



Assessment of Pharmaceutical Equivalence: Difference Test or Equivalence Test?

Felipe R. LOURENÇO* & Terezinha J.A. PINTO

*Departamento de Farmácia, Faculdade de Ciências Farmacêuticas, Universidade de São Paulo,
Av. Prof. Lineu Prestes, 580, Cidade Universitária São Paulo, SP, Brazil*

SUMMARY. Pharmaceutical equivalence is an important step towards the confirmation of similarity and interchangeability among pharmaceutical products, particularly regarding those that will not be tested for bioequivalence. The aim of this paper is to compare traditional difference testing to two one-side equivalence tests in the assessment of pharmaceutical equivalence, by means of equivalence studies between similar, generic and reference products of acyclovir cream, atropine sulfate injection, meropenem for injection, and metronidazole injection. All tests were performed in accordance with the Brazilian Pharmacopeia or the United States Pharmacopeia. All four possible combinations of results arise in these comparisons of difference testing and equivalence testing. Most of the former did not show significant difference, whereas the latter presented similarity. We concluded that equivalence testing is more appropriate than difference testing, what can make it a useful tool to assess pharmaceutical equivalence in products that will not be tested for bioequivalence.

KEY WORDS: Difference test, Equivalence test, Pharmaceutical equivalence.

* Author to whom correspondence should be addressed. *E-mail:* feliperl@usp.br