Nitto Avecia Pharma Services

We're dedicated to advancing your analytical development needs with a wide range of cutting-edge testing services.

GENE THERAPY

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

CRISPR-based Cas9 and Cas12 Testing

Quality Attributes	Test
Purity	CE-SDS
Strength	soloVPE
Identity	Peptide Map-MS
Identity	Intact Mass by LCMS
Impurity	DNA by qPCR
Impurity	RNA by RT-PCR
Impurity	DNAse
Impurity	RNAse
Potency	Enzyme Activity by microplate assay
Quality	MALS

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GENE THERAPY

Nitto Avecia Pharma Services

THE TRUE PARTNERSHIP DIFFERENCE

We make your goals achievable through a dedicated approach. Every project is led by a **single point of contact**, ensuring seamless communication, strategic planning, consistent reporting, and high-quality data from start to finish.

Partner with Nitto Avecia Pharma Services for reliable, high-quality analytical chemistry support across all stages of drug development. Since 1988, we have built a strong reputation for delivering flexible outsourcing solutions tailored to your development priorities.

OUR CORE CAPABILITIES

COMPREHENSIVE COMPENDIAL TESTING

Cost-effective analysis (USP/NF, EP, BP, ACS, and custom monographs) for raw materials, in-process samples, and finished products.

STABILITY PROGRAM MANAGEMENT

Let us help with the logistics for your stability programs, including storage in a wide range of ICH-listed conditions.

BROAD EXPERTISE

Drug substances, drug products, diverse dosage forms, and vendor qualification.

EXTRACTABLES & LEACHABLES

Broad expertise in PVC blister packs, injectables, medical device, IV bags, and single-use systems.

DEDICATED PROJECT MANAGEMENT TEAM

A single, dependable point of contact who guides and runs meetings, generates agendas and minutes, provides high-quality data and metrics, and conducts detailed post-project follow-up.

MICROBIOLOGY

Comprehensive cGMP microbiological testing for sterility, endotoxins, bioburden, and environmental monitoring.

PACKAGING & DEVICE TESTING

Expert analysis of elastomers, glass, and plastics. We can assist with navigating extractables and leachables.

BIOPHARMA

Integrated analytical support to enable development and commercialization of complex biologics.

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