handbook of modern pharmaceutical analysis

#Pharmaceutical Analysis #Modern Drug Analysis #Analytical Chemistry Pharmaceuticals #Pharmacopoeia Methods #Quality Control Drugs

Explore the foundational principles and cutting-edge methodologies defining modern pharmaceutical analysis. This comprehensive handbook offers invaluable insights for scientists, researchers, and students engaged in drug development, quality control, and regulatory compliance, ensuring the safety and efficacy of medicinal products from conception to market.

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Handbook of Modern Pharmaceutical Analysis

Handbook of Modern Pharmaceutical Analysis, Second Edition, synthesizes the complex research and recent changes in the field, while covering the techniques and technology required for today's laboratories. The work integrates strategy, case studies, methodologies, and implications of new regulatory structures, providing complete coverage of quality assurance from the point of discovery to the point of use. Treats pharmaceutical analysis (PA) as an integral partner to the drug development process rather than as a service to it Covers method development, validation, selection, testing, modeling, and simulation studies combined with advanced exploration of assays, impurity testing, biomolecules, and chiral separations Features detailed coverage of QA, ethics, and regulatory guidance (quality by design, good manufacturing practice), as well as high-tech methodologies and technologies from "lab-on-a-chip" to LC-MS, LC-NMR, and LC-NMR-MS

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Handbook of Modern Pharmaceutical Analysis

This book describes the role modern pharmaceutical analysis plays in the development of new drugs. Detailed information is provided as to how the quality of drug products is assured from the point of discovery until the patient uses the drug. Coverage includes state-of-the-art topics such as analytics for combinatorial chemistry and high-throughput screening, formulation development, stability studies, international regulatory aspects and documentation, and future technologies that are likely to impact the field. Emphasis is placed on current, easy-to-follow methods that readers can apply in their laboratories. No book has effectively replaced the very popular text, Pharmaceutical Analysis, that was

edited in the 1960s by Tak Higuchi. This book will fill that gap with an up-to-date treatment that is both handy and authoritative.

Handbook of Modern Pharmaceutical Analysis

High pressure liquid chromatography—frequently called high performance liquid chromatography (HPLC or, LC) is the premier analytical technique in pharmaceutical analysis and is predominantly used in the pharmaceutical industry. Written by selected experts in their respective fields, the Handbook of Pharmaceutical Analysis by HPLC Volume 6, provides a complete yet concise reference guide for utilizing the versatility of HPLC in drug development and quality control. Highlighting novel approaches in HPLC and the latest developments in hyphenated techniques, the book captures the essence of major pharmaceutical applications (assays, stability testing, impurity testing, dissolution testing, cleaning validation, high-throughput screening). A complete reference guide to HPLC Describes best practices in HPLC and offers 'tricks of the trade' in HPLC operation and method development Reviews key HPLC pharmaceutical applications and highlights currents trends in HPLC ancillary techniques, sample preparations, and data handling

Handbook of Pharmaceutical Analysis by HPLC

A comprehensive introduction for scientists engaged in new drug development, analysis, and approvals Each year the pharmaceutical industry worldwide recruits thousands of recent science graduates—especially chemistry, analytical chemistry, pharmacy, and pharmaceutical majors—into its ranks. However, because of their limited background in pharmaceutical analysis most of those new recruits find making the transition from academia to industry very difficult. Designed to assist both recent graduates, as well as experienced chemists or scientists with limited regulatory, compendial or pharmaceutical analysis background, make that transition, Pharmaceutical Analysis for Small Molecules is a concise, yet comprehensive introduction to the drug development process and analysis of chemically synthesized, small molecule drugs. It features contributions by distinguished experts in the field, including editor and author, Dr. Behnam Davani, an analytical chemist with decades of technical management and teaching experience in compendial, regulatory, and industry. This book provides an introduction to pharmaceutical analysis for small molecules (non-biologics) using commonly used techniques for drug characterization and performance tests. The driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to regulatory bodies for drug approval in order to market their products. In addition, related required supporting studies including good laboratory/documentation practices including analytical instrument qualification are highlighted in this book. Topics covered include: Drug Approval Process and Regulatory Requirements (private standards) Pharmacopeias and Compendial Approval Process (public standards) Common methods in pharmaceutical analysis (typically compendial) Common Calculations for assays and impurities and other specific tests Analytical Method Validation, Verification, Transfer Specifications including how to handle out of specification (OOS) and out of trend (OOT) Impurities including organic, inorganic, residual solvents and elemental impurities Good Documentation Practices for regulatory environment Management of Analytical Laboratories Analytical Instrument Qualifications including IQ, OQ, PQ and VQ Due to global nature of pharmaceutical industry, other topics on both regulatory (ICH) and Compendial harmonization are also highlighted. Pharmaceutical Analysis for Small Molecules is a valuable working resource for scientists directly or indirectly involved with the drug development process, including analytical chemists, pharmaceutical scientists, pharmacists, and quality control/quality assurance professionals. It also is an excellent text/reference for graduate students in analytical chemistry, pharmacy, pharmaceutical and regulatory sciences.

Pharmaceutical Analysis for Small Molecules

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 degrada-

tion 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 (Tm) 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.

Handbook of Analysis of Oligonucleotides and Related Products

Exploring the analysis of pharmaceuticals, including polymorphic forms, this book discusses regulatory requirements in pharmaceutical product development and pharmaceutical testing. It covers methods of drug separation and procedures such as capillary electrophoresis for chromatographic separation of molecules. Additional topics include drug formulation analysis using vibrational and magnetic resonance spectroscopy and identification of drug metabolites and decomposition products using such techniques as mass spectrometry. The book provides more than 300 tables, equations, drawings, and photographs, and convenient, easy-to-use indices, facilitating quick access to each topic.

Handbook of Pharmaceutical Analysis

This book presents an authoritative review of analytical methods used for diagnostics, medical therapy and for forensic purposes. Divided into 4 parts, the book discusses new challenges in bioanalytics, covers bioanalysis as a source of clinical, pharmaceutical and forensic information, explores natural resources as a source of biologically active compounds, and offers new analytical strategies and equipment solutions. Written by interdisciplinary expert academics, this work will appeal to a wide readership of students, researchers and professionals interested in the fields of medicine, chemistry, pharmaceutical, life and health sciences, engineering and environmental protection. Clinicians and employees of forensic laboratories will also find this work instructive and informative.

Handbook of Bioanalytics

Handbook of Thermal Analysis and Calorimetry: Recent Advances, Techniques and Applications, Volume Six, Second Edition, presents the latest in a series that has been well received by the thermal analysis and calorimetry community. This volume covers recent advances in techniques and applications that complement the earlier volumes. There has been tremendous progress in the field in recent years, and this book puts together the most high-impact topics selected for their popularity by new editors Sergey Vyazovkin, Nobuyoshi Koga and Christoph Schick—all editors of Thermochimica Acta. Among the important new techniques covered are biomass conversion; sustainable polymers; polymer nanocompsoties; nonmetallic glasses; phase change materials; propellants and explosives; applications to pharmaceuticals; processes in ceramics, metals, and alloys; ionic liquids; fast-scanning calorimetry, and more. Features 19 all-new chapters to bring readers up to date on the current status of the field Provides a broad overview of recent progress in the most popular techniques and applications Includes chapters authored by a recognized leader in each field and compiled by a new team of editors, each with at least 20 years of experience in the field of thermal analysis and calorimetry Enables applications across a wide range of modern materials, including polymers, metals, alloys, ceramics, energetics and pharmaceutics Overviews the current status of the field and summarizes recent progress in the most popular techniques and applications

Handbook of Thermal Analysis and Calorimetry

Handbook of Advanced Chromatography /Mass Spectrometry Techniques is a compendium of new and advanced analytical techniques that have been developed in recent years for analysis of all types of molecules in a variety of complex matrices, from foods to fuel to pharmaceuticals and more. Focusing on areas that are becoming widely used or growing rapidly, this is a comprehensive volume that describes both theoretical and practical aspects of advanced methods for analysis. Written by authors who have published the foundational works in the field, the chapters have an emphasis on lipids, but

reach a broader audience by including advanced analytical techniques applied to a variety of fields. Handbook of Advanced Chromatography / Mass Spectrometry Techniques is the ideal reference for those just entering the analytical fields covered, but also for those experienced analysts who want a combination of an overview of the techniques plus specific and pragmatic details not often covered in journal reports. The authors provide, in one source, a synthesis of knowledge that is scattered across a multitude of literature articles. The combination of pragmatic hints and tips with theoretical concepts and demonstrated applications provides both breadth and depth to produce a valuable and enduring reference manual. It is well suited for advanced analytical instrumentation students as well as for analysts seeking additional knowledge or a deeper understanding of familiar techniques. Includes UHPLC, HILIC, nano-liquid chromatographic separations, two-dimensional LC-MS (LCxLC), multiple parallel MS, 2D-GC (GCxGC) methodologies for lipids analysis, and more Contains both practical and theoretical knowledge, providing core understanding for implementing modern chromatographic and mass spectrometric techniques Presents chapters on the most popular and fastest-growing new techniques being implemented in diverse areas of research

Handbook of Advanced Chromatography / Mass Spectrometry Techniques

Discover new keys to solving analytical problems using the Latest sample preparation methods Commonly viewed of as a routine task rather than as an integral component in the analytical process, sample preparation has long been undervalued as a science and underdeveloped as a technology. In an effort to reverse this trend, Handbook of Sample Preparation shows why sample preparation deserves closer scientific scrutiny, and makes a compelling case for colleges and professional laboratories to devote more resources to promote the benefits of its correct application. Handbook of Sample Preparation includes: A solid overview of standard sampling methodologies and their analytical capabilities An introduction of non-traditional sampling technologies, which address the need for solvent-free alternatives, automation, and miniaturization A discussion of the analytical shift toward performing sampling on-site, rather than in the laboratory An examination of various extraction technologies and their applications for different types of matrices A look at how to take advantage of new sampling strategies to streamline laboratory procedures, reduce research costs, and increase overall productivity An excellent primer on the fundamentals of extraction as well as a sound guide on the latest technological upgrades influencing current sampling techniques, this versatile text serves as an important and accessible tool for both students and seasoned practitioners as they seek new avenues for improving the accuracy of their analyses.

Handbook of Sample Preparation

This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Pharmaceutical Manufacturing Handbook

Exploring the analysis of pharmaceuticals, including polymorphic forms, this book discusses regulatory requirements in pharmaceutical product development and pharmaceutical testing. It covers methods of drug separation and procedures such as capillary electrophoresis for chromatographic separation of molecules. Additional topics include drug formulation analysis using vibrational and magnetic resonance spectroscopy and identification of drug metabolites and decomposition products using such techniques as mass spectrometry. The book provides more than 300 tables, equations, drawings, and photographs, and convenient, easy-to-use indices, facilitating quick access to each topic.

Handbook of Pharmaceutical Analysis

Pharmaceutical analysis determines the purity, concentration, active compounds, shelf life, rate of absorption in the body, identity, stability, rate of release etc. of a drug. Testing a pharmaceutical product involves a variety of chemical, physical and microbiological analyses. It is reckoned that over £10 billion is spent annually in the UK alone on pharmaceutical analysis, and the analytical processes described in this book are used in industries as diverse as food, beverages, cosmetics, detergents, metals, paints, water, agrochemicals, biotechnological products and pharmaceuticals. This is the key textbook

in pharmaceutical analysis, now revised and updated for its fourth edition. Worked calculation examples Self-assessment Additional problems (self tests) Practical boxes Key points boxes New chapter on Biotech products. New chapter on electrochemical methods in diagnostics. Greatly extended chapter on molecular emission spectroscopy to accommodate developments and innovations in the area. Now on StudentConsult

Pharmaceutical Analysis E-Book

About the Book: During the past two decades, there have been magnificent and significant advances in both analytical instrumentation and computerized data handling devices across the globe. In this specific context the remarkable proliferation of windows

Pharmaceutical Drug Analysis

This revision brings the reader completely up to date on the evolving methods associated with increasingly more complex sample types analyzed using high-performance liquid chromatography, or HPLC. The book also incorporates updated discussions of many of the fundamental components of HPLC systems and practical issues associated with the use of this analytical method. This edition includes new or expanded treatments of sample preparation, computer assisted method development, as well as biochemical samples, and chiral separations.

Practical HPLC Method Development

Handbook of Statistical Analysis and Data Mining Applications, Second Edition, is a comprehensive professional reference book that guides business analysts, scientists, engineers and researchers, both academic and industrial, through all stages of data analysis, model building and implementation. The handbook helps users discern technical and business problems, understand the strengths and weaknesses of modern data mining algorithms and employ the right statistical methods for practical application. This book is an ideal reference for users who want to address massive and complex datasets with novel statistical approaches and be able to objectively evaluate analyses and solutions. It has clear, intuitive explanations of the principles and tools for solving problems using modern analytic techniques and discusses their application to real problems in ways accessible and beneficial to practitioners across several areas—from science and engineering, to medicine, academia and commerce. Includes input by practitioners for practitioners Includes tutorials in numerous fields of study that provide step-by-step instruction on how to use supplied tools to build models Contains practical advice from successful real-world implementations Brings together, in a single resource, all the information a beginner needs to understand the tools and issues in data mining to build successful data mining solutions Features clear, intuitive explanations of novel analytical tools and techniques, and their practical applications

Handbook of Statistical Analysis and Data Mining Applications

Die umfassend überarbeitete 2. Auflage enthält ein neues Kapitel zur chemischen Analyse von Biopharmazeutika, in dem die Identifizierung, Reinheitsprüfung und die Analyse on Peptiden und proteinbasierten Formulierungen erläutert werden. Die neue Auflage bietet ebenfalls verbesserte farbige Abbildungen und Tabellen, eine gestraffte Kapitelstruktur und überarbeitete Inhalte, die das Fachgebiet klarer und verständlicher präsentieren. - Bietet eine Einführung in die grundlegenden Konzepte der pharmazeutischen analytischen Chemie und Statistik. - Untersucht systematisch pharmazeutische Anwendungen, die in anderen Lehrbüchern zu dem Fachgebiet fehlen. - Untersucht verschiedene Analysetechniken, die in der Regel in Pharmalaboren zur Anwendung kommen. - Präsentiert Fragestellungen aus der Praxis, aktuelle praktische Beispiele und detaillierte Illustrationen. - Die aktualisierten Inhalte entsprechen den aktuellen europäischen und US-amerikanischen Arzneibuchvorschriften und -richtlinien.

Introduction to Pharmaceutical Analytical Chemistry

This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

Handbook of Stability Testing in Pharmaceutical Development

Bayesian analysis has developed rapidly in applications in the last two decades and research in Bayesian methods remains dynamic and fast-growing. Dramatic advances in modelling concepts and computational technologies now enable routine application of Bayesian analysis using increasingly realistic stochastic models, and this drives the adoption of Bayesian approaches in many areas of science, technology, commerce, and industry. This Handbook explores contemporary Bayesian analysis across a variety of application areas. Chapters written by leading exponents of applied Bayesian analysis showcase the scientific ease and natural application of Bayesian modelling, and present solutions to real, engaging, societally important and demanding problems. The chapters are grouped into five general areas: Biomedical & Health Sciences; Industry, Economics & Finance; Environment & Ecology; Policy, Political & Social Sciences; and Natural & Engineering Sciences, and Appendix material in each touches on key concepts, models, and techniques of the chapter that are also of broader pedagogic and applied interest.

The Oxford Handbook of Applied Bayesian Analysis

Adopting a practical approach, the authors provide a detailed interpretation of the existing regulations (GMP, ICH), while also discussing the appropriate calculations, parameters and tests. The book thus allows readers to validate the analysis of pharmaceutical compounds while complying with both the regulations as well as the industry demands for robustness and cost effectiveness. Following an introduction to the basic parameters and tests in pharmaceutical validation, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmaceutists, QA officers, and public authorities.

Method Validation in Pharmaceutical Analysis

This two-volume reference serves as a handbook containing a wealth of information for all isotope chemists working in a wide range of disciplines including anthropology to ecology; drug detection methodology to toxicology; nutrition to food science; and the atmospheric sciences to geochemistry. Complementing the first volume, Volume II includes matters that are not strictly confined to the analytical techniques themselves, but relate to analysis of stable isotopes, such as the views on the development of mass spectrometers, isotopic scales, standards and references, and directives for setting up a laboratory. ALSO AVAILABLE: Volume I: Dec. 2004, 0444511148/9780444511140, \$176.00 Volume I and II (set): Oct. 2007, 0444511164/9780444511164, \$205.00 * Presents an encyclopedic overview of stable isotope analytical techniques in an objective way * Includes descriptions of methods and diagrams of analytical devices * Addresses how older techniques formed the basis for present-day techniques, which can be useful in constructing modern analytical systems * Completments Volume I of the set

Handbook of Stable Isotope Analytical Techniques

This handbook provides a straightforward introduction to spectroscopy, showing what it can do and how it does it, together with a clear, integrated and objective account of the wealth of information that can be derived from spectra. The sequence of chapters covers a wide range of the electromagnetic spectrum, and the physical processes involved, from nuclear phenomena to molecular rotation processes. - A day-by-day laboratory guide: its design based on practical knowledge of spectroscopists at universities, industries and research institutes - A well-structured information source containing methods and applications sections framed by sections on general topics - Guides users to a decision about which spectroscopic method and which instrumentation will be the most appropriate to solve their own practical problem - Rapid access to essential information - Correct analysis of a huge number of measured spectra data and smart use of such information sources as databases and spectra libraries

Handbook of Spectroscopy

Handbook on Miniaturization in Analytical Chemistry: Application of Nanotechnology provides a source of authoritative fundamentals, interdisciplinary knowledge and primary literature for researchers who want to fully understand how nano-technologies work. Covering all stages of analysis, from sample preparation to separation and detection, the book discusses the design and manufacturing technology of miniaturization and includes an entire section on safety risks, ethical, legal and social issues

(ELSI), the economics of nanotechnologies, and a discussion on sustainability with respect to nanoand lab-on-chip technologies. This guide for students and researchers working on applications of nanotechnology in modern systems for analysis gives readers everything they need to know to bring their current practices up-to-date. Details the impacts of miniaturization and nanotechnology Includes coverage of the current challenges for scaling up nano-miniaturization design and manufacturing technology for analysis Provides the latest reference materials, including websites of interest and details on the latest research in every chapter

Handbook on Miniaturization in Analytical Chemistry

A complete reference to the cutting edge procedures used to test today's materials and details measuring techniques for the long term durability of new types of concrete and concrete technologies, with contributions by 24 leading scientists and chapters that cover chemical and thermal analysis.

Handbook of Analytical Techniques in Concrete Science and Technology

Vols. -3: Edited by Roger E. Schirmer.

Mod Methods of Pharmaceutical Analysis

This book reviews several of the newer methods that find wide application in pharmaceutical analysis, as well as several older methods of unique importance. The principle of each technique is discussed with emphasis on factors that directly affect its proper application to analytical problems.

Pharmaceutical Analysis

Healthcare providers, consumers, researchers and policy makers are inundated with unmanageable amounts of information, including evidence from healthcare research. It has become impossible for all to have the time and resources to find, appraise and interpret this evidence and incorporate it into healthcare decisions. Cochrane Reviews respond to this challenge by identifying, appraising and synthesizing research-based evidence and presenting it in a standardized format, published in The Cochrane Library (www.thecochranelibrary.com). The Cochrane Handbook for Systematic Reviews of Interventions contains methodological guidance for the preparation and maintenance of Cochrane intervention reviews. Written in a clear and accessible format, it is the essential manual for all those preparing, maintaining and reading Cochrane reviews. Many of the principles and methods described here are appropriate for systematic reviews applied to other types of research and to systematic reviews of interventions undertaken by others. It is hoped therefore that this book will be invaluable to all those who want to understand the role of systematic reviews, critically appraise published reviews or perform reviews themselves.

Modern Methods of Pharmaceutical Analysis

Handbook of Analytical Quality by Design addresses the steps involved in analytical method development and validation in an effort to avoid quality crises in later stages. The AQbD approach significantly enhances method performance and robustness which are crucial during inter-laboratory studies and also affect the analytical lifecycle of the developed method. Sections cover sample preparation problems and the usefulness of the QbD concept involving Quality Risk Management (QRM), Design of Experiments (DoE) and Multivariate (MVT) Statistical Approaches to solve by optimizing the developed method, along with validation for different techniques like HPLC, UPLC, UFLC, LC-MS and electrophoresis. This will be an ideal resource for graduate students and professionals working in the pharmaceutical industry, analytical chemistry, regulatory agencies, and those in related academic fields. Concise language for easy understanding of the novel and holistic concept Covers key aspects of analytical development and validation Provides a robust, flexible, operable range for an analytical method with greater excellence and regulatory compliance

Cochrane Handbook for Systematic Reviews of Interventions

A comprehensive collection of the applications of Nuclear Magnetic Resonance (NMR), Magnetic Resonance Imaging (MRI) and Electron-Spin Resonance (ESR). Covers the wide ranging disciplines in which these techniques are used: * Chemistry; * Biological Sciences; * Pharmaceutical Sciences; * Medical uses; * Marine Science; * Materials Science; * Food Science. Illustrates many techniques through the applications described, e.g.: * High resolution solid and liquid state NMR; * Low resolution

NMR, especially important in food science; * Solution State NMR, especially important in pharmaceutical sciences; * Magnetic Resonance Imaging, especially important for medical uses; * Electron Spin Resonance, especially important for spin-labelling in food, marine and medical studies.

Handbook of Analytical Quality by Design

Handbook of Radioactivity Analysis is written by experts in the measurement of radioactivity. The book describes the broad scope of analytical methods available and instructs the reader on how to select the proper technique. It is intended as a practical manual for research which requires the accurate measurement of radioactivity at all levels, from the low levels encountered in the environment to the high levels measured in radioisotope research. This book contains sample preparation procedures, recommendations on steps to follow, necessary calculations, computer controlled analysis, and high sample throughput techniques. Each chapter includes practical techniques for application to nuclear safety, nuclear safeguards, environmental analysis, weapons disarmament, and assays required for research in biomedicine and agriculture. The fundamentals of radioactivity properties, radionuclide decay, and methods of detection are included to provide the basis for a thorough understanding of the analytical procedures described in the book. Therefore, the Handbook can also be used as a teaching text. Key Features * Includes sample preparation techniques for matrices such as soil, air, plant, water, animal tissue, and surface swipes * Provides procedures and guidelines for the analysis of commonly encountered na

Modern Magnetic Resonance

A large number of examples are given that will assist in the selection of a method, including thin-layer chromatography, capillary electrophoresis and membrane separations." "This book will be a reliable guide for those just starting out in pharmaceutical and related industries, as well as those with experience in the field."--Jacket.

Handbook of Radioactivity Analysis

Since its commercial introduction in 2004, UHPLC (Ultra-High Performance Liquid Chromatography) has begun to replace conventional HPLC in academia and industry and interest in this technique continues to grow. Both the increases in speed and resolution make this an attractive method; particularly to the life sciences and more than 1500 papers have been written on this strongly-evolving topic to date. This book provides a solid background on how to work with UHPLC and its application to the life sciences. The first part of the book covers the basics of this approach and the specifics of a UHPLC system, providing the reader with a solid background to working properly with such a system. The second part examines the application of UHPLC to the life sciences, with a focus on drug analysis strategies. UHPLC-MS, a key technique in pharmaceutical and toxicological analyses, is also examined in detail. The editors (Davy Guillarme and Jean-Luc Veuthey) were some of the earliest adopters of UHPLC and have published and lectured extensively on this topic. Between them they have brought together an excellent team of contributors from Europe and the United States, presenting a wealth of expertise and knowledge. This book is an essential handbook for anyone wishing to adopt an UHPLC system in either an academic or industrial setting and will benefit postgraduate students and experienced workers alike.

Chiral Separations by Chromatography

This carefully edited collection synthesizes the state of the art in the theory and applications of designed experiments and their analyses. It provides a detailed overview of the tools required for the optimal design of experiments and their analyses. The handbook covers many recent advances in the field, including designs for nonlinear models and algorithms applicable to a wide variety of design problems. It also explores the extensive use of experimental designs in marketing, the pharmaceutical industry, engineering and other areas.

UHPLC in Life Sciences

Pharmaceutical Quality by Design: Principles and Applications discusses the Quality by Design (QbD) concept implemented by regulatory agencies to ensure the development of a consistent and high-quality pharmaceutical product that safely provides the maximum therapeutic benefit to patients. The book walks readers through the QbD framework by covering the fundamental principles of QbD,

the current regulatory requirements, and the applications of QbD at various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk and assessment, and clinical trials. Contributions from global leaders in QbD provide specific insight in its application in a diversity of pharmaceutical products, including nanopharmaceuticals, biopharmaceuticals, and vaccines. The inclusion of illustrations, practical examples, and case studies makes this book a useful reference guide to pharmaceutical scientists and researchers who are engaged in the formulation of various delivery systems and the analysis of pharmaceutical product development and drug manufacturing process. Discusses vital QbD precepts and fundamental aspects of QbD implementation in the pharma, biopharma and biotechnology industries Provides helpful illustrations, practical examples and research case studies to explain QbD concepts to readers Includes contributions from global leaders and experts from academia, industry and regulatory agencies

Handbook of Design and Analysis of Experiments

Discover how biomarkers can boost the success rate of drug development efforts As pharmaceutical companies struggle to improve the success rate and cost-effectiveness of the drug development process, biomarkers have emerged as a valuable tool. This book synthesizes and reviews the latest efforts to identify, develop, and integrate biomarkers as a key strategy in translational medicine and the drug development process. Filled with case studies, the book demonstrates how biomarkers can improve drug development timelines, lower costs, facilitate better compound selection, reduce late-stage attrition, and open the door to personalized medicine. Biomarkers in Drug Development is divided into eight parts: Part One offers an overview of biomarkers and their role in drug development. Part Two highlights important technologies to help researchers identify new biomarkers. Part Three examines the characterization and validation process for both drugs and diagnostics, and provides practical advice on appropriate statistical methods to ensure that biomarkers fulfill their intended purpose. Parts Four through Six examine the application of biomarkers in discovery, preclinical safety assessment, clinical trials, and translational medicine. Part Seven focuses on lessons learned and the practical aspects of implementing biomarkers in drug development programs. Part Eight explores future trends and issues, including data integration, personalized medicine, and ethical concerns. Each of the thirty-eight chapters was contributed by one or more leading experts, including scientists from biotechnology and pharmaceutical firms, academia, and the U.S. Food and Drug Administration. Their contributions offer pharmaceutical and clinical researchers the most up-to-date understanding of the strategies used for and applications of biomarkers in drug development.

Pharmaceutical Quality by Design

This new edition brings you up-to-date on the role of pharmaceutics and its future paradigms in the design of medicines. Contributions from over 30 international thought leaders cover the core disciplines of pharmaceutics and the impact of biotechnology, gene therapy, and cell therapy on current findings. Modern Pharmaceutics helps you stay current with the basic sciences, systems, applications, and advances in drug development—from materials used in formulations and dosage form design and manufacture, to testing in clinical trials. Improve research and development strategies with brand new content on: • methods of in vivo imaging of dosage forms • excipients, tablets, and aerosols—from physical chemistry to dosage form • solid state drug delivery • biotechnology-based pharmaceuticals • modern evaluation techniques for medicinal products • pharmaceutical nanotechnology • pharmaceutical physics • pediatric and geriatric medication • routes of administration • paradigms in pharmaceutical research

Biomarkers in Drug Development

Recent advances in the pharmaceutical sciences and biotechnology have facilitated the production, design, formulation and use of various types of pharmaceuticals and biopharmaceuticals. This book provides detailed information on the background, basic principles, and components of techniques used for the analysis of pharmaceuticals and biopharmaceuticals. Focusing on those analytical techniques that are most frequently used for pharmaceuticals, it classifies them into three major sections and 19 chapters, each of which discusses a respective technique in detail. Chiefly intended for graduate students in the pharmaceutical sciences, the book will familiarize them with the components, working principles and practical applications of these indispensable analytical techniques.

Modern Pharmaceutics, Two Volume Set, Fifth Edition

Essentials of Pharmaceutical Analysis

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