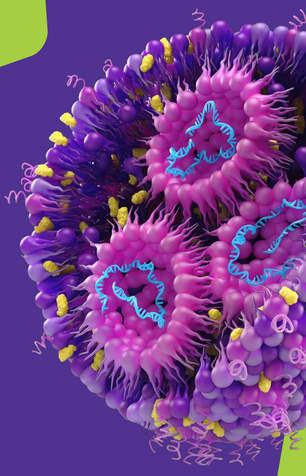
MilliporeSigma

De-Risk mRNA

Regulatory Approvals

Critical Quality Attribute Characterization & Lot Release Testing



3 Testing packages for mRNA starting materials, drug substance, and drug product

50+ Assays to confirm critical quality attributes

20+ Enabling technologies

mRNA Drug Substance

Identity
- Sequence identification (NGS)

Strength
- mRNA content (UV spec.)

Potency
- Drug substance potency

Process-Related Impurities
- dsRNA (ELISA)
- Residual DNA templates (qPCR)
- Residual capping reagents and NTPs
- Residual protein and enzymes

Purity
- 5′ capping efficiency (IPRP-LC/MS)
- Poly(A) tail length and distribution (IPRP-LC/MS)
- RNA integrity (CE and IPRP-LC)

Safety
- Bioburden (USP)
- Endotoxins (USP)

mRNA-LNP Drug Product

Identity
- Lipid ID (RP-HPLC-CAD)
- Sequence identification (NGS)

Strength
- mRNA content (UV spec.)

Potency
- Drug substance potency (Cell-based assay)

Purity
- RNA integrity (CE and IPRP-LC)

Process-Related Impurities
- Residual solvents (USP)

Product Characterization and Quality
- Encapsulation efficiency (Ribogreen)
- LNP size (DLS)
- LNP polydispersity (DLS)
- Lipid content (RP-HPLC-CAD)

Safety
- Sterility (USP)
- Endotoxins (USP)

Comprehensive product characterization of plasmid DNA templates and a full suite of compendial testing

Explore services at
SigmaAldrich.com/mRNATesting

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