

DE-RISK MRNA

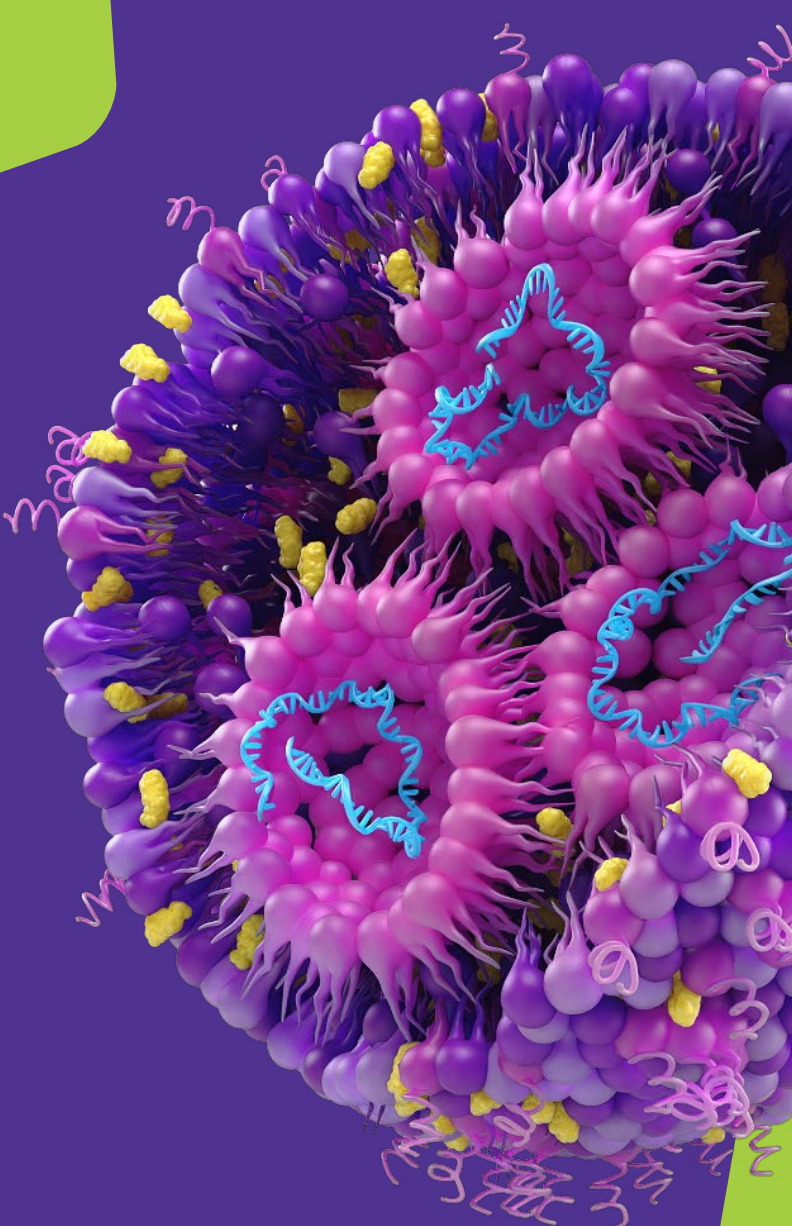
Regulatory Approvals

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)

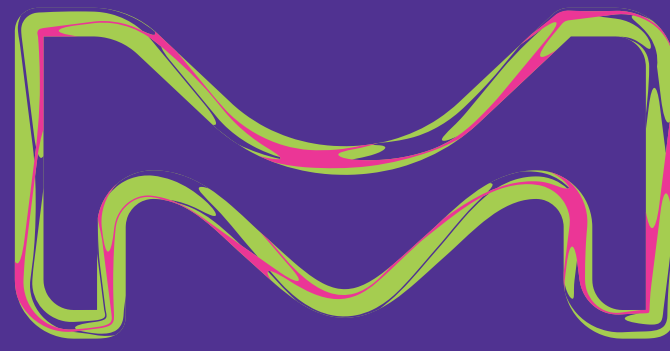


SAFETY

- 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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