gene THERAPY

Avecia Pharma Services will work with you to advance your gene therapy programs with pride, ownership and responsibility.

Comprehensive platform and flexible programs to support Process Development, Manufacturing and Regulatory Filings

- AAV-based Drug Product Testing
- Raw Material Testing for CAR-T Manufacturing
- Retroviral / Lentiviral Vectors
- Adenovirus
- Method Development and Phase-Appropriate Validation
- Pre-clinical to Commercial phase Release and Stability programs to support IND and BLA submission

CART-T Release Testing for Growth Media, Cytokines, Growth Factors, and Enzymes

Quality Attributes	Method	Test
Impurity	qPCR	Residual DNA
Safety	qPCR	Replication (Retrovirus/Lentivirus)
Identity	Western Blot	Immunoreactivity
Identity	Amino Acid Analysis	Composition
Identity/Purity	SDS-PAGE/SEC-MALS	Size/aggregate
Strength	SoloVPE	Protein Concentration
Safety	USP <71>, <85>, USP <61> and <62>	Sterility, Endotoxin and bioburden

AAV - Virus Capsid Testing, Protein Expression, and Genomic Analysis

Quality Attributes	Method	Test
Quality/Safety	SEC-MALS	Viral Capsid Purity/Aggregates
Quality	icIEF	Viral Vector Charge Identity
Quality	CE-LIF	Viral Protein/Capsid/Serotypes
Purity	CE-LIF	Genome Purity/Plasmid isoforms
Strength	qPCR	Vector Genome Titer
Potency	Multiplex Chemiluminescence	In vivo Potency
Potency	Capillary Chemiluminescence	In vivo Potency
Safety	USP <71>, <85>, USP <61> and <62>	Sterility, Endotoxin and Bioburden
Identity	MRM/MS-MS	Viral Proteome

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