

Pharmaceutical Analysis Raw Material Analysis

Advanced Instrumentation Technology for Pharmaceutical Analysis Dr.V.N.Indulatha & Dr. R.Priyadarsini.2023-11-08 This book helps to know the basic Instrumentation techniques in related to Pharmaceutical analysis for the graduate and post graduate scholars in the field of Pharmacy and Pharm D students mainly based on the syllabus prescribed by Pharmacy Council of India. In the important quality control screening of Pharmaceutical components like raw materials, bulk components and finished products, Analytical validation and Product and process development, Thermal analytical methods and X Ray diffraction studies and to know about the modern analytical methods in the Characterisation of interpretation of spectral analytical methods and Chromatographic techniques for the research and development in the field of Pharmaceutical science.

Pharmaceutical Chemical Analysis Ole Pedersen.2006-01-13 Complete, referenced information in an easy-to-use format Many of the monographs in the European Pharmacopoeia, the industry standard test for certain groups of ingredients and excipients, do not describe the tests in full, but reference general methods based on test-tube chemistry. When a test fails, you need to know what went wrong, how it can be f

Quality by Design for Biopharmaceuticals Anurag S. Rathore,Rohin Mhatre.2011-09-20 The concepts, applications, and practical issues of Quality by Design Quality by Design (QbD) is a new framework currently being implemented by the FDA, as well as EU and Japanese regulatory agencies, to ensure better understanding of the process so as to yield a consistent and high-quality pharmaceutical product. QbD breaks from past approaches in assuming that drug quality cannot be tested into products; rather, it must be built into every step of the product creation process. Quality by Design: Perspectives and Case Studies presents the first systematic approach to QbD in the biotech industry. A comprehensive resource, it combines an in-depth explanation of basic concepts with real-life case studies that illustrate the practical aspects of QbD implementation. In this single source, leading authorities from the biotechnology industry and the FDA discuss such topics as: The understanding and development of the product's critical quality attributes (CQA) Development of the design space for a manufacturing process How to employ QbD to design a formulation process Raw material analysis and control strategy for QbD Process Analytical Technology (PAT) and how it relates to QbD Relevant PAT tools and applications for the pharmaceutical industry The uses of risk assessment and management in QbD Filing QbD information in regulatory documents The application of multivariate data analysis (MVDA) to QbD Filled with vivid case studies that illustrate QbD at work in companies today, Quality by Design is a core reference for scientists in the biopharmaceutical industry, regulatory agencies, and students.

Introduction to Pharmaceutical Chemical Analysis Steen Hansen,Steen Honoré Hansen,Stig Pedersen-Bjergaard,Knut Rasmussen.2011-12-12 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

Pharmaceutical Analysis I V. Gawande.2015

Handbook of Modern Pharmaceutical Analysis Satinder Ahuja,Stephen Scypinski.2001 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 Analytical Quality by Design Sarwar Beg,Md Saquib Hasnain,Mahfoozur Rahman,Waleed H Almalki.2021-01-09 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

Pharmaceutical Quality by Design Walkiria S. Schlindwein,Mark Gibson.2018-01-11 A practical guide to Quality by Design for pharmaceutical product development Pharmaceutical Quality by Design: A Practical Approach outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This important resource: Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development Puts the focus on the industrial aspects of the new QbD approach Includes several illustrative examples of applications of QbD in practice Offers advanced specialist topics that can be systematically applied to industry Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products.

Pharmaceutical Analysis for Small Molecules Behnam Davani.2017-08-14 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.

A Textbook of Pharmaceutical Analysis Kenneth Antonio Connors.1975

High-Performance Thin-Layer Chromatography for the Analysis of Medicinal Plants Eike Reich, Anne Schibli.2011-01-01 High-Performance Thin-Layer Chromatography for the Analysis of Medicinal Plants presents the theoretical and technical information needed to perform reliable and reproducible high-performance thin-layer chromatography (HPTLC) to establish the identity, purity, quality, and stability of raw materials, extracts, and finished botanical products. The text provides a complete overview of the technique and common applications of HPTLC in herbal analysis. It will help the analyst answer questions such as: Am I paying for a high-quality material, but getting a cheap adulterant? Is this raw material worth its price? Does this product comply with the claim on its label? Has the composition of this product changed after being on the shelf for more than a year? Practical examples provided by renowned experts help the reader gain a firm understanding of HPTLC methodologies. More than 300 full-color illustrations aid comprehension of complex concepts, and easy-to-reference text boxes provide summaries of key information. This book is essential for analysts, quality assurance professionals, and regulators seeking a comprehensive text on how to use HPTLC to determine whether botanicals comply with current, good manufacturing practices. It will also benefit students in pharmacognosy, phytopharmacy, pharmaceutical biology, and analytical chemistry programs.

Pharmaceutical Analysis P. D. Chaithanya Sudha. Pharmaceutical Analysis is a compulsory subject offered to all the under graduate students of Pharmacy. This book on Pharmaceutical Analysis has been designed considering the syllabi requirements laid down by AICTE and other premier institutes/universities. The book covers both the Titrimetric and Instrumental aspects of Pharmaceutical analysis which is helpful for use in multiple semesters.

Analysis of Pharmaceuticals by Capillary Electrophoresis Kevin D. Altria.2013-04-17 Dieser erste Titel einer ganzen Serie von anwendungsbezogenen Handbüchern zur Kapillarelektrophorese beschäftigt sich mit der Analytik von pharmazeutischen Substanzen. Dabei werden verschiedene Techniken praxisnah erläutert. Jeder, der im Labor - ob wissenschaftlich oder praxisnah - mit der Analyse von oft chiralen Pharmazeutika konfrontiert ist, wird viele Hinweise und Tips für seine Arbeit finden. USP: Einzige Monographie zur Analyse von Pharmazeutika mit CE This book describes the current state of the art for the analysis of pharmaceuticals by capillary electrophoresis and contains several hundred references to specific applications and methods. The main purpose of the book is to present the application possibilities of CE and therefore tabulated application data are provided. Chapters of the book are devoted to providing details of individual application areas such as chiral analysis, determination of drug related impurities, determination of drug counter-ions, drug residue monitoring and main component assay. An introductory chapter provides theoretical background to CE and related techniques. A chapter is dedicated to capillary electrochromatography which highlights the importance this technique currently possesses. Successful regulatory acceptance of CE methods is also described. A comprehensive chapter covers method validation aspects. Other chapters include discrete areas such as the use of non-aqueous solvents, forensic applications of CE, the application of experimental designs, determination of drugs in biofluids, and the analysis of vitamins by CE.

Pharmaceutical Analysis James W. Munson.1984-01-01

Handbook of Pharmaceutical Analysis Lena Ohannesian, Anthony Streeter.2001-11-09 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.

Introduction to Pharmaceutical Analytical Chemistry Stig Pedersen-Bjergaard, Bente Gammelgaard, Trine G. Halvorsen.2019-02-11 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.

Modern Methods of Pharmaceutical Analysis, Second Edition Roger E. Schirmer.1990-11-30

Handbook of Modern Pharmaceutical Analysis Satinder Ahuja, Stephen Scypinski.2001-08-02 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.

Compatibility of Pharmaceutical Solutions and Contact Materials Dennis Jenke.2013-02-26 Compatibility of Pharmaceutical Products and Contact Materials Dennis Jenke Important safety aspects of compatibility for therapeutic products and their manufacturing systems, delivery devices, and containers Compatibility of Pharmaceutical Products and Contact Materials helps pharmaceutical, toxicology, analytical, and regulatory affairs professionals assess the safety of leachable and extractable chemicals associated with drug product packaging, manufacturing systems, and devices. The most comprehensive resource available, its coverage includes the strategies, tactics, and regulatory requirements for performing safety assessments, along with the means for interpreting results. Structured around a logical framework for an extractables and leachables safety assessment and closely linked to the pharmaceutical product development process, *Compatibility of Pharmaceutical Products and Contact Materials* directly addresses the fundamental questions of what activities need to be performed to completely, efficiently, and effectively address the issue of product safety from an extractables and leachables perspective? and when do the various required activities need to be performed? Specifically, the chapters describe: Pertinent regulations and practical ways to meet guidelines Coordinating manufacturing, storage, and delivery systems development and qualification with therapeutic product development Materials characterization and the materials screening process Component and/or system qualification (illustrated by several case studies) Performing validation/migration studies and interpreting and reporting the results Creating a product registration dossier and putting it through regulatory review Product maintenance (Change Control) from an extractables and leachables perspective Likely future developments in extractables and leachables assessment Additionally, the book's appendix provides a database, including CAS registry numbers, chemical formulas and molecular weights of extractable/leachable substances that have been reported in the chemical literature. Detailing the interconnected roles played by analytical chemistry, biological science, toxicology, and regulatory science, *Compatibility of Pharmaceutical Products and Contact Materials* supplies a much-needed, comprehensive resource to all those in pharmaceutical product or medical device development.

Essentials of Pharmaceutical Analysis Muhammad Sajid Hamid Akash, Kanwal Rehman.2019-12-17 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.

Pharmaceutical Analysis Jerome Irwin Bodin.1961

Mod Methods of Pharmaceutical Analysis Roger E. Schirmer.1982-01-05 Vols. -3: Edited by Roger E. Schirmer.

Modern Methods of Pharmaceutical Analysis Roger E. Schirmer.1990-12-19 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 .

Measuring Elemental Impurities in Pharmaceuticals Robert Thomas.2018-01-29 Recent regulations on heavy metal testing have required the pharmaceutical industry to monitor a suite of elemental impurities in pharmaceutical raw materials, drug products and dietary supplements. These new directives are described in the new United States Pharmacopeia (USP) Chapters , , and , together with Q3D, Step 4 guidelines for elemental impurities, drafted by the ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use), a consortium of global pharmaceutical associations, including the European Pharmacopeia (Ph.Eur.), the Japanese Pharmacopeia (JP) and the USP. This book provides a complete guide to the analytical methodology, instrumental techniques and sample preparation procedures used for measuring elemental impurities in pharmaceutical and nutraceutical materials. It offers readers the tools to better understand plasma spectrochemistry to optimize detection capability for the full suite of elemental PDE (Permitted Daily Exposure) levels in the various drug delivery categories. Other relevant information covered in the book includes: The complete guide to measuring elemental impurities in pharmaceutical and nutraceutical materials. Covers heavy metals testing in the pharmaceutical industry from an historical perspective. Gives an overview of current USP Chapters and and ICH Q3D Step 4 Guidelines. Explains the purpose of validation protocols used in Chapter , including how J-values are calculated Describes fundamental principles and practical capabilities of ICP-MS and ICP-OES. Offers guidelines about the optimum strategy for risk assessment Provides tips on how best to prepare and present your data for regulatory inspection. An indispensable resource, the fundamental principles and practical benefits of ICP-OES and ICP-MS are covered in a reader-friendly format that a novice, who is carrying out elemental impurities testing in the pharmaceutical and nutraceutical communities, will find easy to understand.

A TEXTBOOK OF PHARMACEUTICAL ANALYSIS, 3RD ED Kenneth A. Connors.2007-09 Market_Desc: For undergraduate courses in pharmaceutical analysis. Graduate students and professional pharmacists will find it a useful reference. About The Book: This book is a detailed, systematic treatment of analytical chemistry, focusing on drug analysis. It covers both classical techniques and modern approaches. It includes new sections on immunoassay, derivative formation, and statistical interpretation of data. Also includes an expanded treatment of liquid chromatography, as well as over 250 problems, many with solutions provided.

Method Validation in Pharmaceutical Analysis Joachim Ermer, John H. McB. Miller.2006-03-06 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, pharmacutists, QA officers, and public authorities.

HPLC Methods for Pharmaceutical Analysis George Lunn, Norman R. Schuff.1997 Full text included in Knovel Library within the subject area of Chemistry and Chemical Engineering.

Pharmaceutical Analysis David C Lee, Michael L. Webb.2009-02-12 The use of analytical sciences in the discovery, development and manufacture of pharmaceuticals is wide-ranging. From the analysis of minute amounts of complex biological materials to the quality control of the final dosage form, the use of analytical technology covers an immense range of techniques and disciplines. This book concentrates on the analytical aspects of drug development and manufacture, focusing on the analysis of the active ingredient or drug substance. It provides those joining the industry or other areas of pharmaceutical research with a source of reference to a broad range of techniques and their applications, allowing them to choose the most appropriate analytical technique for a particular purpose. The volume is directed at analytical chemists, industrial pharmacists, organic chemists, pharmaceutical chemists and biochemists.

Analytical Testing for the Pharmaceutical GMP Laboratory Kim Huynh-Ba.2022-04-19 Provides practical guidance on pharmaceutical analysis, written by leading experts with extensive industry experience *Analytical Testing for the Pharmaceutical GMP Laboratory* presents a thorough overview of the pharmaceutical regulations, working processes, and drug development best practices used to maintain the quality and integrity of medicines. With a focus on smaller molecular weight drug substances and products, the book provides the knowledge necessary for establishing the pharmaceutical laboratory to support Quality Systems while maintaining compliance with Good Manufacturing Practices (GMP) regulations. Concise yet comprehensive chapters contain up-to-date coverage of drug regulations, pharmaceutical analysis methodologies, control strategies, testing development and validation, method transfer, electronic data documentation, and more. Each chapter includes a table of contents, definitions of acronyms, a reference list, and ample tables and figures. Addressing the principal activities and regulatory challenges of analytical testing in the development and manufacturing of pharmaceutical drug products, this authoritative resource: Describes the

structure, roles, core guidelines, and GMP regulations of the FDA and ICH. Covers the common analytical technologies used in pharmaceutical laboratories, including examples of analytical techniques used for the release and stability testing of drugs. Examines control strategies established from quality systems supported by real-world case studies. Explains the use of dissolution testing for products such as extended-release capsules, aerosols, and inhalers. Discusses good documentation and data reporting practices, stability programs, and the Laboratory Information Management System (LIMS) to maintain compliance. Includes calculations, application examples, and illustrations to assist readers in day-to-day laboratory operations. Contains practical information and templates to structure internal processes or common Standard Operating Procedures (SOPs). Analytical Testing for the Pharmaceutical GMP Laboratory is a must-have reference for both early-career and experienced pharmaceutical scientists, analytical chemists, pharmacists, and quality control professionals. It is also both a resource for GMP laboratory training programs and an excellent textbook for undergraduate and graduate courses of analytical chemistry in pharmaceutical sciences or regulatory compliance programs.

Performance of Pharmaceutical Companies in India Mainak Mazumdar.2012-10-19 This book explains how government support and institutional set up facilitated the evolution of the Indian pharmaceutical industry and provides an economic analysis of firm strategies due to recent policy changes. The book is useful for researchers interested in understanding the transition of a lifeline sector for an emerging economy like India.

Students of public policy, health administrators and health economists who are interested in the functioning of the pharmaceutical sector that produces life saving drugs in developing nations will find this book useful. The book also provides good coverage on data envelopment analysis (DEA), a useful technique for understanding productivity and efficiency. It can provide guidance to the research students on the applicability of DEA technique to address various research questions for analysis. The book will be a valuable addition to libraries in colleges of pharmacy and medicine as well as to all other academic and research centers.

Pharmaceutical Analysis Kar.2007-02-01

Analytical Techniques in the Pharmaceutical Sciences Anette Müllertz,Yvonne Perrie,Thomas Rades.2016-08-30 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.

Pharmaceutical Analysis Vol. - I Dr. A. V. Kasture.2008-11-07

Pharmaceutical Drug Analysis Ashutosh Kar.2005-12 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

Recent Trends in Pharmaceutical Analytical Chemistry Constantinos K. Zacharis.2021-09-01 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.

Modern Methods of Pharmaceutical Analysis Roger E. Schirmer.1982

HPLC in the Pharmaceutical Industry Godwin W. Fong.1991-03-14 A practical guide for chemists in the pharmaceutical industry to making automated analyses of drugs that will meet the standards of regulatory agencies. Reviews the standard techniques of high-performance liquid chromatography, specialized detection methods, automation in pharmaceutical analysis, an

Identification and Determination of Impurities in Drugs S. Görög.2000-05-19 Impurity profiling is the common name of a group of analytical activities, the aim of which is the detection, identification/structure elucidation and quantitative determination of organic and inorganic impurities, as well as residual solvents in bulk drugs and pharmaceutical formulations. Since this is the best way to characterise the quality and stability of bulk drugs and pharmaceutical formulations, this is the core activity in modern drug analysis. Due to the very rapid development of the analytical methodologies available for this purpose and the similarly rapid increase of the demands as regards the purity of drugs it is an important task to give a summary of the problems and the various possibilities offered by modern analytical chemistry for their solution. That is the aim of this book. The book is methodology-oriented. In the first chapter some important aspects of the background of impurity-related analytical studies (toxicological, pharmacopoeial aspects, the characterisation of the sources of impurities and the role of impurity profiling in various fields of drug research, production and therapeutic use) are summarised. Chapter two deals with related organic impurities, the strategies for impurity profiling, the use of chromatographic and related separation methods, spectroscopic, and hyphenated techniques. The subject of the third chapter is the identification and determination of residual solvents. The determination of inorganic impurities is discussed in chapter four. The special problems of degradation products as impurities are dealt with in chapter five. A separate chapter has been compiled to deal with one of the most up-to-date problems in contemporary pharmaceutical analysis, the estimation of enantiomeric purity of chiral drugs. Chapter seven is devoted to various approaches to solve the problem of polymorphic modifications as impurities. Since in the broader sense of the word the microbiological purity of drugs and drug products also belongs to this circle, the most important information from this field is summarised in chapter eight. After the mainly methodology-oriented chapters, the final one concentrates on four groups of drugs (peptides, biotechnological products, antibiotics and steroids) in order to demonstrate the use of the methods described earlier.

Supercritical Fluid Chromatography Gregory K. Webster.2014-02-04 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.

Method Validation in Pharmaceutical Analysis Joachim Ermer,Phil W. Nethercote.2014-11-10 This second edition of a global bestseller has been completely redesigned and extensively rewritten to take into account the new Quality by Design (QbD) and lifecycle concepts in pharmaceutical manufacturing. As in the first edition, the fundamental requirements for analytical method validation are covered, but the second edition describes

how these are applied systematically throughout the entire analytical lifecycle. QbD principles require adoption of a systematic approach to development and validation that begin with predefined objectives. For analytical methods these predefined objectives are established as an Analytical Target Profile (ATP). The book chapters are aligned with recently introduced standards and guidelines for manufacturing processes validation and follow the three stages of the analytical lifecycle: Method Design, Method Performance Qualification, and Continued Method Performance Verification. Case studies and examples from the pharmaceutical industry illustrate the concepts and guidelines presented, and the standards and regulations from the US (FDA), European (EMA) and global (ICH) regulatory authorities are considered throughout. The undisputed gold standard in the field.

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Pharmaceutical Analysis Raw Material Analysis Introduction

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