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Containing four new chapters, along with several new and updated sections, this third edition reviews the latest progress of activities and results in bioavailability and bioequivalence on regulatory requirements, scientific and practical issues, and statistical methodology. It presents the current status of regulations on bioavailability and bioequivalence, including guidelines/guidances issued by the FDA, EMEA, and WHO. This edition addresses frequently asked questions and explores sample size determination, meta-analysis, and pharmacokinetics. It also offers a basic version of PharmaSoftware Solutions, Inc.'s BABE Solution 2008, with bioequivalence assessment for in vivo bioequivalence studies.

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