

## 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. Lipid nanoparticle (LNP) 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):

- » Analysis of mRNA size and purity/integrity by uHPLC (IP-RP or SEC)
- » Identity confirmation by mRNA fingerprinting and Nanopore sequencing
- » Determination of poly(A) tail length and polydispersity by uHPLC with UV and ESI-MS
- » Analysis of capping structure and capping efficiency by uHPLC with UV and with ESI-MS
- » Determination of residual NTPs, plasmid or protein
- » Base composition analysis
- » Thermodynamic analysis by UV, CD or DSC
- » Determination of dsRNA impurities by ELISA



## Our capabilities continued:

### Characterisation of mRNA-LNP Drug Product (non-GMP/GMP):

- » Determination of mRNA label claim by uHPLC
- » Determination of mRNA encapsulation
- » Analysis of lipid content and composition
- » Analysis of particle size, polydispersity and zeta-potential by DLS
- » mRNA and mRNA-LNP bioanalysis
- » PK and biodistribution of mRNA (GLP/GCP) mRNA pharmacology
- » Proof-of-concept studies in mice
- » *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 20+ years of experience in the development of oligonucleotide therapeutics and has access to an excellent infrastructure. For more information visit [axolabs.com](https://axolabs.com)

## CONTACT

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