Biopharmaceutics Practical Manual

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Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems McGraw Hill Professional
Laboratory Manual of Biopharmaceutics and PharmacokineticsLaboratory Manual for Pharmaceutical Technology and Biopharmaceutics ExperimentsPractical guide of biopharmaceutics and pharmacokinetics for B.pharm studentsBlue Rose Publishers
Aulton's Pharmaceutics Elsevier Health Sciences
The third edition of this introductory text covers the factors which influence the release of the drug from the drug product and how the body handles the drug. A stronger focus has been placed on the basics with clear explanations and illustrated examples. There is also more information on statistics and population pharmacokinetics and new chapters on drug distribution, computer applications, enzyme kinetics and pharmacokinetics models.
Biopharmaceutics and Pharmacokinetics Createspace Independent Publishing Platform
The most comprehensive text on the practical applications of biopharmaceuticals and pharmacokinetics! 4 STAR DOODY'S REVIEW! "The updated edition provides the reader with a solid foundation in the basic principles of pharmacokinetics and biopharmaceutics. Students will be able to apply the information to their clinical practice and researchers will find this to be a valuable reference. This modestly priced book should be the gold standard for student use."--Doody's Review Service The primary emphasis of this book is on the application and understanding of concepts. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided, along with illustrative examples and practice problems and solutions to help the student gain skill in practical problem solving.
Healthcare Biotechnology John Wiley & Sons
This book volume provides complete and updated information on the applications of Design of Experiments (DoE) and related multivariate techniques at various stages of pharmaceutical product development. It discusses the applications of experimental designs that shall include oral, topical, transdermal, injectables preparations, and beyond for nanopharmaceutical product development, leading to dedicated case studies on various pharmaceutical experiments through illustrations, art-works, tables and figures. This book is a valuable guide for all academic and industrial researchers, pharmaceutical and biomedical scientists, undergraduate and postgraduate research scholars, pharmacists, biostatisticians, biotechnologists, formulations and process engineers, regulatory affairs and quality assurance personnel.
Handbook of Bioequivalence Testing CRC Press
Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in final form on January 24, 2011. The book also provides guidelines and current practices, as well as industrial case studies illustrating the different approaches that can be taken for successful validation of biopharmaceutical processes. Case studies include Process validation for membrane chromatography Leveraging multivariate analysis tools to qualify scale-down models A matrix approach for process validation of a multivalent bacterial vaccine Purification validation for a therapeutic monoclonal antibody expressed and secreted by Chinese Hamster Ovary (CHO) cells Viral clearance validation studies for a product produced in a human cell line A much-needed resource, this book presents process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing, including chromatography, chemical modification reactions, ultrafiltration, and microfiltration. It also provides practical methods to test raw materials and in-process samples. Stressing the importance of taking a risk-based approach towards computerized system compliance, this book will help you and your team ascertain process validation is carried out and exceeds expectations.
Pharmaceutical Biotechnology CRC Press
**** A must have book for every cancer patient ****THIRD REVISED EDITION NEW CHAPTERS ADDED**** This book provides both an introduction of Dr. Budwig's cancer research and treatment. Johanna Budwig (1908-2003) who was nominated for the Nobel Prize seven times was one of Germany's leading scientists of the 20th Century, a biochemist and Cancer specialist with a special interest in essential fats.Otto Warburg proved that prime cause of cancer oxygen-deficiency in the cells. In absence of oxygen cells ferment glucose to produce energy, lactic acid is formed as a byproduct of fermentation. He postulated that sulfur containing protein and some unknown fat is required to attract oxygen in the cell.In 1951 Dr. Budwig developed Paper Chromatography to identify fats. With this technique she proved that electron rich highly unsaturated Linoleic and Linolenic fatty acids were the undiscovered mysterious decisive fats in respiratory enzyme function that Otto Warburg had been unable to find. She studied the electromagnetic function of pi-electrons of the linolenic acid in the membranes of the microstructure of protoplasm, for all nerve function, secretions, mitosis, as well as cell break-down. This immediately caused lot of excitement in the scientific community. New doors could open in Cancer research. Hydrogenated fats, including all Trans fatty acids were proved as respiratory poisons.Then Budwig decided to have human trials and gave flaxseed oil and quark to cancer patients. After three months, the patients began to improve in health and strength, the yellow green substance in their blood began to disappear, tumors gradually receded and at the same time the nutrients began to rise. This way Dr. Budwig had found a cure for cancer. It was a great victory and first milestone in the battle against cancer. Her treatment protocol is based on the consumption of flax seed oil with low fat cottage cheese, raw organic diet, mild exercise, and the healing powers of the sun. She treated approx. 2500 cancer patients during a 50 year period with this protocol till her death with over 90% documented success.She was nominated 7 times for Nobel Prize but with a condition that she will use chemotherapy and radiotherapy with her protocol. They did not want to collapse the 200 billion business over night. She always refused to support the damaging chemo and radio for the sake of humanity.Lothar Hirneise - Great supporter of Budwig ProtocolLothar Hirneise is founder and President of People Against Cancer, Germany. He travels a lot in search of finding most successful alternative cancer therapies. He has been student of Dr. Johanna Budwig. He is a great researcher and writer on alternative healing. He is successfully treating thousands of cancer patients at his 3-E center in Germany. In the last few years he has interviewed several hundred final stage so-called survivors, meaning patients who were in the final stage of cancer and who are all healthy again today. Based on his findings he proposed a 3 E Program - The Mnemonic of Cancer Treatment.1) Eat well2) Eliminate3) EnergyHe noticed that 100% of all survivors, did the energy work. In approximately - say 80% of all patients, He found a change in diet. And in at least 60% of all patients, took intensive detoxification rituals. This is the basis of his, so much talked about 3E Program for healing cancer.Lothar strongly supports holistic and spiritual approach and includes Visualization, Tumor Contract, Meditation, mild Yoga, Emotional Freesom Technique EFT, Dr. Ryke Geerd Hamer's New German Medicine (Connection of unresolved stress and cancer), Detoxification techniques (Soda Bicarb bath, Epsom bath, Colon Hydrotherapy, Coffee Enema etc.) in his so much talked about 3 E Program.The book also, describes about rare and miraculous herbs used in the treatment of Cancer like Turmeric, Black seed, Ginger, Mistle Toe, Aloe vera, Echinecea, Lobelia, Essiac Tea, Pau d'arco Tea, Dandelion, Milk Thistle.
High Throughput Screening CRC Press
Pharmaceutical Microbiology: Essentials for Quality Assurance and Quality Control presents that latest information on protecting pharmaceutical and healthcare products from spoilage by microorganisms, and protecting patients and consumers. With both sterile and non-sterile products, the effects can range from discoloration to the potential for fatality. The book provides an overview of the function of the pharmaceutical microbiologist and what they need to know, from regulatory filing and GMP, to laboratory design and management, and compendia tests and risk assessment tools and techniques. These key aspects are discussed through a series of dedicated chapters, with topics covering auditing, validation, data analysis, bioburden, toxins, microbial identification, culture media, and contamination control. Contains the applications of pharmaceutical microbiology in sterile and non-sterile products Presents the practical aspects of pharmaceutical microbiology testing Provides contamination control risks and remediation strategies, along with rapid microbiological methods Includes bioburden, endotoxin, and specific microbial risks Highlights relevant case studies and risk assessment scenarios
Manual of Laboratory Pharmacokinetics CRC Press
Foreseeing and planning for all of the possibilities and pitfalls involved in bringing a biotechnology innovation from inception to widespread therapeutic use takes strong managerial skills and a solid grounding in biopharmaceutical research and development procedures. Unfortunately there has been a dearth of resources for this aspect of the field.
Biopharmaceutics Modeling and Simulations McGraw-Hill Education / Medical
The six years that have passed since the publication of the first edition have brought significant advances in both biofilm research and biofilm engineering, which have matured to the extent that biofilm-based technologies are now being designed and implemented. As a result, many chapters have been updated and expanded with the addition of sections
Practical Guide to Hot-Melt Extrusion McGraw Hill Professional
Over the past few decades, hot-melt extrusion (HME) techniques have been shown to exhibit remarkable potential for the manufacture of various pharmaceutical products. HME is an emerging processing technology used primarily for the manufacture of pharmaceutical solid dispersions, combining the advantages of a solvent-free process with fewer production steps making it suitable for easy to scale-up and continuous manufacturing applications. A single unit HME based operation, employing heat and mechanical shear, has displayed a significant potential to retain the stability even of thermo-labile therapeutics e.g., proteins. HME has now explicitly been established from a quality-by-design viewpoint for in-line data monitoring as per the recent guidelines issued by the US Food and Drugs Administration (FDA).This book will focus primarily on the foregoing subject areas and will be of significant interest to a broad/interdisciplinary readership across the industries and academia for, (but not limited to) the following reasons:- Emerging HME processes and applications for multiple drug delivery.- Solid-state engineering, solubility enhancement, controlled release, taste masking and sustained release case studies from a continuous manufacturing view-point.- Means to explore the potential of continuous manufacture of co-crystals for promoting solvent free production methods.- Scale-up case study and issue considerations and studies on the regulatory guidelines (FDA) for continuous manufacturing involving emerging HME techniques.
Applied Biopharmaceutics & Pharmacokinetics, Eigth Edition Woodhead Publishing
As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct efficient and successful bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence, and advances in the analytical technology used to detect drug and metabolite levels have made
Catalog of Copyright Entries. Third Series John Wiley & Sons
Martin's Physical Pharmacy and Pharmaceutical Sciences is considered the most comprehensive text available on the application of the physical, chemical and biological principles in the pharmaceutical sciences. It helps students, teachers, researchers, and industrial pharmaceutical scientists use elements of biology, physics, and chemistry in their work and study. Since the first edition was published in 1960, the text has been and continues to be a required text for the core courses of Pharmaceutics, Drug Delivery, and Physical Pharmacy. The Sixth Edition features expanded content on drug delivery, solid oral dosage forms, pharmaceutical polymers and pharmaceutical biotechnology, and updated sections to cover advances in nanotechnology.
Pharmaceutics – Practical Manual (According to the PCI new Syllabus as per ER-2020) D. Pharm- First year Springer Science & Business Media
A comprehensive introduction to using modeling and simulation programs in drug discovery and development Biopharmaceutical modeling has become integral to the design and development of new drugs. Influencing key aspects of the development process, including drug substance design, formulation design, and toxicological exposure assessment, biopharmaceutical modeling is now seen as the

linchpin to a drug's future success. And while there are a number of commercially available software programs for drug modeling, there has not been a single resource guiding pharmaceutical professionals to the actual tools and practices needed to design and test safe drugs. A guide to the basics of modeling and simulation programs, Biopharmaceutics Modeling and Simulations offers pharmaceutical scientists the keys to understanding how they work and are applied in creating drugs with desired medicinal properties. Beginning with a focus on the oral absorption of drugs, the book discusses: The central dogma of oral drug absorption (the interplay of dissolution, solubility, and permeability of a drug), which forms the basis of the biopharmaceutical classification system (BCS) The concept of drug concentration How to simulate key drug absorption processes The physiological and drug property data used for biopharmaceutical modeling Reliable practices for reporting results With over 200 figures and illustrations and a peerless examination of all the key aspects of drug research—including running and interpreting models, validation, and compound and formulation selection—this reference seamlessly brings together the proven practical approaches essential to developing the safe and effective medicines of tomorrow.

Biopharmaceutics Applications in Drug Development Springer Science & Business Media

This is an essential guide to the study of absorption, distribution, metabolism and elimination of drugs in the body.

The Road from Nanomedicine to Precision Medicine Smithers Rapra

The book has been designed for pharmacy students as per the new syllabus (ER-2020) prescribed by Pharmacy Council of India (PCI). This book contains essential information that students gathered knowledge for formulation various dosage forms and prepare for competitive as well as annual or semester examination. Its primary objective is to provide knowledge about various formulation aspect which helpful for formulating a dosage form. This textbook has been written in easy language to ensure a lower reading level and understandable contents than ever. This book covers all major pharmaceutics dosage forms formulation. This book contains many chapters, each providing a description of various dosage forms formulation and their evaluation like syrup, suspension, emulsion, cream, ointment, lotion, lineaments, gel, tablets capsule, dusting powder, effervescent powder, injection, cosmetic preparation, evaluation of tablets, capsule, emulsion, parenteral products, and use of insulin pen, inhalers and spacer.

KY Publications

The highly experienced authors here present readers with step-wise, detail-conscious information to develop quality pharmaceuticals. The book is made up of carefully crafted sections introducing key concepts and advances in the areas of dissolution, BA/BE, BCS, IVIC, and product quality. It provides a specific focus on the integration of regulatory considerations and includes case histories highlighting the biopharmaceutics strategies adopted in development of successful drugs.

Fundamentals of Biofilm Research Springer Science & Business Media

FDA Regulatory Affairs is a roadmap to prescription drug, biologics, and medical device development in the United States. Written in plain English, the concise and jargon-free text demystifies the inner workings of the US Food and Drug Administration (FDA) and facilitates an understanding of how the agency operates with respect to compliance and product approval, including clinical trial exemptions, fast track status, advisory committee procedures, and more. The Third Edition of this highly successful publication: Examines the harmonization of the US Federal Food, Drug, and Cosmetic Act with international regulations on human drug, biologics and device development, research, manufacturing, and marketing Includes contributions from experts at organizations such as the FDA, National Institutes of Health (NIH), and PAREXEL Focuses on the new drug application (NDA) process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements Provides updates to the FDA Safety and Innovation Act (FDASIA), incorporating pediatric guidelines and follow-on biologics regulations from the 2012 Prescription Drug User Fee Act (PDUFA) V Explains current FDA inspection processes, enforcement options, and how to handle FDA meetings and required submissions Co-edited by an industry leader (Mantus) and a respected academic (Pisano), FDA Regulatory Affairs, Third Edition delivers a compilation of the selected US laws and regulations as well as a straightforward commentary on the FDA product approval process that ' s broadly useful to both business and academia.

Laboratory Manual of Biopharmaceutics and Pharmacokinetics Laboratory Manual of Biopharmaceutics and PharmacokineticsLaboratory Manual for Pharmaceutical Technology and Biopharmaceutics ExperimentsPractical guide of biopharmaceutics and pharmacokinetics for B.pharm students This book is prepared to cover the practicals of biopharmaceutics and pharmacokinetics to be performed during the B.Pharm curriculum. The practicals cover different topics of biopharmaceutics and pharmacokinetics related to analysis of pharmacokinetic parameters by different methods. The special emphasis is given on the procedure of practicals which will be helpful for the teachers as well as students with greater ease of understanding the concepts of biopharmaceutics and pharmacokinetics. Many books are available which deal with theoretical aspects of the subject but very few such books are available that deal with practical aspects. So this book will be very helpful to the academicians as well as the industry in understanding the concepts of biopharmaceutics and pharmacokinetics. This book is written in simple language to help in understanding the concepts of biopharmaceutics and pharmacokinetics.

Cancer - Cause and Cure BFC Publications

Pharmaceutical Biotechnology is a unique compilation of reviews addressing frontiers in biologicals as a rich source for innovative medicines. This book fulfills the needs of a broad community of scientists interested in biologicals from diverse perspectives—basic research, biotechnology, protein engineering, protein delivery, medicines, pharmaceuticals and vaccinology. The diverse topics range from advanced biotechnologies aimed to introduce novel, potent engineered vaccines of unprecedented efficacy and safety for a wide scope of human diseases to natural products, small peptides and polypeptides engineered for discrete prophylaxis and therapeutic purposes. Modern biologicals promise to dramatically expand the scope of preventive medicine beyond the infectious disease arena into broad applications in immune and cancer treatment, as exemplified by anti-EGFR receptors antibodies for the treatment of breast cancer. The exponential growth in biologicals such as engineered proteins and vaccines has been boosted by unprecedented scientific breakthroughs made in the past decades culminating in an in-depth fundamental understanding of the scientific underpinnings of immune mechanisms together with knowledge of protein and peptide scaffolds that can be deliberately manipulated. This has in turn led to new strategies and processes. Deciphering the human, mammalian and numerous pathogens ' genomes provides opportunities that never before have been available—identification of discrete antigens (genomes and antigenomes) that lend themselves to considerably improved antigens and monoclonal antibodies, which with more sophisticated engineered adjuvants and agonists of pattern recognition receptors present in immune cells, deliver unprecedented safety and efficacy. Technological development such a nanobiotechnologies (dendrimers, nanobodies and fullerenes), biological particles (viral-like particles and bacterial ghosts) and innovative vectors (replication-competent attenuated, replication-incompetent recombinant and defective helper-dependent vectors) fulfill a broad range of cutting-edge research, drug discovery and delivery applications. Most recent examples of breakthrough biologicals include the human papilloma virus vaccine (HPV, prevention of women genital cancer) and the multivalent Pneumoccocal vaccines, which has virtually eradicated in some populations a most prevalent bacterial ear infection (i.e., otitis media). It is expected that in the years to come similar success will be obtained in the development of vaccines for diseases which still represent major threats for human health, such as AIDS, as well as for the generation of improved vaccines against diseases like pandemic flu for which vaccines are currently available. Furthermore, advances in comparative immunology and innate immunity revealed opportunities for innovative strategies for ever smaller biologicals and vaccines derived from species such as llama and sharks, which carry tremendous potential for innovative biologicals already in development stages in many pharmaceutical companies. Such recent discoveries and knowledge exploitations hold the promise for breakthrough biologicals, with the coming decade. Finally, this book caters to individuals not directly engaged in the pharmaceutical drug discovery process via a chapter outlining discovery, preclinical development, clinical development and translational medicine issues that are critical the drug development process. The authors and editors hope that this compilation of reviews will help readers rapidly and completely update knowledge and understanding of the frontiers in pharmaceutical biotechnologies.

Pharmaceutical Manufacturing Handbook Blue Rose Publishers

This book is an invaluable source designed to meet the needs of pharm.D and other pharmacy courses. This book was made according to the PCI syllabus. This book covers topics like syrups, elixirs, linctus, solutions, liniments, suspensions, emulsions, powders, suppositories, incompatibilities, with an introduction before it. This book helps the student to write the academic pharmaceutics record more easily. It has been noticed that practical of pharmaceutics leave students a little confused, especially during their examination. Finally, this book aims to present the practicals in a student friendly style so that they can easily grasp and do the practicals in the lab more easily by own which interns will help them to achieve the best grades in examinations.