Validation Hplc Techniques Pharmaceutical Analysis | d40f34ab5a5f338e2c29ddec64bb13f3


This book covers the most recent research trends and applications of Pharmaceutical Analytical Chemistry. The included topics range from the adulteration of dietary supplements, to the determination of drugs in biological samples with the aim to investigate their pharmacokinetic properties. 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) Pharmacoepias 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. 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. Master's Thesis from the year 2013 in the subject Medicine - Pharmacology, course: MASTER OF PHARMACY (Quality Assurance Techniques), language: English, abstract: A number of new drug entities, modifications of existing ones, and multi-component formulations are entering the market, every year. Development of simple analytical methods for analysis of various drugs in multi-component formulations is a tricky task for an analytical researcher. As analytical techniques are used throughout drug development, manufacturing, release of drug products, the reliability of their results is essential. Chromatographic methods are most useful and powerful techniques for qualitative and quantitative determination of drug/s. Therefore, appropriate validation to demonstrate the performance and suitability of the analytical method is much more than a formal requirement. Hence, there is need to develop and validate correct analytical method for these medicine/s. This book details, -Development and validation of HPTLC - densitometric method for concurrent estimation of metformin hydrochloride, pioglitazone hydrochloride and gliclazide in combined dosage form. -Development and validation of HPTLC method for simultaneous estimation of moxifloxacin hydrochloride and dexamethasone sodium phosphate in combined pharmaceutical dosage form. -Development and validation of RP - HPLC method for simultaneous estimation of ciprofloxacin hydrochloride and dexamethasone in combined dosage form, which is better alternative to existing one. 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) guidelines. Developed analytical methods could boost analytical researcher to work more efficiently in the field of analytical method development and validation of Pharmaceutical dosage forms. 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 phaseProteomic Profiling and Analytical Chemistry: The Crossroads, Second Edition helps scientists without a strong background in analytical chemistry to understand principles of the multistep proteomic experiment necessary for its successful completion. It also helps researchers who do have an analytical chemistry background to break into the proteomics field. Highlighting points of junction between proteomics and analytical chemistry, this resource links experimental design with analytical measurements, data analysis, and quality control. This targeted point of view will help both biologists and chemists to better understand all components of a complex proteomic study. The book provides detailed coverage of experimental aspects such as sample preparation, protein extraction and precipitation, gel electrophoresis, microarrays, dynamics of fluorescent dyes, and more. The key feature of this book is a direct link between multistep proteomic strategy and quality control routinely applied in analytical chemistry. This second edition features a new chapter on SWATH-MS, substantial updates to all chapters, including proteomic database search and analytical quantification, expanded discussion of post-hoc statistical tests, and additional content on validation in proteomics. Covers the analytical consequences of protein and peptide modifications that may have a profound effect on how and what researchers actually measure Includes practical examples illustrating the importance of problems in quantitation and validation of biomarkers Helps in designing and executing proteomic experiments with sound analytics.
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. This book describes the role modern pharmaceutical analysis plays in the development of new drugs. Detailed information is provided as to how the quality of drug products is assured from the point of discovery until the patient uses the drug. Coverage includes state-of-the-art topics such as analytics for combinatorial chemistry and high-throughput screening, formulation development, stability studies, international regulatory aspects and documentation, and future technologies that are likely to impact the field.

Emphasis is placed on current, easy-to-follow methods that readers can apply in their laboratories. No book has effectively replaced the very popular text, Pharmaceutical Analysis, that was edited in the 1960s by Tak Higuchi. This book will fill that gap with an up-to-date treatment that is both handy and authoritative. 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.

High-pressure liquid chromatography (HPLC) used in the analytical development to quantify the biological sample concentration, the active pharmaceutical ingredient (API) and to evaluate the impurity and degradation product profiles of the drug substances (DS) and drug products (DP). Additional uses of HPLC include determination of content uniformity of dosage form, monitoring of dissolution profiles, determination of antioxidants and preservative content and supporting of cleaning validations. UV spectroscopy is one of the most frequent used techniques in pharmaceutical analysis. It involves the measurement of UV radiation absorbed by a substance in solution. The wavelength range of UV radiation is 200-400nm (180-380 nm) and the UV radiation has a sufficient energy to excite valence electrons in many atoms or molecules; consequently, UV is involved with electronic excitation. Nicorandil is an Anti-anginal drug. There are several methods like HPLC, LC-MS, Ultraviolet Spectroscopy etc. are available for the estimation of Nicorandil in biological fluids and Pharmaceutical dosage form. We could not trace Single HPLC Method with short Retention Time (RT). So to develop and validate a HPLC method for the estimation of Nicorandil in Pharmaceutical with the retention time around 5 min. HPLC method for estimation of Nicorandil in its dosage form was developed. The developed HPLC method was validated for specificity, linearity and range, accuracy, method and intermediate precision, robustness, system suitability and applied to pharmaceutical formulation and the % Assay of Nicorandil Tablets was found to be in the range of 98-102%. For developing HPLC technique for analysis of Nicorandil tablet. Numbers of trials were taken for selection of column, mobile phase. The developed method was validated as per ICH guideline. The advantages of chromatographic techniques were higher accuracy, small sample size and less consumating, however it requires costly HPLC grade solvents and availability of HPLC instrument. This method can be successfully applied for the estimation. The coherent body of research described in the existing published work is concerned with new assay method development and validation using novel systematic approaches for pharmaceutical and diagnostic compounds. The first stage of the research was to study how analytical method development and validation are typically carried out at present and to formulate this into a simple step-by-step approach. Such a template and protocol was not only used as the foundation of this research programme but could also serve as a simple systematic guide for other practitioners and those new to the field. Furthermore, it was recognised that this protocol should satisfy the requirements of the most strategically important regulatory agencies. The second stage of this research involved evaluation and application of the above validation approach to new methods that were developed for a diverse range of analytes and samples. A new purity assay for 1,10-phenanthroline-5,6-dione and 4,7-phenanthroline-5,6-dione using high-performance liquid chromatography (HPLC) was developed and validated. Impurities in these compounds were identified by liquid chromatography-mass spectrometry (LCMS). Best practice in method development and validation is equally important in the analysis of both active components and excipients in formulated products. In the first case, a liquid chromatography assay method for determining the content of 2-(diethylamino)-N-(2,6-dimethylphenyl) acetamide in a gel formulation was developed and validated. In the second case, the individual contents of three phorboxy benzoic acid ester preservatives in a complex multi-component sample were determined following the development and validation of a liquid chromatography method. Finally, the validation approach was evaluated as applied to another analytical technique. Here, gas chromatography (GC) successfully used to develop a novel assay for p-cymene in tea tree oil formulations presented different analytical problems because of the very complex nature of this natural product. Stability study information to increase the shelf life of the product and validation data for the analytical method for p-cymene content was critically evaluated. In essence, the critical review of the requirements for method validation for various agencies and the subsequent preparation of guidelines on how to go about method validation have had a significant impact on how analytical practitioners worldwide go about method development and, more importantly, method validation.
it was possible to apply these guidelines to conduct a series of effective, successful method validation for assays involving a range of typical pharmaceutical samples. 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, 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 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. This second edition of a global bestseller has been completely redesigned and extensively rewritten to take into account the new Quality by Design (QbD) and lifecycle concepts in pharmaceutical manufacturing. As in the first edition, the fundamental requirements for analytical method validation are covered, but the second edition describes how these are applied systematically throughout the entire analytical lifecycle. QbD principles require adoption of a systematic approach to development and validation that begin with predefined objectives. For analytical methods these predefined objectives are established as an Analytical Target Profile (ATP). The book chapters are aligned with recently introduced standards and guidelines for manufacturing processes validation and follow the three stages of the analytical lifecycle: Method Design, Method Performance Qualification, and Continued Method Performance Verification. Case studies and examples from the pharmaceutical industry illustrate the concepts and guidelines presented, and the standards and regulations from the US (FDA), European (EMA) and global (ICH) regulatory authorities are considered throughout. The undisputed gold standard in the field. A comprehensive 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 intermediate 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. HPLC in Pharmaceutical Analysis provides a survey of the applicability of HPLC in pharmaceutical analysis and discusses the latest developments in HPLC, as well as the practical aspects of applying HPLC for solving various analytical problems. Each chapter provides a summary and critical review of HPLC methods, considering physicochemical properties of the compounds classified according to their basic chemical structures. The book also focuses on problems associated with sample preparation (rather than satisfactory detectability and/or insufficient resolution) and the methods suitable for achieving significant improvements. Special HPLC techniques, applications, and practical examples that demonstrate the superiority of HPLC methods for solving delicate analytical problems in each chapter are also presented. The book covers all aspects of pharmaceutical analysis, including phase system selection, optimization and validation of the developed HPLC methods, and their applications. HPLC in Pharmaceutical Analysis will prove to be an important reference resource for researchers in pharmaceutical industries, medical schools, and various university departments.
samples in different environments: therapeutic drug monitoring, drugs in sport, postmortem examinations, etc. Following the developments of LC-MS in the last decade and its establishment as the method of choice in the pharmaceutical industry (analytical R&D), the technique has gained favour in other scientific disciplines including analytical toxicology. This is notably due to the fact that purchase and operative costs of the equipment have gradually decreased over the same period. Many scientists in the field of analytical toxicology have already adopted LC-MS in their daily work, and this is illustrated by the increasing numbers of research papers published and presented at relevant conferences (The International Association of Forensic Toxicologists, Society of Forensic Toxicologists).

Practical approaches to ensure that analytical methods and instruments meet GMP standards and requirements Complementing the authors’ first book, Analytical Method Validation and Instrument Performance Verification, this new volume provides coverage of more advanced topics, focusing on additional and supplemental methods, instruments, and electronic systems that are used in pharmaceutical, biopharmaceutical, and clinical testing. Readers will gain new and valuable insights that enable them to avoid common pitfalls in order to seamlessly conduct analytical method validation as well as instrument operation qualification and performance verification. Part 1, Method Validation, begins with an overview of the book’s risk-based approach to phase appropriate validation and instrument qualification; it then focuses on the strategies and requirements for early phase drug development, including validation of specific techniques and functions such as process analytical technology, cleaning validation, and validation of laboratory information management systems Part 2, Instrument Performance Verification, explores the underlying principles and techniques for verifying instrument performance coverage includes analytical instruments that are increasingly important to the pharmaceutical industry, such as NIR spectrometers and particle size analyzers and offers readers a variety of alternative approaches for the successful verification of instrument performance based on the needs of their labs At the end of each chapter, the authors examine important practical problems and share their solutions. All the methods covered in this book follow Good Analytical Practices (GAP) to ensure that reliable data are generated in compliance with current Good Manufacturing Practices (cGMP). Analysts, scientists, engineers, technologists, and technical managers should turn to this book to ensure that analytical methods and instruments are accurate and meet GMP standards and requirements.

Specification of Drug Substances and Products: Development and Validation of Analytical Methods, Second Edition, presents a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products, with an emphasis on phase-appropriate development, validation of analytical methods, and their application in practice. This thoroughly revised second edition covers topics not covered or not substantially covered in the first edition, including method development and validation in the clinical phase, method transfer, process analytical technology, analytical life cycle management, special challenges with generic drugs, genotoxic impurities, topical products, nasal sprays and inhalation products, and biotechnology products. The book’s authors have been carefully selected as former members of the ICH Expert Working Groups charged with developing the ICH guidelines, and/or subject-matter experts in the industry, academia and in government laboratories. Presents a critical assessment of the application of ICH guidelines on method validation and specification setting Written by subject-matter experts involved in the development and application of the guidelines Provides a comprehensive treatment of the analytical methodologies used in the analysis, control and specification of new drug substances and products Covers the latest statistical approaches (including analytical quality by design) in the development of specifications, method validation and shelf-life prediction This handbook is concerned with new chromatographic method development and validation using novel systematic approaches for pharmaceutical compounds. The first stage of the research was to study how method development and validation are typically carried out at present and to formulate this into a simple step-by-step approach. Such a template and protocol was not only used as the foundation of this research programme but could also serve as a simple systematic guide for other practitioners in the pharmaceutical industry. Furthermore, it was recognised that this protocol should satisfy the requirements of the major regulatory agencies. The second stage of this research involved evaluation and application of the above validation approach to new methods that were developed for a diverse range of analytes using HPLC, LC-MS and GC. In essence, the critical review of the requirements for method validation for various agencies and the subsequent preparation of single guidelines on how to go about method validation have had a significant impact on analytical practitioners worldwide. The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients. Pharmaceutical Dosage Forms: Tablets, Third Edition is a comprehensive resource of the design, formulation, manufacture, and evaluation of the tablet dosage form, anChromatography may be defined as a nondestructive procedure for separating mixture of components into individual components through equilibrium distribution between two phases. The technique of chromatography is based on the differences in the rate at which the components of a mixture move through a porous medium under the influence of solvent or gas. The importance of Chromatography is increasing rapidly in pharmaceutical analysis in exact differentiation, selective identification and quantitative determination of structurally closely related compounds. Another important field of application of chromatographic methods is the purity testing of final products and intermediates (detection of decomposition products and by-products). As a consequence of the above points, chromatographic methods are occupying an ever-expanding position in the latest editions of the
pharmacopoeias and other testing standards. Chromatography is one of the most powerful and versatile analytical techniques available to the modern chemist. Its power arises from its capacity to determine quantitatively many individual components present in a mixture in a single analytical run. Its versatility comes from its capacity to handle wide variety of samples that may be gaseous, liquid or solid in nature. The sample can range in complexity from a simple substance to a multicomponent mixture containing widely different chemical species. Another aspect of versatility is that the analysis can be carried out on a very complex instrument and on the other hand on a simple inexpensive thin-layer plate. The modern form of column chromatography has been called high performance, high pressure, high resolution and high speed liquid chromatography. High Performance Liquid Chromatography (HPLC) is a special branch of column chromatography in which the mobile phase is forced through the column at high speed. As a result the analysis time is reduced by 1-2 orders of magnitude relative to classical column chromatography and the use of much smaller particles of the adsorbent or support becomes possible increasing the column efficiency substantially. A comprehensive 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 for 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 intermediate 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 technique. 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, pharmaceuticalists, QA officers, and public authorities. The third edition of the Encyclopedia of Analytical Science is a definitive collection of articles covering the latest technologies in application areas such as medicine, environmental science, food science and geology. Meticulously organized, clearly written and fully interdisciplinary, the Encyclopedia of Analytical Science provides foundational knowledge across the scope of modern analytical chemistry, linking fundamental topics with the latest methodologies. Articles will cover three broad areas: analytical techniques (e.g., mass spectrometry, liquid chromatography, atomic spectrometry); areas of application (e.g., forensic, environmental and clinical); and analytes (e.g., arsenic, nucleic acids and polycyclic aromatic hydrocarbons), providing a one-stop resource for analytical scientists. Offers readers a one-stop resource with access to information across the entire scope of modern analytical science. Presents articles split into three broad areas: analytical techniques, areas of application and analytes, creating an ideal resource for students, researchers and professionals. Provides concise and accessible information that is ideal for non-specialists and readers from undergraduate levels and higher. The first book devoted exclusively to a highly popular, relatively new detection technique Charged Aerosol Detection for Liquid Chromatography and Related Separation Techniques presents a comprehensive review of CAD theory, describes its advantages and limitations, and offers extremely well-informed recommendations for its practical use. Using numerous real-world examples based on contributors' professional experiences, it provides priceless insights into the actual and potential applications of CAD across a wide range of industries. Charged aerosol detection can be combined with a variety of separation techniques and in numerous configurations. While it has been widely adapted for an array of industrial and research applications with great success, it is still a relatively new technique, and its fundamental performance characteristics are not yet fully understood. This book is intended as a tool for scientists seeking to identify the most effective and efficient uses of charged aerosol detection for a given application. Moving naturally from basic to advanced topics, the author relates fundamental principles, practical uses, and applications across a range of industrial settings, including pharmaceuticals, petrochemicals, biotech, and more. Offers timely, authoritative coverage of the theory, experimental techniques, and end-user applications of charged aerosol detection. Includes contributions from experts from various fields of applications who explore CAD's advantages over traditional HPLC techniques, as well as its limitations. Provides a current theoretical and practical understanding of CAD, derived from authorities on aerosol technology and separation sciences. Features numerous real-world examples that help relate fundamental properties and general operational variables of CAD to its performance in
a variety of conditions Charged Aerosol Detection for Liquid Chromatography and Related Separation Techniques is a valuable resource for scientists who use chromatographic techniques in academic research and across an array of industrial settings, including the biopharmaceutical, biotechnology, biofuel, chemical, environmental, and food and beverage industries, among others. Although capillary electrophoresis (CE) technology has evolved quickly from the research laboratory into practical application in numerous fields, many scientists still debate its merits. While the body of international CE literature continues to expand dramatically, experts still question whether it has provided the speed, resolving power, peak capacity, sensitivity, robustness, and cost-reduction promised by its pioneers. Responding to these criticisms, this third edition brings together cutting-edge researchers to demonstrate the utility of CE across a broad spectrum of disciplines including: forensic science, medical diagnostics, pharmaceutical science, genetic analysis, biotechnology, fluid mechanics, environmental science, biomedical research, nanotechnology, proteomics, detailed analysis of new methodologies and applications. Eagerly awaited by researchers and technicians who transformed the first two editions into bestsellers, this latest volume once again delivers. Emphasizing microseparations and microfluidics, the handbook of Capillary and Microchip Electrophoresis, Third Edition features new chapters describing the use of microchip electrophoresis and associated microtechniques, with a focus on the extraordinary breadth of work undertaken to expand CE methodologies in recent years. Aided by contributions from leading international experts, this text remains a seminal reference for numerous chemistry, biology, and engineering fields. The present edited book is the presentation of 18 in-depth national and international contributions from eminent professors, scientists and instrumental chemists from educational institutes, research organizations and industries providing their views on their experience, handling, observation and research outputs on HPTLC, a multi-dimensional instrumentation. The book describes the recent advancements made on TLC which have revolutionized and transformed it into a modern instrumental technique HPTLC. The book addresses different chapters on HPTLC fundamentals: principle, theory, understanding; instrumentation: implementation, optimization, validation, automation and qualitative and quantitative analysis; applications: phytochemical analysis, biomedical analysis, herbal drug quantification, analytical analysis, finger print analysis and potential for hyphenation: HPTLC future to combinatorial approach, HPTLC-MS, HPTLC-FTIR and HPTLC-Scanning Diode Laser. The chapters in the book have been designed in such a way that the reader follows each step of the HPTLC in logical order. The book explains the principles and fundamentals of Green Analytical Chemistry (GAC) and highlights the current developments and future potential of the analytical green chemistry-oriented applications of various solutions. The book consists of sixteen chapters, including the history and milestones of GAC; issues related to teaching of green analytical chemistry and greening the university laboratories; evaluation of impact of analytical activities on the environmental and human health, direct techniques of detection, identification and determination of trace constituents; new achievements in the field of extraction of trace analytes from samples characterized by complex composition of the matrix; green nature of the derivatization process in analytical chemistry; passive techniques of sampling of analytes; green sorption materials used in analytical procedures; new types of solvents in the field of analytical chemistry. In addition green chromatography and related techniques, fast tests for assessment of the wide spectrum of pollutants in the different types of the medium, remote monitoring of environmental pollutants, qualitative and comparative evaluation, quantitative assessment, and future trends and perspectives are discussed. This book appeals to a wide readership of the academic and industrial researchers. In addition, it can be used in the classroom for undergraduate and graduate Ph.D. students focusing on elaboration of new analytical procedures for organic and inorganic compounds determination in different kinds of samples characterized by complex matrices composition. Jacek Namieśnik was a Professor at the Department of Analytical Chemistry, Gdańsk University of Technology, Poland. Justyna Plotka-Wasyłka is a teacher and researcher at the same department. 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. 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. Analytical chemists in the pharmaceutical industry are always looking for more-efficient techniques to meet the analytical challenges of today's pharmaceutical industry. One technique that has made steady advances in pharmaceutical analysis is supercritical fluid chromatography (SFC). SFC is meeting the chromatography needs of the industry by providing efficient and selective testing capabilities on the analytical and preparative scale. The supercritical fluid mobile phase, consisting mainly of CO2, facilitates cost reduction costs and helps the industry in meeting green chemistry standards. This book provides a comprehensive overview of the use of SFC in pharmaceutical analysis. Supercritical Fluid Chromatography reviews the use of SFC in drug-discovery applications and discusses its application in drug development. When a drug is developed and brought to market, it is tested many times for impurities and degradants, enantiomeric purity, and analytical and preparative isolation. It is tested during discovery and development and for under-regulated and unregulated methodologies. The book describes the use of SFC for each of these applications and discusses more in-depth topics, such as the use of SFC in mass spectrometric and polarographic detection. The book also sheds light on the role of SFC in drug development from natural products and the advancement of SFC with new technologies and its use in pilot-scale operations as a chromatographic technique. 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. 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. 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. 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. 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. Method validation is an important...
activity for pharmaceutical evaluations to ensure that analytical methods are suitable for their intended use. With particular focus on active ingredient and impurities, the implementation of different categories of method validation are explained for qualitative and quantitative methods. Detailed explanations with example approaches are provided for the key aspects of method validation, namely specificity, accuracy, linearity, limits of detection/quantitation, precision, robustness, and method range. While all of the sections outlined for method validation are generally applicable for a variety of techniques commonly used in pharmaceutical analysis (id est, UV and HPLC instrumentation), focused attention is provided for examples that have been implemented using high performance thin layer chromatographic techniques. 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