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and extent characteristics (metrics) for multiple-dose studies
2.4 ConclusionsReferences; 3 Basic statistical considerations; 3.1 Introduction; 3.2 Additive and multiplicative model; 3.2.1 The normal distribution; 3.2.2 The lognormal distribution; 3.3 Hypotheses testing; 3.3.1 Consumer and producer risk; 3.3.2 Types of hypotheses; 3.3.2.1 Test for difference; 3.3.2.2 Test for superiority; 3.3.2.3 Test for noninferiority; 3.3.2.4 Test for equivalence; 3.3.3 Difference versus ratio of expected means; 3.3.3.1 The normal distribution; 3.3.3.2 The lognormal distribution; 3.4 The RT/TR crossover design assuming an additive model
3.4.1 Additive model and effects3.4.2 Parametric analysis based on t-tests; 3.4.2.1 Test for difference in carryover effects; 3.4.2.2 Test for difference in formulation effects; 3.4.2.3 Test for difference in period effects; 3.4.3 Nonparametric analysis based on Wilcoxon rank sum tests; 3.4.3.1 Test for difference in carryover effects; 3.4.3.2 Test for difference in formulation effects; 3.4.3.3 Test for difference in period effects; References; 4 Assessment of average bioequivalence in the RT/TR design; 4.1 Introduction; 4.2 The RT/TR crossover design assuming a multiplicative model
5 Power and sample size determination for testing average bioequivalence in the RT/TR design

Sommario/riassunto

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 r