CaptuVir100

Device Information

v5

1. DESCRIPTION

CaptuVir100 is a ready-to-use device for the purification of large biopharmaceuticals such as viruses, virus vectors, and virus-like particles (VLPs) by membrane-based steric exclusion chromatography (SXC).

SXC technology offers size-based selectivity to concentrate, purify, and buffer-exchange a wide variety of viruses relevant in gene therapy and vaccine applications.

Benefits of membrane-based SXC:

- **Higher product yields:** 20–50% higher product yield compared to other chromatography methods and resins mean less wasted product and smaller columns needed for purification
- **One-size-fits-all recipe:** a single recipe for a wide variety of viruses and serotypes shortens process development & deployment
- **Faster processes:** flow rates 10–20× higher compared to resins thanks to convective flow
- **Single-use:** avoids impurity carry-over and cross-contamination and reduces CapEx & OpEx
- **Increased product stability:** avoids extreme pH and salt concentrations
- **Scalability:** increases capacity by increasing membrane surface

For more information, see the QR code or visit https://www.contivir.com/dsp-sxc

2. TECHNICAL INFORMATION

Stationary phase	Cellulose membranes
Total surface	100 cm^2
Device volume (DV)	1.0 mL
Minimal capacities per device	≈3×10^{12} vg[a] (AAV) ≈6×10^{9} PFU[b] (yellow fever virus) ≈3.7×10^{9} $TCID_{50}$[c] (MVA virus) ≈1.3×10^{6} $TCID_{50}$[c] (VSV-NDV) ≈9×10^{5} HAU[d] (influenza virus) ≈47 μg_{HA}[e] (influenza virus) ≈4×10^{10} IU[f] (hepatitis C virus)
Recommended flow rate	5 mL/min (max. 10 mL/min)
Maximum operating pressure	2.0 MPa (20 bar)
pH stability	2–12 (operational) 2–14 (cleaning-in-place)
Storage	20% (v/v) ethanol in water 2–8°C

a vg: viral genomes; AAV: adeno-associated virus

b PFU: plaque forming units

c TCID50: tissue culture 50% infective dose; MVA: Modified Vaccinia Ankara; VSV: vesicular stomatitis virus; NDV: Newcastle disease virus

d HAU: hemagglutination activity units

e HA: hemagglutinin antigen

f IU: international units

3. HOW TO USE

CaptuVir100 can be used manually, with a peristaltic pump or a chromatography system. Operation with a chromatography system is highly recommended.

Reagents

- **Binding buffer:** 16% PEG-6000, PBS 1× (for viruses of >80 nm) or 20% PEG-6000, PBS 1× for viruses of <80 nm)
- **Equilibration/Wash buffer:** dilute Binding buffer 1:1 with PBS 1×
- **Elution buffer:** PBS 1×

Device and method set-up

· Connect the device to the appropriate system ports using fingertight 1/16˝ male connectors and PEEK tubing of 1 mm internal diameter.
· Program a new method in the chromatography system. If choosing from a pre-defined method, an affinity purification template with a step elution is appropriate.

Experimental procedure

- **Clarify the crude virus solution** by centrifugation and microfiltration.
- **Equilibration:** Flush the device with ≥10 DV of Equilibration/Wash buffer.
- **Sample loading:** a 1:1 in-line dilution of the clarified virus harvest with the Binding buffer is preferable over conditioning the sample with PEG off-line
- **Wash:** flush the device with ≥10 DV of Equilibration/Wash buffer or until UV signal is baseline and stabled.
- **Elution:** recover the product by flushing the device with PBS 1×

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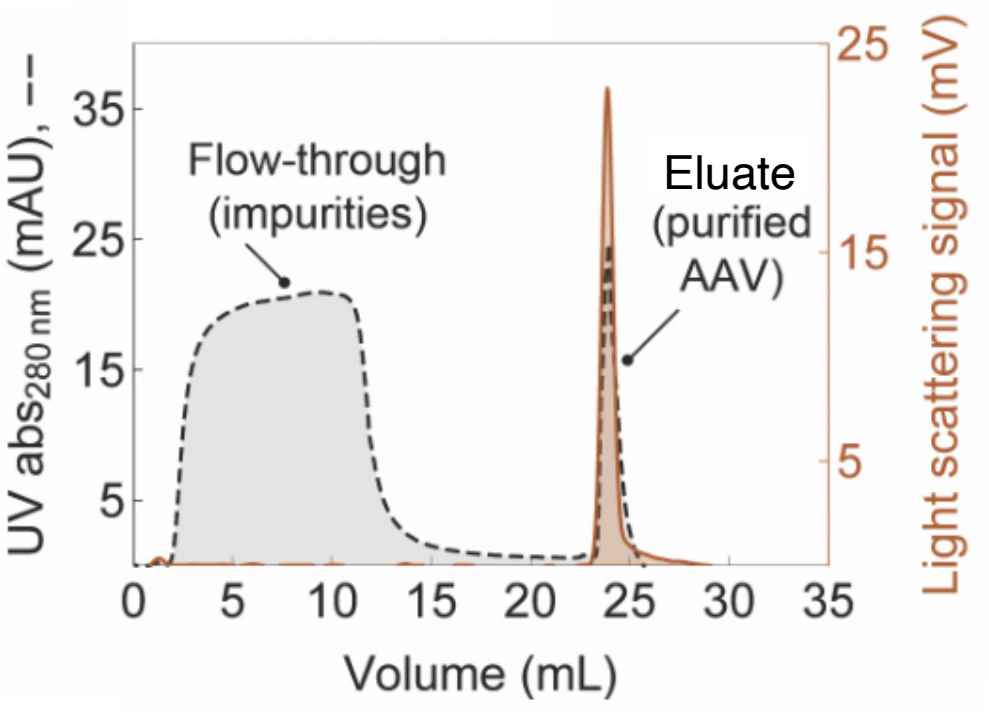
4. EXAMPLE

CaptuVir100 can be used to purify different AAV particles with >95% product yield from both cell lysates and supernatants using the same process conditions. At least 10 different AAV serotypes and display mutants have been purified, including: AAV1, AAV2, AAV6, AAV8, AAV9, and AAV-DJP2.

The diagram below shows a chromatogram (A), a transduction assay of the purified eluate (B) and a TEM picture (C) of the purified AAV particles and illustrates the successful purification of biologically active AAV.

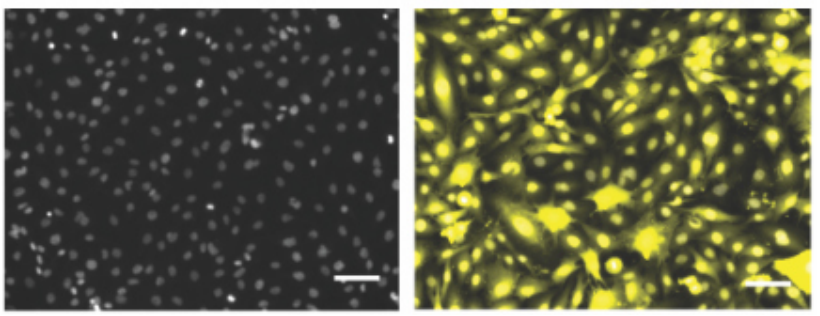
A



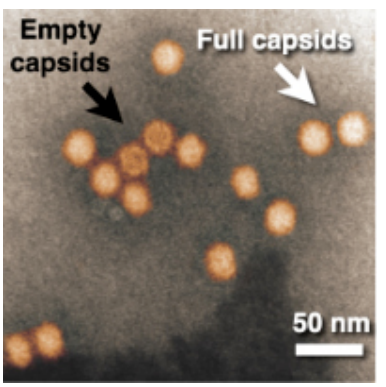
B Cell transduction from SXC fractions

Flow-through (no transduction)

Eluate (successful transduction)



C TEM picture



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Enabling Bedside Manufacturing of Viral Vaccines & Gene Therapies

ContiVir is a research project of the Max Planck Institute for Dynamics of Complex Technical Systems.

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