



Handbook of Analysis of Oligonucleotides and Related Products

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Oligonucleotides represent one of the most significant pharmaceutical breakthroughs in recent years, showing great promise as diagnostic and therapeutic agents for malignant tumors, cardiovascular disease, diabetes, viral infections, and many other degenerative disorders. The **Handbook of Analysis of Oligonucleotides and Related Products** is an essential reference manual on the practical application of modern and emerging analytical techniques for the analysis of this unique class of compounds. A strong collaboration among thirty leading analytical scientists from around the world, the book provides readers with a comprehensive overview of the most commonly used analytical techniques and their advantages and limitations in assuring the identity, purity, quality, and strength of an oligonucleotide intended for therapeutic use.

Topics discussed include:

- Strategies for enzymatic or chemical degradation of chemically modified oligonucleotides toward mass spectrometric sequencing
- Purity analysis by chromatographic or electrophoretic methods, including RP-HPLC, AX-HPLC, HILIC, SEC, and CGE
- Characterization of sequence-related impurities in oligonucleotides by mass spectrometry and chromatography
- Structure elucidation by spectroscopic methods (IR, NMR, MS) as well as base composition and thermal melt analysis (T_m)
- Approaches for the accurate determination of molar extinction coefficient of oligonucleotides
- Accurate determination of assay values
- Assessment of the overall quality of oligonucleotides, including microbial analysis and determination of residual solvents and heavy metals
- Strategies for determining the chemical stability of oligonucleotides
- The use of hybridization techniques for supporting pharmacokinetics and drug metabolism studies in preclinical and clinical development
- Guidance for the presentation of relevant analytical information towards meeting current regulatory expectations for oligonucleotide therapeutics

This resource provides a practical guide for applying state-of-the-art analytical techniques in research, development, and manufacturing settings.

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