



# **Design and Analysis of Bioavailability and Bioequivalence Studies (Statistics: a Series of Textbooks and Monographs)**

*Shein-Chung Chow, Jen-Pei Liu*

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This practical reference/text, written at a basic mathematical and statistical level, presents important statistical concepts for assessing bioequivalence through "real" examples and provides a thorough, unified discussion of the design and analysis of bioavailability and bioequivalence studies. Furnishing a comprehensive overview of the field and comparing average bioavailability methods, "Design and Analysis of Bioavailability and Bioequivalence Studies": supplies a simple formula for sample size determination; explains techniques for checking model assumptions and detecting outlying data; compares the additive model and the multiplicative model; demonstrates statistical methods of assessing more than two formulations; and delineates bioequivalence assessment with negligible plasma levels. As a fundamental text in the classroom or for self-education, "Design and Analysis of Bioavailability and Bioequivalence Studies": contains various study designs based on different needs and objectives; offers over 400 display equations but requires no mathematics beyond simple algebra; and incorporates time-saving SAS programmes and an appendix of statistical tables. "Design and Analysis of Bioavailability and Bioequivalence Studies" is intended for biostatisticians; applied statisticians; biometricians; pharmacologists; clinical, industrial and research pharmacists; and drug regulatory personnel; as well as an for all upper-level undergraduate and graduate courses in bioavailability and bioequivalence, pharmacokinetics, pharmaceuticals and biostatistics.

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