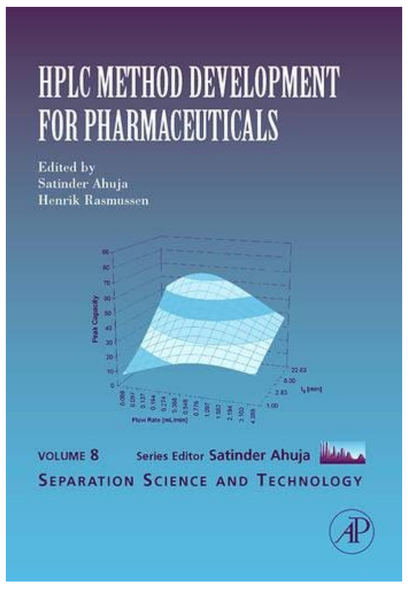

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HPLC Method Development for Pharmaceuticals-Satinder Ahuja 2011-09-21 High pressure, or high performance, liquid chromatography (HPLC) is the method of choice for checking purity of new drug candidates, monitoring changes during scale up or revision 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

HPLC Method Development for Pharmaceuticals-Satinder Ahuja 2007 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

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

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.

Analytical Method Development and Validation-Michael E. Swartz 1997-05-16 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.

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.

Development And Validation Of Chromatographic Methods For Simultaneous Quantification Of Drugs In Bulk And In Their Formulations: HPLC And HPTLC Techniques-Satish Y. Gabhe 2014-08 This book details: 1. Development and validation of a HPTLC-densitometric method for concurrent estimation of metformin hydrochloride, pioglitazone hydrochloride and gliclazide in combined dosage form. 2. Development and validation of a HPTLC method for simultaneous estimation of moxifloxacin hydrochloride and dexamethasone sodium phosphate in combined pharmaceutical dosage form. 3. Development and validation of a RP-HPLC method for simultaneous estimation of ciprofloxacin hydrochloride and dexamethasone in combined dosage form, which is a better alternative to existing ones. The developed analytical methods are simple, selective, accurate, robust, and precise with shorter analysis time for the analysis of drug/s in combined pharmaceutical dosage forms. All the developed HPTLC and HPLC methods have been validated as per ICH Q2 (R1) guideline. Developed analytical methods could boost analytical researchers to work more efficiently in the field of analytical method development and validation of Pharmaceutical dosage forms.

Electrophoresis-Oana-Maria Boldura 2018-09-12 Electrophoresis is a widely used method in the field of life sciences, having multiple practical applications in physical, chemical, biochemical, and molecular biology domains. This book contains 8 chapters depicting various applications of this technique in biochemistry, molecular biology, and physical chemistry. This book presents the link between the exposed method and its applications in a very explicit manner and offers a wide range of practical examples. The book provides not only a vision of actual methods but also their necessary further improvements and suggested developments. Therefore, a particular attention was given to the described techniques as true guidelines in the fields where electrophoresis is recommended, being useful for not only the scientists but also the laboratory clinicians.

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

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.

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.

Practical HPLC Method Development-Lloyd R. Snyder 2012-12-03 This revision brings the reader completely up to date on the evolving methods associated with increasingly more complex sample types analyzed using high-performance liquid chromatography, or HPLC. The book also incorporates updated discussions of many of the fundamental components of HPLC systems and practical issues associated with the use of this analytical method. This edition includes new or expanded treatments of sample preparation, computer assisted method development, as well as biochemical samples, and chiral separations.

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.

Capillary Electrophoresis Methods for Pharmaceutical Analysis-Satinder Ahuja 2011-08-09 Capillary electrophoresis (CE) is a powerful analytical technique that is widely used in research and development and in quality control of pharmaceuticals. Many reports of highly efficient separations and methods have been published over the past 15 years. CE offers several advantages over high-pressure or high-performance liquid chromatography (HPLC). These include simplicity, rapid analysis, automation, ruggedness, different mechanisms for selectivity, and low cost. Moreover, EC requires smaller sample size and yet offers higher efficiency and thus greater resolution power over HPLC. These characteristics are very attractive in research and development, even more so in pharmaceutical quality control (QC) and stability monitoring (SM) studies. This book will provide busy pharmaceutical scientists a complete yet concise reference guide for utilizing the versatility of CE in new drug development and quality control. - Provides current status and future developments in CE analysis of pharmaceuticals. - Explains how to develop and validate methods. - Includes major pharmaceutical applications including assays and impurity testing.

Handbook of Analytical Validation-Michael E. Swartz 2012-04-24 Written for practitioners in both the drug and biotechnology industries, the Handbook of Analytical Validation carefully compiles current regulatory requirements on the validation of new or modified analytical methods. Shedding light on method validation from a practical standpoint, the handbook:Contains practical, up-to-date guidelines for analyti

HPLC and UHPLC for Practicing Scientists-Michael W. Dong 2019-08-06 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.

Software-assisted Method Development In High Performance Liquid Chromatography-Szabolcs Fekete 2018-08-01 'The book is a useful contribution in the field of HPLC, and may represent a valuable tool for chromatography practitioners in different fields, as well as teachers and instructors. The 12 chapters provide comprehensive insights of current day retention and resolution modelling in HPLC, and its applications for small and large molecule analysis. It may be a useful reference for specialists in pharmaceuticals but not limited to ... It may be a valuable resource to assist scientists involved in method development, aiming to achieve the best results with reduced costs, time, and efforts.'Analytical and Bioanalytical ChemistryThis handbook gives a general overview of the possibilities in recent developments in chromatographic retention modeling. As a result of the latest developments in modeling software, several new features are now accessible, opening a new level in HPLC method development.Many of these current possibilities in software assisted liquid chromatographic method modeling for analytical purposes are presented. Several modes of chromatography, including Reversed-Phase Liquid Chromatography (RPLC), Ion Exchange Chromatography (IEX), Hydrophobic Interaction Chromatography (HIC), and Hydrophilic Interaction Liquid Chromatography (HILIC) are explained in detail. For all these chromatographic modes, the most important variables for tuning retention and selectivity are exposed.Beside the industrial and practical benefits of retention modeling, the possibilities in teaching and education are also illustrated. Finally, numerous representative industrial examples are shown, to highlight the benefits, time and cost savings offered by state-of-the-art software assisted HPLC method development.

Handbook of Modern Pharmaceutical Analysis-Satinder Ahuja 2010-11-11 Handbook of Modern Pharmaceutical Analysis, Second Edition, synthesizes the complex research and recent changes in the field, while covering the techniques and technology required for today's laboratories. The work integrates strategy, case studies, methodologies, and implications of new regulatory structures, providing complete coverage of quality assurance from the point of discovery to the point of use. Treats pharmaceutical analysis (PA) as an integral partner to the drug development process rather than as a service to it Covers method development, validation, selection, testing, modeling, and simulation studies combined with advanced exploration of assays, impurity testing, biomolecules, and chiral separations Features detailed coverage of QA, ethics, and regulatory guidance (quality by design, good manufacturing practice), as well as high-tech methodologies and technologies from "lab-on-a-chip" to LC-MS, LC-NMR, and LC-NMR-MS

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.

Development and Validation of Analytical Methods-Christopher M. Riley 1996-05-29 The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and parameters that must be considered in the development and validation of analytical methods. In addition to the critical issues surrounding method validation, this book also deals with other related factors such as method development, data acquisition, automation, cleaning validation and regulatory considerations. The book is divided into three parts. Part One, comprising two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters. Part Two (Chapters 3, 4 and 5) of the book focuses on the regulatory perspective of analytical validation. Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples. Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations, biotechnology products, biological samples, analytical methods for cleaning procedures and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic. This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of assay validation will always remain, to a certain extent, a matter of the personal preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

Chromatographic Methods Development-Gregory K. Webster 2019-10-28 This book is a comprehensive compilation of modern and cutting-edge chromatographic techniques written by pharmaceutical industry experts, academics, and vendors in the field. This book is an inclusive guide to developing all chromatographic methods (such as liquid chromatography and gas chromatography). It covers modern techniques for developing methods using chromatographic development software, requirements for validations, discussion on orthogonality, and how to transfer methods from HPLC to UHPLC. The text introduces some newer techniques that are heavily employed by chemists analyzing proteins and RNAi, as well as novel techniques such as counter current chromatography. This book is valuable for both the novice starting out in undergraduate labs and those who are new to the pharmaceutical industry and is a useful reference for seasoned analysts.

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

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.

Evaluating Water Quality to Prevent Future Disasters- 2019-05-24 Evaluating Water Quality to Prevent Future Disasters, volume 11 in the Separation Science and Technology series, covers various separation methods that can be used to avoid water catastrophes arising from climate change, arsenic, lead, algal bloom, fracking, microplastics, flooding, glyphosphates, triazines, GenX, and oil contamination. This book provides a valuable resource that will help the reader solve their potential water contamination problems and help them develop their own new approaches to monitor water contamination. Highlights reasons for potential water catastrophes Provides separation methods for monitoring water contamination Encourages development of new methods for monitoring water contamination

Handbook of Stability Testing in Pharmaceutical Development-Kim Huynh-Ba 2008-11-16 This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

HPLC Columns-Uwe D. Neue 1997-07-28 An in-depth guide to HPLC column technology High-performance liquid chromatography and its derivative techniques have become the dominant analytical separation tools in the pharmaceutical, chemical, and food industries; environmental laboratories; and therapeutic drug monitoring. Although the column is the heart of the HPLC instrument and essential to its success, until now, no book has focused on the theory and practice of column technology. HPLC Columns provides thorough, state-of-the-art coverage of HPLC column technology for the practicing technician and academician alike. Along with a comprehensive discussion of the chemical and physical processes of the HPLC column, it includes fundamental principles, separation mechanisms and available technologies, column selection criteria, and special techniques. Special features include: * Comprehensive overview of state-of-the-art HPLC column technology * Explanation of the underlying principles of HPLC columns * Methods for selecting columns * Practical advice on using and applying columns, including examples * Section by M. Zoubair El Fallah on methods development * Special techniques, including preparative chromatography, continuous chromatography, and the simulated moving bed * Troubleshooting section HPLC Columns helps laboratory practitioners make better choices in column selection, methods development, and troubleshooting: it is also an excellent textbook for graduate-level courses and HPLC short courses.

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.

Selectivity and Detectability Optimizations in HPLC-Satinder Ahuja 1989-06-06 High Performance Liquid Chromatography Edited by Phyllis Brown and Richard Hartwick This contributed volume is designed to consolidate the basic theories of chromatography along with the more exciting developments in the field. This monograph addresses some questions that concern researchers in separation science, including: what is the current state of the art in liquid chromatography; has the development of liquid chromatography plateaued; if so, what new methods will take its place or complement it; and if not, where will the new frontiers be and what direction will liquid chromatography take? 1989 (0 471-84506-X) 688 pp. Quantitative Structure-Chromatographic Retention Relationships R. Kaliszan Written by a pioneer in the field, this book extends and updates research on quantitative structure retention relationships by consolidating and critically reviewing the extensive literature on the subject, while also providing the basic theoretical and practical information required in all investigations involving chromatography, analytical chemistry, biochemistry, and pharmaceutical research. Among the topics covered are the nature of chromatographic interactions, molecular interpretation of distribution processes in chromatography, topological indices as retention descriptors, and multiparameter structure-chromatographic retention relationships. 1987 (0 471-85983-4) 303 pp. Detectors for Liquid Chromatography Edited by Edward S. Yeung With its singular coverage of this fast-growing field, Detectors for Liquid Chromatography presents the state of the art in this subject area. It offers a comprehensive examination of the basic principles behind the detector response, instrumentation, and selected applications for comparison and evaluation of potential. Specifically, topics given in-depth coverage include polarimetric, indirect absorbance, refractive index detectors, absorption detectors for HPLC, FTIR and fluorometric detection, detection based on electrical and electromechanical measurements, and mass spectroscopy as an on-line detector for HPLC. 1986 (0 471-82169-1) 366 pp.

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.

Validation in Chemical Measurement-Paul De Bièvre 2005-01-12 The validation of analytical methods is based on the characterisation of a measurement procedure (selectivity, sensitivity, repeatability, reproducibility). This volume collects 31 outstanding papers on the topic, mostly published in the period 2000-2003 in the journal "Accreditation and Quality Assurance". They provide the latest understanding, and possibly the rationale why it is important to integrate the concept of validation into the standard procedures of every analytical laboratory. In addition, this anthology considers the benefits to both: the analytical laboratory and the user of the measurement results.

Calibration and Validation of Analytical Methods-Mark Stauffer 2018-04-25 This book seeks to introduce the reader to current methodologies in analytical calibration and validation. This collection of contributed research articles and reviews addresses current developments in the calibration of analytical methods and techniques and their subsequent validation. Section 1, "Introduction," contains the Introductory Chapter, a broad overview of analytical calibration and validation, and a brief synopsis of the following chapters. Section 2 "Calibration Approaches" presents five chapters covering calibration schemes for some modern analytical methods and techniques. The last chapter in this section provides a segue into Section 3, "Validation Approaches," which contains two chapters on validation procedures and parameters. This book is a valuable source of scientific information for anyone interested in analytical calibration and validation.

Analytical Method Validation and Instrument Performance Verification-Chung Chow Chan 2004-04-23 Validation describes the procedures used to analyze pharmaceutical products so that the data generated will comply with the requirements of regulatory bodies of the US, Canada, Europe and Japan. Calibration of Instruments describes the process of fixing, checking or correcting the graduations of instruments so that they comply with those regulatory bodies. This book provides a thorough explanation of both the fundamental and practical aspects of biopharmaceutical and bioanalytical methods validation. It teaches the proper procedures for using the tools and analysis methods in a regulated lab setting. Readers will learn the appropriate procedures for calibration of laboratory instrumentation and validation of analytical methods of analysis. These procedures must be executed properly in all regulated laboratories, including pharmaceutical and biopharmaceutical laboratories, clinical testing laboratories (hospitals, medical offices) and in food and cosmetic testing laboratories.

Handbook of HPLC-Danilo Corradini 2016-04-19 High performance liquid chromatography (HPLC) is one of the most widespread analytical and preparative scale separation techniques used for both scientific investigations and industrial and biomedical analysis. Now in its second edition, this revised and updated version of the Handbook of HPLC examines the new advances made in this field since the

Chiral Separation Methods for Pharmaceutical and Biotechnological Products-Satinder Ahuja 2011-03-31 Discusses chiral separations and offers guidance for selectingthe optimum method for desired results Chiral separations represent the most intriguing and, by somemeasures, most difficultseparations of chemical compounds. Thisbook provides researchers and students an under-standing of chiralseparations and offers a convenient route to selecting the bestseparation method, saving considerable time and cost in productdevelopment. Considering chiral separations in the biotechnological andpharmaceutical industries, as well as for food applications, Dr.Ahuja provides insights into a broad range of topics. Opening witha broad overview of chiral separations, regulatory considerationsin drug product development, and basic issues in methoddevelopment, the book: Covers a variety of modern methods such as gas chromatography,high performance liquid chromatography, supercritical fluidchromatography, and capillary electrophoresis Deals with the impact of chirality on the biological activity ofsmall and large molecules Provides detailed information on useful chiral stationary phases(CSPs) for HPLC Includes handy information on selection of an appropriate CSP,including mechanistic studies Offers strategies for fast method development with HPLC, SFC,and CE Discusses preparatory methods utilized in the pharmaceuticalindustry With in-depth discussions of the current state of the field aswell as suggestions to assist future developments, ChiralSeparation Methods for Pharmaceutical and BiotechnologicalProducts is an essential text for laboratory investigators,managers, and regulators who are involved in chiral separations inthe pharmaceutical industry, as well as students preparing forcareers in these fields.

Instrumental Methods of Chemical Analysis-Dr. B. K. Sharma 1981

Chromatography and Separation Science-Satinder Ahuja 2003-01-11 The basic objectives of this book are to: provide basic information on chromatography and separation science; show how simple extraction and partition processes provide the basis for development of chromatography and separation science; describe the role of chromatography and separation science in various fields; discuss the role of chromatography and separation science in development of new methodology; and present new evolving methods and how to select an optimum method. · The book covers the fundamental physical and chemical phenomena involved in separations · Provides a concise overview of the basics of transport phenomena and thermodynamics · Shows the importance of chromatography within separation science

Advances in Water Purification Techniques-Satinder Ahuja 2018-11-29 Advances in Water Purification Techniques: Meeting the Needs of Developed and Developing Countries provides a variety of approaches to water purification that can help assist readers with their research and applications. Water contamination problems occur frequently worldwide, hence the most updated knowledge on water purification systems can be helpful in employing the right type of filter or other mechanism of decontamination. The problems with arsenic contamination of water in Bangladesh and the lead problem in Flint, Michigan remind us of the need to monitor water pollution rigorously, from both point and non-point sources. Provides a valuable resource on how to solve water contamination problems or develop new approaches to water purification Presents advanced methods for monitoring water contamination Describes various approaches to water purification Encourages new developments in water purification techniques Includes methods for assessing and monitoring environmental contaminants Covers recent advancement in molecular techniques

Chemistry and Water-Satinder Ahuja 2016-11-23 After air, water is the most crucial resource for human survival. To achieve water sustainability, we will have to deal with its scarcity and quality, and find ways to reclaim it from various sources. Chemistry and Water: The Science Behind Sustaining the World's Most Crucial Resource applies contemporary and sophisticated separation science and chromatographic methods to address the pressing worldwide concerns of potable water for drinking and safe water for irrigation to raise food for communities around the world. Edited and authored by world-leading analytical chemists, the book presents the latest research and solutions on topics including water quality and pollution, water treatment technologies and practices, watershed management, water quality and food production, challenges to achieving sustainable water supplies, water reclamation techniques, and wastewater reuse. Explores the role water plays to assure our survival and maintain life Provides valuable information from world leaders in chemistry and water research Addresses water challenges and solutions globally to ensure sustainability

HPLC of Peptides and Proteins-Marie-Isabel Aguilar 2004 Hands-on experts from academia and industry comprehensively describe how to successfully perform all the critical HPLC techniques needed for the analysis of peptides and proteins. The methods range from commonly used techniques to those for capillary to large-scale preparative isolation. The authors have also presented a number of specific applications as case studies to illustrate the analytical approaches to a particular separation or assay challenge, with examples drawn from contemporary fields in biochemistry and biotechnology. Follow step-by-step instructions that ensure experimental success Develop your own separation and analytical protocols for peptide and protein analysis.

LC/MS-Marvin C. McMaster 2005-08-08 A practical guide to using and maintaining an LC/MS system The combination of liquid chromatography (LC) and mass spectrometry(MS) has become the laboratory tool of choice for a broad range ofindustries that require the separation, analysis, and purificationof mixtures of organic compounds. LC/MS: A Practical User's Guide provides LC/MS users with aneasy-to-use, hands-on reference that focuses on the practicalapplications of LC/MS and introduces the equipment and techniquesneeded to use LC/MS successfully. Following a thorough explanationof the basic components and operation of the LC/MS system, theauthor presents empirical methods for optimizing the techniques,maintaining the instrumentation, and choosing the appropriate MS orLC/MS analyzer for any given problem. LC/MS covers everything users need to know about: The latest equipment, including quadrupole, time-of-flight, andion trap analyzers Cutting-edge processes, such as preparing HPLC mobile phasesand samples; handling and maintaining a wide variety of silica,zirconium, and polymeric separation columns; interpreting andquantifying mass spectral data; and using MS interfaces Current and future applications in the pharmaceutical andagrochemical industries, biotechnology, clinical research,environmental studies, and forensics An accompanying PowerPoint® slide-set on CD-ROM provides vitalteaching tools for instructors and new equipment operators.Abundantly illustrated and easily accessible, the text is designedto help students and practitioners acquire optimum proficiency inthis powerful and rapidly advancing analytical application.