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RUSH ROLAND

Advances and Applications in Pharmaceutical Analysis Elsevier
Delineating its usage in separation, purification and detection processes across a variety of disciplines, from industry to applied research, this work discusses the principles, techniques and instrumentation involving HPLC within a detailed framework. Over 100 tables present previously scattered experimental data.
Handbook of Pharmaceutical Excipients Wiley-Interscience
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
Capillary Electrophoresis Methods for Pharmaceutical Analysis John Wiley & Sons
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
Practical Handbook of Pharmaceutical Analysis CRC Press
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.
Production, Chemistry, Techniques and Technology Elsevier
This book described about the concept and procedure involved in instrumental analytical techniques, with all the possible explanation. This book clearly explains the post experiment calculations with the performed experiments, that will be helpful to the students to understand and obtain the accurate and precise results. This book covers the entire Instrumental analytical experiments as per the Pharmacy council of India’s B. Pharm and Pharm D syllabus.
The Oxford Handbook of the Economics of the Biopharmaceutical Industry Woodhead Publishing
Analytical chemists in the pharmaceutical industry are always looking for more-efficient techniques to meet the analytical challenges of today’s pharmaceutical industry. One technique that has made steady advances in pharmaceutical analysis is supercritical fluid chromatography (SFC). SFC is meeting the chromatography needs of the industry by providing efficient and selective testing capabilities on the analytical and preparative scale. The supercritical fluid mobile phase, consisting mainly of CO2, facilitates cost reduction costs and helps the industry in meeting green chemistry standards. This book provides a comprehensive overview of the use of SFC in pharmaceutical analysis. Supercritical Fluid Chromatography reviews the use of SFC in drug-discovery applications and describes its application in drug development. When a drug is developed and brought to market, it is tested many times for impurities and degradants, enantiomeric purity, and analytical and preparative isolations—it is tested during discovery and development and for under-regulated and unregulated methodologies. The book describes the use of SFC for each of these applications and discusses more in-depth topics, such as the use of SFC in mass spectrometric and polarographic detection. The book also sheds light on the role of SFC in drug development from natural products and the advancement of SFC with new technologies and its use in pilot-scale operations as a chromatographic technique.
Measuring Elemental Impurities in Pharmaceuticals John Wiley & Sons
This book provides a broad account of various applied aspects of microbiology for quality and safety evaluations in food, water, soil, environment and pharmaceutical sciences. The work is timely, as the safety and quality of various commodities such as water and wastewater, food, pharmaceutical medications and medical devices are of paramount concern in developing countries globally for improved public health quality in areas ranging from food security to disease exposure. The book offers an introduction to basic concepts of biosafety and related microbiological practices and applies these methodologies to a multitude of disciplines in subject-focused chapters. Each chapter offers experiments and exercises pertaining to the specific area of interest in microbiological research, which will allow readers to apply the knowledge gained in a laboratory or classroom setting to see the microbiological methods discussed in practice. The book will be useful for industrialists, researchers, academics and undergraduate/graduate students of microbiology, biotechnology, botany and pharmaceutical sciences. The text aims to be a significant contribution in effectively guiding scientists, analysts, lab technicians and quality managers working with microbiology in industrial and commercial fields.
A Practical Guide CRC Press
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 requlatory 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 degredation products.
CRC Press
The biopharmaceutical industry has been a major driver of technological change in health care, producing unprecedented benefits for patients, cost challenges for payers, and profits for shareholders. As consumers and companies benefit from access to new drugs, policymakers around the globe seek mechanisms to control prices and expenditures commensurate with value. More recently the 1990s productivity boom of new products has turned into a productivity bust, with fewer and more modest innovations, and flat or declining revenues for innovative firms as generics replace their former blockbuster products. This timely volume examines the economics of the biopharmaceutical industry, with eighteen chapters by leading academic health economists. Part one examines the economics of biopharmaceutical innovation including determinants of the costs and returns to new drug development; how capital markets finance R&D and how costs of financing the biopharmaceutical industry compare to financing costs for other industries; the effects of safety and efficacy regulation by the Food and Drug Administration (FDA) and of price and reimbursement regulation on incentives for innovation; and the role of patents and regulatory exclusivities. Part two examines the market for biopharmaceuticals with chapters on prices and reimbursement in the US, the EU, and other industrialized countries, and in developing countries. It looks at the optimal design of insurance for drugs and the effects of cost sharing on spending and on health outcomes; how to measure the value of pharmaceuticals using pharmacoeconomics, including theory, practical challenges, and policy issues; how to measure pharmaceutical price growth over time and recent evidence; empirical evidence on the value of pharmaceuticals in terms of health outcomes; promotion of pharmaceuticals to physicians and consumers; the economics of vaccines; and a review of the evidence on effects of mergers, acquisitions and alliances. Each chapter summarizes the latest insights from theory and recent empirical evidence, and outlines important unanswered questions and areas for future research. Based on solid economics, it is nevertheless written in terms accessible to the general reader. The book is thus recommended reading for academic economists and non-economists, and for those in industry and policy who wish to understand the economics of this fascinating industry.
Pharmaceutical Manufacturing Handbook John Wiley & Sons
The pharmaceutical sector offers some of the most exciting financial and business opportunities today. This essential and practical guide gives you all the tools you need to assess such opportunities. The second edition of the respected Pharmaceutical Equities, it has been thoroughly revised and updated to reflect the changes, especially in life sciences, since the first edition. The book is international in outlook, and explains the rules of the game not just for wise investing, but also for understanding how this uniquely complex and highly regulated business works. The authors explain: HOW to evaluate the technology and research and development, as well as the sales potential of ensuing products WHAT key issues will affect and influence companies in the next few years HOW to balance potential high returns on breakthrough products against accompanying risks The book begins with a look at the global pharmaceutical industry, from its history to the structure of present day companies. The second part explores how to analyse and value pharmaceutical and biotechnology companies. The final part deals with trading itself and looks at share price movement and the main equity markets throughout the world. Both practical and comprehensive, this handbook will be essential reading for investors, analysers and corporate planners - and is the ONLY book which will show you how to actually value pharmaceutical companies.
Handbook of Pharmaceutical Biotechnology CRC Press
This book provides an overview of the state of the art in pharmaceutical applications of UV-VIS spectroscopy. This book presents the fundamentals for the beginner and, for the expert, discusses both qualitative and quantitative analysis problems. Several chapters focus on the determination of drugs in various matrices, the coupling of chromatographic and spectrophotometric methods, and the problems associated with the use of chemical reactions prior to spectrophotometric measurements. The final chapter provides a survey of the spectrophotometric determination of the main families of drugs, emphasizing the achievements of the last decade.
Valuing Pharmaceutical Companies Educreation Publishing
The introduction of combinatorial chemistry technology has increased the amount of compounds generated in a year from 50 to 2000. Conventional analytical approaches simply cannot keep up. These circumstances have caused drug discovery to take on the shape of a bottleneck, like traffic through a toll booth. In order to break the bottleneck, a corres
HPLC Method Development for Pharmaceuticals John Wiley & Sons
Aqueous solubility is one of the major challenges in the early stages of drug discovery. One of the most common and effective methods for enhancing solubility is the addition of an organic solvent to the aqueous solution. Along with an introduction to cosolvency models, the Handbook of Solubility Data for Pharmaceuticals provides an extensive database of solubility for pharmaceuticals in mono solvents and binary solvents. Aqueous solubility data can be found in the Handbook of Aqueous Solubility Data by Samuel Yalkowsky and Yan He. Visit www.crcpress.com for more information. In addition to the experimental efforts to measure the solubility of drugs in mono and mixed solvents,

this book discusses the advantages and limitations of a number of mathematical models used to predict the solubility in mono or mixed solvent systems. It covers the pharmaceutical cosolvents and other organic solvents that are used in syntheses, separations, and other pharmaceutical processes. The solutes featured include the available data for official drugs, drug candidates, precursors of drugs, metabolites, and degradation products of pharmaceuticals. The author also presents the solubilities of amino acids since they play an important role in peptide drug properties. Collecting drug solubilities in various cosolvents, this time-saving handbook includes the mixtures and model constants needed to predict undetermined solubilities. It describes mathematical models that enable data to be derived and provides estimates on how drugs are likely to behave in a given cosolvent. A software program and associated user manual are available on the author's website.

Handbook of Modern Pharmaceutical Analysis Springer Science & Business Media

Capillary electrophoresis (CE) is a powerful analytical technique that is widely used in research and development and in quality control of pharmaceuticals. Many reports of highly efficient separations and methods have been published over the past 15 years. CE offers several advantages over high-pressure or high-performance liquid chromatography (HPLC). These include simplicity, rapid analysis, automation, ruggedness, different mechanisms for selectivity, and low cost. Moreover, EC requires smaller sample size and yet offers higher efficiency and thus greater resolution power over HPLC. These characteristics are very attractive in research and development, even more so in pharmaceutical quality control (QC) and stability monitoring (SM) studies. This book will provide busy pharmaceutical scientists a complete yet concise reference guide for utilizing the versatility of CE in new drug development and quality control. - Provides current status and future developments in CE analysis of pharmaceuticals. - Explains how to develop and validate methods. - Includes major pharmaceutical applications including assays and impurity testing.

Handbook of Pharmaceutical Controlled Release Technology Springer Nature

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.

Regulations, Methodologies, and Best Practices Academic Press

Polymers are one of the most fascinating materials of the present era finding their applications in almost every aspects of life. Polymers are either directly available in nature or are chemically synthesized and used depending upon the targeted applications.Advances in polymer science and the introduction of new polymers have resulted in the significant development of polymers with unique properties. Different kinds of polymers have been and will be one of the key in several applications in many of the advanced pharmaceutical research being carried out over the globe. This 4-partset of books contains precisely referenced chapters, emphasizing different kinds of polymers with basic fundamentals and practicality for application in diverse pharmaceutical technologies. The volumes aim at explaining basics of polymers based materials from different resources and their chemistry along with practical applications which present a future direction in the pharmaceutical industry. Each volume offer deep insight into the subject being treated. Volume 1: Structure and Chemistry Volume 2: Processing and Applications Volume 3: Biodegradable Polymers Volume 4: Bioactive and Compatible Synthetic/Hybrid Polymers

HPLC for Pharmaceutical Scientists Academic Press

Handbook of Pharmaceutical Analysis by HPLCElsevier

Applications for the Clinical and Pharmaceutical Industries Elsevier

The Handbook of Pharmaceutical Controlled Release Technology reviews the design, fabrication, methodology, administration, and classifications of various drug delivery systems, including matrices, and membrane controlled reservoir, bioerodible, and pendant chain systems. Contains cutting-edge research on the controlled delivery of biomolecules!

Principles and Applications New Age International

This textbook is written as a unified approach to various topics, ranging from drug discovery to manufacturing, techniques and technology, regulation and marketing. The key theme of the book is pharmaceuticals - what every student of pharmaceutical sciences should know: from the active pharmaceutical ingredients to the preparation of various dosage forms along with the relevant chemistry, this book makes pharmaceuticals relevant to undergraduate students of pharmacy and pharmaceutical sciences. This book explains how a particular drug was discovered and then converted from lab-scale to manufacturing scale, to the market. It explains the motivation for drug discovery, the reaction chemistry involved, experimental difficulties, various dosage forms and the reasoning behind them, mechanism of action, quality assurance and role of regulatory agencies. After having a course based on this book, the student will be able to understand: 1) the career prospects in the pharmaceutical industry, 2) the need for interdisciplinary teamwork in science, 3) the techniques and technology involved in making pharmaceuticals starting from bulk drugs, and 4) different dosage forms and critical factors in the development of pharmaceutical formulations in relation to the principles of chemistry. A few blockbuster drugs including atorvastatin, sildanefil, ranitidine, ciprofloxacin, amoxicillin, and the longest serving drugs such as aspirin and paracetamol are discussed in detail. Finally, the book also covers the important current pharmaceutical issues like quality control, safety, counterfeiting and abuse of drugs, and future prospects for pharmaceutical industry. Unified approach explaining drug discovery, bulk drug manufacturing, formulation of dosage forms, with pharmacological and therapeutic actions Manufacturing processes of representative active pharmaceutical ingredients and their chemistry plus formulation of dosage forms presented in this book are based on actual industrial processes Covers many aspects relevant to students of the pharmaceutical sciences or newly employed pharmaceutical researchers/employees. It contains summary information about regulatory agencies of different countries

Thermal Analysis of Pharmaceuticals John Wiley & Sons

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