A modified two one-sided test for reference-scaled average bioequivalence

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Abstract

The US FDA has released the first revision of the draft guidance “Statistical Approaches to Establishing Bioequivalence” at the end of 2023. In this revision, the reference-scaled average bioequivalence (RSABE) is recommended for in-vitro permeation tests and assessments of narrow therapeutic index drugs. The corresponding test is suggested to be based on an upper confidence bound by Howe method for the linear combination of squared mean difference and variance(s). The statistical chrematistics for the confidence bound is difficult to derive and, hence, the sample size determination is often based on simulation. In this study, we proposed a modified two one-sided test (MTSOT) alternatively with corresponding sample size determination. Simulation shows that the proposed MTOST can control the type I error rate and provide sufficient level of power. Moreover, it is powerful than the Howe method.

Keyword: reference-scaled average bioequivalence; sample size determination; two one-sided test