Handbook of Bioequivalence Testing (Drugs and the Pharmaceutical Sciences)

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As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct efficient and successful bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence, and advances in the analytical technology used to detect drug and metabolite levels have made bioequivalence testing more difficult to conduct and summarize. **The Handbook of Bioequivalence Testing** offers a complete description of every aspect of bioequivalence testing.

Features:

- Describes the current analytical methods used in bioequivalence testing, as well as their respective strengths and limitations
- Discusses worldwide regulatory requirements for filing for approval of generic drugs
- Covers GLP, GCP, and 21 CFR compliance requirements for qualifying studies for regulatory submission and facility certification
- Includes actual examples of reports approved by regulatory authorities to illustrate various scientific, regulatory, and formatting aspects
- Provides a list of vendors for the software used to analyze bioequivalence studies and recommendations
- Explains how to apply for a waiver, how to secure regulatory approval of reports, and how to obtain regulatory certification of facilities conducting bioequivalence studies

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