TriLink BioTechnologies Analytical Services

Analytical testing is a critical component of every manufacturing program. As a CDMO with an ISO 9001:2015 certification and ICH Q7 Section 19 compliant quality system, we understand that successful biotherapeutic development and manufacturing are supported by comprehensive testing. We offer unparalleled expertise in phase-appropriate method development and analytical testing to further support your mRNA, plasmid, small molecule and oligonucleotide manufacturing process.

Accelerate Your Product Development with Optimized Testing Services

With over 20 years of experience, we understand your analytical objectives from process development (PD) to scale-up and cGMP manufacturing. TriLink has developed extensive capabilities in **custom method development** and **analytical testing** to ensure a high quality manufacturing process. We work with you to ensure effective method development that meets your objectives at each stage of product development.

Plasmid

Active Moiety Quantification:
- Concentration and Purity (UV Spec), % Supercoiled

Identification:
- Sequencing, Restriction Digest Pattern

Safety (Microbial):
- Endotoxin, Bioburden

Impurity Quantification:
- Residual Protein, Residual gDNA, Isoform Analysis & % RNA (HPLC)

Product Characterization:
- Appearance

Oligonucleotide

Active Moiety Quantification:
- HPLC, Concentration (UV-Vis)

Identification:
- MS, Retention Time

Purity:
- IP-RP HPLC, AX-HPLC

Safety (Microbial):
- Endotoxin, Bioburden

Impurity Quantification:
- Residual Solvents, ICP-MS

Product Characterization:
- Karl Fischer, Thermal Properties [Solution], NMR, Dynamic Vapor Sorption [Lyophilized]

mRNA

Active Moiety Quantification:
- Concentration

Identification:
- Sanger Sequencing, PCR, Length, *In Vitro* Translation, RNase Digestion, Analytical Transcription

Safety (Microbial):
- Endotoxin, Bioburden, Mycoplasma

Impurity Quantification:
- Residual Protein, Residual DNA, Residual Solvents

Qualitative Assessment:
- Residual dsRNA, Residual Protein, Agarose Gel, DNase and RNase Detection

Product Characterization:
- Appearance, pH, Osmolality, Conductivity, Poly A Tail Length, Capping Efficiency, Integrity

NTPs, CleanCap® and Other Cap Analogs

Active Moiety Quantification:
- Concentration (UV-Vis)

Identification:
- MS, ^{1}H NMR

Purity:
- IP-RP HPLC, AX-HPLC, ^{31}P NMR

Safety (Microbial):
- Endotoxin, Bioburden

Qualitative Assessment:
- DNase and RNase Detection, Transcription Functional Test

Product Characterization:
- Conductivity, pH

Products containing CleanCap technology are for research use only. License is required for commercial use of CleanCap and CleanCap Products. For license restrictions and patent(s) information, refer to https://www.trilinkbiotech.com/legal-notices

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