Analytical Services: Pharmaceutical Development to Market

OLIGONUCLEOTIDE AND SMALL MOLECULE EXPERTISE

Oligonucleotide Analytical Methods

- Method development and Phase-appropriate validation
- UPLC and LC/MS methods
- Moisture, Sodium content, Thermal Melt T_m
- Residual solvents and Elemental impurities
- Microbial and endotoxin testing
- Forced degradation studies

cGMP Release and Stability Testing

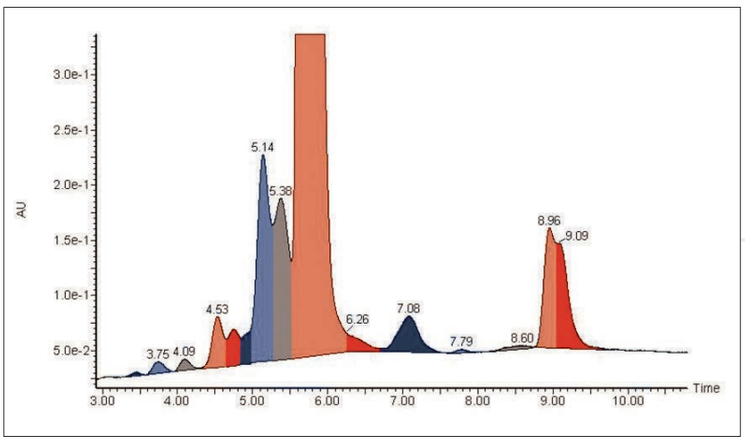
- Raw materials
- Reference standard Qualification and management
- Oligonucleotide Drug Substance and Drug Product
- ICH storage conditions (Trending and Data evaluation)
- Regulatory support: Submission-ready results reporting

Characterization and Research Studies

- Physiochemical properties
- Sequencing
- Impurity identification and characterization by NMR and MS

Nitto Avecia provides comprehensive analytical services for all phases of drug development. Our experience in oligonucleotide therapeutics covers a wide range of types including siRNA, RNAi, longmers, mRNA, antisense, and aptamers with or without conjugation. We partner with you at every step of the drug development process from method development, transfer, and validation to ICH stability studies in support of the Chemistry Manufacturing and Controls (CMC) documentation for your regulatory filings worldwide. At Nitto Avecia, we combine our cumulative years of analytical experience with oligonucleotides and modern instrumentation to provide the specialized services required for your programs success.

Expanded UPLC Chromatogram for Oligonucleotide Purity Analysis



NEXT STEPS: For information on oligonucleotide analytical services, contact OligoInfo@Avecia.com, and for small molecule services, contact SmallMolecules@Avecia.com. Or call 508-532-2500 to discuss how Nitto Avecia's expertise in analytical services can advance your project.

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