

Testing Support for Cell and Gene Therapy (ATMPs)

Advanced Therapeutic Medicinal Products (ATMPs) represent a revolutionary and fast-growing class of therapies at the forefront of modern medicine, distinct from traditional biopharmaceuticals. These innovative treatments leverage the power of cutting-edge technologies, such as gene therapy, cell therapy, and tissue engineering, to address unmet medical needs in a range of diseases, including cancer, genetic disorders, and autoimmune diseases, and offer new hope to patients.

Cell therapy involves the isolation, modification, and reinfusion of cells to restore or enhance cellular functions, using either the patient's own cells (autologous cells) or those of a donor (allogeneic cells). These therapies encompass a wide range of techniques, such as cell transfer for haematological disorders and chimeric antigen receptor (CAR) T-cell therapy for cancer.

Gene therapy, on the other hand, targets diseases at the genetic level by replacing, inactivating, or introducing therapeutic genes into cells - either inside (in vivo) or outside of the body (ex vivo). Breakthroughs in genetic engineering, vector development, and delivery methods have led to the approval of several gene therapy products, offering hope for the treatment of genetic disorders, cancer, and infections.

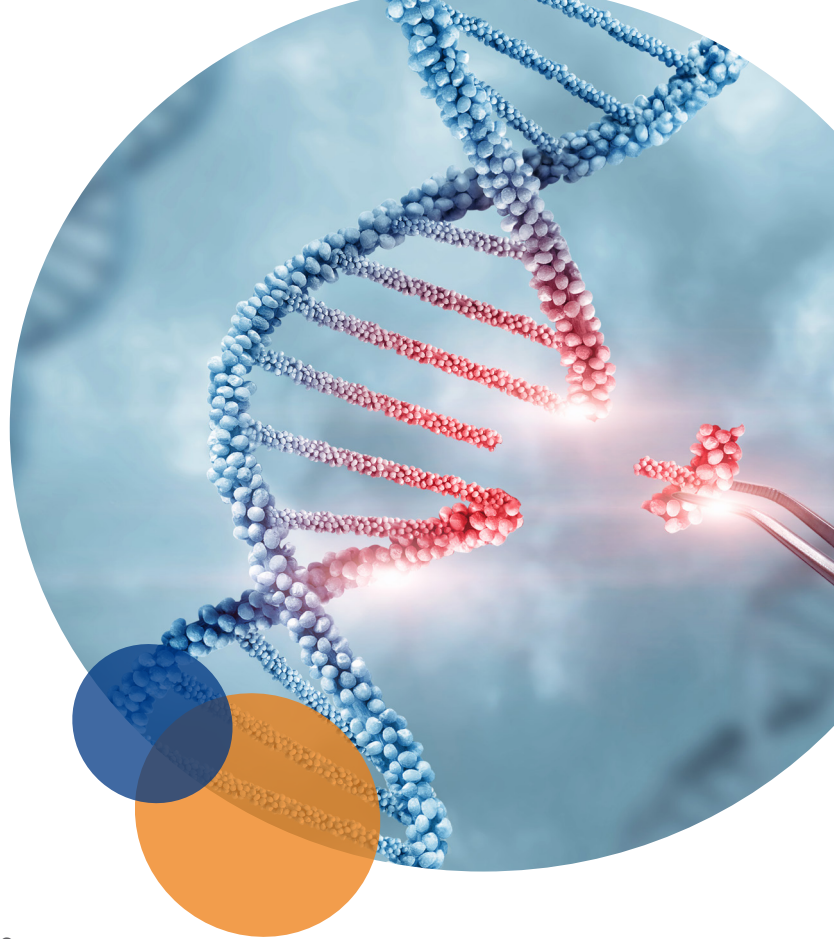
ATMP Testing Services

Eurofins BioPharma Product Testing provides comprehensive analytical solutions tailored to the unique challenges of therapeutic ATMPs, from early development to commercial release. We provide comprehensive GMP-compliant testing support to ensure the identity, potency, purity, and safety of starting materials, intermediates, vectors, and finished drug products.

Our Portfolio:

- Method Development and Validation
- Product release testing
- ICH stability storage and testing
- Virological assays (e.g. viral vector purity and vector identity)
- Compendial and Potency testing
- Product- and process-related impurity testing

We have supported numerous studies involving cell and gene therapies, mRNA, plasmid DNA-based products, as well as Adenovirus and Adeno-Associated Virus (AAV). In our specialized GMP laboratories, we handle Class I (wildtype BSL-1) and Class II (genetically modified (GMO) BSL-2) biological organisms. A summary of our testing portfolio is provided below.



Parameter	Method	Equipment
Safety	Bioburden	None
	Replication Competent Virus	Cell-based with qPCR or ELISA (Microplate reader)
	Sterility	e.g. rapid technologies
	Mycoplasma	PCR
	Pyrogen / Endotoxin	Microplate reader
Physical Chemistry	Appearance: Color, Clarity, and Degree of opalescence	Turbidimeter TL2350 (HACH), Apollo II Liquid Viewer (Adelphi)
	Visible Particles/Subvisible Particles pH	HIAC9703+ (Beckman Coulter) pH meter
	Osmolality	Osmometer 3320 (Advanced Instruments)
Process-related impurities	Host Cell Protein	ELISA
	Residual DNA	qPCR or ddPCR
	Residual Plasmids	qPCR or ddPCR
Characterisation	Purity	CE-SDS, MS, HPLC, SDS-Page
	Full/Empty Capsid	SV-AUC, TEM, AEC
	Aggregation	DLS, SEC-MALLS
	Capsid Content	AUC, TEM, SEC-MALLS or UV
Product Specific	Physical titer	ELISA
	Genomic titer	qPCR or ddPCR
	Infectious titer	Cell-based (TCID50)
	Potency	Cell-based bioassays / ELISA / Flow Cytometry
	Transgene expression	qPCR, ddPCR ELISA, Flow Cytometry
	Capsid Identity	ELISA

Advanced Analytical Technologies for ATMPs

Equipped with cutting-edge technologies and a dedicated expert team, we are committed to driving your success. Our advanced technologies include:

1. qPCR (quantitative Polymerase Chain Reaction): Utilize our state-of-the-art qPCR technology for precise quantification of residual DNA, genetic variation detection, and accurate gene expression monitoring.
2. ddPCR (digital droplet PCR): Achieve absolute quantification with high sensitivity, ideal for detecting residual DNA down to the fg scale, quantifying copy numbers, and assessing gene expression with confidence.
3. KingFisher: Automate nucleic acid extraction with fast, reliable, and cost-effective magnetic bead-based technology, ensuring high reproducibility and quality.
4. Flow Cytometry: Uncover cellular complexities with advanced flow cytometry (known as “FACS”), enabling high-speed, high-resolution analysis of cell characteristics, and cell signalling pathways.

Long-Standing Expertise in Relative Potency Assays

Our laboratory has extensive experience in performing relative potency assays, offering valuable insights into the biological activity and efficacy of your therapeutic products. Rely on our expertise to manage complex products with multiple mode of actions, ensure regulatory compliance, and support informed decision-making throughout your development process.

COMPREHENSIVE GMP TESTING SERVICES

Method Development & Validation • Release Testing • Raw Materials Testing
 Cell Banking Services • Virology Services • Facility & Process Validation
 Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
 Stability Testing & Storage • Primary & Secondary Package Testing

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Product Testing