Pharmaceutical Analysis Raw Material

BRIGHT LYRIC

Analysis of Pharmaceuticals by Capillary Electrophoresis Springer Nature
Data integrity is the hottest topic in the pharmaceutical industry. Global regulatory agencies have issued guidance, after guidance after guidance in the past few years, most of which does not offer practical advice on how to implement policies, procedures and processes to ensure integrity. These guidances state what but not how. Additionally, key stages of analysis that impact data integrity are omitted entirely. The aim of this book is to provide practical and detailed help on how to implement data integrity and data governance for regulated analytical laboratories working in or for the pharmaceutical industry. It provides clarification of the regulatory issues and trends, and gives practical methods for meeting regulatory requirements and guidance. Using a data integrity model as a basis, the principles of data integrity and data governance are expanded into practical steps for regulated laboratories to implement. The author uses case study examples to illustrate his points and provides instructions for applying the principles of data integrity and data governance to individual laboratory needs. This book is a useful reference for analytical chemists and scientists, management and senior management working in regulated laboratories requiring either an understanding about data integrity or help in implementing practical solutions. Consultants will also benefit from the practical guidance provided.
Results of the Survey on Raw Material Needs of the Drug and Pharmaceutical Industry John Wiley & Sons
This textbook is the first to present a systematic introduction to chemical analysis of pharmaceutical raw materials, finished pharmaceutical products, and of drugs in biological fluids, which are carried out in pharmaceutical laboratories worldwide. In addition, this textbook teaches the fundamentals of all the major analytical techniques used in the pharmaceutical laboratory, and teaches the international pharmacopoeias and guidelines of importance for the field. It is primarily intended for the pharmacy student, to teach the requirements in “analytical chemistry” for the 5 years pharmacy curriculum, but the textbook is also intended for analytical chemists moving into the field of pharmaceutical analysis. Addresses the basic concepts, then establishes the foundations for the common analytical methods that are currently used in the quantitative and qualitative chemical analysis of pharmaceutical drugs Provides an understanding of common analytical techniques used in all areas of pharmaceutical development Suitable for a foundation course in chemical and pharmaceutical sciences Aimed at undergraduate students of degrees in Pharmaceutical Science/Chemistry Analytical Science/Chemistry, Forensic analysis Includes many illustrative examples
Separation Methods in Drug Synthesis and Purification CRC Press
The emerging field of green analytical chemistry is concerned with the development of analytical procedures that minimize consumption of hazardous reagents and solvents, and maximize safety for operators and the environment. In recent years there have been significant developments in methodological and technological tools to prevent and reduce the deleterious effects of analytical activities; key strategies include recycling, replacement, reduction and detoxification of reagents and solvents. The Handbook of Green Analytical Chemistry provides a comprehensive overview of the present state and recent developments in green chemical analysis. A series of detailed chapters, written by international specialists in the field, discuss the fundamental principles of green analytical chemistry and present a catalogue of tools for developing environmentally friendly analytical techniques. Topics covered include: Concepts: Fundamental principles, education, laboratory experiments and publication in green analytical chemistry. The Analytical Process: Green sampling techniques and sample preparation, direct analysis of samples, green methods for capillary electrophoresis, chromatography, atomic spectroscopy, solid phase molecular spectroscopy, derivative molecular spectroscopy and electroanalytical methods. Strategies: Energy saving, automation, miniaturization and photocatalytic treatment of laboratory wastes. Fields of Application: Green bioanalytical chemistry, biodiagnostics, environmental analysis and industrial analysis. This advanced handbook is a practical resource for experienced analytical chemists who are interested in implementing green approaches in their work.
Practical Implementation in Regulated Laboratories CRC Press
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.
Practical and Clinical Applications, Fifth Edition Springer Science & Business Media
Solid-State Properties of Pharmaceutical Materials -- Contents -- Preface -- Acknowledgments -- 1 Solid-State Properties and Pharmaceutical Development -- 1.1 Introduction -- 1.2 Solid-State Forms -- 1.3 ICH Q6A Decision Trees -- 1.4 "Big Questions" for Drug Development -- 1.5 Accelerating Drug Development -- 1.6 Solid-State Chemistry in Preformulation and Formulation -- 1.7 Learning Before Doing and Quality by Design -- 1.8 Performance and Stability in Pharmaceutical Development -- 1.9 Moisture Uptake -- 1.10 Solid-State Reactions -- 1.11 Noninteracting Formulations: Physical Characterizations -- References -- 2 Polymorphs -- 2.1 Introduction -- 2.2 How Are Polymorphs Formed? -- 2.3 Structural Aspect of Polymorphs -- 2.3.1

Configurational Polymorphs -- 2.3.2 Conformational Polymorphs -- 2.4 Physical, Chemical, and Mechanical Properties -- 2.4.1 Solubility -- 2.4.2 Chemical Stability -- 2.4.3 Mechanical Properties -- 2.5 Thermodynamic Stability of Polymorphs -- 2.5.1 Monotropy and Enantiotropy -- 2.5.2 Burger and Rambergers Rules -- 2.5.3 vant Hoff Plot -- 2.5.4 DG/Temperature Diagram -- 2.6 Polymorph Conversion -- 2.6.1 Solution-Mediated Transformation -- 2.6.2 Solid-State Conversion -- 2.7 Control of Polymorphs -- 2.8 Polymorph Screening -- 2.9 Polymorph Prediction -- References -- 3 Solvates and Hydrates -- 3.1 Introduction -- 3.2 Pharmaceutical Importance of Hydrates -- 3.3 Classification of Pharmaceutical Hydrates -- 3.4 Water Activity -- 3.5 Stoichiometric Hydrates -- 3.6 Nonstoichiometric Hydrates -- 3.7 Hydration/Dehydration -- 3.8 Preparation and Characterization of Hydrates and Solvates -- References -- 4 Pharmaceutical Salts -- 4.1 Introduction -- 4.2 Importance of Pharmaceutical Salts -- 4.3 Weak Acid, Weak Base, and Salt -- 4.4 pH-Solubility Profiles of Ionizable Compounds

Principles and Applications Academic Press

Separation Methods in Drug Synthesis and Purification

Pharmaceutical Analysis for Small Molecules John Wiley & Sons

The dramatic development of chromatographic techniques, specially high per formance or high pressure liquid chromatography (HPLC) has made possible the easy analysis of organic compounds, including drugs and drug components, for last two decades. This rapid increase and improvement of analytical methodology with HPLC has enabled researchers and scientists to cope with other scientific and instru mental developments in their fields of work. Thousands of impressive and original scientific publications, text books and monographs describe the techniques for drug analysis with high performance liquid chromatography. However, no concise presentation of the general proper ties of the drugs and their HPLC methodology exists together in the market. This work contains the general properties necessary for the analysis of 232 drugs as well as the HPLC methods for many other drugs and drug components. It is hoped that it will fill a gap and provide a precise survey of the HPLC methods for drug analysis. It is intended as an immediate guide in the laboratory and will be of help to the scientists, researchers and technicians in the field of analysis.

Data Integrity and Data Governance CRC Press

New Developments for Nanosensors in Pharmaceutical Analysis presents an overview of developments in nanosensor usage in pharmaceutical analysis, thereby helping pharmaceutical companies attain reliable, precise, and accurate analysis of pharmaceuticals. This book presents very simple, precise, sensitive, selective, fast, and relatively inexpensive methods for pre-treatment, prior to analysis. These methods may be considered for further application in clinical studies and assays. The book includes the manufacturing of sensors for pharmaceutical analysis at nano- or smaller scales, and gives simple and relatable designs for the fabrication of sensors. Twelve chapters cover an introduction to the topic, immobilization techniques, mechanism effect of nanomaterials on structure, optical nanosensors for pharmaceutical detection, chemical nanosensors in pharmaceutical analysis, noble metal nanoparticles in electrochemical analysis of drugs, photo-electrochemical nanosensors for drug analysis, molecularly imprinted polymer based nanosensors for pharmaceutical analysis, nanomaterials for drug delivery systems, nanomaterials enriched nucleic acid-based biosensors, nanosensors in biomarker detection, and nanomaterials-based enzyme biosensors for electrochemical applications. Presents nanosensor types, synthesis, immobilizations and applications in different fields Gives simple repeatable designs for the fabrication of sensors for pharmaceutical analysis Details how to carry out sensitive analysis of pharmaceuticals using nanosensors Describes how to synthesize and immobilize nanosensors, and how nanosensors can be applied in drug assay Proposes innovative ways to optimize pharmaceutical processes with nanosensors

PRACTICAL PHARMACEUTICAL ANALYTICAL TECHNIQUES John Wiley & Sons

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

Results of the Survey on Raw Material Needs of the Drug and Pharmaceutical Industry Springer Science & Business Media

Introduction to Pharmaceutical Chemical AnalysisJohn Wiley & Sons

A Textbook for Pharmacy Students and Pharmaceutical Chemists John Wiley & Sons

An introductory text, written with the needs of the student in mind, which explains all the most important techniques used in the analysis of pharmaceuticals - a key procedure in ensuring the quality of drugs. The text is enhanced throughout with keypoints and self-assessment boxes, to aid student learning.

NMR Spectroscopy in Pharmaceutical Analysis Elsevier

The aim of this book is to present a range of analytical methods that can be used in formulation design and development and focus on how these systems can be applied to understand formulation components and the dosage form these build. To effectively design and exploit drug delivery systems, the underlying characteristic of a dosage form must be understood--from the characteristics of the individual formulation components, to how they act and interact within the formulation, and finally, to how this formulation responds in different biological environments. To achieve this, there is a wide range of analytical techniques that can be adopted to understand and elucidate the mechanics of drug delivery and drug formulation. Such methods include e.g. spectroscopic analysis, diffractometric analysis, thermal investigations, surface analytical techniques, particle size analysis, rheological techniques, methods to characterize drug stability and release, and biological analysis in appropriate cell and animal models. Whilst each of these methods can encompass a full research area in their own right, formulation scientists must be able to effectively apply these methods to the delivery system they are considering. The information in this book is designed to support researchers in their ability to fully characterize and analyze a range of delivery systems, using an appropriate selection of analytical techniques. Due to its consideration of regulatory approval, this book will also be suitable for industrial researchers both at early stage up to pre-clinical research.

Handbook of Pharmaceutical Analysis John Wiley & Sons Incorporated

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.

Principles and Case Studies Elsevier

This monograph offers the reader a complete overview on both principles and applications of CE-MS. Starting with an introductory chapter on detection in CE, also related and more specialized techniques such as electrophoretic and chromatographic preconcentration are discussed. A special emphasis is put on CE-MS interfaces, which are described in detail. In a separate chapter, attention is paid to sheath-liquid interfacing. The developments and possibilities of microchip CE-MS are also described. Applications to all relevant areas are discussed in distinct chapters, each written by experts in the respective fields. Besides applications in pharmaceutical analysis and bioanalysis, recent implementations in food science, forensic analysis, analysis of intact proteins, metabolomics and proteomics are highlighted. MS is a perfectly appropriate detection system for CE, as efficient separation is coupled to sensitive and selection detection. Moreover, MS can provide structure information on the separated compounds. CE-MS has now been developed into a strong hyphenated system complementary to LC-MS. This monograph is an unique source of knowledge for everyone dealing with and interested in CE-MS.

Analytical Techniques in the Pharmaceutical Sciences John Wiley & Sons

Now in one volume-all the raw materials used in the ceramic and glass industries A basic understanding of where raw materials come from and how they are processed is critical to attaining consistent raw material batches-an essential factor to maintaining steady production. The solution is Raw Materials for Glass and Ceramics, a complete resource of up-to-date information and analysis on the raw materials used in the glass and ceramic industries. Raw Materials for Glass and Ceramics presents all classes of materials, the roles they play, their sources and extraction processes, and quality control issues and regulations impacting the industry, as well as: A thorough description of the formation and evaluation of raw material deposits and location of the important sources Complete analysis of all the raw materials used in the ceramic and glass industries, including natural, processed, recycled, and synthetic materials An explanation of the raw materials industry, including transportation, environmental and health concerns, and quality specifications

Handbook of Modern Pharmaceutical Analysis Krishna Prakashan Media

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.

Raw Materials for Glass and Ceramics John Wiley & Sons

Practical Pharmaceutical Analytical Techniques book is meant for undergraduate and postgraduate pharmacy and science students. Chemistry is a fascinating branch of science. Practical aspects of chemistry are interesting due to colour reactions, synthesis of drugs, analysis and observation of beautiful crystal development. The important aspects involved in the practicals of pharmaceutical analytical chemistry have been comprehensively covered in the book. I hope the students studying practical aspects of pharmaceutical analysis would be benefitted from this book. In the book, different pharmaceutical analytical techniques (PAT) have discussed with their applications followed by general and specific safety notes in detail. Explanation of some common laboratory processes are given followed by a number of equipments, apparatuses and glass wares used in a pharmaceutical analytical chemistry lab. Limit tests with explanation have been given. Basic concepts related to spectroscopic and chromatographic techniques are discussed. Procedure to calibrate a UV spectrometer is provided with concept. Preparation of calibration curve followed by assay method for analysis of ciprofloxacin, metformin, and rifampicin are explained. Interpretation of IR spectra of ethanol, acetone, formaldehyde and aspirin has been explained in simple language. The working of HPLC instrument is given with its parts. Paracetamol`s assay by HPLC is discussed.TLC experiments of amino acid, food dye pigments, and an OTC drug are also furnished. Preparation of commonly used reagents has also been given.

A Guide to Best Practice Introduction to Pharmaceutical Chemical Analysis

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.

Pharmaceutical Analysis Royal Society of Chemistry

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.

Safety Assessments of Extractables and Leachables for Pharmaceutical Products Elsevier Health Sciences

Through the use of practical examples and solutions, Pharmaceutical Statistics: Practical and Clinical Applications, Fifth Edition provides the most complete and comprehensive guide to the various statistical applications and research issues in the pharmaceutical industry, particularly in clinical trials and bioequivalence studies.

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