An Introduction To Hplc For Pharmaceutical Analysis Oona Mcpolin

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Quantitative Estimation of Bioactives in Pharmaceutical Dosage Forms Palanirajan Vijayaraj Kumar 2012 An important feature of modern pharmaceutical analysis is the introduction of more refined and sensitive methods of physico-chemical analysis such as spectroscopy (colorimetry, spectrometry including UV, visible and IR regions, fluorimetry, nephlometry or turbidometry, NMR and Mass) and chromatography (GLC, HPLC and HPTLC) that enable us to ascertain the quality of drugs more accurately and with the smallest consumption of the analyte, reagents in less time. Reverse phase high performance liquid chromatography with ultra violet detection is the most accepted method of analysis by the pharmacopeias of the developed countries at present. UV-Visible spectrophotometry is one of the classical and widely used methods for the routine analysis of drugs. This book describes about new, simple, selective, sensitive and economical RP-HPLC and UV-Spectrophotometric methods for the quantification of drugs, such as pregabalin, azithromycin, sumatriptan succinate, imatinib mesylate, imatinib mesylate and ambroxol from bulk and pharmaceutical dosage forms. All these methods were validated as per ICH guidelines.
Pharmaceutical Analysis for Small Molecules Behnam Davani 2017-08-01 A comprehensive introduction for scientists engaged in new drug development, analysis, and approvals Each year the pharmaceutical industry worldwide recruits thousands of recent science graduates—especially chemistry, analytical chemistry, pharmacy, and pharmaceutical majors—into its ranks. However, because of their limited background in pharmaceutical analysis most of those new recruits find making the transition from academia to industry very difficult. Designed to assist both recent graduates, as well as experienced chemists or scientists with limited regulatory, compendial or pharmaceutical analysis background, make that transition, Pharmaceutical Analysis for Small Molecules is a concise, yet comprehensive introduction to the drug development process and analysis of chemically synthesized, small molecule drugs. It features contributions by distinguished experts in the field, including editor and author, Dr. Behnam Davani, an analytical chemist with decades of technical management and teaching experience in compendial, regulatory, and industry. This book provides an introduction to pharmaceutical analysis for small molecules (non-biologics) using commonly used techniques for drug characterization and performance tests. The driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to regulatory bodies for drug approval in order to market their products. In addition, related required supporting studies including good laboratory/documentation practices including analytical instrument qualification are highlighted in this book. Topics covered include: Drug Approval Process and Regulatory Requirements (private standards) Pharmacopeias and Compendial Approval Process (public standards) Common methods in pharmaceutical analysis (typically compendial) Common Calculations for assays and impurities and other specific tests Analytical Method Validation, Verification, Transfer Specifications including how to handle out of specification (OOS) and out of trend (OOT) Impurities including organic, inorganic, residual solvents and elemental impurities Good Documentation Practices for regulatory environment Management of Analytical Laboratories Analytical Instrument Qualifications including IQ, OQ, PQ and VQ Due to global nature of pharmaceutical industry, other topics on both regulatory (ICH) and Compendial harmonization are also highlighted. Pharmaceutical Analysis for Small Molecules is a valuable working resource for scientists directly or indirectly involved with the drug development process, including analytical chemists, pharmaceutical scientists, pharmacists, and quality control/quality assurance professionals. It also is an excellent text/reference for graduate students in analytical chemistry, pharmacy, pharmaceutical and regulatory sciences.
Pharmaceutical Analysis E-Book David G. Watson 2015-12-24 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
An Introduction to HPLC for Pharmaceutical Analysis Oona McPolin 2009-03-01 If you are new to HPLC, this book provides an invaluable guide to how HPLC is actually used when analysing pharmaceuticals. It is full of practical advice on the operation of HPLC systems combined with the necessary theoretical knowledge to ensure understanding of the technique. Key features include: A thorough discussion of the stationary phase enabling the reader to make sense of the many parameters used to describe a HPLC column; Practical advice and helpful hints for the preparation and use of mobile phase; A complete overview of each of the different components which together make up a HPLC system; A description of the contents of a typical HPLC analytical method and how to interpret these; A step-by-step guide on how to follow a method and set up a HPLC analysis; A discussion of system suitability criteria and how to interpret the values obtained during an analysis; Explanation of the common methods of calibration and quantification used for pharmaceutical analysis.
Handbook of Analytical Quality by Design Sarwar Beg 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
Development of Novel Stability Indicating Methods Using Liquid Chromatography Mukesh Maithani 2019-08-07 Reversed-phase high-performance liquid chromatography (RP-HPLC) has become the most widely used method for pharmaceutical analysis, as it ensures accuracy, specificity and reproducibility for the quantification of drugs, while avoiding interference from any of the excipients that are normally present in pharmaceutical dosage forms. This book presents a simple methodology for developing stability-indicating methods and offers a ‘how-to guide’ to creating novel stability-indicating methods using liquid chromatography. It provides the detailed information needed to devise a stability-indicating method for drug substances and drug products that comply with international regulatory guidelines. As such, it is a must-read for anyone engaged in analytical and bioanalytical chemistry: professionals at reference, test, and control laboratories; students and academics at research laboratories, and scientists working for chemical, pharmaceutical, and biotechnology companies.
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.
HPLC for Pharmaceutical Scientists Yuri V. Kazakevich 2007-02-16 HPLC for Pharmaceutical Scientists is an excellent book for both novice and experienced pharmaceutical chemists who regularly use HPLC as an analytical tool to solve challenging problems in the pharmaceutical industry. It provides a unified approach to HPLC with an equal and balanced treatment of the theory and practice of HPLC in the pharmaceutical industry. In-depth discussion of retention processes, modern HPLC separation theory, properties of stationary phases and columns are well blended with the practical aspects of fast and effective method development and method validation. Practical and pragmatic approaches and actual examples of effective development of selective and rugged HPLC methods from a physico-chemical point of view are provided. This book elucidates the role of HPLC throughout the entire drug development process from drug candidate inception to marketed drug product and gives detailed specifics of HPLC application in each stage of drug development. The latest advancements and trends in hyphenated and specialized HPLC techniques (LC-MS, LC-NMR, Preparative HPLC, High temperature HPLC, high pressure liquid chromatography) are also discussed.
Liquid Chromatography in Pharmaceutical Development Irving W. Wainer 1985
Pharmaceutical Analysis David C Lee 2009-02-12 The use of analytical sciences in the discovery, development andmanufacture of pharmaceuticals is wide-ranging. From the analysisof minute amounts of complex biological materials to the qualitycontrol of the final dosage form, the use of analytical technologycovers an immense range of techniques and disciplines. This book concentrates on the analytical aspects of drugdevelopment and manufacture, focusing on the analysis of the activeingredient or drug substance. It provides those joining theindustry or other areas of pharmaceutical research with a source ofreference to a broad range of techniques and their applications,allowing them to choose the most appropriate analytical techniquefor a particular purpose. The volume is directed at analytical chemists, industrialpharmacists, organic chemists, pharmaceutical chemists andbiochemists.
High Performance Liquid Chromatography W.J. Lough 1995-09-30 High performance liquid chromatography (HPLC) has long been recognized as one of the most useful and versatile analytical techniques. It has now progressed from being a highly expensive method of analysis to a routine technique with wide applications. Consequently there is a requirement in many chemistry and chemistry-related courses for students to acquire a detailed understanding of the principles and practice of HPLC. Written in a manner suitable for undergraduate students studying analytical chemistry and learning about chromatographic analytical techniques applied to pharmaceutical analysis, biochemistry and related disciplines, High-performance Liquid Chromatography: Fundamental Principles and Practice introduces the fundamentals of HPLC. Loosely structured in three parts, the text begins with a thorough introduction of the subject and then progresses through the essential knowledge of the instrumentation needed for HPLC. The final part covers with the applications of HPLC in real-world situations. Developed by a team of international experts from a wide cross-section of disciplines, the text is relevant to a wide range of courses.
Practice of High Performance Liquid Chromatography Heinz Engelhardt 2012-12-06 During its short 20 year history High Performance Liquid Chro matography (HPLC) has won itself a firm place amongst the instrumental methods of analysis. HPLC has caused a revolution in biological and pharmaceutical chemistry. Approximately two thirds of the publications on HPLC are concerned with problems from this area of life science. Biotechnology, where it is necessary to isolate substances from complicated mixtures, is likely to give further impetus to the dissemination of modern liquid chromatog raphy in columns, particularly on the preparative scale. This book presents, by means of examples, the application of HPLC to various fields, as well as fundamental discussions of chromatographic methods. The quality of the analytical result is decisively dependent on the qualities of the equipment employed (by Colin, Guiochon, and Martin). Especially the demands are discussed that are placed on the components of the instrument including those for data acquisition and processing. The section on "quantitative analy sis" (by ABhauer, Ullner) covers besides the principles also the problems of ensuring the quality of the data in detail. The basic problems arising by enlarging the sample size to preparative di mensions and the requirements put on the aparatus are discussed in the section on "preparative applications" (by Wehrli).
HPLC and UHPLC for Practicing Scientists Michael W. Dong 2019-07-23 A concise yet comprehensive reference guide on HPLC/UHPLC that focuses on its fundamentals, latest developments, and best practices in the pharmaceutical and biotechnology industries Written for practitioners by an expert practitioner, this new edition of HPLC and UHPLC for Practicing Scientists adds numerous updates to its coverage of high-performance liquid chromatography, including comprehensive information on UHPLC (ultra-high-pressure liquid chromatography) and the continuing migration of HPLC to UHPLC, the modern standard platform. In addition to introducing readers to HPLC’s fundamentals, applications, and developments, the book describes basic theory and terminology for the novice, and reviews relevant concepts, best practices, and modern trends for the experienced practitioner. HPLC and UHPLC for Practicing Scientists, Second Edition offers three new chapters. One is a standalone chapter on UHPLC, covering concepts, benefits, practices, and potential issues. Another examines liquid chromatography/mass spectrometry (LC/MS). The third reviews at the analysis of recombinant biologics, particularly monoclonal antibodies (mAbs), used as therapeutics. While all chapters are revised in the new edition, five chapters are essentially rewritten (HPLC columns, instrumentation, pharmaceutical analysis, method development, and regulatory aspects). The book also includes problem and answer sections at the end of each chapter. Overviews fundamentals of HPLC to UHPLC, including theories, columns, and instruments with an abundance of tables, figures, and key references Features brand new chapters on UHPLC, LC/MS, and analysis of recombinant biologics Presents updated information on the best practices in method development, validation, operation, troubleshooting, and maintaining regulatory compliance for both HPLC and UHPLC Contains major revisions to all chapters of the first edition and substantial rewrites of chapters on HPLC columns, instrumentation, pharmaceutical analysis, method development, and regulatory aspects Includes end-of-chapter quizzes as assessment and learning aids Offers a reference guide to graduate students and practicing scientists in pharmaceutical, biotechnology, and other industries Filled with intuitive explanations, case studies, and clear figures, HPLC and UHPLC for Practicing Scientists, Second Edition is an

essential resource for practitioners of all levels who need to understand and utilize this versatile analytical technology. It will be a great benefit to every busy laboratory analyst and researcher.
Introduction to Pharmaceutical Analytical Chemistry Stig Pedersen-Bjergaard 2019-04-22 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.
Pharmaceutical Analysis E-Book David G. Watson 2012-07-15 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. Features Includes worked calculations to demonstrate mathematics in use for pharmaceutical analysis. Focuses on key points rather than a large number of facts to help readers really understand the field as well as pass exams. Includes self-assessment, focussing on simple arithmetical calculation results from analytical data. Additional section on basic calculations in pharmaceutical analysis More detail on the capillary electrophoresis of proteins A discussion of some of the new types of HPLC column and on solvent selectivity in HPLC Additional material inserted on the control of the quality of analytical methods, mass spectrometry and high pressure liquid chromatography Additional self-assessment exercises
Chromatographic Analysis of Pharmaceuticals John A. Adamovics 2017-09-29 Updated and revised throughout. Second Edition explores the chromatographic methods used for the measurement of drugs, impurities, and excipients in pharmaceutical preparations--such as tablets, ointments, and injectables. Contains a 148-page table listing the chromatographic data of over 1300 drugs and related substances--including sample matrix analyzed, sample handling procedures, column packings, mobile phase, mode of detection, and more.
HPLC Methods for Clinical Pharmaceutical Analysis Hermann Mascher 2012-02-13 Filling a gap in the literature for a hands-on guide focusing on everyday laboratory challenges, this English edition has been expanded and revised using the feedback received on the successful German precursor. Throughout the book, Professor Mascher draws on his 30 years of experience and provides abundant practical advice, troubleshooting and other hints highlighted in boxes, as well as a broad selection of walkthrough case studies. Based on a course taught by the author, the first part of the book intuitively explains all steps of routine bioanalysis and explains how to set up a robust, inexpensive and effi cient method for a given substance. In the second part he includes 20 worked example cases that highlight common challenges and how to overcome them. With its appendix containing tried-and-tested analytical methods for 100 clinically relevant substances from the author`s own laboratory, complete with spectral and MS data as well as literature references and basic pharmacokinetic information, this is a life-long companion for everyone working in clinical, pharmaceutical and biochemical analysis. Comments to the German book: "The book comes to life through its examples, showing not only what did work in the author's laboratory, but also what didn't." ChemieReport "Indispensable for novices, while even old hands will be able to expand their knowledge. A collection of analytical data for ca. 100 substances completes the book's offering, leaving almost nothing to be desired." pharmind
Robustness of Analytical Chemical Methods and Pharmaceutical Technological Products M.M.W.B. Hendriks 1996-12-11 In analytical chemistry and pharmaceutical technology attention is increasingly focussed on improving the quality of methods and products. This book aims at fostering the awareness of the potential of existing mathematical and statistical methods to improve this quality. It provides procedures and ideas on how to make a product or a method less sensitive to small variations in influencing factors. Major issues covered are robustness and stability improvement and ruggedness testing. General strategies and a theoretical introduction to these methods are described, and thorough overviews of methods used in both application areas and descriptions of practical applications are given. Features of this book: • Gives a good overview of mathematical and statistical methods used in two application areas, i.e. pharmaceutical technology and analytical chemistry • Illustrates the different approaches available to attain robustness • Gives ideas on how to use methods in practical situations. The book is intended for those who develop and optimize, and are responsible for the overall quality of, analytical methods and pharmaceutical technological products and procedures.
Analytical Method Development and Validation Michael E. Swartz 2018-10-03 Describes analytical methods development, optimization and validation, and provides examples of successful methods development and validation in high-performance liquid chromatography (HPLC) areas. The text presents an overview of Food and Drug Administration (FDA)/International Conference on Harmonization (ICH) regulatory guidelines, compliance with validation requirements for regulatory agencies, and methods validation criteria stipulated by the US Pharmacopia, FDA and ICH.
Biochemical Analysis Tools Oana-Maria Boldura 2020-06-24 This book explores the role of nucleic acid analysis and the advances it has led to in the field of life sciences. The first section is a collection of chapters covering experimental methods used in molecular biology, the techniques adjacent to these methods, and the steps of analysis before and after obtaining raw DNA data. The second section deals with the principles of chromatography, method development, sample preparation, and industrial applications.
The HPLC Expert Stavros Kromidas 2016-08-08 The rapid development of HPLC instrumentation and technology opens numerous possibilities - and entails new questions. Which column should I choose to obtain best results, which gradient fits to my analytical problem, what are recent and promising trends in detection techniques, what is state of the art regarding LC-MS coupling? All these questions are answered by experts in ten self-contained chapters. Besides these more hardware-related and technical chapters, further related areas of interest are covered: Comparison of recent chromatographic data systems and integration strategies, smart documentation, efficient information search in internet, and tips for a successful FDA inspection. This practical approach offers in a condensed manner recent trends and hints, and will also display the advanced reader mistakes and errors he was not aware of so far.
Validation of Analytical Methods for Pharmaceutical Analysis Oona McPolin 2009-05-01 This book provides a comprehensive guide on validating analytical methods. Key features: Full review of the available regulatory guidelines on validation and in particular, ICH. Sections of the guideline, Q2(R1), have been reproduced in this book with the kind permission of the ICH Secretariat; Thorough discussion of each of the validation characteristics (Specificity; Linearity; Range; Accuracy; Precision; Detection Limit; Quantitation Limit; Robustness; System Suitability) plus practical tips on how they may be studied; What to include in a validation protocol with advice on the experimental procedure to follow and selection of appropriate acceptance criteria; How to interpret and calculate the results of a validation study including the use of suitable statistical calculations; A fully explained case study demonstrating how to plan a validation study, what to include in the protocol, experiments to perform, setting acceptance criteria, interpretation of the results and reporting the study.
Applications of High Performance Liquid Chromatography S. Pryde 1979-01-31
Bioanalysis of Pharmaceuticals Steen HonorÃ© Hansen 2015-07-20 Bioanalysis of Pharmaceuticals: Sample Preparation, Separation Techniques and Mass Spectrometry is the first student textbook on the separation science and mass spectrometry of pharmaceuticals present in biological fluids with an educational presentation of the principles, concepts and applications. It discusses the chemical structures and properties of low- and high-molecular drug substances; the different types of biological samples and fluids that are used; how to prepare the samples by extraction, and how to perform the appropriate analytical measurements by chromatographic and mass spectrometric methods. Bioanalysis of Pharmaceuticals: Sample Preparation, Separation Techniques and Mass Spectrometry: Is an introductory student textbook discussing the different principles and concepts clearly and comprehensively, with many relevant and educational examples Focuses on substances that are administered as human drugs, including low-molecular drug substances, peptides, and proteins Presents both the basic principles that are regularly taught in universities, along with the practical use of bioanalysis as carried out by researchers in the pharmaceutical industry and in hospital laboratories Is aimed at undergraduate students, scientists, technicians and researchers in industry working in the areas of pharmaceutical analyses, biopharmaceutical analyses, biological and life sciences The book includes multiple examples to illustrate the theory and application, with many practical aspects including calculations, thus helping the student to learn how to convert the data recorded by instruments into the real concentration of the drug substances within the biological sample.
Essentials of Pharmaceutical Analysis Muhammad Sajid Hamid Akash 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.
High Performance Liquid Chromatography Omar Al Sayed Omar 2022-02-21 The book provides an indispensable guide on how to use HPLC in pharmaceutical analysis and drug control. Following a hands-on approach, the authors give practical advices how to prepare stationary and mobile phases, choose a suitable detector and set up an HPLC analysis. The publication gives insight into the key pharmaceutical applications of HPLC and the latest requirements of the major regulatory agencies.
Mass Spectrometry in Medicinal Chemistry Klaus Wanner 2007-04-09 This first overview of mass spectrometry-based pharmaceutical analysis is the key to improved high-throughput drug screening, rational drug design and analysis of multiple ligand-target interactions. The ready reference opens with a general introduction to the use of mass spectrometry in pharmaceutical screening, followed by a detailed description of recently developed analytical systems for use in the pharmaceutical laboratory. Applications range from simple binding assays to complex screens of biological activity and systems containing multiple targets or ligands -- all highly relevant techniques in the early stages in drug discovery, from target characterization to hit and lead finding.
HPLC Methods for Recently Approved Pharmaceuticals George Lunn 2005-05-06 An indispensable resource for busy researchers Your time is valuable-too valuable to spend hunting through thetechnical literature in search of the right HPLC assay techniquesfor your projects. With HPLC Methods for Recently ApprovedPharmaceuticals, you'll quickly identify and replicate the idealprocedures for your project needs, without having to refer tooriginal source publications. More of your time can then be spentin the lab, not the library. Covering the relevant world literature through 2003, this bookpicks up where Dr. Lunn's acclaimed HPLC Methods for PharmaceuticalAnalysis left off. It arms you with established HPLC assaytechniques for hundreds of newly approved drugs, as well as drugsfor which assay methods were only recently developed. Combiningdetailed descriptions of procedures with specially annotatedreferences, this practical handbook gives you: * HPLC methods for 390 commonly prescribed pharmaceuticalcompounds * Various procedures for each drug listed together-making it easyto mix and match for customized approaches * Methods for drugs in biological fluids and for bulk andformulated drugs * Chemical structures, molecular weights and formulas, and CASRegistry Numbers * Cross-references to The Merck Index * Retention times of other drugs that can be assayed using the samemethods
HPLC of Polymers Harald Pasch 2012-12-06 Polymers are mainly characterized by molar mass, chemical composition, functionality and architecture. The determination of the complex structure of polymers by chromatographic and spectroscopic methods is one of the major concerns of polymer analysis and characterization. This lab manual describes the experimental approach to the chromatographic analysis of polymers. Different chromatographic methods, their theoretical background, equipment, experimental procedures and applications are discussed. The book will enable polymer chemists, physicists and material scientists as well as students of macromolecular and analytical science to optimize chromatographic conditions for a specific separation problem. Special emphasis is given to the description of applications for homo- and copolymers and polymer blends.
Method Validation in Pharmaceutical Analysis Joachim Ermer 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, pharmaceutists, QA officers, and public authorities.
HPLC Method Development for Pharmaceuticals Satinder Ahuja 2011-09-21 High pressure, or high performance, liquid chromatography (HPLC) is the method of choice for checking purity of new drug candidates, monitoring changes during scale up or revision of synthetic procedures, evaluating new formulations, and running control/assurance of the final drug product. HPLC Method Development for Pharmaceuticals provides an extensive overview of modern HPLC method development that addresses these unique concerns. Includes a review and update of the current state of the art and science of HPLC, including theory, modes of HPLC, column chemistry, retention mechanisms, chiral separations, modern instrumentation (including ultrahigh-pressure systems), and sample preparation. Emphasis has been placed on implementation in a pharmaceutical setting and on providing a practical perspective. HPLC Method Development for Pharmaceuticals is intended to be particularly useful for both novice and experienced HPLC method development chemists in the pharmaceutical industry and for managers who are seeking to update their knowledge. Covers the requirements for HPLC in a pharmaceutical setting including strategies for software and hardware validation to allow for use in a regulated laboratory Provides an overview of the pharmaceutical development process (clinical phases, chemical and pharmaceutical development activities) Discusses how HPLC is used in each phase of pharmaceutical development and how methods are developed to support activities in each phase
Modern Methods of Pharmaceutical Analysis, Second Edition 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 .
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
Introduction to Modern Liquid Chromatography Lloyd R. Snyder 2011-09-20 The latest edition of the authoritative reference to HPLC High-performance liquid chromatography (HPLC) is today the leading technique for chemical analysis and related applications, with an ability to separate, analyze, and/or purify virtually any sample. Snyder and Kirkland's Introduction to Modern Liquid Chromatography has long represented the premier reference to HPLC. This Third Edition, with John Dolan as added coauthor, addresses important improvements in columns and equipment, as well as major advances in our understanding of HPLC separation, our ability to solve problems that were troublesome in the past, and the application of HPLC for new kinds of samples. This carefully considered Third Edition maintains the strengths of the previous edition while significantly modifying its organization in light of recent research and experience. The text begins by introducing the reader to HPLC, its use in relation to other modern separation techniques, and its history, then leads into such specific topics as: The basis of HPLC separation and the general effects of different experimental conditions Equipment and detection The column—the

"heart" of the HPLC system Reversed-phase separation, normal-phase chromatography, gradient elution, two-dimensional separation, and other techniques Computer simulation, qualitative and quantitative analysis, and method validation and quality control The separation of large molecules, including both biological and synthetic polymers Chiral separations, preparative separations, and sample preparation Systematic development of HPLC separations—new to this edition Troubleshooting tricks, techniques, and case studies for both equipment and chromatograms Designed to fulfill the needs of the full range of HPLC users, from novices to experts, Introduction to Modern Liquid Chromatography, Third Edition offers the most up-to-date, comprehensive, and accessible survey of HPLC methods and applications available.
Handbook of Pharmaceutical Analysis Lena Ohannesian 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.
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 an 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 an 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.
Handbook of Pharmaceutical Analysis by HPLC Satinder Ahuja 2005-02-09 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
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.
Modern HPLC for Practicing Scientists Michael W. Dong 2016-04-06 A comprehesive yet concise guide to Modern HPLC Written for practitioners by a practitioner, Modern HPLC for Practicing Scientists is a concise text which presents the most important High-Performance Liquid Chromatography (HPLC) fundamentals, applications, and developments. It describes basic theory and terminology for the novice, and reviews relevant concepts, best practices, and modern trends for the experienced practitioner. Moreover, the book serves well as an updated reference guide for busy laboratory analysts and researchers. Topics covered include: HPLC operation Method development Maintenance and troubleshooting Modern trends in HPLC such as quick-turnaround and "greener" methods Regulatory aspects While broad in scope, this book focuses particularly on reversed-phase HPLC, the most common separation mode, and on applications for the pharmaceutical industry, the largest user segment. Accessible to both novice and intermedate HPLC users, information is delivered in a straightforward manner illustrated with an abundance of diagrams, chromatograms, tables, and case studies, and supported with selected key references and Web resources. With intuitive explanations and clear figures, Modern HPLC for Practicing Scientists is an essential resource for practitioners of all levels who need to understand and utilize this versatile analytical technology.
Introduction to Pharmaceutical Chemical Analysis Steen Hansen 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