AAV Manufacturing & Testing Platform

Developing successful AAV-based therapeutics requires overcoming significant scientific, time, and regulatory challenges. uBriGene's AAV manufacturing platform can help clients reduce time to clinic with off-the-shelf access to qualified cell line and AAV helper plasmids while producing high quality vector up to 2000L scale.

- Fully developed production platform for AAV2, AAV5, AAV8, and AAV9
- DMF for AAV helper plasmids and 293XS suspension cells
- AAV GMP manufacturing with 10L- 2000L production capacity
- Strongest regulatory record with >50 GMP batches produced
- High full/empty capsid ratio
- Fill/finish, fully automated, >10,000 vials

ubrigene®

uBriGene's Excellence in Plasmid & AAV Upstream Processing

GMP plasmid production platform

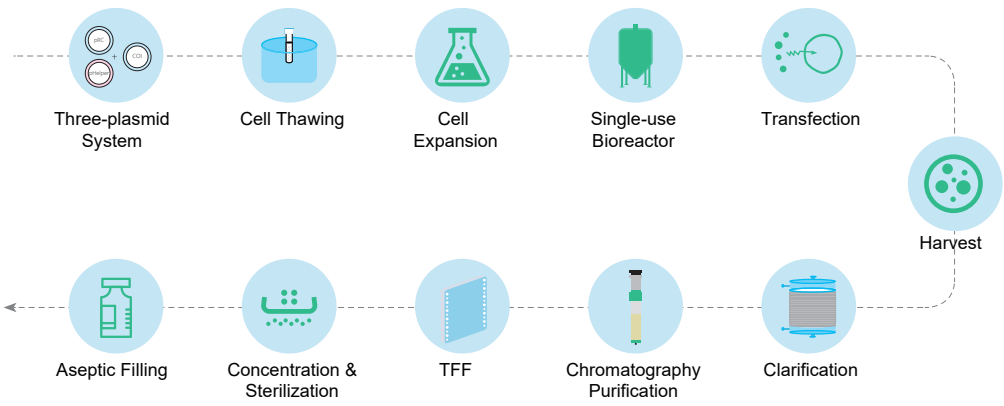
Scalable AAV production

Streamline the path from gene to vector with uBriGene' s upstream process expertise, offering high-throughput plasmid production and state-of-the-art cell line development for AAV generation.

GMP Plasmid Production	Scalable AAV Production
High-capacity fermentation yielding up to 1 g/L of plasmid DNA.	Proprietary 293XSTM cell line for high-yielding AAV production
Animal-derived ingredient and antibiotic-free processes.	Culture densities reaching 1E7 cells/ml, with AAV yields exceeding 1E14VG/L.
Scalable up to 200L, ensuring cost-effectiveness and adaptability.	Scalable production from 50L to 2000L, supporting projects of any size
Two-step purification process, significantly reducing costs while maintaining high purity levels.	Advanced downstream purification methods tailored for maximum efficiency and purity.

uBriGene's Proven AAV Manufacturing Flow

AAV GMP production process



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Commitment to Quality Assurance in AAV Manufacturing

uBriGene stands as your quality assurance partner with your AAV therapeutics developed in compliance with the highest standards of quality control and regulatory oversight.

QC Items		QC Method
Identity	Capsid protein identity	SDS-PAGE
	AAV genome identity	Second generation sequencing
Physical Properties	Physical appearance	Visual inspection
	Quantity filled	Density Measurement
	Visible foreign bodies	Clarity illuminator
	Insoluble particles	Light obscuration particle count test
	Particle size	DLS
Chemical Properties	pH	pH meter
	Osmolality	Freezing point depression
Content	Physical titer	ELISA
	Genome titer	qPCR
	Infection titer	TCID50
Purity	Capsid protein purity	SDS-PAGE
	Empty capsid rate	EM, AUC
		AUC

QC Items		QC Method
Residuals	Host protein residual	ELISA
	Host DNA residual	qPCR
	DNA residue fragment sizing	Capillary electrophoresis
	Tween-20 residual	HPLC
	AAV affinity ligand residual	ELISA
	Plasmid DNA residual	qPCR
	PEI residual	HPLC
	Nuclease residuals	ELISA
	E1A residual	PCR
Safety	Endotoxin	(LAL) gel clot
	rcAAV	Cell culture + qPCR
	sterility	direct inoculation
	Mycoplasma	qPCR (solution preparation)
		cell culture (end of production cell)
	Abnormal toxicity	Abnormal toxicity test (outsourced)
Excipient	Poloxamer 188	HPLC

GMP AAV manufacturing experience:

10+batches of 50L scale; dozens of batches of 200L scale

Project (application)	Phase
AAV (ophthalmology)	IIT+IND+clinical trial phase I/II
AAV (hemophilia)	IIT+IND+clinical trial phase I/II
AAV (ALS)	IIT+IND
AAV (nervous system disease)	IIT

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