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Data Sheet

# 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** ≥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 ±4% over the 5 cycles tested with virus recovery at 88% ±4%. Similarly, hcDNA and HCP clearance remained consistent over the 5 cycles with CIP, **Table 1**.

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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.

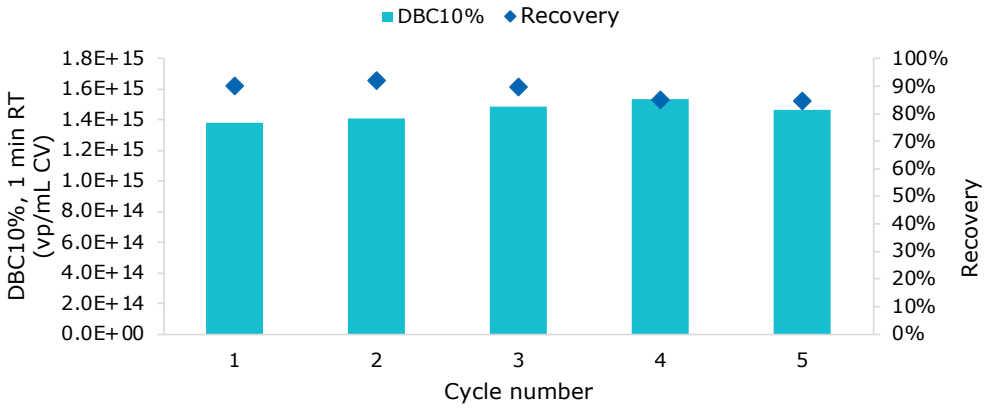


**Figure 1**: Eshmuno® AAV9 DBC10% and recovery after 5 cycles with CIP (0.5 M NaOH, 30 min per cycle)

**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.

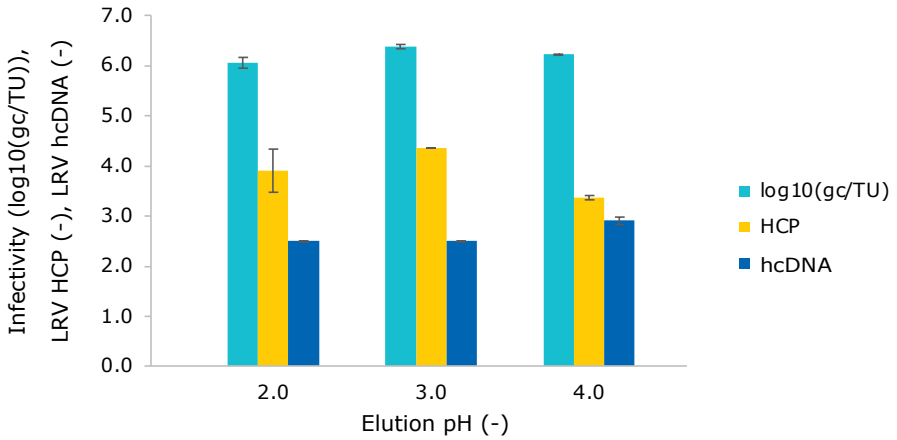


**Figure 2**: Infectivity, HCP LRV and hcDNA clearance at different elution pH

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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 *Escherichia coli* |
| 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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