

# FectoVIR<sup>®</sup>-AAV Transfection Reagent

Large-Scale rAAV  
Manufacturing



## Product Information

FectoVIR<sup>®</sup>-AAV represents a new generation of synthetic transfection reagents specifically developed for industrial-scale production of recombinant AAV (rAAV) in both suspension and adherent HEK293-derived cell systems. FectoVIR<sup>®</sup>-AAV transfection reagent supports higher rAAV titers, improves scalability for large-scale production, and de-risks the manufacturing process with its GMP-grade availability. FectoVIR<sup>®</sup>-AAV-GMP is manufactured under a validated and aseptic process in compliance with ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

## Features and Benefits

- Process economics: High AAV productivity to reduce manufacturing costs
- Industrial scalability: Low complexation volume and high complex stability
- GMP grade availability: Validated manufacturing process following ICH Q7 guidelines
- Risk mitigation: Residual test and toxicity statement available

# Introduction

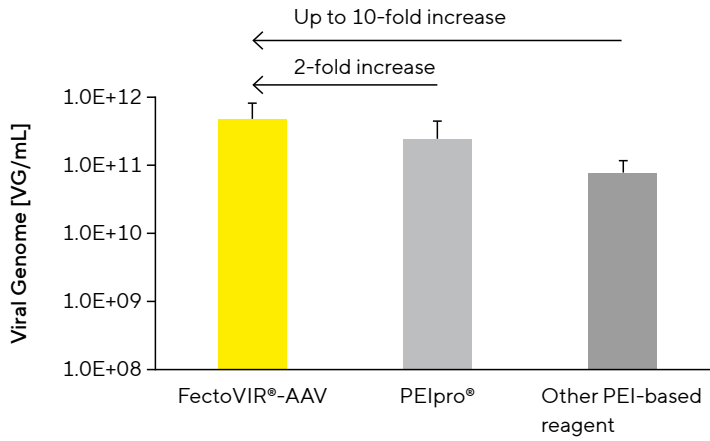
## Relevant Applications

- Cell and gene therapy
- rAAV production
- Academic research

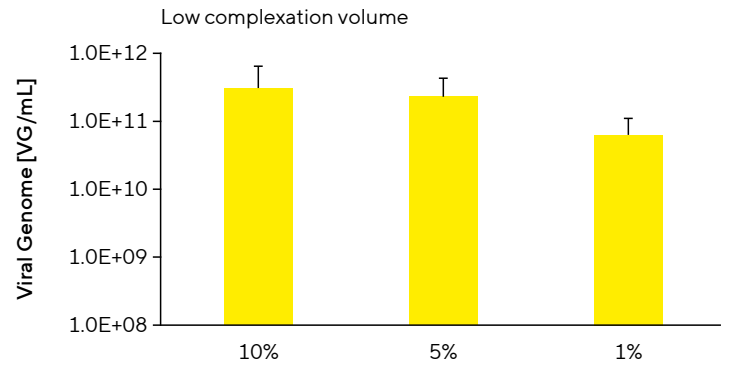
## Relevant Process Steps

- Upstream process
- Transfection

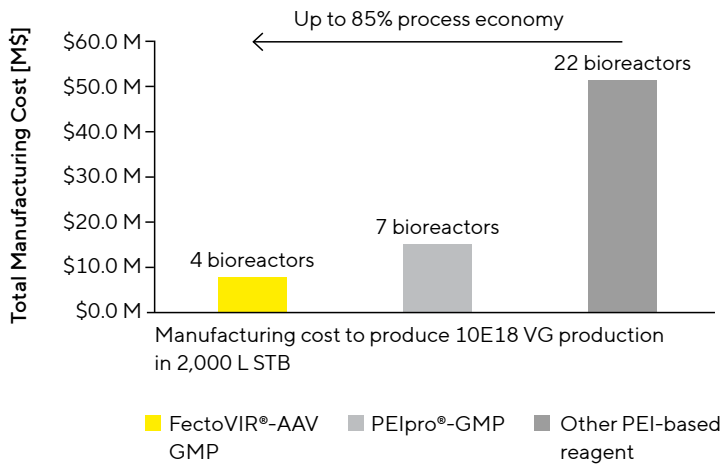
**Figure 1:** FectoVIR®-AAV Improves rAAV Productivity Compared to Other Transfection Reagents



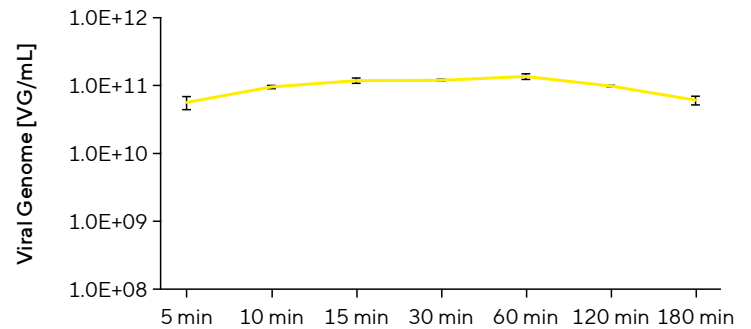
**Figure 3a:** FectoVIR®-AAV Is Scalable by Reducing the Complexation Volume



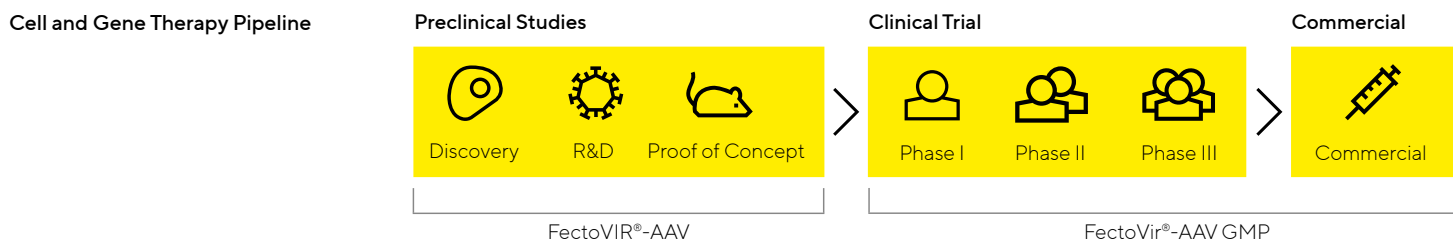
**Figure 2:** FectoVIR®-AAV Decreases Manufacturing Costs (2–5 Fold) by Substantially Improving Upstream AAV Productivity



**Figure 3b:** FectoVIR®-AAV Is Scalable by Increasing the Complex Stability



**Figure 4:** FectoVIR®-AAV GMP Is Provided With a Full Set of Documentation and Analytical Methods to Support Both IND and BLA Submissions



Characteristics	FectoVIR®-AAV	FectoVIR®-AAV GMP	
Manufacture in compliance with	ISO 9001:2015	ICH Q7 GMP Part II	
Product documentation	Certificate of analysis	■	
	Certificate of origin	■	
	Safety datasheet	■	
Regulatory documentation	Certificate of compliance	■	
	Drug master file	■	
	TSE   BSE	■	
	Regulatory support package	Sample available	■
	Identity testing protocol		■
	Activity testing protocol		■
Quality documentation	Quality agreement	■	
	Risk assessment	■	
Residual assay	■	■	
Scientific support and DOE service	■	■	
Regulatory support		■	

## Technical Specifications

Attribute	FectoVIR®-AAV 1 mL	FectoVIR®-AAV 10 mL	FectoVIR®-AAV 100 mL	FectoVIR®-AAV 1 L
Quality grade	Research grade	Research grade	Research grade	Research grade
Type of container	Vial	Bottle	Bottle	Bottle
Material	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Neck diameter [mm]	n/a	13.7 ± 0.05	17.5 ± 0.05	27.4 ± 0.08
Height with closure [mm]	n/a	58.4 ± 1.5	100.8 ± 2.0	215.9 ± 2.5
Height without closure [mm]	n/a	55.9 ± 1.5	98.6 ± 2.0	212.1 ± 2.5
Bottle diameter [mm]	n/a	24.9 ± 1.0	50.3 ± 1.5	91.4 ± 2.0

Attribute	FectoVIR®-AAV GMP 100 mL	FectoVIR®-AAV GMP 1 L	FectoVIR®-AAV GMP Satellite Bag 100 mL
Quality grade	GMP	GMP	GMP (for ID test)
Type of container	Bottle	Flexsafe® 2D Bag 1 L	Flexsafe® 2D Bag 1 L
Material	PETG (sterile)	S80 Polyethylene film	S80 Polyethylene film
Neck diameter [mm]	27.94 ± 0.64	n/a	n/a
Height with closure [mm]	108.2 ± 2.0	n/a	n/a
Height without closure [mm]	103.6 ± 2.0	n/a	n/a
Bottle diameter [mm]	52.3 ± 1.5	n/a	n/a
Bag dimension (W×H) [mm]	n/a	240 × 310	240 × 310
Connector	n/a	MPC (coupling male ¼")	MPC (coupling male ¼")
Other	n/a	Weldable tubing	Weldable tubing

# Ordering Information

Item	Volume	Description	Order Number
FectoVIR®-AAV	1 mL	Vial	101000044
FectoVIR®-AAV	10 mL	Bottle	101000022
FectoVIR®-AAV	100 mL	Bottle	101000004
FectoVIR®-AAV	1 L	Bottle	101000054
FectoVIR®-AAV GMP	100 mL	Bottle	102000006
FectoVIR®-AAV GMP	1 L	Bag	102000009
FectoVIR®-AAV GMP SatBag	100 mL (in 1 L bag)	Bag	102000012

## To Order Polyplus® Products, Visit

[www.polyplus-sartorius.com](http://www.polyplus-sartorius.com)

[www.polyplus-sartorius.com/products/fectovir-aav](http://www.polyplus-sartorius.com/products/fectovir-aav)

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Specifications subject to change without notice.

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