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

Jacqueline de SOUZA 1*; Eunice K. KANO 1, Eunice E. M. KOONO 2, Simone G. SCHRAMM 2, Valentina PORTA 3 & Sílvia STORPIRTIS 3

1 DEFAR, Escola de Farmácia – Universidade Federal de Ouro Preto - UFOP, Rua Costa Sena, 171 Centro – Ouro Preto MG – Brasil
2 Laboratório BIOFAR, Faculdade de Ciências Farmacêuticas da USP (FCF – USP);
3 Departamento de Farmácia, FCF/USP Av. Prof. Lineu Prestes, 560 Cidade Universitária – Butantã – São Paulo – SP – Brasil

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 (AUC0-τ) and absorption rate (Cmax) fell within 80 to 125% for log-transformed parameters. Test and reference products present data of AUC0-τ, Cmax refers to lamivudine and data of ASC∞ referents to zidovudine, in agreement of these limits. The result of Cmax (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.

* Author to whom correspondence should be addressed. E-mail: jacouza@ef.ufop.br