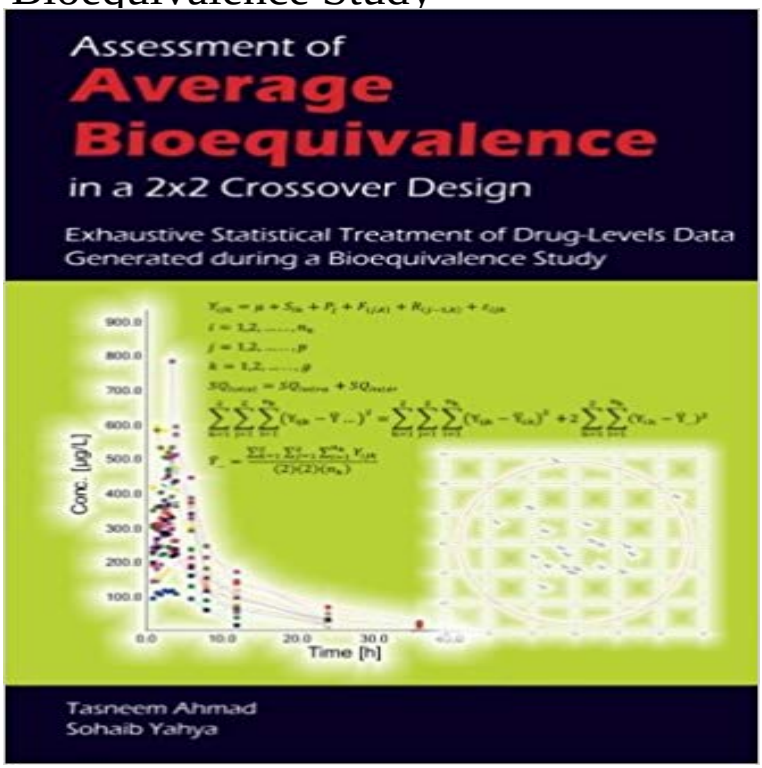
Assessment of Average Bioequivalence in a 2x2 Crossover Design: Exhaustive Statistical Treatment of Drug Levels-Data Generated during a Bioequivalence Study



This book examines the biopharmaceutics, pharmacokinetics and biostatistics involved in a 2x2 crossover bioequivalence study. It enlightens every topic in required detail with solved examples of biostatistical and mathematical analysis, data presentation and results with interpretation. This book facilitates the reader to plan a bioequivalence study through sample size and power calculation methods, verify via checking the significance of confounding effects like Period, Sequence, Subject and Formulation effects using Analysis of variance. It also helps analyze the BE studies data with the help of numerous statistical methods including parametric and non-parametric approaches used in the evaluation of bioequivalence. The last chapter of the book reviews the issue of outliers in the BE Studies and attitude of regulatory authorities towards inclusion or exclusion of the data of the outlying subjects. It also includes the latest techniques to detect the outliers which may impact outcome of BE studies.

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