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The Immunoassay Handbook John Wiley & Sons
This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and

biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Handbook of Pharmaceutical Analysis by HPLC John Wiley & Sons

The fourth volume in the six-volume Handbook of Pharmaceutical Manufacturing Formulations, this book covers semi-solid drugs. It includes ointments, lotions, gels, and suppositories, from publicly available but widely dispersed information from FDA New Drug Applications (NDA), patent applications, and the BASF book of generic formulations. Each entry begins with a fully validated scaleable manufacturing formula that includes compendial specification requirement for each ingredient, in-process controls for manufacturing and release of product, a summary of manufacturing process, and details of packaging.

Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook CRC Press

Pharmaceutical formulations remain as much an art today as they have evolved into complex science. With exponential growth of generic formulations, the need for ready formulations has increased. Essentially a cookbook for making drugs, the six-volume handbook contains the recipes and process steps for over 2000 drugs, including a number of biotechnology drugs. This first volume covers tablets, both coated and uncoated and oral powders. The author has painstakingly assembled this book from FDA New Drug Applications, patent

applications and the BASF book of generic formulations, all supplemented by his 30-plus years of experience in pharmaceutical formulations.

Handbook of Pharmaceutical Manufacturing Formulations CRC Press

In the view of most experts pharmacology is on drugs, targets, and actions. In the context the drug as a rule is seen as an active pharmaceutical ingredient and not as a complex mixture of chemical entities of a well defined structure. Today, we are becoming more and more aware of the fact that delivery of the active compound to the target site is a key. The present volume gives a topical overview on various modern approaches to drug targeting covering today's options for specific carrier systems allowing successful drug treatment at various sites of the body difficult to address and allowing to increase the benefit-risk-ratio to the optimum possible.

Drug Delivery Elsevier

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

Handbook of Pharmaceutical Excipients Springer Science & Business Media

The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients. Pharmaceutical Dosage Forms: Tablets, Third Edition is a comprehensive resource of the

design, formulation, manufacture, and evaluation of the tablet dosage form, an

Handbook of Polymers for Pharmaceutical Technologies, Structure and Chemistry American Bar Association

Describes tradename products and generic chemicals and materials, available from worldwide manufacturers, that function as pharmaceutical additives. Entires include chemical description, uses, regulatory, properties, and storage.

The Certified Pharmaceutical GMP Professional Handbook, Second Edition John Wiley & Sons

The purpose of this handbook is to assist individuals for the Certified Pharmaceutical Good Manufacturing Practices Professional (CPGP) examination and provide a reference for the practitioner. The second edition reflects the Body of Knowledge which was updated in 2015. This edition has also incorporated additional information including updated references. The updates reflect the current trends and expectations of the evolving pharmaceutical industry driven by consumer expectations and regulatory oversight. This handbook covers compliance with good manufacturing practices (GMPs), as

regulated and guided by national and international agencies for the pharmaceutical industry. It covers finished human and veterinary drugs and biologics, and combination devices, as well as their component raw materials (including active pharmaceutical ingredients (APIs) and excipients), and packaging and labeling operations.

Fermentation and Biochemical Engineering Handbook, 2nd Ed.

CRC Press

Revised to reflect significant advances in pharmaceutical production and regulatory expectations, Handbook of Validation in Pharmaceutical Processes, Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive. This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions. As the industry's leading source for validation of sterile pharmaceutical processes for more than 10 years, this greatly expanded work is a

comprehensive analysis of all the fundamental elements of pharmaceutical and bio-pharmaceutical production processes. Handbook of Validation in Pharmaceutical Processes, Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals. Key Features: Provides an in-depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program, and suggests the newest and most advanced solutions Explores distinctive and specific process steps, and identifies critical process control points to reach acceptable results New chapters include disposable systems, combination products, nano-technology, rapid microbial methods, contamination control in non-sterile products, liquid chemical sterilization, and medical device manufacture

Pharmaceutical Manufacturing Handbook

CRC Press

A practical overview of a full rangeof approaches to discovering, selecting, and producing biotechnology-derived drugs The Handbook of Pharmaceutical Biotechnology helps pharmaceutical scientists develop biotech drugs through a comprehensive framework that spans the process from discovery, development, and manufacturing through validation and registration. With chapters written by leading practitioners in their specialty areas, this reference: Provides an overview of biotechnology used in the drug development process Covers extensive applications, plus regulations and validation methods Features fifty chapters covering all the major approaches to the challenge of identifying, producing, and formulating new biologically derived therapeutics With its unparalleled breadth of topics and approaches, this handbook is a core reference for pharmaceutical scientists, including development researchers, toxicologists, biochemists, molecular biologists, cell biologists, immunologists, and formulation chemists. It is also a great resource for quality a ssurance/assessment/co ntrol managers, biotechnology technicians, and others in the biotech industry.

Pharmaceutical

Manufacturing Handbook Quality Press

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 regulatory 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.

Handbook of Drug Metabolism, Third Edition CRC Press

Aqueous solubility is one of the major challenges in the early stages of drug discovery. One of the most common and effective methods for enhancing solubility is the addition of an organic solvent to the aqueous solution. Along with an introduction to cosolvency models, the Handbook of Solubility Data for Pharmaceuticals provides an extensive database of solubility for pharmaceuticals in mono solvents and binary solvents. Aqueous solubility data can be found in the Handbook of Aqueous Solubility Data by Samuel Yalkowsky and Yan He. Visit

www.crcpress.com for more information. In addition to the experimental efforts to measure the solubility of drugs in mono and mixed solvents, this book discusses the advantages and limitations of a number of mathematical models used to predict the solubility in mono or mixed solvent systems. It covers the pharmaceutical cosolvents and other organic solvents that are used in syntheses, separations, and other pharmaceutical processes. The solutes featured include the available data for official drugs, drug candidates, precursors of drugs, metabolites, and degradation products of pharmaceuticals. The author also presents the solubilities of amino acids since they play an important role in peptide drug properties. Collecting drug solubilities in various cosolvents, this time-saving handbook includes the mixtures and model constants needed to predict undetermined solubilities. It describes

mathematical models that enable data to be derived and provides estimates on how drugs are likely to behave in a given cosolvent. A software program and associated user manual are available on the author’s website.

Pharmaceutical Dosage Forms - Tablets CRC Press

With the improvements in formulation science and certain transdermal delivery technologies, the non-invasive mode of drug delivery is now ready to compete with traditional methods of oral and injectible routes of drug delivery. The Handbook of Non-Invasive Drug Delivery Systems encompasses the broad field of non-invasive drug delivery systems that include drug delivery via topical, transdermal-passive, transdermal-active (device- aided enhanced penetration), trans-mucosal membrane, trans-ocular membrane as well as delivery via alveolar membrane from inhaled medication. Patient compliance has been found to be much higher when administrated by non-invasive routes and therefore they are considered to be a preferred mode of drug delivery. The book includes both science and technological aspects of new drug delivery systems. Its unique focus is that it is on new drug delivery systems that are considered to be "non-invasive". Other unique features include a chapter on

Regulatory Aspects of non-invasive systems and one on FDA guidance for topical nano-drug delivery. Two chapters covering market trends and perspectives, as well as providing guidance to those marketing such systems are also included.

Handbook of Pharmaceutical Biotechnology Synapse Information Resources Incorporated

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 Drug Administration via Enteral Feeding Tubes, 3rd edition CRC Press

Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises

of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is ‘current good manufacturing practice (CGMP)’‘, which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and

implementing quality assurance systems in the pharmaceutical sector.

Handbook of Pharmaceutical Manufacturing Formulations Amer Pharmacists Assn

The third volume in the six-volume Handbook of Pharmaceutical Manufacturing Formulations, this book covers liquid drugs, which include formulations of non-sterile drugs administered by any route in the form of solutions (monomeric and multimeric), suspensions (powder and liquid), drops, extracts, elixirs, tinctures, paints, sprays, colloidons, emul

Handbook of Isolation and Characterization of Impurities in Pharmaceuticals CRC Press

Stay up to date with changes in the biopharmaceutical products market! With the growth rate of biopharmaceutical products ascending rapidly since the 1980s, the number of biotechnology companies has risen to more than 1200 new businesses in the Unites States alone. This dramatic increase creates a new set of challenges in education, putting demands on teachers and students to keep pace with innovations in terminology and techniques. The Handbook of

Pharmaceutical Biotechnology is essential in meeting those challenges. A practical compendium of biotechnology-produced drugs, the Handbook of Pharmaceutical Biotechnology covers general principles of biotechnology and pharmaceuticals, putting usable information in the hands of those who need it most. The book presents descriptions that break down each pharmaceutical product by pharmacology, pharmacokinetics, clinical applications, toxicities, and dosage guidelines. It also reviews prescription products, discussing clinical uses and trials, adverse reactions, and more. Tables, figures, and extensive references add to each comprehensive summary. The Handbook of Pharmaceutical Biotechnology also includes up-to-date information on: monoclonal antibodies (Abciximab, Muromonab-CD3) enzymes and regulators of enzyme activity (Alteplase, clotting factors, Dornase alpha) anticytokines olgonucleotide and gene therapy hematopoietic growth factors (interleukins, interferons, colony stimulating factors, erythropoietin) As the worldwide production and sales of biotechnology-derived pharmaceuticals and diagnostics continues to grow, teachers, students, and clinical pharmacists need to maintain a clear and current understanding of the field. The Handbook of

Pharmaceutical Biotechnology presents a thoughtful and thorough guide to keeping pace in this evolving industry.

Handbook of Bioequivalence Testing John Wiley & Sons

Exploring the analysis of pharmaceuticals, including polymorphic forms, this book discusses regulatory requirements in pharmaceutical product development and pharmaceutical testing. It covers methods of drug separation and procedures such as capillary electrophoresis for chromatographic separation of molecules. Additional topics include drug formulation analysis using vibrational and magnetic resonance spectroscopy and identification of drug metabolites and decomposition products using such techniques as mass spectrometry. The book provides more than 300 tables, equations, drawings, and photographs, and convenient, easy-to-use indices, facilitating quick access to each topic.

Handbook of Research Methodology Elsevier Health Sciences

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.

Handbook of Pharmaceutical Biotechnology Royal Society of Chemistry

With its coverage of Food and Drug Administration regulations, international regulations, good

manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.