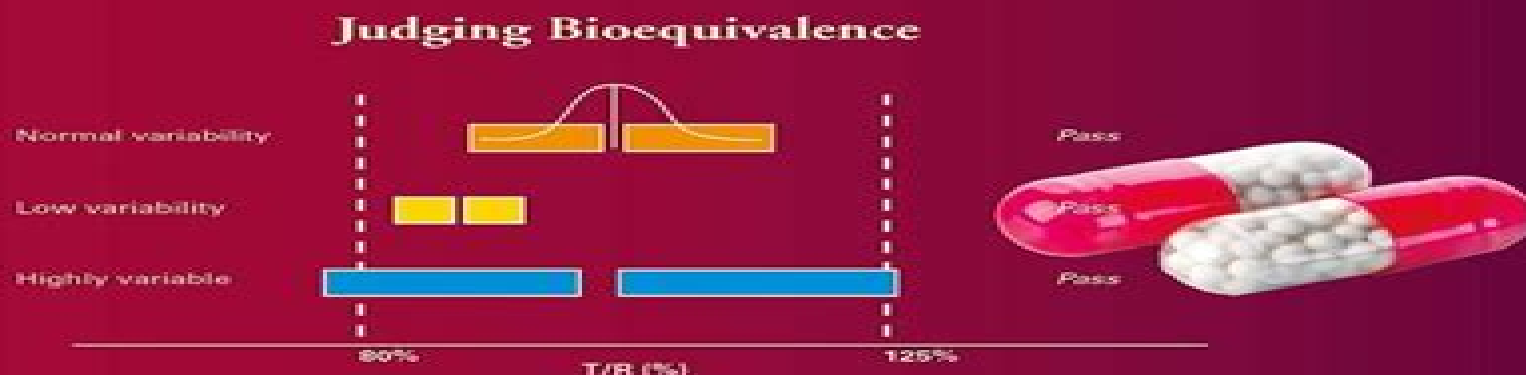


DRUGS AND THE PHARMACEUTICAL SCIENCES

Volume 213

HANDBOOK OF BIOEQUIVALENCE TESTING

Second Edition



Sarfraz K. Niazi

Handbook Of Bioequivalence Testing 002 Drugs And The Pharmaceutical Sciences

Emile P. Chen



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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 QbD 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

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The Future of Pharmaceuticals Sarfaraz K. Niazi, 2022-02-28 Before now biological systems could only be expressed in terms of linear relationships however as knowledge grows and new techniques of analysis on biological systems is made available we are realizing the non linearity of these systems The concepts and techniques of nonlinear analysis allow for more realistic and accurate models in science The Future of Pharmaceuticals A Nonlinear Analysis provides an opportunity to understand the

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