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VOLUME 210

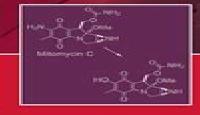
PHARMACEUTICAL STRESS TESTING

PREDICTING DRUG DEGRADATION

SECOND EDITION







Steven W. Baertschi Karen M. Alsante Robert A. Reed



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Hickey, Sandro on current good design practices R. da Rocha, 2019-03-26 This fully revised and updated third edition of Pharmaceutical Inhalation Aerosol Technology encompasses the scientific and technical foundation for the rationale design componentry assembly and quality performance metrics of therapeutic inhalers in their delivery of pharmaceutical aerosols to treat symptoms or the underlying causes of disease It focuses on the importance of pharmaceutical engineering as a foundational element of all inhaler products and their application to pulmonary drug delivery The expanded scope considers previously unaddressed aspects of pharmaceutical inhalation aerosol technology and the patient interface by including aerosol delivery lung deposition and clearance that are used as measures of effective dose delivery Key Features Provides a thoroughly revised and expanded reference with authoritative discussions on the physiologic pharmacologic metabolic molecular cellular and physicochemical factors influencing the efficacy and utilization of pharmaceutical aerosols Emphasizes the importance of pharmaceutical engineering as a foundational element of all inhaler products and their application to pulmonary drug delivery Addresses the physics chemistry and engineering principles while establishing disease relevance Expands the technology focus of the original volumes to address the title more directly Offers an impressive breadth of coverage as well as an international flavour from outstanding editors and contributors 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

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must be approved as the approved as the rapeutic equivalents to the brand name alternative in order to be interchangeable. The demonstration of bioequivalence is an important comp **Biotechnology** Ronald P. Evens, 2020-06-04 The over riding premise for biotechnology in this book is bringing novel products to market to substantially advance patient care and disease mitigation Biotechnology over its relatively brief existence of 40 years has experienced a mercurial growth The vast educational need for 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 Generic Drug Product Development Leon Shargel, Isadore Kanfer, 2013-10-24 In this era of increased pharmaceutical industry competition success for generic drug companies is dependent on their ability to manufacture therapeutic equivalent drug products in an economical and timely manner while also being cognizant of patent infringement and other legal and regulatory concerns Generic Drug Product Development Solid Oral Dosage Forms Second Edition presents in depth discussions from more than 30 noted specialists describing the development of generic drug products from the raw materials to the development of a therapeutic equivalent drug product to regulatory approval Major topics discussed include Active pharmaceutical ingredients Experimental formulation development including a new section on Quality by Design ObD Scale up Commercial product formulation Quality control and bioequivalence Drug product performance ANDA regulatory process Post approval changes Post marketing surveillance Legislative and patent challenges This second edition also contains a new chapter on the relationship between the FDA and the United States Pharmacopeia and in Chapter 4 using specific examples the application of Quality by Design QbD during formulation development is examined The book is a thorough guide to the development of solid oral generic dosage formulations This textbook is ideal for the pharmaceutical industry graduate programs in pharmaceutical sciences and health professionals working in the area of generic drug development **Oral Drug Absorption** Jennifer B. Dressman, Christos Reppas, 2016-04-19 Oral Drug Absorption Second Edition thoroughly examines the special equipment and methods used to test whether drugs are released adequately when administered orally The contributors discuss methods for accurately establishing and validating in vitro in vivo correlations for both MR and IR formulations as well as alternative approaches for MR an Handbook of Pharmaceutical Granulation Technology Dilip M. Parikh, 2016-04-19 The Third Edition presents all pharmaceutical industry personnel and those in academia with critical updates on the recent advances in granulation technology and changes in FDA regulatory guidelines Addressing precisely how these recent innovations and revisions affect

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