

# Bioequivalence And Pharmacokinetic Evaluation Of Ijcpr

**Bio-International** Kamal K. Midha 1993  
*Pharmacokinetic Evaluation and Modeling of Clinically Significant Drug Metabolites*

Constantin Mircioiu 2021-07-14

## **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

*Revising Oral Pharmacokinetics, Bioavailability and Bioequivalence Based on the Finite*

*Absorption Time Concept* Panos Macheras

2024-01-03 This book casts new light on the field of oral drug absorption. It outlines both the concept of the past and the novel concept of Finite Absorption Time (FAT). In addition, the authors explore the correlated need for re-definition of bioavailability, bioequivalence providing a plethora of experimental data. Accordingly, this book is intended for academics/students or scientists working in pharmaceutical industries, regulatory agencies, and contract research organizations. It can be used for teaching purposes in under- and post-graduate courses dealing with biopharmaceutics, pharmacokinetics and biomedical engineering.

## **Bioequivalence Studies in Drug**

**Development** Dieter Hauschke 2007-03-13

Studies in bioequivalence are the commonly accepted method to demonstrate therapeutic equivalence between two medicinal products. Savings in time and cost are substantial when using bioequivalence as an established surrogate marker of therapeutic equivalence. For this reason the design, performance and evaluation of bioequivalence studies have received major attention from academia, the pharmaceutical industry and health authorities. Bioequivalence Studies in Drug Development focuses on the planning, conducting, analysing and reporting of

bioequivalence studies, covering all aspects required by regulatory authorities. This text presents the required statistical methods, and with an outstanding practical emphasis, demonstrates their applications through numerous examples using real data from drug development. Includes all the necessary pharmacokinetic background information. Presents parametric and nonparametric statistical techniques. Describes adequate methods for power and sample size determination. Includes appropriate presentation of results from bioequivalence studies. Provides a practical overview of the design and analysis of bioequivalence studies. Presents the recent developments in methodology, including population and individual bioequivalence. Reviews the regulatory guidelines for such studies, and the existing global discrepancies. Discusses the designs and analyses of drug-drug and food-drug interaction studies. Bioequivalence Studies in Drug Development is written in an accessible style that makes it ideal for pharmaceutical scientists, clinical pharmacologists, and medical practitioners, as well as biometricians working in the pharmaceutical industry. It will also be of great value for professionals from regulatory bodies assessing bioequivalence studies.

## **Bioequivalence And Pharmacokinetic Evaluation Of Ijcpr**

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