Process Analytical Technology Spectroscopic Tools And Implementation Strategies For The Chemical And Pharmaceutical Industries

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Handbook of Process Chromatography - Gunter Jagschies 2007-12-08
This book will update the original edition published in 1997. Since the publication of the first edition, the biotechnology and biologics industries have gained extensive knowledge and experience in downstream processing using chromatography and other technologies associated with recovery and purification unit operations. This book will tie that experience together for the next generation of readers. Updates include: - sources and productivity - types of products made today - experiences in clinical and licensed products - economics - current status of validation - illustrations and tables - automated column packing - automated systems New topics include: - the use of disposables - multiproduct versus dedicated production - design principles for chromatography media and filters - ultrafiltration principles and optimization - risk assessments - characterization studies - design space - platform technologies - process analytical technologies (PATs) - biogenerics - comparability assessments Key Features: - new approaches to process optimiaztion - use of patform technologies - applying risk assessment to process design

Applied Spectroscopy - 2009

Predictive Modeling of Pharmaceutical Unit Operations - Preetanshu Pandey 2016-09-26
The use of modeling and simulation tools is rapidly gaining prominence in the pharmaceutical industry covering a wide range of applications. This book focuses on modeling and simulation tools as they pertain to drug product manufacturing processes, although similar principles and tools may apply to many other areas. Modeling tools can improve fundamental process understanding and provide valuable insights into the manufacturing processes, which can result in significant process improvements and cost savings. With FDA mandating the use of Quality by Design (QbD) principles during manufacturing, reliable modeling techniques can help to alleviate the costs associated with such efforts, and be used to create in silico formulation and process design space. This book is geared toward detailing modeling techniques that are utilized for the various unit operations during drug product manufacturing. By way of examples that include case studies, various modeling principles are explained for the nonexpert end users. A discussion on the role of modeling in quality risk management for manufacturing and application of modeling for continuous manufacturing and biologics is also included. Explains the commonly used modeling and simulation tools Details the modeling of various unit operations commonly utilized in solid dosage drug product manufacturing Practical examples of the application of modeling tools through case studies Discussion of modeling techniques used for a risk-based approach to regulatory filings Explores the usage of modeling in upcoming areas such as continuous manufacturing and biologics manufacturingBullet points

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

Near-infrared Technology - Phil Williams 2001-01-01

Encyclopedia of Analytical Science - 2019-04-02
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 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

Continuous Biomanufacturing - Ganapathy Subramanian 2017-09-12
This is the most comprehensive treatise of this topic available, providing invaluable information on the technological and economic benefits to be gained from implementing continuous processes in the biopharmaceutical industry. Top experts from industry and academia cover the latest technical developments in the field, describing the use of single-use technologies alongside perfusion production platforms and downstream operations. Special emphasis is given to process control and monitoring, including such topics as 'quality by design' and automation. The book is supplemented by case studies that highlight the enormous potential of continuous manufacturing for biopharmaceutical production facilities.

PAT Applied in Biopharmaceutical Process Development And Manufacturing - Cenk Undey 2011-12-07
As with all of pharmaceutical production, the regulatory environment for the production of therapeutics has been changing as a direct result of the US FDA-initiated Quality by Design (QbD) guidelines and corresponding activities of the International Committee for Harmonization (ICH). Given the rapid growth in the biopharmaceutical area and the complexity of the molecules, the optimum use of which are still being developed, there is a great need for flexible and proactive teams in order to satisfy the regulatory requirements during process development. Process Analytical Technologies (PAT) applied in biopharmaceutical process development and manufacturing have received significant attention in recent years as an enabler to the QbD paradigm. PAT Applied in Biopharmaceutical Process Development and Manufacturing covers technological advances in measurement sciences, data acquisition, monitoring, and control. Technical leaders present real-life case studies in areas including measuring and monitoring raw materials, cell culture, purification, and cleaning and lyophilization processes via advanced PAT. They also explore how data are collected and analyzed using advanced analytical techniques such as multivariate data analysis, monitoring, and control in real-time. Invaluable for experienced practitioners in PAT in biopharmaceuticals, this book is an excellent reference guide for regulatory officials and a vital training aid for students who need to learn the state of the art in this interdisciplinary and exciting area.
Process Analytical Technology - Katherine A. Bakeev 2010-04-01
Process Analytical Technology explores the concepts of PAT and its application in the chemical and pharmaceutical industry from the point of view of the analytical chemist. In this new edition all of the original chapters have been updated and revised, and new chapters covering the important topics of sampling, NMR, fluorescence, and acoustic chemometrics have been added. Coverage includes: Implementation of Process Analytical Technologies UV-Visible Spectroscopy for On-line Analysis Infrared Spectroscopy for Process Analytical Applications Process Raman Spectroscopy Process NMR Spectrscopy: Technology and On-line Applications Fluorescent Sensing and Process Analytical Applications Chemometrics in Process Analytical Technology (PAT) On-Line PAT Applications of Spectroscopy in the Pharmaceutical Industry Future Trends for PAT for Increased Process Understanding and Growing Applications in Biomanufacturing NIR Chemical Imaging This volume is an important starting point for anyone wanting to implement PAT and is intended not only to assist a newcomer to the field but also to provide up-to-date information for those who practice process analytical chemistry and PAT. It is relevant for chemists, chemical and process engineers, and analytical chemists working on process development, scale-up and production in the pharmaceutical, fine and specialty chemicals industries, as well as for academic chemistry, chemical engineering, chemometrics and pharmaceutical science research groups focussing on PAT. Review from the First Edition “The book provides an excellent first port of call for anyone seeking material and discussions to understand the area better. It deserves to be found in every library that serves those who are active in the field of Process Analytical Technology.”—Current Engineering Practice
Chemometric Methods in Analytical Spectroscopy Technology - Xiaoli Chu 2022-05-23
This book discusses chemometric methods for spectroscopy analysis including NIR, MIR, Raman, NMR, and LIBS, from the perspective of practical applied spectroscopy. It covers all aspects of chemometrics associated with analytical spectroscopy, including representative sample selection algorithm, outlier detection algorithm, model updating and maintenance algorithm and strategy and calibration performance evaluation methods.To provide a systematic and comprehensive overview the latest progress of chemometric methods including recent scientific research and practical applications are presented. In addition the book also highlights the improvement of classical algorithms and the extension of common strategies. It is therefore useful as a reference book for researchers engaged in analytical spectroscopy technology, chemometrics, analytical instruments and other related fields.
Analytical Instrumentation - Gillian McMahon 2008-03-11
This valuable resource covers the principles of analytical instrumentation used by today's chemists and biologists and presents important advances in instrumentation, such as the drive to miniaturise and lab-on-a-chip devices. In terms of the lab-based analytical instrumentation, the five main categories of technique—spectroscopic, chromatographic, electrochemical, imaging and thermoanalytical, are included and presented in a practical, not theoretical way. Including relevant examples and applications in a number of fields such as healthcare, environment and pharmaceutical industry this book provides a complete overview of the instruments used within the chemistry industry, making this an important tool for professionals and students alike.
Single-Use Technology in Biopharmaceutical Manufacture - Regine Eibl 2019-07-24
Authoritative guide to the principles, characteristics, engineering aspects, economics, and applications of disposables in the manufacture of biopharmaceuticals The revised and updated second edition of Single-Use Technology in Biopharmaceutical Manufacture offers a comprehensive examination of the most-commonly used disposables in the manufacture of biopharmaceuticals. The authors—noted experts on the topic—provide the essential information on the principles, characteristics, engineering aspects, economics, and applications. This authoritative guide contains the basic knowledge and information about disposable equipment. The author also discusses biopharmaceuticals’ applications through the lens of case studies that clearly illustrate the role of manufacturing, quality assurance, and environmental influences. This updated second edition revises existing information with recent developments that have taken place since the first edition was published. The book also presents the latest advances in the field of single-use technology and explores topics including applying single-use devices for microorganisms, human mesenchymal stem cells, and T-cells. This important book: • Contains an updated and end-to-end view of the development and manufacturing of single-use biologics • Helps in the identification of appropriate disposables and relevant vendors • Offers illustrative case studies that examine manufacturing, quality assurance, and environmental influences • Includes updated coverage on cross-functional/transversal dependencies, significant improvements made by suppliers, and the successful application of the single-use technologies Written for biopharmaceutical manufacturers, process developers, and biological and chemical engineers, Single-Use Technology in Biopharmaceutical Manufacture, 2nd Edition provides the information needed for professionals to come to an easier decision for or against disposable alternatives and to choose the appropriate system.
Developing Solid Oral Dosage Forms - Yihong Qiu 2009-03-10
Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms. It covers essential principles of physical pharmacy, biopharmaceutics and industrial pharmacy as well as various aspects of state-of-the-art techniques and approaches in pharmaceutical sciences and technologies along with examples and/or case studies in product development. The objective of this book is to offer updated (or current) knowledge and skills required for rational oral product design and development. The specific goals are to provide readers with: Basics of modern theories of physical pharmacy, biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation, formulation/process design, characterization and scale-up in pharmaceutical sciences and technologies New developments, challenges, trends, opportunities, intellectual property issues and regulations in solid product development The first book (ever) that provides comprehensive and in-depth coverage of what's required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market, including the most updated science and technologies, practice, applications, regulation, intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well-established authors/co-authors of diverse background, knowledge, skills and experience from industry, academia and regulatory agencies
Process Analytical Technology for the Food Industry - Colm P. O'Donnell 2014-11-03
The Process Analytical Technology (PAT) initiative aims to move from a paradigm of ‘testing quality in’ to ‘building quality in by design’. It can be defined as the optimal application of process analytical technologies, feedback process control strategies, information management tools, and/or product–process optimization strategies. Recently, there have been significant advances in process sensors and in model-based monitoring and control methodologies, leading to enormous opportunities for improved performance of food manufacturing processes and for the quality of food products with the adoption of PAT. Improvements in process efficiency, reduced product variability, enhanced traceability, process

understanding, and decreased risk of contamination are some of the benefits arising from the introduction of a PAT strategy in the food industry. Process Analytical Technology for the Food Industry reviews established and emerging PAT tools with potential application within the food processing industry. The book will also serve as a reference for industry, researchers, educators, and students by providing a comprehensive insight into the objectives, challenges, and benefits of adopting a Process Analytical Technology strategy in the food industry.

Development of soft sensors for monitoring and control of bioprocesses - Robert Gustavsson 2018-10-31

In the manufacture of bio-therapeutics the importance of a well-known process is key for a high product titer and low batch to batch variations. Soft sensors are based on the concept that online sensor signals can be used as inputs to mathematical models to derive new valuable process information. This information could then be used for better monitoring and control of the bioprocess. The aim of the present thesis has been to develop soft sensor solutions for upstream bioprocessing and demonstrate their usefulness in improving robustness and increase the batch-to-batch reproducibility in bioprocesses. The thesis reviews the potential and possibilities with soft sensors for use in production of bio-therapeutics to realize FDA´s process analytical technology (PAT) initiative. Modelling and hardware sensor alternatives which could be used in a soft sensor setup are described and critically analyzed. Different soft sensor approaches to control glucose feeding in fed-batch cultures of Escherichia coli are described. Measurements of metabolic fluxes and specific carbon dioxide production was used as control parameters to increase product yield and decrease the variability of produced recombinant proteins. Metabolic heat signals were used in uninduced cultures to estimate and control the specific growth rate at a desired level and thereby also estimate the biomass concentration online. The introduction of sequential filtering of the signal enabled this method to be used in a down-scaled system. The risk and high impact of contaminations in cell cultures are also described. An in situ microscope (ISM) was used as an online tool to estimate cell concentration and also to determine cell diameter size which enabled the detection of contaminant cells at an early stage. The work presented in this thesis supports the idea that soft sensors can be a useful tool in the strive towards robust and reliable bioprocesses, to ensure high product quality and increased economic profit.

Infrared Spectroscopy in Conservation Science - Michele R. Derrick 2000-03-16

This book provides practical information on the use of infrared (IR) spectroscopy for the analysis of materials found in cultural objects. Designed for scientists and students in the fields of archaeology, art conservation, microscopy, forensics, chemistry, and optics, the book discusses techniques for examining the microscopic amounts of complex, aged components in objects such as paintings, sculptures, and archaeological fragments. Chapters include the history of infrared spectroscopy, the basic parameters of infrared absorption theory, IR instrumentation, analysis methods, sample collection and preparation, and spectra interpretation. The authors cite several case studies, such as examinations of Chumash Indian paints and the Dead Sea Scrolls. The Institute’s Tools for Conservation series provides practical scientific procedures and methodologies for the practice of conservation. The series is specifically directed to conservation scientists, conservators, and technical experts in related fields.

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.

Near Infrared Technology - Phil Williams 2019-09-16

Imagine an analytical technique that uses no chemicals, gives accurate and precise results in minutes or even continuously, and is simple to install and safe to use. Near-infrared spectroscopy (NIRS) supplies this dream. This book covers all of the essential features for successful NIRS application in a practical and easily understandable format. The driving force behind compiling this book is to provide knowledge on all aspects of NIRS to potential users, and to users who would like to delve a little deeper into the technology. We have assembled the book, mainly to help in the application of near-infrared (NIR) instruments and technology in industry.

Specification of Drug Substances and Products - Christopher M. Riley 2020-07-23

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

Industrial Crystallization Process Monitoring and Control - Angelo Chianese 2012-04-06

Crystallization is an important technique for separation and purification of substances as well as for product design in chemical, pharmaceutical and biotechnological process industries. This ready reference and handbook draws on research work and industrial practice of a large group of experts in the various areas of industrial crystallization processes, capturing the essence of current trends, the markets, design tools and technologies in this key field. Along the way, it outlines trouble free production, provides laboratory controls, analyses case studies and discusses new challenges. First the instrumentation and techniques used to measure the crystal size distribution, the nucleation and solubility points, and the chemical composition of the solid and liquid phase are outlined. Then the main techniques adopted to control industrial crystallizers, starting from fundamental approaches to the most advanced ones, including

the multivariable predictive control are described. An overview of the main crystallizer types is given with details of the main control schemes adopted in industry as well as the more suitable sensors and actuators.
Analytical Techniques in the Pharmaceutical Sciences - Anette Müllertz 2016-08-30
The aim of this book is to present a range of analytical methods that can be used in formulation design and development and focus on how these systems can be applied to understand formulation components and the dosage form these build. To effectively design and exploit drug delivery systems, the underlying characteristic of a dosage form must be understood--from the characteristics of the individual formulation components, to how they act and interact within the formulation, and finally, to how this formulation responds in different biological environments. To achieve this, there is a wide range of analytical techniques that can be adopted to understand and elucidate the mechanics of drug delivery and drug formulation. Such methods include e.g. spectroscopic analysis, diffractometric analysis, thermal investigations, surface analytical techniques, particle size analysis, rheological techniques, methods to characterize drug stability and release, and biological analysis in appropriate cell and animal models. Whilst each of these methods can encompass a full research area in their own right, formulation scientists must be able to effectively apply these methods to the delivery system they are considering. The information in this book is designed to support researchers in their ability to fully characterize and analyze a range of delivery systems, using an appropriate selection of analytical techniques. Due to its consideration of regulatory approval, this book will also be suitable for industrial researchers both at early stage up to pre-clinical research.
Process Systems Engineering for Pharmaceutical Manufacturing - Ravendra Singh 2018-03-16
Process Systems Engineering for Pharmaceutical Manufacturing: From Product Design to Enterprise-Wide Decisions, Volume 41, covers the following process systems engineering methods and tools for the modernization of the pharmaceutical industry: computer-aided pharmaceutical product design and pharmaceutical production processes design/synthesis; modeling and simulation of the pharmaceutical processing unit operation, integrated flowsheets and applications for design, analysis, risk assessment, sensitivity analysis, optimization, design space identification and control system design; optimal operation, control and monitoring of pharmaceutical production processes; enterprise-wide optimization and supply chain management for pharmaceutical manufacturing processes. Currently, pharmaceutical companies are going through a paradigm shift, from traditional manufacturing mode to modernized mode, built on cutting edge technology and computer-aided methods and tools. Such shifts can benefit tremendously from the application of methods and tools of process systems engineering. Introduces Process System Engineering (PSE) methods and tools for discovering, developing and deploying greener, safer, cost-effective and efficient pharmaceutical production processes Includes a wide spectrum of case studies where different PSE tools and methods are used to improve various pharmaceutical production processes with distinct final products Examines the future benefits and challenges for applying PSE methods and tools to pharmaceutical manufacturing
Handbook of Spectroscopy - Gi¿nter Gauglitz 2014-06-09
This second, thoroughly revised, updated and enlarged edition provides a straightforward introduction to spectroscopy, showing what it can do and how it does it, together with a clear, integrated and objective account of the wealth of information that may be derived from spectra. It also features new chapters on spectroscopy in nano-dimensions, nano-optics, and polymer analysis. Clearly structured into sixteen sections, it covers everything from spectroscopy in nanodimensions to medicinal applications, spanning a wide range of the electromagnetic spectrum and the physical processes involved, from nuclear phenomena to molecular rotation processes. In addition, data tables provide a comparison of different methods in a standardized form, allowing readers to save valuable time in the decision process by avoiding wrong turns, and also help in selecting the instrumentation and performing the experiments. These four volumes are a must-have companion for daily use in every lab.
Spectroscopic Analyses - Eram Sharmin 2017-12-06
The book presents developments and applications of these methods, such as NMR, mass, and others, including their applications in pharmaceutical and biomedical analyses. The book is divided into two sections. The first section covers spectroscopic methods, their applications, and their significance as characterization tools; the second section is dedicated to the applications of spectrophotometric methods in pharmaceutical and biomedical analyses. This book would be useful for students, scholars, and scientists engaged in synthesis, analyses, and applications of materials/polymers.
Hot-Melt Extrusion - Dennis Douroumis 2012-04-24
Hot-melt extrusion (HME) - melting a substance and forcing it through an orifice under controlled conditions to form a new material - is an emerging processing technology in the pharmaceutical industry for the preparation of various dosage forms and drug delivery systems, for example granules and sustained release tablets. Hot-Melt Extrusion: Pharmaceutical Applications covers the main instrumentation, operation principles and theoretical background of HME. It then focuses on HME drug delivery systems, dosage forms and clinical studies (including pharmacokinetics and bioavailability) of HME products. Finally, the book includes some recent and novel HME applications, scale -up considerations and regulatory issues. Topics covered include: principles and die design of single screw extrusion twin screw extrusion techniques and practices in the laboratory and on production scale HME developments for the pharmaceutical industry solubility parameters for prediction of drug/polymer miscibility in HME formulations the influence of plasticizers in HME applications of polymethacrylate polymers in HME HME of ethylcellulose, hypromellose, and polyethylene oxide bioadhesion properties of polymeric films produced by HME taste masking using HME clinical studies, bioavailability and pharmacokinetics of HME products injection moulding and HME processing for pharmaceutical materials laminar dispersive & distributive mixing with dissolution and applications to HME technological considerations related to scale-up of HME processes devices and implant systems by HME an FDA perspective on HME product and process understanding improved process understanding and control of an HME process with near-infrared spectroscopy Hot-Melt Extrusion: Pharmaceutical Applications is an essential multidisciplinary guide to the emerging pharmaceutical uses of this processing technology for researchers in academia and industry working in drug formulation and delivery, pharmaceutical engineering and processing, and polymers and materials science. This is the first book from our brand new series Advances in Pharmaceutical Technology. Find out more about the series here.
Resource Efficiency of Processing Plants - Stefan Krämer 2017-12-14
This monograph provides foundations, methods, guidelines and examples for monitoring and improving resource efficiency during the operation of processing plants and for improving their design. The measures taken to improve their energy and resource efficiency are strongly influenced by regulations and standards which are covered in Part I of this book. Without changing the actual processing equipment, the way how the processes are operated can have a strong influence on the resource efficiency of the plants and this potential can be exploited with much smaller investments than needed for the introduction of new process technologies. This aspect is the focus of Part II. In Part III we discuss physical changes of the process technology such as heat integration, synthesis and realization of optimal processes, and industrial symbiosis. The last part deals with the people that are needed to make these changes possible and discusses the path towards a resource efficiency culture. Written with industrial solutions in mind, this text will benefit practitioners as well as the academic community.
Green Chemical Engineering - 2018-07-06
Green chemistry and chemical engineering belong together and this twelth volume in the successful Handbook of Green Chemistry series represents the perfect one-stop reference on the topic. Written by an international team of specialists with each section edited by international leading experts, this book provides first-hand insights into the field, covering chemical engineering process design, innovations in unit operations and manufacturing, biorefining and much more besides. An indispensable source for every chemical engineer in industry and academia.
Continuous Manufacturing of Pharmaceuticals - Peter Kleinebudde 2017-09-05
A comprehensive look at existing technologies and processes for continuous manufacturing of pharmaceuticals As rising costs outpace new drug development, the pharmaceutical industry has come under intense pressure to improve the efficiency of its manufacturing processes. Continuous process manufacturing provides a proven solution. Among its many benefits are: minimized waste, energy consumption, and raw material use; the accelerated introduction of new drugs; the use of smaller

production facilities with lower building and capital costs; the ability to monitor drug quality on a continuous basis; and enhanced process reliability and flexibility. Continuous Manufacturing of Pharmaceuticals prepares professionals to take advantage of that exciting new approach to improving drug manufacturing efficiency. This book covers key aspects of the continuous manufacturing of pharmaceuticals. The first part provides an overview of key chemical engineering principles and the current regulatory environment. The second covers existing technologies for manufacturing both small-molecule-based products and protein/peptide products. The following section is devoted to process analytical tools for continuously operating manufacturing environments. The final two sections treat the integration of several individual parts of processing into fully operating continuous process systems and summarize state-of-art approaches for innovative new manufacturing principles. Brings together the essential know-how for anyone working in drug manufacturing, as well as chemical, food, and pharmaceutical scientists working on continuous processing Covers chemical engineering principles, regulatory aspects, primary and secondary manufacturing, process analytical technology and quality-by-design Contains contributions from researchers in leading pharmaceutical companies, the FDA, and academic institutions Offers an extremely well-informed look at the most promising future approaches to continuous manufacturing of innovative pharmaceutical products Timely, comprehensive, and authoritative, Continuous Manufacturing of Pharmaceuticals is an important professional resource for researchers in industry and academe working in the fields of pharmaceuticals development and manufacturing.

Handbook of Near-Infrared Analysis - Emil W. Ciurczak 2021-05-20

Rapid, inexpensive, and easy-to-deploy, near-infrared (NIR) spectroscopy can be used to analyze samples of virtually any composition, origin, and condition. The Handbook of Near Infrared Analysis, Fourth Edition, explores the factors necessary to perform accurate and time- and cost-effective analyses across a growing spectrum of disciplines. This updated and expanded edition incorporates the latest advances in instrumentation, computerization, chemometrics applied to NIR spectroscopy, and method development in NIR spectroscopy, and underscores current trends in sample preparation, calibration transfer, process control, data analysis, instrument performance testing, and commercial NIR instrumentation. This work offers readers an unparalleled combination of theoretical foundations, cutting-edge applications, and practical experience. Additional features include the following: Explains how to perform accurate as well as time- and cost-effective analyses. Reviews software-enabled chemometric methods and other trends in data analysis. Highlights novel applications in pharmaceuticals, polymers, plastics, petrochemicals, textiles, foods and beverages, baked products, agricultural products, biomedicine, nutraceuticals, and counterfeit detection. Underscores current trends in sample preparation, calibration transfer, process control, data analysis, and multiple aspects of commercial NIR instrumentation. Offering the most complete single-source guide of its kind, the Handbook of Near Infrared Analysis, Fourth Edition, continues to offer practicing chemists and spectroscopists an unparalleled combination of theoretical foundations, cutting-edge applications, and detailed practical experience provided firsthand by more than 50 experts in the field.

Near-Infrared Spectroscopy - Yukihiro Ozaki 2020-11-13

This book provides knowledge of the basic theory, spectral analysis methods, chemometrics, instrumentation, and applications of near-infrared (NIR) spectroscopy—not as a handbook but rather as a sourcebook of NIR spectroscopy. Thus, some emphasis is placed on the description of basic knowledge that is important in learning and using NIR spectroscopy. The book also deals with applications for a variety of research fields that are very useful for a wide range of readers from graduate students to scientists and engineers in both academia and industry. For readers who are novices in NIR spectroscopy, this book provides a good introduction, and for those who already are familiar with the field it affords an excellent means of strengthening their knowledge about NIR spectroscopy and keeping abreast of recent developments.

Infrared Spectroscopy for Food Quality Analysis and Control - Da-Wen Sun 2009-03-05

Written by an international panel of professional and academic peers, the book provides the engineer and technologist working in research, development and operations in the food industry with critical and readily accessible information on the art and science of infrared spectroscopy technology. The book should also serve as an essential reference source to undergraduate and postgraduate students and researchers in universities and research institutions. Infrared (IR) Spectroscopy deals with the infrared part of the electromagnetic spectrum. It measure the absorption of different IR frequencies by a sample positioned in the path of an IR beam. Currently, infrared spectroscopy is one of the most common spectroscopic techniques used in the food industry. With the rapid development in infrared spectroscopic instrumentation software and hardware, the application of this technique has expanded into many areas of food research. It has become a powerful, fast, and non-destructive tool for food quality analysis and control. Infrared Spectroscopy for Food Quality Analysis and Control reflects this rapid technology development. The book is divided into two parts. Part I addresses principles and instruments, including theory, data treatment techniques, and infrared spectroscopy instruments. Part II covers the application of IRS in quality analysis and control for various foods including meat and meat products, fish and related products, and others. *Explores this rapidly developing, powerful and fast non-destructive tool for food quality analysis and control *Presented in two Parts -- Principles and Instruments, including theory, data treatment techniques, and instruments, and Application in Quality Analysis and Control for various foods making it valuable for understanding and application *Fills a need for a comprehensive resource on this area that includes coverage of NIR and MVA

Developments in Near-Infrared Spectroscopy - Konstantinos Kyprianidis 2017-03-15

Over the past few decades, exciting developments have taken place in the field of near-infrared spectroscopy (NIRS). This has been enabled by the advent of robust Fourier transform interferometers and diode array solutions, coupled with complex chemometric methods that can easily be executed using modern microprocessors. The present edited volume intends to cover recent developments in NIRS and provide a broad perspective of some of the challenges that characterize the field. The volume comprises six chapters overall and covers several sectors. The target audience for this book includes engineers, practitioners, and researchers involved in NIRS system design and utilization in different applications. We believe that they will greatly benefit from the timely and accurate information provided in this work.

Pharmaceutical Applications of Raman Spectroscopy - Slobodan Sasic 2008-02-15

Raman spectroscopy has advanced in recent years with increasing use both in industry and academia. This is due largely to steady improvements in instrumentation, decreasing cost, and the availability of chemometrics to assist in the analysis of data. Pharmaceutical applications of Raman spectroscopy have developed similarly and this book will focus on those applications. Carefully organized with an emphasis on industry issues, Pharmaceutical Applications of Raman Spectroscopy, provides the basic theory of Raman effect and instrumentation, and then addresses a wide range of pharmaceutical applications. Current applications that are routinely used as well as those with promising potential are covered. Applications cover a broad range from discovery to manufacturing in the pharmaceutical industry and include identifying polymorphs, monitoring real-time processes, imaging solid dosage formulations, imaging active pharmaceutical ingredients in cells, and diagnostics.

Chemical Engineering - 2006

Forensic Chemistry - Jay A. Siegel 2015-10-05

Forensic Chemistry: Fundamentals and Applications presents a new approach to the study of applications of chemistry to forensic science. It is edited by one of the leading forensic scientists with each chapter written by international experts specializing in their respective fields, and presents the applications of chemistry, especially analytical chemistry, to various topics that make up the forensic scientists toolkit. This comprehensive, textbook includes in-depth coverage of the major topics in forensic chemistry including: illicit drugs, fibers, fire and explosive residues, soils, glass and paints, the chemistry of fingerprint recovery on porous surfaces, the chemistry of firearms analysis, as well as two chapters on the key tools of forensic science, microscopy and chemometrics. Each topic is explored at an advanced college level, with an emphasis, throughout the text, on the use of chemical tools in evidence analysis. Forensic Chemistry: Fundamentals and Applications is essential reading for advanced students of forensic science and analytical chemistry, as well as forensic science practitioners, researchers and faculty, and anyone who wants to learn about the fascinating subject of forensic chemistry in some depth. This book is published as part of the AAFS series 'Forensic Science in Focus'.

Infrared and Raman Spectroscopic Imaging - Reiner Salzer 2014-08-07
This second edition of the successful ready reference is updated and revised with approximately 30% new content to reflect the numerous instrumental developments and improvements, as well as the significant expansion of this rapidly developing field. For example, the combination of IR imaging with AFM has enhanced the achievable lateral resolution by an order of magnitude down to a few hundred nanometers, thus launching a multiplicity of new applications in material science. Furthermore, Raman and IR spectroscopic imaging have become key technologies for the life sciences and today contribute tremendously to a better and more detailed understanding of numerous biological and medical research topics. The topical structure of this new edition is now subdivided into four parts. The first treats the fundamentals of the instrumentation for infrared and Raman imaging and mapping and an overview on the chemometric tools for image analysis. The second part describes a wide varie-ty of applications ranging from biomedical via food, agriculture and plants to polymers and pharmaceuticals. This is followed by a description of imaging techniques operating beyond the diffraction limit, while the final part covers special methodical developments and their utility in specific fields. With its many valuable practical tips, this is a must-have overview for researchers in academic and industrial laboratories wishing to obtain reliable results with this method.
Beyond the Molecular Frontier - National Research Council 2003-03-19
Chemistry and chemical engineering have changed significantly in the last decade. They have broadened their scopeâ€"into biology, nanotechnology, materials science, computation, and advanced methods of process systems engineering and controlâ€"so much that the programs in most chemistry and chemical engineering departments now barely resemble the classical notion of chemistry. Beyond the Molecular Frontier brings together research, discovery, and invention across the entire spectrum of the chemical sciencesâ€"from fundamental, molecular-level chemistry to large-scale chemical processing technology. This reflects the way the field has evolved, the synergy at universities between research and education in chemistry and chemical engineering, and the way chemists and chemical engineers work together in industry. The astonishing developments in science and engineering during the 20th century have made it possible to dream of new goals that might previously have been considered unthinkable. This book identifies the key opportunities and challenges for the chemical sciences, from basic research to societal needs and from terrorism defense to environmental protection, and it looks at the ways in which chemists and chemical engineers can work together to contribute to an improved future.
Quality by Design for Biopharmaceuticals - Anurag S. Rathore 2011-09-20
The concepts, applications, and practical issues of Quality byDesign Quality by Design (QbD) is a new framework currently beingimplemented by the FDA, as well as EU and Japanese regulatoryagencies, to ensure better understanding of the process so as toyield a consistent and high-quality pharmaceutical product. QbDbreaks from past approaches in assuming that drug quality cannot betested into products; rather, it must be built into every step ofthe product creation process. Quality by Design: Perspectives and Case Studies presentsthe first systematic approach to QbD in the biotech industry. Acomprehensive resource, it combines an in-depth explanation ofbasic concepts with real-life case studies that illustrate thepractical aspects of QbD implementation. In this single source, leading authorities from thebiotechnology industry and the FDA discuss such topics as: The understanding and development of the product's criticalquality attributes (CQA) Development of the design space for a manufacturingprocess How to employ QbD to design a formulation process Raw material analysis and control strategy for QbD Process Analytical Technology (PAT) and how it relates toQbD Relevant PAT tools and applications for the pharmaceuticalindustry The uses of risk assessment and management in QbD Filing QbD information in regulatory documents The application of multivariate data analysis (MVDA) toQbD Filled with vivid case studies that illustrate QbD at work incompanies today, Quality by Design is a core reference forscientists in the biopharmaceutical industry, regulatory agencies,and students.
Carbon Dioxide Chemistry, Capture and Oil Recovery - Iyad Karamé 2018-08-16
Fossil fuels still need to meet the growing demand of global economic development, yet they are often considered as one of the main sources of the CO2 release in the atmosphere. CO2, which is the primary greenhouse gas (GHG), is periodically exchanged among the land surface, ocean, and atmosphere where various creatures absorb and produce it daily. However, the balanced processes of producing and consuming the CO2 by nature are unfortunately faced by the anthropogenic release of CO2. Decreasing the emissions of these greenhouse gases is becoming more urgent. Therefore, carbon sequestration and storage (CSS) of CO2, its utilization in oil recovery, as well as its conversion into fuels and chemicals emerge as active options and potential strategies to mitigate CO2 emissions and climate change, energy crises, and challenges in the storage of energy.
Spectroscopic Methods for Nanomaterials Characterization - Sabu Thomas 2017-05-19
Nanomaterials Characterization Techniques, Volume Two, part of an ongoing series, offers a detailed analysis of the different types of spectroscopic methods currently being used in nanocharacterization. These include, for example, the Raman spectroscopic method for the characterization of carbon nanotubes (CNTs). This book outlines the different kinds of spectroscopic tools being used for the characterization of nanomaterials and discusses under what conditions each should be used. The book is intended to cover all the major spectroscopic techniques for nanocharacterization, making it an important resource for both the academic community at the research level and the industrial community involved in nanomanufacturing. Explores how spectroscopy and X-ray-based nanocharacterization techniques are applied in modern industry Analyzes all the major spectroscopy and X-ray-based nanocharacterization techniques, allowing the reader to choose the best for their situation Presents a method-orientated approach that explains how to successfully use each technique