

Analytics of mRNA Therapeutics

Axolabs is a world leading service provider in oligonucleotide- & mRNA-based therapeutics. We are the single organisation to deliver best solutions for nucleic acid therapeutics' development, ranging from lead ID, across all clinical stages, to commercial supply.

For mRNAs, Axolabs' portfolio includes LC-MS based methods to confirm mRNA identity, capping efficacy as well as poly(A) tail length & polydispersity characterisation. In addition, mRNA integrity & purity can be assessed by

HPLC/UPLC analysis. LipidNanoParticle formulations can be characterised for size, polydispersity, surface charge & payload encapsulation together with quantitative analysis of lipid & mRNA-composition. All analytical services can be conducted under GMP.

Services to analyse pharmacological properties of mRNA formulations include in vitro & in vivo analysis of activity & safety, as well as pharmacokinetics & biodistribution to support GLP-Tox studies as well as clinical trials.

Our capabilities include:

Characterisation of mRNA Drug Substance (non GMP/GMP):

- » Identity confirmation by mRNA fingerprinting
 - Information on poly(A) tail length and dispersity
 - » Capping assay by HPLC-UV with ESI-MS
 - Quantitative assessment of capping efficacy
- Analysis of capping side products e.g. UNCAP vs. CAP-0 vs. CAP-1
 - » Analysis of mRNA purity/integrity
 - HPLC and Tape Station
 - » Determination of molar absorption coefficient
 - » Base composition analysis
 - » Analysis of residual plasmid, protein and nucleotides



Our capabilities continued:

Characterisation of mRNA-LNP Drug Product:

- » Analysis of size and mRNA encapsulation in formulations (Dynamic Light Scattering and Ribogreen)
- » Analysis of lipid composition and content (HPLC with CAD)
- » Determination of mRNA content by HPLC

mRNA and mRNA-LNP bioanalysis

- » PK and bio-distribution of mRNA (GxP)
- » PK and bio-distribution of cationic lipids

mRNA pharmacology

- » Mouse proof-of-concept studies
- » In vitro and in vivo safety analysis
- » Cell-based assays to study mRNA therapeutics
 - Target expression/function (ELISA, Luminex and MSD platforms, cell viability, flow cytometry)

Axolabs is the leading custom research organisation providing high-end solutions and consultancy in the field of preclinical and clinical development of oligonucleotide therapeutics and nucleic acid medicines.

Our expert team has 21+ years of experience in the development of oligonucleotide therapeutics and has access to an excellent infrastructure. For more information visit [axolabs.com](https://www.axolabs.com)

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