TECHNICAL FACT SHEET

Oligonucleotide characterization and analysis

Oligonucleotides are synthetically derived, often extensively modified, short nucleotide sequences. They have been developed as therapeutic agents, diagnostic tools, and gene-editing elements. Of particular significance are oligonucleotide-based pharmaceuticals.

As these therapeutics progress from research to the clinic and beyond, rigorous analytical regimens are crucial to ensure their safety, efficacy, identity, purity, and quality. SGS supports oligonucleotide development with analytical services from discovery to commercialization. Its expertise, capacity, and GMP/GLP/GCP standards ensure regulatory compliance and client satisfaction.

Despite their synthetic origin, oligonucleotide therapeutics are often complex, incorporating a variety of structural features into the final drug substance. This requires the use of a range of sophisticated analytical technologies such as HR-MS/MS, capillary electrophoresis, and NMR.

The portfolio of necessary techniques often becomes even more diverse when considering a final product, which may integrate delivery systems such as those composed of LNPs. For potency evaluation, SGS frequently employs bespoke methods designed for a specific therapeutic product.

Both the design and execution of any testing strategy for oligonucleotide therapeutics commonly require a multidisciplinary approach, leveraging expertise from a number of different molecular specialists. Such expertise is readily available within the SGS network, where teams of dedicated scientists are available to support all your analytical project needs, regardless of size and scope.

SGS also provides support during the progression of oligonucleotide therapeutics into the clinic through its state-of-the-art clinical research group and Clinical Pharmacology Unit, combined with bioanalytical testing facilities across Europe, North America, and Asia.

Typical technologies used for oligonucleotide quality attributes

PURITY

HPLC / UPLC / LC-MS:
- Impurity profiling

Electrophoresis:
- Purity assessment

SEC-MALS:
- Aggregates

ICP-MS / GCMS:
- Residuals

SAFETY

Microbiology:
- Sterility
- Bioburden
- LAL

Light Scattering:
- Particulate Matter

POTENCY

Spectroscopy / LC:
- Concentration

Binding and enzymatic assay
- Bespoke

Function
- Cell-based bespoke

IDENTITY

Mass Spectrometry:
- Mol Mass
- Sequence
- Modifications

PCR:
- Sequence

Spectroscopy (UV, CD):
- Melting Temp
- % Duplex

QUALITY

Compedia
- Appearance
- pH
- Osmolality
- Moisture

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When you need to be sure