Pharmaceutical Analysis By S Ravi Shankar

The United Nation's Sustainable Development Goals call for the establishment of Good Health and Well-being and target a universal digital healthcare ecosystem by 2030. However, existing technology infrastructure is ineffectual in achieving the envisioned target and requires massive reconfiguration to achieve its intended outcome. This book suggests a way forward with fair and efficient digital health networks that provide resource efficiencies and inclusive access to those who are currently under-served. Specifically, a fair and efficient digital health network that provides a common platform to its key stakeholders to facilitate sharing of information with a view to promote cooperation and maximise benefits. A promising platform for this critical application is ‘cloud technology’ with its offer of computing as a utility and resource sharing. This is an area that has attracted much scholarly attention as it is well-suited to foster such a network and bring together diverse players who would otherwise remain fragmented and be unable to reap the benefits that accrue from cooperation. The fundamental premise is that the notion of value in a digital-health ecosystem is brought about by the sharing and exchange of digital information. However, notwithstanding the potential of information and communication technology to transform the healthcare industry for the better, there are several barriers to its adoption, the most significant one being misaligned incentives for some stakeholders. This book suggests among other findings, that e-health in its true sense can become fair and efficient if and only if a regulatory body concerned assumes responsibility as the custodian of its citizens’ health information so that ‘collaboration for value’ will replace ‘competition for revenue’ as the new axiom in delivering the public good of healthcare through digital networks.

Used routinely in drug control laboratories, forensic laboratories, and as a research tool, thin layer chromatography (TLC) plays an important role in pharmaceutical drug analyses. It requires less complicated or expensive equipment than other techniques, and has the ability to be performed under field conditions. Filling the need for an up-to-date

This comprehensive volume discusses approaches for a systematic selection of delivery systems for various classes of therapeutic agents including small molecule, protein, and nucleic acid drugs. Specific topics covered in this book include: Solution, suspension, gel, nanoparticle, microparticle, and implant dosage forms Refillable and microneedle devices Intravitreal, suprachoroidal, intrascleral, transscleral, systemic, and topical routes of delivery Physical methods including iontophoresis for drug delivery Rational selection of routes of administration and delivery systems Noninvasive and continuous drug monitoring Regulatory path to drug product development Clinical endpoints for drug product development Emerging and existing drugs and drug targets Drug Product Development for the Back of the Eye is authored by renowned ocular drug delivery experts, representing academic, clinical, and industrial organizations and serves as indispensable resource for ophthalmic researchers, drug formulation scientists, drug delivery and drug disposition scientists, as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases. This book is also relevant for students in various disciplines including ophthalmology, pharmaceutical sciences, drug delivery, and biomedical engineering. Refillable and microneedle devices Intravitreal, suprachoroidal, intrascleral, transscleral, systemic, and topical routes of delivery Physical methods including iontophoresis for drug delivery Rational selection of routes of administration and delivery systems Noninvasive and continuous drug monitoring Regulatory path to drug product development Clinical endpoints for drug product development Emerging and existing drugs and drug targets Drug Product Development for the Back of the Eye is authored by renowned ocular drug delivery experts, representing academic, clinical, and industrial organizations and serves as indispensable resource for ophthalmic researchers, drug formulation scientists, drug delivery and drug disposition scientists, as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases. This book is also relevant for students in various disciplines including ophthalmology, pharmaceutical sciences, drug delivery, and biomedical engineering. Refillable and microneedle devices Intravitreal, suprachoroidal, intrascleral, transscleral, systemic, and topical routes of delivery Physical methods including iontophoresis for drug delivery Rational selection of routes of administration and delivery systems Noninvasive and continuous drug monitoring Regulatory path to drug product development Clinical endpoints for drug product development Emerging and existing drugs and drug targets Drug Product Development for the Back of the Eye is authored by renowned ocular drug delivery experts, representing academic, clinical, and industrial organizations and serves as indispensable resource for ophthalmic researchers, drug formulation scientists, drug delivery and drug disposition scientists, as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases. This book is also relevant for students in various disciplines including ophthalmology, pharmaceutical sciences, drug delivery, and biomedical engineering.

There are unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-MS and presents manufacturing techniques such as granulation, compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for pharmaceutical scientists, regulators, and graduate students.

This volume, the first of the two-volume Drug Delivery Approaches and Nanosystems series, presents a full picture of the state-of-the-art research and development in drug delivery systems using nanotechnology and its applications. It addresses the ever-expanding application of nanotechnology or nano-sized materials in the medical field and the real-world challenges and complexities of current drug delivery methodologies and techniques. Many methods of drug delivery systems have been used, but very few of them have been validated for medical use. A major reason for the above situation, the editors believe, is the gap between academia and research, and the gap between academic research and real-time clinical applications and needs. This volume addresses that gap. This volume presents 12

chapters that provide information about the preparation and characterization of nanocomposite materials used in drug delivery systems; advanced research of carbon nanotubes, nanocomposite materials, and polymer-clay, ceramics, and silicate glass-based nanocomposites; and the functionality of graphene nanocomposites. The book also provides detailed information on the application of nanotechnology in drug delivery systems in health care systems and medicine. The book describes how nanostructures are synthesized and draws attention to wide variety of nanostructures available for biological research and treatment applications. This valuable volume provides a wealth of information that will be valuable to scientists and researchers, faculty, and students. Volume 2 of the two-volume series is subtitled Drug Targeting Aspects of Nanotechnology. The volumes are available separately or as a set.

This study, first published in 1996, investigates the effects that local labor market conditions may have on the economic status of women and blacks, relative to their white male counterparts. More precisely, it examines the impact that local labor market conditions have on estimates of labor market discrimination investigated in this study are wage discrimination and occupational discrimination. This title will be of interest to students of sociology, gender studies and urban studies.

CD-ROM includes animations, living graphs, biochemistry in 3D structure tutorials.

This publication is based on peer-reviewed manuscripts from the 2019 Conference on Drug Design & Discovery Technologies (CDDT) held at Ramaiah University of Applied Sciences, India. Providing a wide range of up to date topics on the latest advancements in drug design and discovery technologies, this book ensures the reader receives a good understanding of the scope of the field. Aimed at scientists, students, regulators, academics and consultants throughout the world, this book is an ideal resource for anyone interested in the state of the art in drug design and discovery.

Dr Alagarsamy's Textbook of Medicinal Chemistry is a much-awaited masterpiece in its arena. Targeted mainly to B. Pharm. students, this book will also be useful for M. Pharm. as well as M. Sc. organic chemistry and pharmaceutical chemistry students. It aims at eliminating the inadequacies in teaching and learning of medicinal chemistry by providing enormous information on all the topics in medicinal chemistry of synthetic drugs. Salient Features Contains clear classification, synthetic schemes, mode of action, metabolism, assay, pharmacological uses with the dose and structure–activity relationship (SAR) of the following classes of drugs: Drugs acting on inflammation Drugs acting on respiratory system Drugs acting on digestive system Drugs acting on blood and blood-forming organs Drugs acting on endocrine system Contains a complete section on chemotherapy and the various classes of chemotherapeutic agents. Also includes recent topics like anti-HIV agents Contains brief introduction about the physiological and pathophysiological conditions of diseases and their treatment under each topic Provides well-illustrated synthetic schemes and alternative synthetic routes for majority of drugs that help in quick and enhanced understanding of the subject Covers the syllabi of majority of Indian universities

This book comprehensively reviews drug stability and chemical kinetics: how external factors can influence the stability of drugs, and the reaction rates that trigger these effects. Explaining the important theoretical concepts of drug stability and chemical kinetics, and providing numerous examples in the form of illustrations, tables and calculations, the book helps readers gain a better understanding of the rates of reactions, order of reactions, types of degradation and how to prevent it, as well as types of stability studies. It also offers insights into the importance of the rate at which the drug is degraded and/or decomposed under various external and internal conditions, including temperature, pH, humidity and light. This book is intended for researchers, PhD students and scientists working in the field of pharmacy, pharmacology, pharmaceutical chemistry, medicinal chemistry and biopharmaceutics.

This volume explores the application of Quality by Design (QbD) to biopharmaceutical drug product development. Twenty-eight comprehensive chapters cover dosage forms, liquid and lyophilized drug products. The introductory chapters of this book define key elements of QbD and examine how these elements are integrated into drug product development. These chapters also discuss lessons learned from the FDA Office of Biotechnology Products pilot program. Following chapters demonstrate how QbD is used for formulation development ranging from screening of formulations to developability assessment to development of lyophilized and liquid formats. The next few chapters study the use of small-scale and surrogate models as well as QbD application to drug product processes such as drug substance freezing and thawing, mixing, sterile filtration, filling, lyophilization, inspection and shipping and handling. Later chapters describe more specialized applications of QbD in the drug product realm. This includes the use of QbD in primary containers, devices and combination product development. The volume also explores QbD applied to vaccine development, automation, mathematical modeling and monitoring, and controlling processes and defining control strategies. It concludes with a discussion on the application of QbD to drug product technology transfer as well as overall regulatory considerations and lifecycle management. Quality by Design for Biopharmaceutical Drug Product Development is an authoritative resource for scientists and researchers interested in expanding their knowledge on QbD principles and uses in creating better drugs.

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.

Retaining the successful previous editions' programmed instructional format, this book improves and updates an authoritative textbook to keep pace with compounding trends and calculations – addressing real-world calculations pharmacists perform and allowing students to learn at their own pace through examples. Connects well with the current emphasis on self-paced and active learning in pharmacy schools Adds a new chapter dedicated to practical calculations

used in contemporary compounding, new appendices, and solutions and answers for all problems Maintains value for teaching pharmacy students the principles while also serving as a reference for review by students in preparation for licensure exams Rearranges chapters and rewrites topics of the previous edition, making its content ideal to be used as the primary textbook in a typical dosage calculations course for any health care professional Reviews of the prior edition: "...a well-structured approach to the topic..." (Drug Development and Industrial Pharmacy) and "...a perfectly organized manual that serves as a expert guide..." (Electric Review)

This volume provides an introduction to medicinal chemistry. It covers basic principles and background, and describes the general tactics and strategies involved in developing an effective drug.

New edition of succesful standard reference book for the pharmaceutical industry and pharmaceutical physicians! The Textbook of Pharmaceutical Medicine is the coursebook for the Diploma in Pharmaceutical Medicine, and is used as a standard reference throughout the pharmaceutical industry. The new edition includes greater coverage of good clinical practice, a completely revised statistics chapter, and more on safety. Covers the course information for the Diploma in Pharmaceutical Medicine Fully updated, with new authors Greater coverage of good clinical practice and safety New chapters on regulation of medical devices in Europe and regulation of therapeutic products in Australia

Pharmaceutical analysis determines the purity, concentration, active compounds, shelf life, rate of absorption in the body, identity, stability, rate of release etc. of a drug. Testing a pharmaceutical product involves a variety of chemical, physical and microbiological analyses. It is reckoned that over £10 billion is spent annually in the UK alone on pharmaceutical analysis, and the analytical processes described in this book are used in industries as diverse as food, beverages, cosmetics, detergents, metals, paints, water, agrochemicals, biotechnological products and pharmaceuticals. This is the key textbook in pharmaceutical analysis, now revised and updated for its fourth edition. Worked calculation examples Self-assessment Additional problems (self tests) Practical boxes Key points boxes New chapter on Biotech products. New chapter on electrochemical methods in diagnostics. Greatly extended chapter on molecular emission spectroscopy to accommodate developments and innovations in the area. Now on StudentConsult

This new two-volume set, Drug Delivery Approaches and Nanosystems, Volume 1: Novel Drug Carriers and Volume 2: Drug Targeting Aspects of Nanotechnology presents a comprehensive look at the state-of-the-art research and developments in drug delivery systems using nanotechnology and its applications. Many methods of drug delivery systems have been used, but very few of them have been validated for medical use. A major reason for the above situation, the editors believe, is due to the gap between academia and research, and the gap between academic research and real-time clinical applications and needs. These volumes address that gap. Volume 1 addresses the ubiquitous applications of nanotechnology or nano-sized materials in the medical field and the real-world challenges and complexities of current drug delivery methodologies and techniques, while Volume 2 focuses on drug targeting aspects of nanotechnology. Together they provide a thorough review of the applications of nanotechnology or nano-sized materials in the medical field and the real-world challenges and complexities of current drug delivery methodologies and techniques. These two volumes will provide a plethora of real-world information for the application of drug delivery approaches via nanotechnology that will be valuable to scientists and researchers as well as faculty and students. The volumes are available separately or together as a set.

Want to learn the Python language without slogging your way through how-to manuals? With Head First Python, you'll quickly grasp Python's fundamentals, working with the built-in data structures and functions. Then you'll move on to building your very own webapp, exploring database management, exception handling, and data wrangling. If you're intrigued by what you can do with context managers, decorators, comprehensions, and generators, it's all here. This second edition is a complete learning experience that will help you become a bonafide Python programmer in no time. Why does this book look so different? Based on the latest research in cognitive science and learning theory, Head First Pythonuses a visually rich format to engage your mind, rather than a text-heavy approach that puts you to sleep. Why waste your time struggling with new concepts? This multi-sensory learning experience is designed for the way your brain really works.

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

Washed-up public defender Clay Carter's latest case, a routine street killing, takes an unexpected turn when he discovers evidence of a conspiracy involving a large drug company and a lawsuit with a huge potential settlement. Reprint. 35,000 first printing.

A comprehensive introduction for scientists engaged in new drug development, analysis, and approvals Each year the pharmaceutical industry worldwide recruits thousands of recent science graduates—especially chemistry, analytical chemistry, pharmacy, and pharmaceutical majors—into its ranks. However, because of their limited background in pharmaceutical analysis most of those new recruits find making the transition from academia to industry very difficult. Designed to assist both recent graduates, as well as experienced chemists or scientists with limited regulatory, compendial or pharmaceutical analysis background, make that transition, Pharmaceutical Analysis for Small Molecules is a concise, yet comprehensive introduction to the drug development process and analysis of chemically synthesized, small molecule drugs. It features contributions by distinguished experts in the field, including editor and author, Dr. Behnam Davani, an analytical chemist with decades of technical management and teaching experience in compendial, regulatory, and industry. This book provides an introduction to pharmaceutical analysis for small molecules (non-biologics) using commonly used techniques for drug characterization and performance tests. The driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to regulatory bodies for drug approval in order to market their products. In addition, related required supporting studies including good laboratory/documentation practices including analytical instrument qualification are highlighted in this book. Topics covered include: Drug Approval Process and Regulatory Requirements (private standards) Pharmacopeias and Compendial Approval Process (public standards) Common methods in pharmaceutical analysis (typically compendial) Common Calculations for assays and impurities and other specific tests Analytical Method Validation, Verification, Transfer Specifications including how to handle out of specification (OOS) and out of trend (OOT) Impurities including organic, inorganic, residual solvents and elemental impurities Good Documentation Practices for regulatory environment Management of Analytical Laboratories Analytical Instrument Qualifications including IQ, OQ, PQ and VQ Due to global nature of pharmaceutical industry, other topics on both regulatory (ICH) and Compendial harmonization are also highlighted. Pharmaceutical Analysis

for Small Molecules is a valuable working resource for scientists directly or indirectly involved with the drug development process, including analytical chemists, pharmaceutical scientists, pharmacists, and quality control/quality assurance professionals. It also is an excellent text/reference for graduate students in analytical chemistry, pharmacy, pharmaceutical and regulatory sciences.

Volumes in this widely revered series present comprehensive reviews of drug substances and additional materials, with critical review chapters that summarize information related to the characterization of drug substances and excipients. This organizational structure meets the needs of the pharmaceutical community and allows for the development of a timely vehicle for publishing review materials on this topic. The scope of the Profiles series encompasses review articles and database compilations that fall within one of the following six broad categories: Physical profiles of drug substances and excipients; Analytical profiles of drug substances and excipients; Drug metabolism and pharmacokinetic profiles of drug substances and excipients; Methodology related to the characterization of drug substances and excipients; Methods of chemical synthesis; and Reviews of the uses and applications for individual drug substances, classes of drug substances, or excipients. Contributions from leading authorities Informs and updates on all the latest developments in the field

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

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.

The content of the book, Introduction to Pharmaceutical Analysis, has been prepared primarily in accordance to the syllabus prepared by the Pharmacy Council of India for B. Pharm 1st semester course. However, the content of the book is not limited to the syllabus only, it provides the information which are bare necessary to understand a particular concept but beyond the syllabus. Moreover, there are two Appendices, Appendix I and II at the end. These are equally important and need to be known. One is Test solutions and the other one is for Volumetric solutions. In fact, many students do not know the difference between these solutions that are essential for analysis. How to prepare all these solutions are mentioned there. Hence, the book would be a real helpful to all those who are associated to pharmaceutical analysis, may be during their post-graduation and during service pharmaceutical industry.

Covering topics including solvent selection, miniaturization and metrics for the evaluation of greenness this is a useful resource for researchers interested in reducing the risks and environmental impacts of analytical methods.

Recent Advances in Analytical Techniques is a series of updates in techniques used in chemical analysis. Each volume presents information about a selection of analytical techniques. Readers will find information about developments in analytical methods such as chromatography, electrochemistry, optical sensor arrays for pharmaceutical and biomedical analysis. Novel Developments in Pharmaceutical and Biomedical Analysis is the second volume of the series and covers the following topics: o Chromatographic assays of solid dosage forms and their drug dissolution studies o UHPLC method for the estimation of bioactive compounds o HILIC based LC/MS for metabolite analysis o In vitro methods for the evaluation of oxidative stress o Application of vibrational spectroscopy in studies of structural polymorphism of drugs o Electrochemical sensors based on conductive polymers and carbon nanotubes o Optical sensor arrays for pharmaceutical and biomedical analyses o Chemical applications of ionic liquids o New trends in enantioanalysis of pharmaceutical compounds.

This book collects excerpts from many of His Holiness Sri Sri Ravishankar s talks. The journey for this collection began in New Delhi and ended in Rishikesh, India, and included many passages around the world.In this book, Sri Sri discusses topics rangi

This comprehensive textbook for on pharmaceutical organic chemistry fully meets the needs of pharmacy students at the undersgraduate level.

Due to the increase in the consumption of herbal medicine, there is a need to know which scientifically based methods are appropriate for assessing the quality of herbal medicines. Fingerprinting has emerged as a suitable technique for quality estimation. Chemical markers are used for evaluation of herbal medicines. Identification and quantification of these chemical markers are crucial for quality control of herbal medicines. This book provides updated knowledge on methodology, quality assessment, toxicity analysis and medicinal values of natural

compounds.
This book provides a compact, but thorough, introduction to the subject of Real Analysis. It is intended for a senior undergraduate and for a beginning graduate one-semester course.
Global Perspectives on Astaxanthin: From Industrial Production to Food, Health, and Pharmaceutical Applications explores the range of practical applications for this molecule, focusing on nutraceutical, pharmaceutical and cosmeceutical products, along with food and feed. This volume brings together the most relevant research, background and future thinking on astaxanthin, focusing on its health benefits. Chapters cover phytopharmaceuticals, industrial production, feeds, downstream processing, regulations, products, color, pigment, cosmetics, bioactive compounds, relationships to other carotenoids, and skin care. The detailed information on its production, processing, utilization and future applications will be of particular use to academic and industry researchers in pharmaceutical sciences, pharmacology and nutrition. Provides detailed information on astaxanthin, including its production, processing, utilization and future applications Includes discussion on the commercial analysis procedure Offers critical analysis on current and potential applications of astaxanthin as contributed by 121 authors from 22 countries in academia, research institutes and industries
The most comprehensive resource available on the many applications of portable spectrometers, including material not found in any other published work Portable Spectroscopy and Spectrometry: Volume Two is an authoritative and up-to-date compendium of the diverse applications for portable spectrometers across numerous disciplines. Whereas Volume One focuses on the specific technologies of the portable spectrometers themselves, Volume Two explores the use of portable instruments in wide range of fields, including pharmaceutical development, clinical research, food analysis, forensic science, geology, astrobiology, cultural heritage and archaeology. Volume Two features contributions by a multidisciplinary team of experts with hands-on experience using portable instruments in their respective areas of expertise. Organized both by instrumentation type and by scientific or technical discipline, 21 detailed chapters cover various applications of portable ion mobility spectrometry (IMS), infrared and near-infrared (NIR) spectroscopy, Raman and x-ray fluorescence (XRF) spectroscopy, smartphone spectroscopy, and many others. Filling a significant gap in literature on the subject, the second volume of Portable Spectroscopy and Spectrometry: Features a significant amount of content published for the first time, or not available in existing literature Brings together work by authors with assorted backgrounds and fields of study Discusses the central role of applications in portable instrument development Covers the algorithms, calibrations, and libraries that are of critical importance to successful applications of portable instruments Includes chapters on portable spectroscopy applications in areas such as the military, agriculture and feed, hazardous materials (HazMat), art conservation, and environmental science Portable Spectroscopy and Spectrometry: Volume Two is an indispensable resource for developers of portable instruments in universities, research institutes, instrument companies, civilian and government purchasers, trainers, operators of portable instruments, and educators and students in portable spectroscopy courses.
This is a comprehensive source of information on the application of ion chromatography (IC) in the analysis of pharmaceutical drugs and biologicals. This book, with contributors from academia, pharma, the biotech industry, and instrument manufacturing, presents the different perspectives, experience, and expertise of the thought leaders of IC in a comprehensive manner. It explores potential IC applications in different aspects of product development and quality control testing. In addition, an appendix section gives information on critical physical and chromatographic parameters related to IC and information on current manufacturers of IC systems, columns, and other components.
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