DRUGS AND THE PHARMACEUTICAL SCIENCES

Volume 213

HANDBOOK OF BIOEQUIVALENCE TESTING

Second Edition



Sarfaraz K. Niazi



Sarfaraz K. Niazi

Handbook of Bioequivalence Testing Sarfaraz K. Niazi, 2014-10-29 As the generic pharmaceutical industry continues to grow and thrive so does the need to conduct adequate efficient bioequivalence studies In recent years there have been significant changes to the statistical models for evaluating bioequivalence In addition advances in the analytical technology used to detect drug and metabolite levels have m Handbook of Bioequivalence Testing Sarfaraz K. Niazi, 2007-08-22 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 Handbook of Pharmaceutical Granulation Technology Dilip M. Parikh, 2021-05-11 This fully revised edition of Handbook of Pharmaceutical Granulation Technology covers the rapid advances in the science of agglomeration process control process modelling scale up emerging particle engineering technologies along with current regulatory changes presented by some of the prominent scientist and subject matter experts around the globe Learn from more than 50 global subject matter experts who share their years of experience in areas ranging from drug delivery and pharmaceutical technology to advances in nanotechnology Every pharmaceutical scientist should own a copy of this fourth edition resource Key Features Theoretical discussions covering granulation and engineering perspectives Covers new advances in expert systems process modelling and bioavailability Chapters on emerging technologies in particle engineering Updated Current research and developments **Neuropsychopharmacology** Jahangir Moini, Anthony LoGalbo, Jennifer G. in granulation technologies Schnellmann, 2023-05-10 Neuropsychopharmacology reviews the principles of pharmacology with a focus on the central nervous system and autonomic nervous system Beyond autonomic and central nervous system pharmacology this volume uniquely discusses psychiatric disorders and the pharmacological interventions that are available for conditions including depression schizophrenia and anxiety disorders With a focus on these specific body systems readers will see end of chapter questions that offer real world case studies as well as multiple choice questions for further learning Beneficial features and content also include two extensive examination tests which each contain 100 questions for better learning or to be used in teaching and a glossary Helpful appendices cover high alert medications and toxicology effects on the nervous system Each chapter will contain classifications of medications pharmacokinetics mechanism of action clinical indications and toxicities Describes pharmacology principles pertaining to the central and autonomic nervous system Identifies pharmacological interventions for psychiatric disorders including current evidence based interventions for depression schizophrenia and anxiety disorders Features chapter outlines end of chapter questions real world case studies and examinations for deeper learning or teaching A Guide to Particulate Science in Pharmaceutical Product Development Margaret D. Louey, Timothy M. Crowder, Anthony J. Hickey, 2025-08-04 The pharmaceutical applications of powder technology have long been recognized

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auditors is on the rise in all organizations that are required to implement FDA EMA MHRA WHO TGA and PIC S regulations This volume is an essential reference source for those organizations operating in the field of health and presents the basic knowledge needed to perform audits The author also provides useful tips and a selection of samples about GMP audits that are indispensable for professionals and health inspectors working in industry and health authorities Features An essential reference source for those organizations operating in the field of health and presents the basic knowledge needed to perform audits Anyone working in the manufacturing sector needs to be aware of GMP be able to identify operational flaws as well as legal violations and have a clear understanding of how to meet GMP standards Assists readers in understanding the importance of GMP and how they can apply each aspect in their working environment Covers a global regulatory landscape Suitable for relevant degree courses including industrial pharmaceutics and pharmaceutical biotechnology Principles of Research Methodology and Ethics in Pharmaceutical Sciences Vikas Anand Saharan, Hitesh Kulhari, Hemant R Jadhav, 2024-08-30 Pharmaceutical researchers are constantly looking for drug products drug delivery systems and devices for improving the health of society A scientific and systematic search for new knowledge requires a thorough understanding of research methods and hypothesis design This volume presents pharmaceutical research through theoretical concepts methodologies and ethical issues It fulfils publication ethics course work requirements for students Chapters have been designed to cater for the curriculum requirements of universities globally This serves as a guide on how to apply concepts in designing experiments and transforming laboratory research into actual practice Features Complete coverage of research methodology courses for graduate and postgraduate students globally Step by step assistance in writing technical reports projects protocols theses and dissertations Experimental designing in pharmaceutical formulation development and preclinical research designs Ethics in using animals in preclinical research and humans in clinical research Publication ethics best practices and guidelines for ensuring ethical writing Hypothetical and real world case studies on ethical issues and Pharmaceutical Preformulation and Formulation Mark Gibson, 2016-04-19 measures for prevention and control Pharmaceutical Preformulation and Formulation A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug development and launch process as well as the shift from developing small molecules to the growth of biopharmaceuticals The book meets the ne

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biotechnology information in this rapidly burgeoning field is a basic rationale here However a more prominent underpinning is that bringing biotech products to market for patient care involves success in the following four areas of engagement simultaneously scientific advances for healthcare technologies novel and varied products for untreated diseases regulatory authorities and biotech companies Features Comprehensive coverage of biotechnology science topics used in development and manufacturing Addresses all the scientific technologies within biotechnology responsible for products on the market and the pipeline Presents business issues such as marketing and sales of the products as well as companies engaged and how biotech business has evolved Biosimilar Drug Product Development Laszlo Endrenyi, Dr. Paul Declerck, Shein-Chung Chow, 2017-02-24 When a biological drug patent expires alternative biosimilar products are developed. The development of biosimilar products is complicated and involves numerous considerations and steps The assessment of biosimilarity and interchangeability is also complicated and difficult Biosimilar Drug Product Development presents current issues for the development of biosimilars and gives detailed reviews of its various stages and contributing factors as well as relevant regulatory pathways and pre and post approval issues Proteins and Peptides Randall J. Mrsny, Ann Daugherty, 2009-10-19 Addressing the increased use of protein and peptide candidates as treatments for previously untreatable diseases this comprehensive and progressive source provides the reader with a roadmap to an increased understanding of issues critical for successfully developing a protein or peptide therapeutic candidate Proteins and Peptides Drug Delivery Nanoparticles Formulation and Characterization Yashwant Pathak, Deepak Thassu, 2016-04-19 Exploring fundamental concepts Drug Delivery Nanoparticles Formulation and Characterization presents key aspects of nanoparticulate system development for various therapeutic applications and provides advanced methods used to file for regulatory approval This comprehensive guide features Process Analytical Techniques PAT used in manufacturing Na

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