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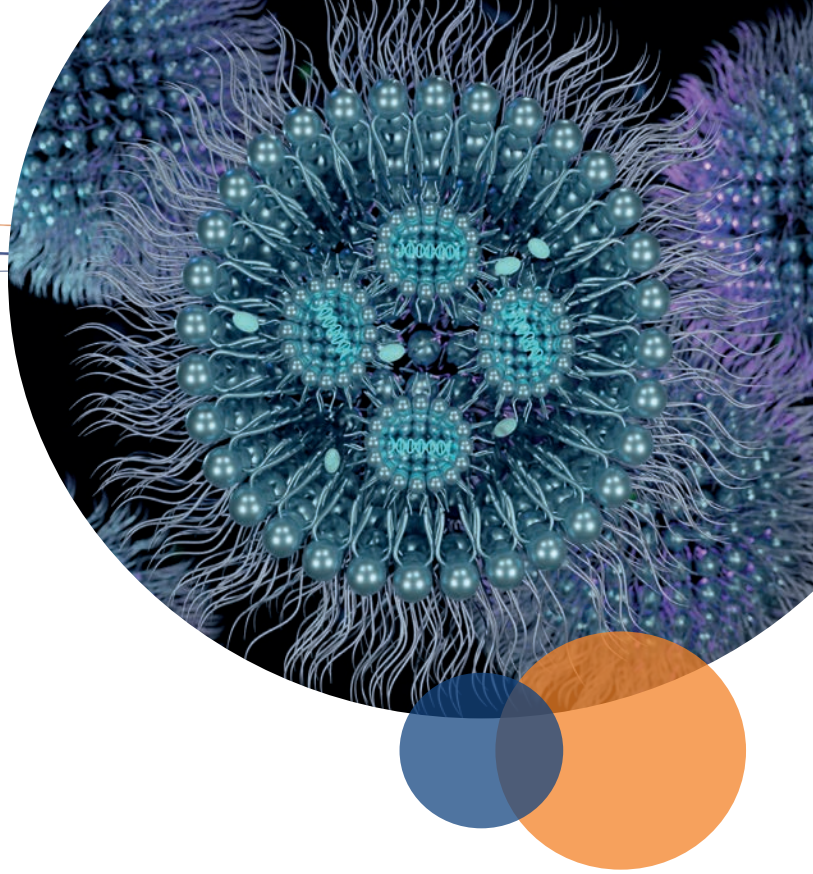
GMP Testing for mRNA-Based Drugs



Messenger RNA (mRNA) is a type of oligonucleotide that is critical to the translation of genetic sequence information of DNA into proteins manufactured in a cell.

The FDA's recent emergency use authorization approval of two RNA-based coronavirus vaccines has taken the typical seven-year vaccine development process to an unprecedented 10-months, resulting in a new focus on mRNA drug development technology.

Distinct from traditional small molecule drugs and biologics such as monoclonal antibodies, mRNA products are considered to be their own unique modality with their own unique analytical challenges. For example, some mRNA vaccines and therapies utilize lipid formulations to deliver the mRNA into the cell.

Eurofins BioPharma Product Testing has supported both mRNA and RNAi development candidates from leading innovators with our broad cGMP testing service portfolio for nearly a decade. We not only can assist in bringing our client's methods to a cGMP ready status, but we also partner with our clients to onboard platform methods to support these drug delivery systems for the project at hand as well as future iterations. This saves the client both time and money when onboarding a new product utilizing the same delivery system.

Why Choose Eurofins BioPharma Product Testing?

Our Scientists have worked on many of the cutting edge mRNA drug products and will bring that experience to your early or late phase project.

Our laboratories have the capacity to support the comprehensive testing needed for these specialized drug products.

Eurofins BioPharma Product Testing has numerous team members who sit on regulatory boards, so we always have the most up-to-date compliance expectations to share with our clients as needed.

Testing Capabilities

- Raw Materials Testing
- Method Establishment & Testing
- Characterization
- Cell Based Bioassay & Potency Testing
- Process Residuals
- Formulation Development Support
- Stability Testing & Storage
- Residual Solvents

Some of the methods employed to characterize the RNA drug substance include:

- Characterization of Exons (5' Cap) and Poly (A) Tails (3'End) by Orthogonal Mass Spec
- Purity/Impurity of Starting Materials by LC/MS

- Purity/Impurity by Ion Exchange, RP-HPLC and CE
- Identity by Reverse Transcription (RT) Sanger Sequencing
- Total RNA by Spectroscopy
- Potency - Cell Based Bioassays
- Residual Solvents and Metals by GC and ICP
- Residual plasmid DNA by PCR
- NGS

Some vaccines, such as two of the current COVID-19 vaccines, are carried into the body by lipid nanoparticles with polyethylene glycol (PEG), adding to their complexity.

Therefore, additional analytical methodologies are employed to characterize the lipid and drug product.

- % RNA encapsulation by Ribogreen
- Lipids by HPLC-CAD
- Particle Size and Dispersity by Light Scattering

As with any biopharmaceutical product, various other characteristics are typically required to support stability and release testing as described in USP/Ph. Eur:

- pH
- Osmolality
- Appearance
- Particulate matter
- Sterility
- Bacterial Endotoxin
- Bioburden