Residual Solvents Determination In Pharmaceutical Products

An internationally acclaimed reference work recognized as one of the most authoritative and comprehensive sources of information on excipients used in pharmaceutical formulation with this new edition providing 340 excipient monographs. Incorporates information on the uses, and chemical and physical properties of excipients systematically collated from a variety of international sources including: pharmacopeias, patents, primary and secondary literature, websites, and manufacturers' data; extensive data provided on the applications, licensing, and safety of excipients; comprehensively cross-referenced and indexed, with many additional excipients described as related substances and an international supplier's directory and detailed information on trade names and specific grades or types of excipients commercially available.

A comprehensive, extensive textual analysis of the principles of solvent selection and use, the handbook is intended to help formulators select ideal solvents, safety coordinators to protect workers, and legislators and inspectors to define and implement technically correct public safeguards for use, handling, and disposal.

The Karl Fischer titration is used in many different ways following its publication in 1935 and further applications are continually being explored. At the present time we are experiencing another phase of expansion, as shown by the development of new titration equipment and new reagents. KF equipment increasingly incorporates microprocessors which enable the course of a titration to be programmed thus sim plifying the titration. Coulometric titrators allow water determinations in the micro gram-range: the KF titration has become a micro-method. The new pyridine-free re agents make its application significantly more pleasant and open up further possibili ties on account of their accuracy. To make the approach to Karl Fischer titrations easier, we have summarized the present knowledge in this monograph and we have complemented it with our own studies and practical experience. As this book should remain "readable", we have tried to keep the fundamentals to a minimum. Historical developments are only mentioned if they seem to be necessary for understanding the KF reaction. The ap plications are

described more fully. Specific details which may interest a particular reader can be found in the original publications cited. The referenced literature is in chronological order as the year of publication may also prove informative. Thus, [6902] for example denotes 69 for 1969 being the year of publication and 02 is a non-recurring progressive number. The referenced litera ture includes summaries which we hope will be of help to find the "right" publica tion easily. [After payment, write to & get a FREE-of-charge, unprotected true-PDF from: Sales@ChineseStandard.net] This Method applies to the determination of residual solvent of pharmaceutical packaging materials. Residual solvent of pharmaceutical packaging materials refers to organic volatile substances which are used in the raw and auxiliary materials and the production process, but are not fully removed during the production process of pharmaceutical packaging materials. The residual quantity of organic solvent in pharmaceutical packaging materials shall be as specified for each product. The types of solvent to be tested shall be determined in accordance with the characteristics of formulas and technologies of products; they are not limited to the solvents described in this Standard.

Analytical Method Validation and Instrument Performance Verification

HPLC for Pharmaceutical Scientists

New Trends and Developments

Quality Management and Quality Control

Public Health Consequences of E-Cigarettes

Test for Residual Solvent of Packaging Materials [After payment, write to & get a FREE-of-charge, unprotected true-PDF from: Sales@ChineseStandard.net]

A comprehensive introduction for scientists engaged in new drug development, analysis, and approvals Each year the pharmaceutical industry worldwide recruits thousands of recent science graduates—especially chemistry, analytical chemistry, pharmacy, and pharmaceutical majors—into its ranks. However, because of their limited background in pharmaceutical analysis most of those new recruits find making the transition from academia to industry very difficult. Designed to assist both recent graduates, as well as experienced chemists or scientists with limited regulatory, compendial or pharmaceutical analysis background, make that transition, Pharmaceutical Analysis for Small Molecules is a concise, yet comprehensive introduction to the drug development process and analysis of chemically synthesized, small molecule drugs. It features contributions by distinguished experts in the field, including editor and author, Dr. Behnam Davani, an analytical chemist with decades of technical management and teaching experience in compendial, regulatory, and industry.

This book provides an introduction to pharmaceutical analysis for small molecules (non-biologics) using commonly used techniques for drug characterization and performance tests. The driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to regulatory bodies for drug approval in order to market their products. In addition, related required supporting studies including good laboratory/documentation practices including analytical instrument qualification are highlighted in this book. Topics covered include: Drug Approval Process and Regulatory Requirements (private standards) Pharmacopeias and Compendial Approval Process (public standards) Common methods in pharmaceutical analysis (typically compendial) Common Calculations for assays and impurities and other specific tests Analytical Method Validation, Verification, Transfer Specifications including how to handle out of specification (OOS) and out of trend (OOT) Impurities including organic, inorganic, residual solvents and elemental impurities Good Documentation Practices for regulatory environment Management of Analytical Laboratories Analytical Instrument Qualifications including IQ, OQ, PQ and VQ Due to global nature of pharmaceutical industry, other topics on both regulatory (ICH) and Compendial harmonization are also highlighted. Pharmaceutical Analysis for Small Molecules is a valuable working resource for scientists directly or indirectly involved with the drug development process, including analytical chemists, pharmaceutical scientists, pharmacists, and quality control/quality assurance professionals. It also is an excellent text/reference for graduate students in analytical chemistry, pharmacy, pharmaceutical and regulatory sciences.

Pharmaceutical analysis 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

Updated and revised throughout. Second Edition explores the chromatographic methods used for the measurement of drugs, impurities, and excipients in pharmaceutical preparations--such as tablets, ointments, and injectables. Contains a 148-page table listing the chromatographic data of over 1300 drugs and related substances--including sample matrix analyzed, sample handling procedures, column packings, mobile phase, mode of detection, and more.

*The only reference to provide both current and thorough coverage of this important analytical technique Static headspace-gas chromatography (HS-GC) is an indispensable technique for analyzing volatile organic compounds, enabling the analyst to assay a variety of sample matrices while avoiding the costly and time-consuming preparation involved with traditional GC. Static Headspace-Gas Chromatography: Theory and Practice has long been the only reference to provide in-depth coverage of this method of analysis. The Second Edition has been thoroughly updated to reflect the most recent developments and practices, and also includes coverage of solid-phase microextraction (SPME) and the purge-and-trap technique. Chapters cover: * Principles of static and*

dynamic headspace analysis, including the evolution of HS-GC methods and regulatory methods using static HS-GC * Basic theory of headspace analysis-physicochemical relationships, sensitivity, and the principles of multiple headspace extraction * HS-GC techniques-vials, cleaning, caps, sample volume, enrichment, and cryogenic techniques * Sample handling * Cryogenic HS-GC * Method development in HS-GC * Nonequilibrium static headspace analysis * Determination of physicochemical functions such as vapor pressures, activity coefficients, and more Comprehensive and focused, Static Headspace-Gas Chromatography, Second Edition provides an excellent resource to help the reader achieve optimal chromatographic results. Practical examples with original data help readers to master determinations in a wide variety of areas, such as forensic, environmental, pharmaceutical, and industrial applications.

Solvent Microextraction

Pharmaceutical Drug Analysis

Development and Validation of Analytical Methods

A Guide to Best Practice

Specification of Drug Substances and Products

Karl Fischer Titration

Identification and Determination of Impurities in DrugsElsevier

[Tips: You may ADDITIONALLY write to Sales@ChineseStandard.net for unprotected true-PDF] This method applies to the determination of residual solvents in pharmaceutical packaging materials. This method is based on the gas - solid balance. Take a certain area of the sample. Place into a sealed container. Under a certain temperature and time conditions, the organic solvent resided in the sample is heated and evaporated. After the equilibrium is reached, take headspace to quantitative inject into the gas chromatograph for analysis. Use the maintaining time to perform qualification. Use the peak area to perform quantitation. Determine according to the determination of residual organic solvents (Part 2, Chinese Pharmacopoeia 2010 edition).

The United States Food and Drug Administration (FDA) and other regulatory bodies around the world require that impurities in drug substance and drug product levels recommended by the International Conference on Harmonisation (ICH) be isolated and characterized. Identifying process-related impurities and degradation products also helps us to understand the production of impurities and assists in defining degradation mechanisms. When this process is performed at an early stage, there is ample time to address various aspects of drug development to prevent or control the production of impurities and degradation products well before the regulatory filing and thus assure production of a high-quality drug product. This book, therefore, has been designed to meet the need for a reference text on the complex process of isolation and characterization of process-related (synthesis and formulation) impurities and degradation products to meet critical requlatory requirements. It's objective is to provide guidance on isolating and characterizing impurities of pharmaceuticals such as drug candidates, drug substances, and drug products. The book outlines impurity identification processes and will be a key resource document for impurity analysis, isolation/synthesis, and characterization. - Provides valuable information on isolation and characterization of impurities. - Gives a regulatory perspective on the subject. - Describes various considerations involved in meeting regulatory requirements. - Discusses various sources of impurities and degredation products.

A great deal of confusion and uncertainty over genotoxic impurity (GTI) identification, assessment, and control exists in the pharmaceutical industry today. Pharmaceutical Industry Practices on Genotoxic Impurities strives to facilitate scientific and systematic consensus on GTI management by presenting rationales, strategies, methods, interpretations, practices, and case studies from the pharmaceutical industry. Featuring the contributions of industry leaders

from nine major pharmaceutical companies, this authoritative text: Explores the safety, quality, and regulatory aspects of GTIs Provides an overview of the latest FDA and EMEA guidelines Explains the how and why of various GTI control tactics and practices Describes genotoxicity evaluation, acceptable exposure calculation, and analytical methods for testing Includes real-life examples of GTI control in drug substance and drug product development processes Containing case studies from large and small pharmaceutical firms in multiple geographical regions, Pharmaceutical Industry Practices on Genotoxic Impurities supplies an overview of—and a current framework for—GTI control in the pharmaceutical industry, demonstrating how proper management of GTIs can occur with the appropriate guidance, a firm grasp of the practical implications, and effective information sharing between disciplines.

Chromatographic Analysis of Pharmaceuticals

Gas Chromatographic Headspace Analysis

Insights Into Pharmaceutical Processes, Management and Regulatory Affairs

Countering the Problem of Falsified and Substandard Drugs

Science and Applications

Theory and Practice

Pharmaceuticals, due to their pseudo-persistence and biological activity as well as their extensive use in human and veterinary medicine, are a class of environmental contaminants that is of emerging concern. In contrast to some conventional pollutants, they are continuously delivered at low levels, which might give rise to toxicity even without high persistence rates. These chemicals are designed to have a specific physiological mode of action and to resist frequently inactivation before exerting their intended therapeutic effect. These features, among others, result in the bioaccumulation of pharmaceuticals which are responsible for toxic effects in aquatic and terrestrial ecosystems. It is extremely important to know how to remove them from the environment and/or how to implement procedures or treatments resulting in their biological inactivation. Although great advances have been made in their detection in aquatic matrices, there remains limited analytical methodologies available for the trace analysis of target and non-target pharmaceuticals in matrices such as soils, sediments, or biota. There are still many gaps in the data on their fate and behavior in the environment as well as on their threats to ecological and human health. This book has included nine current research and three review articles in this field.

Pharmaceutical product development is a multidisciplinary activity involving extensive efforts in systematic product development and optimization in compliance with regulatory authorities to ensure the quality, efficacy and safety of resulting products. Pharmaceutical Product Development equips the pharmaceutical formulation scientist with extensive and up-to-date knowledge of drug product development and covers all steps from the beginning of product conception to the final packaged form that enters the market and lifecycle management thereof. Applications of core scientific principles for product development are also thoroughly discussed in conjunction with the latest approaches involving design of experiment and quality by design with comprehensive illustrations based on practical case studies of several dosage

forms. The book presents pharmaceutical product development information in an easy-to-read mode with simplified theories, case studies and guidelines for students, academicians and professionals in the pharmaceutical industry. It is an invaluable resource and hands-on guide covering managerial, regulatory and practical aspects of pharmaceutical product lifecycle management.

An introductory text, written with the needs of the student in mind, which explains all the most important techniques used in the analysis of pharmaceuticals - a key procedure in ensuring the quality of drugs . The text is enhanced throughout with keypoints and self-assessment boxes, to aid student learning. Features Includes worked calculations to demonstrate mathematics in use for pharmaceutical analysis. Focuses on key points rather than a large number of facts to help readers really understand the field as well as pass exams. Includes self-assessment, focussing on simple arithmetical calculation results from analytical data. Additional section on basic calculations in pharmaceutical analysis More detail on the capillary electrophoresis of proteins A discussion of some of the new types of HPLC column and on solvent selectivity in HPLC Additional material inserted on the control of the quality of analytical methods, mass spectrometry and high pressure liquid chromatography Additional self-assessment exercises About the Book: During the past two decades, there have been magnificent and significant advances in both analytical instrumentation and computerized data handling devices across the globe. In this specific context the remarkable proliferation of windows

Methods of Therapeutic Drug Monitoring Including Pharmacogenetics

Handbook of Analysis of Oligonucleotides and Related Products

Strategies for Identification and Control

Introduction to Pharmaceutical Analytical Chemistry

Pharmaceutical Analysis for Small Molecules

Determination of Water

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.

Quality control is a standard which certainly has become a style of living. With the improvement of technology every day, we meet new and complicated devices and methods in different fields. Quality control explains the directed use of testing to measure the achievement of a specific standard. It is the process, procedures and authority used to accept or reject all components, drug product containers, closures, in-process materials, packaging material, labeling and drug products, and the authority to review production records to assure that no errors have occurred.The quality which is supposed to be achieved is not a concept which can be controlled by easy, numerical or other means, but it is the control over the intrinsic quality of a test facility and its studies. The aim of this book is to share useful and practical knowledge about quality control in several fields with the people who want to improve their knowledge.

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.
This comprehensive up-to-date guide and information source is an instructive companion for all scientists involved in research and development of drugs and, in particular, of pharmaceutical dosage forms. The editors have taken care to address every conceivable aspect of the preparation of pharmaceutical salts and present the necessary theoretical foundations as well as a wealth of detailed practical experience in the choice of pharmaceutically active salts. Altogether, the contributions reflect the multidisciplinary nature of the science involved in selection of suitable salt forms for new drug products.
Handbook of Modern Pharmaceutical Analysis
Taxol
Pharmaceutical Industry Practices on Genotoxic Impurities
Green Chemistry Strategies for Drug Discovery
YBB60062012: Translated English of Chinese Standard. YBB6006-2012
YBB 00312004-2015: Translated English of Chinese Standard. YBB00312004-2015

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.
To facilitate the development of novel drug delivery systems and biotechnology-oriented drugs, the need for new excipients to be developed and approved continues to increase. Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems serves as a comprehensive source to improve understanding of excipients and forge new avenue
Methods of Therapeutic Drug Monitoring Including

Pharmacogenetics, Second Edition, Volume Seven in the Handbook of Analytical Separations series, covers all aspects of drug monitoring, including laboratory work, pharmacokinetic analysis and clinical aspects, thus enabling readers from different fields to understand the whole process of therapeutic drug monitoring and how to avoid common pitfalls. The book contains analytical techniques for the quantification of drugs, along with pharmacogenetic and pharmacogenomic methods. Also included are updates on sample preparation, including dried blood spot technology and microextraction methods. In addition, the book includes new drugs, such as tyrosine kinase inhibitors and the monitoring of immunosuppressant drugs. Presents a unique, interdisciplinary approach that appeals to a wide range of users Written by authors from international labs, providing a global perspective that can be applied in various regulatory environments Features additional therapeutic drugs to reflect the rising number of immunocompromised patients Includes a new mass spectroscopic methods chapter to capture the frequent use in TDM and the improved availability of LC-MS across laboratories

Examining the implications and practical implementation of multi-disciplinary International Conference on Harmonization (ICH) topics, this book gives an integrated view of how the guidelines inform drug development strategic planning and decision-making. • Addresses a consistent need for interpretation, training, and implementation examples of ICH guidelines via case studies • Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines • Uses case studies to help readers understand and apply ICH guidelines • Provides valuable insights into guidelines development, with chapters by authors involved in generating or with experience implementing the guidelines • Includes coverage of stability testing, analytical method validation, impurities, biotechnology drugs and products, and good manufacturing practice (GMP)

The Test Method for Residue of Solvent in Packaging Material [Tips: You may ADDITIONALLY write to Sales@ChineseStandard.net for unprotected true-PDF]

Pharmaceutical Analysis E-Book

Pharmaceutical Residues in the Environment

Method Validation in Pharmaceutical Analysis

An Implementation Guide

This volume brings together all aspects of TAXOL® research, development, and clinical use. It provides comprehensive knowledge of the compound and a perspective of the complex interrelationships needed for its development and production. Each chapter is

written by an authority in the field. Chapters are carefully coordinated to maximize information on key topics while avoiding overlap and duplication. Previously unpublished material is presented along with thorough reviews of each topic.

Learn to implement effective control measures for mutagenic impurities in pharmaceutical development In Mutagenic Impurities: Strategies for Identification and Control, distinguished chemist Andrew Teasdale delivers a thorough examination of mutagenic impurities and their impact on the pharmaceutical industry. The book incorporates the adoption of the ICH M7 guideline and focuses on mutagenic impurities from both a toxicological and analytical perspective. The editor has created a primary reference for any professional or student studying or working with mutagenic impurities and offers readers a definitive narrative of applicable guidelines and practical, tested solutions. It demonstrates the development of effective control measures, including chapters on the purge tool for risk assessment. The book incorporates a discussion of N-Nitrosamines which was arguably the largest mutagenic impurity issue ever faced by the pharmaceutical industry, resulting in the recall of Zantac and similar drugs resulting from N-Nitrosamine contamination. Readers will also benefit from the inclusion of: A thorough introduction to the development of regulatory guidelines for mutagenic and genotoxic impurities, including a historical perspective on the development of the EMEA guidelines and the ICH M7 guideline An exploration of in silico assessment of mutagenicity, including use of structure activity relationship evaluation as a tool in the evaluation of the genotoxic potential of impurities A discussion of a toxicological perspective on mutagenic impurities, including the assessment of mutagenicity and examining the mutagenic and carcinogenic potential of common synthetic reagents Perfect for chemists, analysts, and regulatory professionals, Mutagenic Impurities: Strategies for Identification and Control will also earn a place in the libraries of toxicologists and clinical safety scientists seeking a one-stop reference on the subject of mutagenic impurity identification and control.

A collection of recommended procedures for analysis and specifications for the determination of pharmaceutical substances, excipients and dosage forms intended to serve as source material for reference by any WHO member state.

Millions of Americans use e-cigarettes. Despite their popularity, little is known about their health effects. Some suggest that e-cigarettes likely confer lower risk compared to combustible tobacco cigarettes, because they do not expose users to toxicants produced through combustion. Proponents of e-cigarette use also tout the potential benefits of e-cigarettes as devices that could help combustible tobacco cigarette smokers to quit and thereby reduce tobacco-related health risks. Others are concerned about the exposure to potentially toxic substances contained in e-cigarette emissions, especially in individuals who have never used tobacco products such as youth and young adults. Given their relatively recent introduction, there has been little time for a scientific body of evidence to develop on the health effects of e-cigarettes. Public Health Consequences of E-Cigarettes reviews and critically assesses the state of the emerging evidence about e-cigarettes and health. This report makes recommendations for the improvement of this research and highlights gaps that are a priority for future research.

Wide Spectra of Quality Control

ICH Quality Guidelines

Handbook of Solvents

Leachables and Extractables Handbook

Static Headspace-Gas Chromatography

Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products

The adulteration and fraudulent manufacture of medicines is an old problem, vastly aggravated by modern manufacturing and trade. In the last decade, impotent antimicrobial drugs have compromised the treatment of many deadly diseases in poor countries. More recently, negligent production at a Massachusetts compounding pharmacy sickened hundreds of Americans. While the national drugs regulatory authority (hereafter, the regulatory authority) is responsible for the safety of a country's drug supply, no single country can entirely guarantee this today. The once common use of the term counterfeit to describe any drug that is not what it claims to be is at the heart of the argument. In a narrow, legal sense a counterfeit drug is one that infringes on a registered trademark. The lay meaning is much broader, including any drug made with intentional deceit. Some generic drug companies and civil society groups object to calling bad medicines counterfeit, seeing it as the deliberate conflation of public health and intellectual property concerns. Countering the Problem of Falsified and Substandard Drugs accepts the narrow meaning of counterfeit, and, because the nuances of trademark infringement must be dealt with by courts, case by case, the report does not discuss the problem of counterfeit medicines.

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

Impurity profiling is the common name of a group of analytical activities, the aim of which is the detection, identification/structure elucidation and quantitative determination of organic and inorganic impurities, as well as residual solvents in bulk drugs and pharmaceutical formulations. Since this is the best way to characterise the quality and stability of bulk drugs and pharmaceutical formulations, this is the core activity in modern drug analysis. Due to the very rapid development of the analytical methodologies available for this purpose and the similarly rapid increase of the demands as regards the purity of drugs it is an important task to give a summary of the problems and the various possibilities offered by modern analytical chemistry for their solution. That is the aim of this book. The book is methodology-oriented. In the first chapter some important aspects of the background of impurity-related analytical studies (toxicological, pharmacopoeial aspects, the characterisation of the sources of impurities and the role of impurity profiling in various fields of drug research, production and therapeutic use) are summarised. Chapter two deals with related organic impurities, the strategies for impurity profiling, the use of chromatographic and related separation methods, spectroscopic, and hyphenated techniques. The subject of the third chapter is the identification and determination of residual solvents. The determination of inorganic impurities is discussed in chapter four. The special problems of degradation products as impurities are dealt with in

chapter five. A separate chapter has been compiled to deal with one of the most up-to-date problems in contemporary pharmaceutical analysis, the estimation of enantiomeric purity of chiral drugs. Chapter seven is devoted to various approaches to solve the problem of polymorphic modifications as impurities. Since in the broader sense of the word the microbiological purity of drugs and drug products also belongs to this circle, the most important information from this field is summarised in chapter eight. After the mainly methodology-oriented chapters, the final one concentrates on four groups of drugs (peptides, biotechnological products, antibiotics and steroids) in order to demonstrate the use of the methods described earlier.

"Because leachables are non-drug-related impurities, there are increased concerns regarding the risks of inhaling them on a daily basis. This book describes the development and application of safety thresholds for Orally Inhaled and Nasal Drug Products (OINDP). It discusses best practices for evaluation and management of leachables and extractables throughout the pharma product lifecycle by providing practical knowledge about how and why safety thresholds were developed. This book also illustrates how to apply these concepts and principles to products beyond OINDP, and includes an appendix of experimental protocols for laboratory analysis"--Provided by publisher.

Identification and Determination of Impurities in Drugs

The International Pharmacopoeia

A Textbook for Pharmacy Students and Pharmaceutical Chemists

Handbook of Isolation and Characterization of Impurities in Pharmaceuticals

Handbook of Pharmaceutical Salts Properties, Selection, and Use

Mutagenic Impurities

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

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.

The incorporation of Green Chemistry is a relatively new phenomenon in the drug discovery discipline, since the scale that chemists operate on in drug discovery is smaller than those of process and manufacturing chemistry. The necessary metrics are more difficult to obtain in drug discovery due to the diversity of reactions conducted. However, pharmaceutical companies are realizing that incorporation of green chemistry techniques at earlier stages of drug development can speed the development of a drug candidate. Edited by experts who have pioneered green chemistry efforts within their own institutions, this book provides a practical guide for both academic and industrial labs wanting to know where to start with introducing greener approaches for greatest return on investment. The Editors have taken a comprehensive approach to the topic covering the entire drug discovery process from molecule conception, through synthesis, formulation and toxicology with specific examples and case studies where green chemistry strategies have been implemented. Currently employed as well as emerging techniques for performing greener drug discovery chemistry are addressed as well as cutting-edge topics like biologics discovery. Moreover, important surrounding issues such as intellectual property are included. This book will serve as a practical guide for both academic and industrial chemists who work across the breadth of the drug discovery discipline. Ultimately, readers will learn how to incorporate green chemistry strategies into their everyday workflow without slowing down their science.

This book aims to provide the reader with a working knowledge of the various means of controlling the solubility or dissolution rate of a drug or other solute in an aqueous medium. The book begins with the factors which govern solubility in general and then looks at aqueous solubility in particular, including the properties of liquid mixtures and the thermodynamics of solutions formed from mixing two components. The bulk of the book is then devoted to techniques for altering solubility and dissolution rate of organic compounds in aqueous media. It discusses in detail the most commonly used solubility enhancers: buffers, cosolvents, surfactants, and complexants. Each chapter is self-contained and emphasizes the details for applying the techniques.

Pharmaceutical Product Development

Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems

Solubility and Solubilization in Aqueous Media

Handbook of Pharmaceutical Excipients

Oligonucleotides represent one of the most significant pharmaceutical breakthroughs in recent years, showing great promise as diagnostic and therapeutic agents for malignant tumors, cardiovascular disease, diabetes, viral infections, and many other degenerative disorders. The Handbook of Analysis of Oligonucleotides and Related Products is an essential reference manual on the practical application of modern and emerging analytical techniques for the analysis of this unique class of compounds. A strong collaboration among thirty leading analytical scientists from around the world, the book provides readers with a comprehensive overview of the most commonly used analytical techniques and their advantages and limitations in assuring the identity, purity, quality, and strength of an oligonucleotide intended for therapeutic use. Topics discussed include: Strategies for enzymatic or chemical degradation of chemically modified oligonucleotides toward mass spectrometric sequencing Purity analysis by chromatographic or electrophoretic methods, including RP-HPLC, AX-HPLC, HILIC, SEC, and CGE Characterization of sequence-related impurities in oligonucleotides by mass spectrometry and chromatography Structure elucidation by spectroscopic methods (IR, NMR, MS) as well as base composition and thermal melt analysis

(Tm) Approaches for the accurate determination of molar extinction coefficient of oligonucleotides Accurate determination of assay values Assessment of the overall quality of oligonucleotides, including microbial analysis and determination of residual solvents and heavy metals Strategies for determining the chemical stability of oligonucleotides The use of hybridization techniques for supporting pharmacokinetics and drug metabolism studies in preclinical and clinical development Guidance for the presentation of relevant analytical information towards meeting current regulatory expectations for oligonucleotide therapeutics This resource provides a practical guide for applying state-of-the-art analytical techniques in research, development, and manufacturing settings.

Opisana je teorija in uporabnost headspace tehnike v plinski kromatografiji.

The definitive textbook on the chemical analysis of pharmaceutical drugs – fully revised and updated Introduction to Pharmaceutical Analytical Chemistry enables students to gain fundamental knowledge of the vital concepts, techniques and applications of the chemical analysis of pharmaceutical ingredients, final pharmaceutical products and drug substances in biological fluids. A unique emphasis on pharmaceutical laboratory practices, such as sample preparation and separation techniques, provides an efficient and practical educational framework for undergraduate studies in areas such as pharmaceutical sciences, analytical chemistry and forensic analysis. Suitable for foundational courses, this essential undergraduate text introduces the common analytical methods used in quantitative and qualitative chemical analysis of pharmaceuticals. This extensively revised second edition includes a new chapter on chemical analysis of biopharmaceuticals, which includes discussions on identification, purity testing and assay of peptide and protein-based formulations. Also new to this edition are improved colour illustrations and tables, a streamlined chapter structure and text revised for increased clarity and comprehension. Introduces the fundamental concepts of pharmaceutical analytical chemistry and statistics Presents a systematic investigation of pharmaceutical applications absent from other textbooks on the subject Examines various analytical techniques commonly used in pharmaceutical laboratories Provides practice problems, up-to-date practical examples and detailed illustrations Includes updated content aligned with the current European and United States Pharmacopeia regulations and guidelines Covering the analytical techniques and concepts necessary for pharmaceutical analytical chemistry, Introduction to Pharmaceutical Analytical Chemistry is ideally suited for students of chemical and pharmaceutical sciences as well as analytical chemists transitioning into the field of pharmaceutical analytical chemistry.

This book offers both a practical as well a theoretical approach to Solvent Microextraction (SME) and will help analytical chemists to evaluate SME for a given sample preparation. Introductory chapters overview a comparison of SME with other sample preparation methods, a summary of the technical aspects, and a detailed theoretical treatment of SME. The book then describes the practical aspects of the technique, with detailed "how to" chapters devoted to the preparation and analysis of atmospheric, solid and liquid environmental, clinical and industrial samples. This text will serve as both a handy laboratory desk-reference and an indispensible instructional tool.