

Analytical Profiles Of Drug Substances Volume 16

Profiles of Drug Substances, Excipients and Related Methodology

Analytical Profiles of Drug Substances and Excipients Academic Press

The definitive textbook on the chemical analysis of pharmaceutical drugs – fully revised and updated Introduction to Pharmaceutical Analytical Chemistry enables students to gain fundamental knowledge of the vital concepts, techniques and applications of the chemical analysis of pharmaceutical ingredients, final pharmaceutical products and drug substances in biological fluids. A unique emphasis on pharmaceutical laboratory practices, such as sample preparation and separation techniques, provides an efficient and practical educational framework for undergraduate studies in areas such as pharmaceutical sciences, analytical chemistry and forensic analysis. Suitable for foundational courses, this essential undergraduate text introduces the common analytical methods used in quantitative and qualitative chemical analysis of pharmaceuticals. This extensively revised second edition includes a new chapter on chemical analysis of biopharmaceuticals, which includes discussions on identification, purity testing and assay of peptide and protein-based formulations. Also new to this edition are improved colour illustrations and tables, a streamlined chapter structure and text revised for increased clarity and comprehension. Introduces the fundamental concepts of pharmaceutical analytical chemistry and statistics Presents a systematic investigation of pharmaceutical applications absent from other textbooks on the subject Examines various analytical techniques commonly used in pharmaceutical laboratories Provides practice problems, up-to-date practical examples and detailed illustrations Includes updated content aligned with the current European and United States Pharmacopeia regulations and guidelines Covering the analytical techniques and concepts necessary for pharmaceutical analytical chemistry, Introduction to Pharmaceutical Analytical Chemistry is ideally suited for students of chemical and pharmaceutical sciences as well as analytical chemists transitioning into the field of pharmaceutical analytical chemistry.

There are unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-MS and presents manufacturing techniques such as granulation, compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for pharmaceutical scientists, regulators, and graduate students.

Although the official compendia define a drug substance as to identity, purity, strength, and quality, they normally do not provide other physical or chemical data, nor do they list methods of synthesis or pathways of physical or biological degradation and metabolism. Such information is scattered throughout the scientific literature and the files of pharmaceutical laboratories. Analytical Profiles of Drug Substances brings this information together into one source. The United States Food and Drug Administration (FDA) and other regulatory bodies around the world require that impurities in drug substance and drug product levels recommended by the International Conference on Harmonisation (ICH) be isolated and characterized. Identifying process-related impurities and degradation products also helps us to understand the production of impurities and assists in defining degradation mechanisms. When this process is performed at an early stage, there is ample time to address various aspects of drug development to prevent or control the production of impurities and degradation products well before the regulatory filing and thus assure production of a high-quality drug product. This book, therefore, has been designed to meet the need for a reference text on the complex process of isolation and characterization of process-related (synthesis and formulation) impurities and degradation products to meet critical regulatory requirements. It's objective is to provide guidance on isolating and characterizing impurities of pharmaceuticals such as drug candidates, drug substances, and drug products. The book outlines impurity identification processes and will be a key resource document for impurity analysis, isolation/synthesis, and characterization. - Provides valuable information on isolation and characterization of impurities. - Gives a regulatory perspective on the subject. - Describes various considerations involved in meeting regulatory requirements. - Discusses various sources of impurities and degradation products.

Volumes in this widely revered series present comprehensive reviews of drug substances and additional materials, with critical review chapters that summarize information related to the characterization of drug substances and excipients. This organizational structure meets the needs of the pharmaceutical community and allows for the development of a timely vehicle for publishing review materials on this topic. The scope of the Profiles series encompasses review articles and database compilations that fall within one of the following six broad categories: Physical profiles of drug substances and excipients; Analytical profiles of drug substances and excipients; Drug metabolism and pharmacokinetic profiles of drug substances and excipients; Methodology related to the characterization of drug substances and excipients; Methods of chemical synthesis; and Reviews of the uses and applications for individual drug substances, classes of drug substances, or excipients. Presents comprehensive reviews covering all aspects of drug development and formulation of drugs Profiles creatine monohydrate and fexofenadine hydrochloride, as well as five others Meets the information needs of the drug development community

Circular dichroism is a special technique which provides unique information on dissymmetric molecules. Such compounds are becoming increasingly important in a wide variety of fields, such as natural products chemistry, pharmaceuticals, molecular biology, etc. The content of this book has been selected in order to feature the unique aspects of circular dichroism, and how these strengths can be of assistance to workers in the field. Substantial discussions have been provided regarding the particular phenomena associated with dissymmetric compounds which give rise to the circular dichroism effect. Reviews are also given of the type of instrumentation available for the measurement of these

effects. A number of chapters cover the wide range of applications illustrating the power of the method. Owing to its broad appeal, the book will be of interest to workers in all areas of chemistry and pharmaceutical science.

Analytical Profiles of Drug Substances and Excipients

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.

Whilst following in the footsteps of previous volumes by presenting comprehensive reviews of drug substances and additional materials, this title also heralds a significant expansion of the scope of the series. Traditional contributions will now also be augmented by publication of critical review chapters that summarize information related to the characterization of drug substances and excipients. This change is required to better meet the needs of the pharmaceutical community and to allow the development of a timely vehicle for publishing review materials on this topic. The scope of the Profiles series will encompass review articles and database compilations that fall within one of the following six broad categories: Physical profiles of drug substances and excipients; Analytical profiles of drug substances and excipients; Drug metabolism and pharmacokinetic profiles of drug substances and excipients; Methodology related to the characterization of drug substances and excipients; Methods of chemical synthesis; and Reviews of the uses and applications for individual drug substances, classes of drug substances, or excipients. * Presents comprehensive reviews covering all aspects of drug development and formulation of drugs * Now encompassing critical review chapters * Meets the information needs of the drug development community

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, pharmacists, QA officers, and public authorities.

Intended for medicinal, pharmaceutical and analytical chemists, this book brings together information detailing physical and chemical data defining a drug, and various methods of synthesis of biological/physical degradation and metabolism.

Drug overdose, driven largely by overdose related to the use of opioids, is now the leading cause of unintentional injury death in the United States. The ongoing opioid crisis lies at the intersection of two public health challenges: reducing the burden of suffering from pain and containing the rising toll of the harms that can arise from the use of opioid medications. Chronic pain and opioid use disorder both represent complex human conditions affecting millions of Americans and causing untold disability and loss of function. In the context of the growing opioid problem, the U.S. Food and Drug Administration (FDA) launched an Opioids Action Plan in early 2016. As part of this plan, the FDA asked the National Academies of Sciences, Engineering, and Medicine to convene a committee to update the state of the science on pain research, care, and education and to identify actions the FDA and others can take to respond to the opioid epidemic, with a particular focus on informing FDA's development of a formal method for incorporating individual and societal considerations into its risk-benefit framework for opioid approval and monitoring.

Rare diseases collectively affect millions of Americans of all ages, but developing drugs and medical devices to prevent, diagnose, and treat these conditions is challenging. The Institute of Medicine (IOM) recommends implementing an integrated national strategy to promote rare diseases research and product development.

This comprehensive book covers all major aspects of the design and maintenance of port facilities, including port planning, design loads for today's larger vessel size, seismic design guidelines, and breakwater design. New material addresses environmental concerns, the latest developments on inter-modal hubs and transfer points, and the latest information on port security and procedures being implemented around the world.

Presents a detailed discussion of important solid-state properties, methods, and applications of solid-state analysis Illustrates the various phases or forms that solids can assume and discusses various issues related to the relative stability of solid forms and tendencies to undergo transformation Covers key methods of solid state analysis including X-ray powder diffraction, thermal analysis, microscopy, spectroscopy, and solid state NMR Reviews critical physical attributes of pharmaceutical materials, mainly related to drug substances, including particle size/surface area, hygroscopicity, mechanical properties, solubility, and physical and chemical stability Showcases the application of solid state material science in rational selection of drug solid forms, analysis of various solid forms within drug substance and the drug product, and pharmaceutical product development Introduces appropriate manufacturing and control procedures using Quality by Design, and other strategies that lead to safe and effective products with a minimum of resources and time

Holland-Frei Cancer Medicine, Ninth Edition, offers a balanced view of the most current knowledge of cancer science and clinical oncology practice. This all-new edition is the consummate reference source for medical oncologists, radiation oncologists, internists, surgical oncologists, and others who treat cancer patients. A translational perspective throughout, integrating cancer biology with cancer management providing an in depth understanding of the disease An emphasis on multidisciplinary, research-driven patient care to improve outcomes and optimal use of all appropriate therapies Cutting-edge coverage of personalized cancer care, including molecular diagnostics and therapeutics Concise, readable, clinically relevant text with algorithms, guidelines and insight into the use of both conventional and novel drugs Includes free access to the Wiley Digital Edition providing search across the book, the full reference list with web links, illustrations and photographs, and post-publication updates

This book covers the most recent research trends and applications of Pharmaceutical Analytical Chemistry. The included topics range from the adulteration of dietary supplements, to the determination of drugs in biological samples with the aim to investigate their pharmacokinetic properties.

Drug metabolism/pharmacokinetics and drug interaction studies have been extensively carried out in order to secure the druggability and

safety of new chemical entities throughout the development of new drugs. Recently, drug metabolism and transport by phase II drug metabolizing enzymes and drug transporters, respectively, as well as phase I drug metabolizing enzymes, have been studied. A combination of biochemical advances in the function and regulation of drug metabolizing enzymes and automated analytical technologies are revolutionizing drug metabolism research. There are also potential drug–drug interactions with co-administered drugs due to inhibition and/or induction of drug metabolic enzymes and drug transporters. In addition, drug interaction studies have been actively performed to develop substrate cocktails that do not interfere with each other and a simultaneous analytical method of substrate drugs and their metabolites using a tandem mass spectrometer. This Special Issue has the aim of highlighting current progress in drug metabolism/pharmacokinetics, drug interactions, and bioanalysis.

Although the official compendia define a drug substance as to identity, purity, strength, and quality, they normally do not provide other physical or chemical data, nor do they list methods of synthesis or pathways of physical or biological degradation and metabolism. Such information is scattered throughout the scientific literature and the files of pharmaceutical laboratories. Edited by the Associate Director of Analytical Research and Development for the American Association of Pharmaceutical Scientists, Analytical Profiles of Drug Substances and Excipients brings this information together into one source. The scope of the series has recently been expanded to include profiles of excipient materials.

The book presents developments and applications of these methods, such as NMR, mass, and others, including their applications in pharmaceutical and biomedical analyses. The book is divided into two sections. The first section covers spectroscopic methods, their applications, and their significance as characterization tools; the second section is dedicated to the applications of spectrophotometric methods in pharmaceutical and biomedical analyses. This book would be useful for students, scholars, and scientists engaged in synthesis, analyses, and applications of materials/polymers.

The adulteration and fraudulent manufacture of medicines is an old problem, vastly aggravated by modern manufacturing and trade. In the last decade, impotent antimicrobial drugs have compromised the treatment of many deadly diseases in poor countries. More recently, negligent production at a Massachusetts compounding pharmacy sickened hundreds of Americans. While the national drugs regulatory authority (hereafter, the regulatory authority) is responsible for the safety of a country's drug supply, no single country can entirely guarantee this today. The once common use of the term counterfeit to describe any drug that is not what it claims to be is at the heart of the argument. In a narrow, legal sense a counterfeit drug is one that infringes on a registered trademark. The lay meaning is much broader, including any drug made with intentional deceit. Some generic drug companies and civil society groups object to calling bad medicines counterfeit, seeing it as the deliberate conflation of public health and intellectual property concerns. Countering the Problem of Falsified and Substandard Drugs accepts the narrow meaning of counterfeit, and, because the nuances of trademark infringement must be dealt with by courts, case by case, the report does not discuss the problem of counterfeit medicines.

Critical Issues in Alcohol and Drugs of Abuse Testing, Second Edition, addresses the general principles and technological advances for measuring drugs and alcohol, along with the pitfalls of drugs of abuse testing. Many designer drugs, for example, are not routinely tested in drugs of abuse panels and may go undetected in a drug test. This updated edition is a must-have for clinical pathologists, toxicologists, clinicians, and medical review officers and regulators, bridging the gap between technical and clinical information. Topics of note include the monitoring of pain management drugs, bath salts, spices (synthetic marijuana), designer drugs and date rape drugs, and more. Serves as a ready resource of information for alcohol and drug testing. Ideal resource for making decisions related to the monitoring and interpretation of results. Includes concise content for clinical laboratory scientists, toxicologists and clinicians.

This book provides a compelling overall update on current status of RNA interference

Profiles of Drug Substances, Excipients, and Related Methodology, Volume 46 contains comprehensive profiles of five drug compounds: Darunavir, Bisoprolol, Betaxolol, Rabeprazole and Irbesartan. In addition, the work contains a chapter reviewing Bioassay Methods and Their Applications in Herbal Drug Research. The comprehensive reviews in the book cover all aspects of drug development and the formulation of drugs, helping readers understand how the drug development community remains essential to all phases of pharmaceutical development. In addition, this work answers why such profiles are of immeasurable importance to workers in the field. The scope of the Profiles series encompasses review articles and database compilations that fall within one or more of the following five broad categories: Physical Profiles of Drug Substances and Excipients, Analytical Profiles of Drug Substances and Excipients, ADME Profiles of Drug Substances and Excipients, Methodology Related to the Characterization of Drug Substances and Excipients, and Methods of Chemical Synthesis. Contains contributions from leading authorities. Presents an excellent overview on the physical, chemical and biomedical properties of some regularly prescribed drugs. Includes a cumulative index in each volume.

The most complete guide of its kind, this is the standard handbook for chemical and process engineers. All new material on fluid flow, long pipe, fractionators, separators and accumulators, cooling towers, gas treating, blending, troubleshooting field cases, gas solubility, and density of irregular solids. This substantial addition of material will also include conversion tables and a new appendix, "Shortcut Equipment Design Methods." This convenient volume helps solve field engineering problems with its hundreds of common sense techniques, shortcuts, and calculations. Here, in a compact, easy-to-use format, are practical tips, handy formulas, correlations, curves, charts, tables, and shortcut methods that will save engineers valuable time and effort. Hundreds of common sense techniques and calculations help users quickly and accurately solve day-to-day design, operations, and equipment problems.

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