

Berger, Roger L.; Hsu, Jason C.

Bioequivalence trials, intersection-union tests and equivalence confidence sets. With comments and a rejoinder by the authors. (English) [Zbl 0955.62555](#)
Stat. Sci. 11, No. 4, 283-319 (1996).

Summary: The bioequivalence problem is of practical importance because the approval of most generic drugs in the United States and the European Community (EC) requires the establishment of bioequivalence between the brand-name drug and the proposed generic version. The problem is theoretically interesting because it has been recognized as one for which the desired inference, instead of the usual significant difference, is practical equivalence. The concept of intersection-union tests is shown to clarify, simplify and unify bioequivalence testing. A test more powerful than the one currently specified by the FDA and EC guidelines is derived. The claim that the bioequivalence problem defined in terms of the ratio of parameters is more difficult than the problem defined in terms of the difference of parameters is refuted. The misconception that size- α bioequivalence tests generally correspond to $100(1 - 2\alpha)\%$ confidence sets is shown to lead to incorrect statistical practices, and should be abandoned. Techniques for constructing $100(1 - \alpha)\%$ confidence sets that correspond to size- α bioequivalence tests are described. Finally, multiparameter bioequivalence problems are discussed.

MSC:

62F25 Parametric tolerance and confidence regions

62P10 Applications of statistics to biology and medical sciences; meta analysis

Cited in **60** Documents

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