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Soggetti	Drugs - Analysis Drugs - Spectra Mass spectrometry Contamination (Technology) Public Health Chemistry Techniques, Analytical Investigative Techniques Environment and Public Health Health Care Pharmaceutical Preparations Mass Spectrometry Drug Contamination Health & Biological Sciences Pharmacy, Therapeutics, & Pharmacology
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CHARACTERIZATION OF IMPURITIES AND DEGRADANTS USING MASS SPECTROMETRY; CONTENTS; PREFACE; CONTRIBUTORS; ACRONYMS; PART I: METHODOLOGY; 1. Introduction to Mass Spectrometry; 1.1. History; 1.1.1. Atomic Physics; 1.1.2. Early Applications; 1.1.3. Organic Structural Analysis; 1.1.4. The Biological Mass Spectrometry Revolution; 1.2. Ionization Methods; 1.3. Mass Spectrometer Types; 1.3.1. Magnetic Sector Mass Spectrometers; 1.3.2. Quadrupole Mass Filter and Quadrupole Ion Trap Mass Spectrometers; 1.3.3. Time-of-Flight Mass Spectrometers; 1.3.4. Fourier Transform Ion Cyclotron Resonance Mass Spectrometers; 1.3.5. Orbitrap Mass Spectrometers; 1.4. Tandem Mass Spectrometry; 1.4.1. Ion Isolation; 1.4.2. Ion-Molecule Collisions and Collision-Induced Dissociation; 1.4.3. Electron Capture Dissociation and Electron Transfer Dissociation; 1.5. Separation Techniques Coupled to Mass Spectrometry; 1.5.1. Gas Chromatography-Mass Spectrometry; 1.5.2. Liquid Chromatography-Mass Spectrometry; 1.5.3. Capillary Electrophoresis-Mass Spectrometry; 1.5.4. Ion Mobility Spectrometry-Mass Spectrometry; 1.6. Prospects for Mass Spectrometry; References

2. LC Method Development and Strategies; 2.1. Introduction; 2.2. Column, pH, and Solvent Screening; 2.2.1. Resolution: Goal of Separation; 2.2.2. Screening: Systematic Approach to Seeking Selectivity; 2.2.3. Screening Instrumentation and Controlling Software; 2.3. Gradient and Temperature Optimization; 2.4. Orthogonal Screening; 2.4.1. Method Orthogonality; 2.4.2. Selection of Orthogonal Methods; 2.4.3. Impurity Orthogonal Screening; 2.5. High-Efficiency Separation; 2.6. Conclusions; References

3. Rapid Analysis of Drug-Related Substances using Desorption Electrospray Ionization and Direct Analysis in Real Time Ionization Mass Spectrometry; 3.1. Introduction; 3.2. Ionization Apparatus, Mechanisms, and General Performance; 3.2.1. Desorption Electrospray Ionization (DESI); 3.2.2. Direct Analysis in Real Time (DART); 3.3. Drug Analysis in Biological Matrices using DESI and DART; 3.3.1. DESI Application; 3.3.2. DART Application; 3.4. High-Throughput Analysis; 3.5. Chemical Imaging and Profiling; 3.6. Future Perspectives; References; 4. Orbitrap High-Resolution Applications

4.1. Historical Anecdote; 4.2. General Description of Orbitrap Operating Principles; 4.3. The Orbitrap is a "Fourier Transform" Device; 4.4. Performing Experiments in Trapping Devices; 4.4.1. "Raw" HPLC Data Look Like Infusion Data; 4.4.2. How Much Mass Resolution Should Be Used During HPLC; 4.5. Determining Elemental Compositions of "Unknowns" Using an Orbitrap; 4.6. Orbitrap Figures of Merit in Mass Measurement; 4.6.1. Accuracy; 4.6.2. Precision; 4.6.3. Discussion; 4.7. HPLC Orbitrap MS: Accurate Mass Demonstration and Differentiation of Small Molecule Formulas Very Proximate in Mass/Charge Ratio Space

Sommario/riassunto

The book highlights the current practices and future trends in structural characterization of impurities and degradants. It begins with an overview of mass spectrometry techniques as related to the analysis of impurities and degradants, followed by studies involving characterization of process related impurities (including potential genotoxic impurities), and excipient related impurities in formulated products. Both general practitioners in pharmaceutical research and specialists in analytical chemistry field will benefit from this book that will detail step-by-step approaches and new strateg