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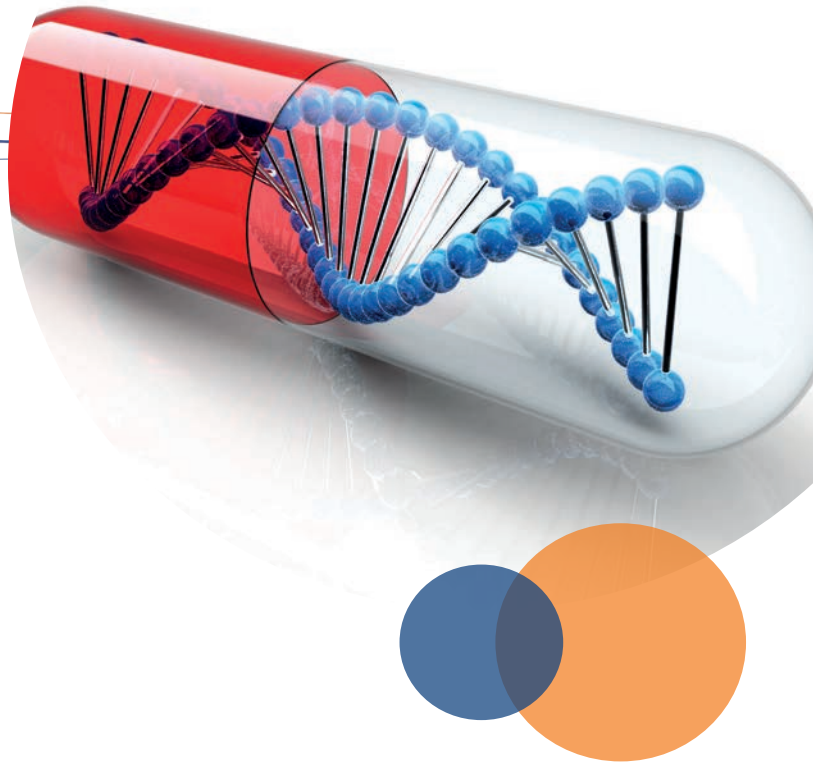

Safety, Characterization, and Release Testing Support for Viral Vectors Used for Gene Therapies

Gene therapies have made significant progress in the treatment of many diseases, including cancer, rare genetic diseases, and autoimmune disorders by replacing, adding, or turning off a patient's genes. With the promise to enhance treatment, greatly reduce side effects, and potentially cure many types of diseases and disorders, these therapies are in high demand, and biopharma companies are in a race to the clinic.

The most common viral vectors include adeno associated (AAV), lenti, adeno, and retro viruses. These vectors are used to carry genetic material into host cells to replace missing or defective genes by direct delivery in vivo or modification of cells ex vivo for delivery back into a patient.

Eurofins BioPharma Product Testing's network of laboratories supports the development of Advanced Therapy Medicinal Products (ATMPs) both for traditional use as well as for use in personalized medicine. We provide comprehensive GMP-compliant CMC testing support to ensure the identity, potency, purity, and safety of starting materials, intermediate products, vectors, and final drug products as well as support for manufacturing process development and validation.

Why Choose Eurofins BioPharma Product Testing?

We offer comprehensive cell and molecular biology, biochemistry, biosafety, and microbiology testing through one testing partner.

We have provided cGMP-compliant testing support to gene therapy sponsors for over 10 years and support most contract manufacturers focused on ATMPs.

We have vast experience in supporting gene therapy manufacturing from early clinical, through process validation, product optimization, and marketed release.

We have the laboratory capacity, BSL2 facilities, and state-of-the-art instrumentation to meet regulatory requirements and turnaround times for gene therapy products.

Our specialized sample delivery and receipt process ensures seamless communication between our lab and yours and expedites your samples into our laboratory.

Our secure 24/7 online data portal, LabAccess.com, provides timely access to your test results, as well as the associated raw data for each test method.

Our experienced project management and technical teams serve as your single-source solution for all of your testing needs.

Therapies Supported

- Viral vectors for *in vivo* and *ex vivo* use
- Nanoparticles
- Plasmid based
- iRNA/mRNA
- Oncolytic Viral Therapies

Comprehensive Gene Therapy Testing Capabilities

Cell Banks for Viral Vector Production

Transitioning to the GMP environment begins with establishing a GMP cell bank. Human cells, such as HEK-293/HEK-293T, and insect cells, including Sf9, are the most common cell substrates used for viral vector manufacturing.

GMP cell banks begin in an environmentally monitored suite with proper cleaning practices and GMP trained personnel. Master or Working cell banks may be used for virus bank manufacturing. After the cell bank has been manufactured, validated test methods must be performed to ensure the cell bank has not been contaminated.

Virus Characterization, Harvest, Drug Substance, and Final Product Testing Considerations

Viral bank manufacturing requires a list of testing very similar to traditional biologics; however, there are several considerations with viral bank testing.

- Will your virus interfere in cell based virology test methods (in vitro adventitious agent)? If so, neutralizing antisera, control cell testing, or NexGen sequencing should be considered.
- Identity testing for viruses is not the same as cell banks, and commonly Sanger sequencing can be used, or NexGen sequencing can be considered.
- Bovine/porcine 9CFR testing may not be needed so long as the cell bank used for manufacturing has tested negative and so long as no bovine or porcine materials were used in the production of the virus bank.
- Do your plasmids have kanamycin or a targeted sequence that can be used for PCR testing? Residual plasmid testing may be needed.

Stability

Stability studies will be needed on viral vectors. ICH Guidelines are a good source for review when building Stability Protocols. All stability studies should include pH, appearance, potency, and sterility at a minimum. Stability studies can be terminated once the vector is no longer stable. Our stability services include:

- Protocol Development
- Development/Optimization/Validation of Methods
- Stability Storage
- Execution of Stability Studies

	Assay	Methodology
Compendial	Visible Particles/Subvisible Particles	USP <787> and <788>
	pH	USP <791> and Ph. Eur. 2.2.3
	Appearance	USP <630>, <790>, <855> and Ph. Eur. 2.2.1, 2.2.2, 2.9.20
	Osmolality	USP <785> and Ph. Eur. 2.2.35
Safety	Sterility	USP <71>
	Mycoplasma	USP <63>, Ph. Eur. 2.6.7, JP, PTC
	Endotoxin	USP <85>
	In Vitro Adventitious Agent	USP <1237>
	Replication Competent Virus (e.g., rcAAV, RCL, RCR, RCA)	Cell Based with qPCR or ELISA Endpoint
Process Residuals	Host Cell Protein	ELISA
	Residual DNA	qPCR
	Residual Plasmids	qPCR
	Benzonase	ELISA
	PEI	LC-CAD, LC-MS/MS
	Tween	LC-UV, LC-MS/MS
Characterization	Purity	CE-SDS, MS
	Empty/Full Capsid	SV-AUC, TEM, AEC
	Aggregation	DLS, SEC-MALS
	Capsid Content	AUC, TEM, SEC-MALS or UV
Product Specific	Physical Titer	ELISA
	Genomic Titer	ddPCR
	Infectious Titer	Cell Based
	Potency	Cell Based with various endpoints (e.g., ddPCR, qPCR, ELISA)
	Capsid Identity	ELISA, LC-MS
	Vector Genome Identity	Sequencing (Sanger or NextGen)

Contact Us

North America: BioPharmaProductTesting@BPT.EurofinsUS.com
Europe: Information@BPT.EurofinsEU.com
APAC: easl.cserv@BPJP.EurofinsAsia.com
www.Eurofins.com/BPT