Latin American Journal of Pharmacy
(formerly *Acta Farmacéutica Bonaerense)*
Lat. Am. J. Pharm. **28** (3): 433-7 (2009)

Original Article

Received: February 16, 2009
Accepted: March 7, 2009

Bioequivalence Test Applied to a New Lamivudine/Zidovudine Combined Formulation Tablet

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***SUMMARY*. A double-center, open-label, two-way crossover study was conducted in 24 healthy volunteers to assess the bioequivalence of a combined lamivudine/zidovudine tablet related to a reference and test drug products. The volunteers were randomly assigned to receive one lamivudine/zidovudine combination tablet of reference or test product with 7-days washout period between. Blood samples were collected up to 36 h post dose. Pharmacokinetic parameters were estimated. Drug products were bioequivalent if 90% confidence intervals for the ratio of least squares (CI 90%) means are under plasma concentration-time curve ($AUC_{0-\tau}$) and absorption rate (C_{max}) fell within 80 to 125% for log-transformed parameters. Test and reference products present data of $AUC_{0-\tau}$, C_{max} referents to lamivudine and data of ASC_{∞} referents to zidovudine, in agreement of these limits. The result of C_{max} (CI 90%) to zidovudine was: 116% (90-141%), it has confirm that the zidovudine has high individual variability of absorption.**

KEY WORDS: Bioequivalence, High variability drugs, Lamivudine, HPLC, Zidovudine.

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