DRUGS AND THE PHARMACEUTICAL SCIENCES

**VOLUME 210** 

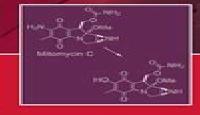
## PHARMACEUTICAL STRESS TESTING

PREDICTING DRUG DEGRADATION

SECOND EDITION







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



Maik J. Jornitz, Maik W. Jornitz, Theodore H. Meltzer

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Taft, Jason T. McConville, 2007-09-25 This title demonstrates how advanced formulation designs and delivery technologies can be used to improve drug efficacy and treatment outcomes in particular therapeutic categories or disease states It discusses nanoparticle systems for cancer treatments and also presents cutting edge immono regulation agents for transplantation and **Dermal Absorption and Toxicity Assessment** Michael S. Roberts, 2007-12-14 The source Dermal Absorption and Toxicity Assessment supplies a state of the art overview of the dermal absorption process and is divided into six well organized sections Written by internationally recognized experts in the field this Second Edition is a complete revised and updated text covering the wide range of methods used to assess skin ab Handbook of Bioequivalence Testing, Second Edition 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 made bioequivalence testing more complex The second edition of Handbook of Bioequivalence Testing has been completely updated to include the most current information available including new findings in drug delivery and dosage form design and revised worldwide regulatory requirements New topics include A historical perspective on generic pharmaceuticals New guidelines governing submissions related to bioequivalency studies along with therapeutic code classifications Models of noninferiority Biosimilarity of large molecule drugs Bioequivalence of complementary and alternate medicines Bioequivalence of biosimilar therapeutic proteins and monoclonal antibodies New FDA guidelines for bioanalytical method validation Outsourcing and monitoring of bioequivalence studies The cost of generic drugs is rising much faster than in the past partly because of the increased costs required for approval including those for bioequivalence testing There is a dire need to re examine the science behind this type of testing to reduce the burden of development costs allowing companies to develop generic drugs faster and at a lower expense The final chapter explores the future of bioequivalence testing and proposes radical changes in the process of biowaivers It suggests how the cost of demonstrating bioequivalence can be reduced through intensive analytical investigation and proposes that regulatory agencies reduce the need for bioequivalence studies in humans Backed by science and updated with the latest research this book is destined to spark continued debate on the efficacy of the current bioequivalence testing paradigm Nanoparticulate Drug Delivery Systems Deepak Thassu, Michel Deleers, Yashwant Vishnupant Pathak, 2007-03-30 With the advent of analytical techniques and capabilities to measure particle sizes in nanometer ranges there has been tremendous interest in the use of nanoparticles for more efficient methods of drug delivery Nanoparticulate Drug Delivery Systems addresses the scientific methodologies formulation processing applications recent trends and e Pharmaceutical Product Development Chilukuri Dakshina Murthy, Gangadhar Sunkara, David Young, 2007-02-12 During the last two decades the pharmaceutical industry has been under pressure to reduce development costs and the time needed to bring drugs to market in order to maximize return on

investment and bring treatments to patients sooner To meet these ends pharmaceutical scientists working in the differing areas of pharmacy pharmaceutics and phar Modern Pharmaceutics Volume 1 Alexander T. Florence, Juergen Siepmann, 2009-05-28 With over 100 illustrations Volume 1 addresses the core disciplines of pharmaceutics absorption PK excipients tablet dosage forms and packaging and explores the challenges and paradigms of pharmaceutics Key topics in Volume 1 include principles of drug absorption chemical kinetics and drug stability pharmacokinetics the effect of rout

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