between pH 2–4; minimizing aggregation and preserving capsid integrity at higher elution pH
- **Effective clearance** of host cell DNA (hcDNA) and host cell protein (HCP)
- **Caustic stability** up to 0.5 M NaOH, improving reuse and reducing costs

High Binding Capacity, Short RT and High Recovery

High binding capacity and AAV9 recovery was observed with a 0.2 mL pre-packed OPUS® MiniChrom® column with Eshmuno® AAV9 resin through 5 cycles of clean-in-place (CIP) using 0.5 M NaOH, for 30 min cycle duration, **Figure 1**. Although Dynamic Binding Capacity at 10% breakthrough (DBC10%) is dependent on the individual AAV9 serotype and lysate conditions, in this study the DBC10% at 1 min RT was $1.5E+15$ vp/mL $\pm 4\%$ over the 5 cycles tested with virus recovery at $88\% \pm 4\%$. Similarly, hcDNA and HCP clearance remained consistent over the 5 cycles with CIP, **Table 1**.

The high binding capacity and reliable cleanability of the Eshmuno® AAV9 resin are key attributes that support the use of this resin as a cost-effective purification solution for enhanced AAV9 capture.

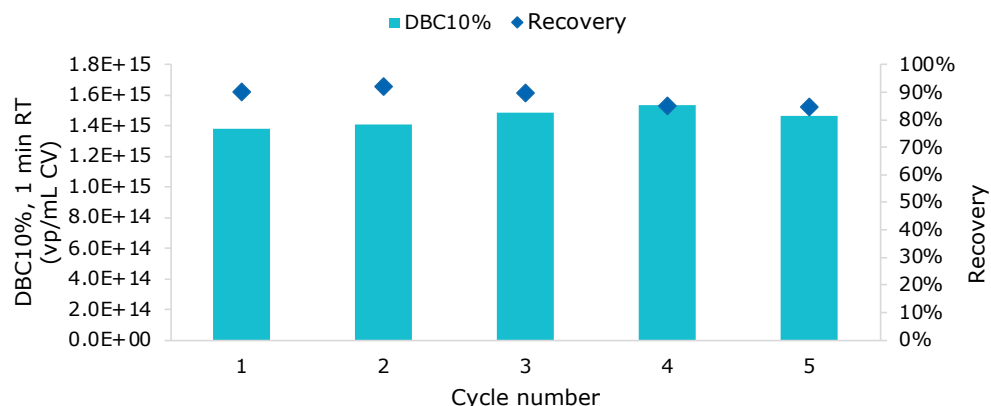


Figure 1: Eshmuno® AAV9 DBC10% and recovery after 5 cycles with CIP (0.5 M NaOH, 30 min per cycle)

Table 1: HCP and hcDNA LRV after 5 cycles with CIP. HCP and hcDNA in the elution pool were below the detection limit of the respective analytical assay.

Impurity Clearance (LRV)			
Cycle number	1	3	5
HCP	≥4.4	≥4.4	≥4.4
hcDNA	≥2.5	≥2.6	≥2.8

Maintaining Viral Infectivity & Efficient Impurity Clearance

In some cases, low pH elution conditions can impact virus infectivity. **Figure 2** shows infectivity of AAV9 wild-type and impurity clearance following elution from a 0.2 mL pre-packed OPUS® MiniChrom® column containing Eshmuno® AAV9 resin. Elution at mild pH minimized structural and functional damage to the virus capsids and maintained virus recovery without compromising impurity clearance.

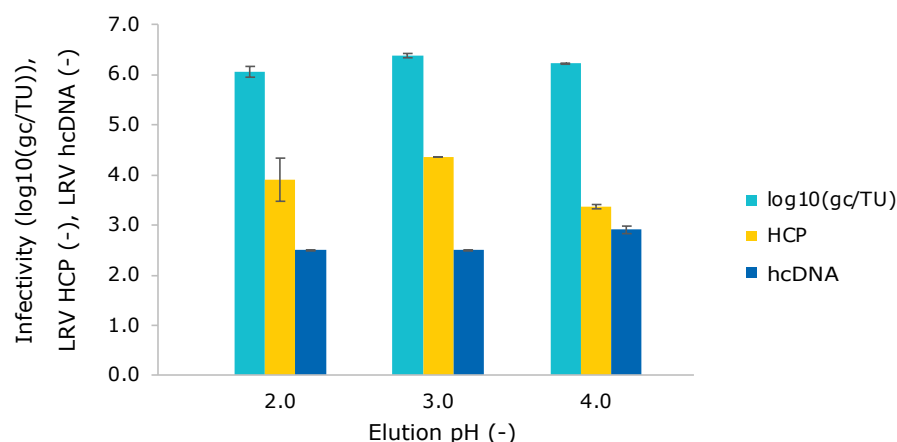


Figure 2: Infectivity, HCP LRV and hcDNA clearance at different elution pH

The Emprove® Program - The Smart Way to Master Compliance and Control

Eshmuno® AAV9 resin is supported by the Emprove® Program which complements our product portfolio and provides convenient access to reliable technical, regulatory and supply information in Emprove® Dossiers to support your risk assessment continuum. A subscription to the Emprove® Suite can help you stay current. In addition to accessing the Emprove® Dossiers, you can also receive notification updates to document changes, as well as current metrics and support.

For more information, please visit: SigmaAldrich.com/Emprove

Specifications

Media Characteristics Overview

Media Characteristics Overview	
Type of chromatography	Affinity
Base material	Rigid hydrophilic polyvinyl ether polymer
Functional group	AAV9-specific Nanofitin® produced in <i>Escherichia coli</i>
Average particle size (d ₅₀)	50 µm
Dynamic binding capacity (DBC10%)*	≥8E+14 vp/mL column volume (CV) at 1 min RT and 10% breakthrough (BT)
pH stability	1.5–13
Chemical compatibility	2-propanol, acetonitrile, urea, dipropylene glycol, acetic acid, phosphoric acid, guanidine hydrochloride
Mechanical stability	8 bar
Linear flow rate	Up to 500 cm/hr (20 cm bed height, <3.0 bar net pressure)
Recommended residence time	1 min
Shipping and storage buffer	20% ethanol, 150 mM sodium chloride
Storage temperature	+2 °C to +8 °C

* The DBC10% is dependent on the individual AAV9, lysate conditions and additives.

Ordering information

Description	Cat. No.
Eshmuno® AAV9 resin 10 mL	1.20690.0010
Eshmuno® AAV9 resin 100 mL	1.20690.0100
Eshmuno® AAV9 resin 500 mL	1.20690.0500
Eshmuno® AAV9 resin 5 L	1.20690.5000
Eshmuno® AAV9 in OPUS® MiniChrom® Column, 5 mm × 10 mm 0.2 mL	1.25198.0012
Eshmuno® AAV9 in OPUS® MiniChrom® Column, 8 mm × 20 mm 1.0 mL	1.25198.0001
Eshmuno® AAV9 in OPUS® MiniChrom® Column, 8 mm × 100 mm 5.0 mL	1.25198.0005
Eshmuno® AAV9 in OPUS® RoboColumn®, 8PC 5 mm × 10 mm 0.2 mL	1.25194.0012

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MS_DS14308EN Ver. 1.0 70104 07/2026

