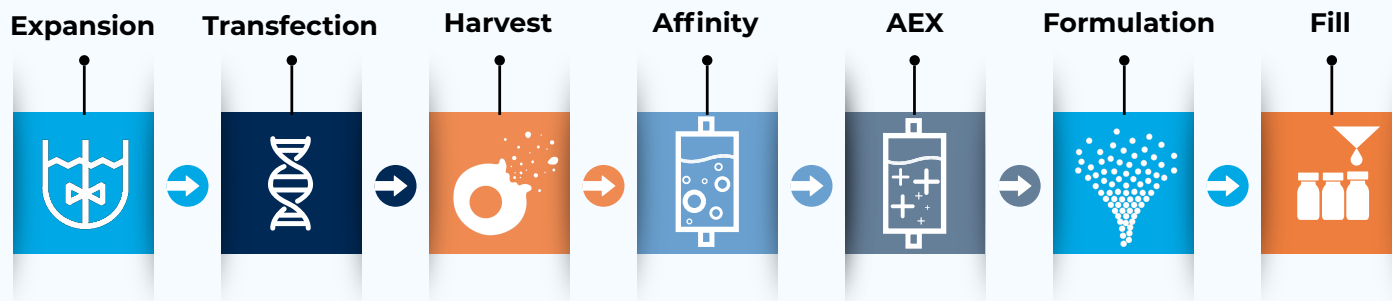


GMP-Like AAV for NHP Studies: Bridging Research to Clinical Success

Manufactured with GMP-identical processes —delivering the highest quality vectors plus critical manufacturability insights for your IND path.



GMP-like AAV Manufacturing Workflow for NHP Studies



- Leverage our **in-house expertise** developed across **100+ serotypes** for reliable vector production.
- Seamless **scale-up potential**, supporting batches up to **2000L**.
- Benefit from **cost-efficient pricing** and **fast delivery** timelines.
- Receive **premium-quality GMP-like material** for your critical NHP studies, and de-risk your path to IND.

Why Choose GMP-Like AAV for Your Upcoming NHP Study?

NHP studies are expensive, time-consuming, and critical to your program's success. Yet many researchers continue to rely solely on research-grade AAV material that can't scale up to GMP manufacturing. This can often create costly delays and technical risks when transitioning to GMP-grade material for IND-enabling studies.

Our **GMP-like AAVs** are manufactured with **GMP platform processes** and rigorously tested using **GMP platform assays** — giving you both premium-quality vectors for pivotal NHP studies and manufacturability data to de-risk your IND path.

	Purity & Safety	GMP-like AAV quality for your critical NHP studies.
	Process Insights	Manufacturability data: productivity, process yield, and product quality.
	Genome Integrity	Verified genome integrity: CE + optional Nanopore sequencing.
	Robust QC Assays	ddPCR titer, CE, SDS-PAGE (silver stain) Endotoxin, Bioburden , and more...
	Scalable Results	Investor-ready data generated from GMP platform processes.
	GMP Transition	Seamless progression to GMP; reduced risk of tech transfer obstacles.

	Research Grade	GMP-Like (NHP-Grade)
Production Process	RUO-scale methods	Same protocols, materials, and equipment as GMP
Purification	Standard Affinity	Affinity + AEX (Empty/Full Separation)
Scale	1E12–5E14 GC	1E13–1E16 GC
Titer	qPCR	ddPCR
Empty Capsids	optional	<20% by TEM
Genome Integrity	optional	CE + Nanopore (optional)
Endotoxin	<10 EU/mL	<1 EU/mL
Bioburden	optional	No Growth
Mycoplasma	optional	Negative
Turnaround	17–25 days	25–35 days

ARE YOU READY TO DE-RISK YOUR PATH TO IND?

Get a customized quote for your program, and the highest quality GMP-like AAV for your NHP study.

Visit us www.packgene.com info@packgene.com 1-866-491-7300



Your AAV Manufacturing Journey: From Research to Clinic

Research
Discovery

**YOU ARE
HERE**

Preclinical /
NHP Studies

IND-Enabling
GMP Production

Clinical Trials
Phase I/II/III

Research Discovery

R D

- Proof-of-concept studies
- Target validation
- Small animal models

Material: Research-Grade AAV

Preclinical / NHP Studies

N H P

- Pivotal efficacy studies in NHP
- Dose-ranging and safety studies
- CMC/process insights
- Investor readiness & stage-gate prep

Material: GMP-Like AAV

IND-Enabling & GMP

I N D

- Toxicology studies
- IND filing preparation
- Clinical trial material production

Material: GMP AAV

Clinical Trials

C T

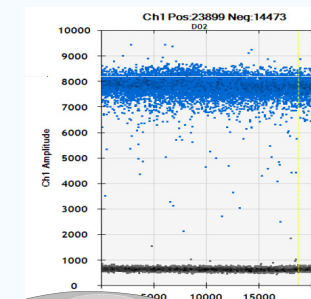
- Phase I/II/III studies
- Commercial-scale production

Material: GMP AAV

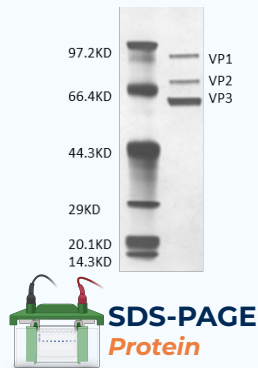
Question: When should I switch to GMP-like AAV?

Answer: You should switch to GMP-like material when you are planning **pivotal NHP efficacy studies**, preparing for **IND-enabling work**, or need **investor-ready data** and **early insight into manufacturability** and **scale-up**.

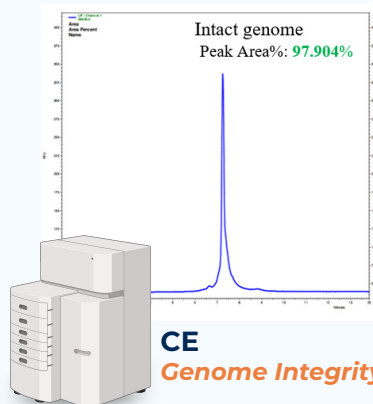
Product Quality You Can Trust



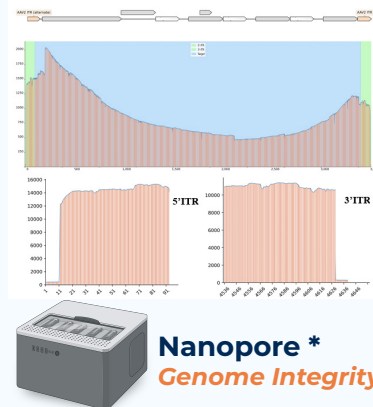
**ddPCR
Titer**



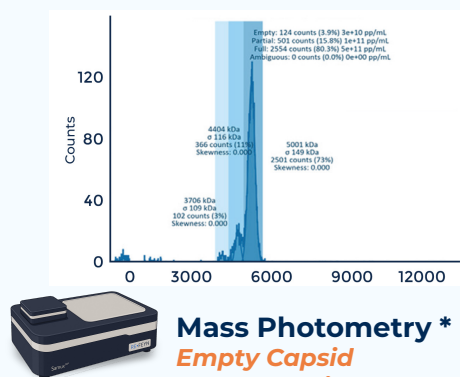
**SDS-PAGE
Protein**



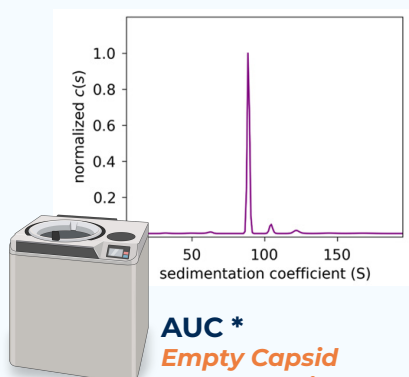
**CE
Genome Integrity**



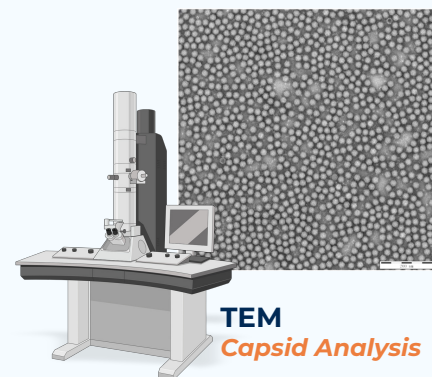
**Nanopore *
Genome Integrity**



**Mass Photometry *
Empty Capsid
& Aggregation**

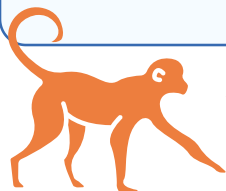


**AUC *
Empty Capsid
& Aggregation**



**TEM
Capsid Analysis**

(* = optional add-on services)



Avoid costly surprises! Maximize the impact of your pivotal NHP studies with GMP-like AAV—manufactured on our GMP production platform to de-risk your path to IND.

