# Bioequivalence Assessment of Two Simvastatin Tablets Healthy Taiwanese Volunteers Journal of Food and Drug Analysis

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摘要

**Abstract**

The pharmacokinetics and bioequivalence of two tablets of simvastatin, Zolotin and ZOCOR®, were evaluated in 26 healthy male Taiwanese volunteers who reside in Taiwan. The experiments were designed as a randomized, two-sequence, two-period and single-dose crossover study. Blood samples were obtained at 0 (pre-dose), 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 14 and 24 hr after oral dosing of one tablet. β-hydroxyacid simvastatin concentrations in plasma were analyzed by a validated LC/MS/MS method. The pharmacokinetic parameters were analyzed by non-compartmental analysis. The analysis of variance was carried out using log-transformed AUC0-t, AUC0-∞ and Cmax. The results revealed that the Cmax of Zolotin and ZOCOR® were 4.78 ± 2.75 ng/mL and 4.52 ± 2.01 ng/mL; the Tmax were 3.80 ± 1.63 hr and 4.31 ± 1.73 hr; the T1/2 were 4.32 ± 1.82 hr and 5.11 ± 2.49 hr; the AUC0-t were 35.6 ± 21.7 ng×hr/mL and 36.5 ± 20.0 ng×hr/mL; and the AUC0-∞ were 38.1 ± 24.3 ng×hr /mL and 40.3 ± 23.6 ng×hr/mL, respectively. The ratios of log-transformed AUC0-t, AUC0-∞, and Cmax values of the plasma β-hydroxyacid simvastatin between two tablets were within the range of 80-125% as judged by 90% confidence intervals and satisfied the bioequivalence criteria. The generic simvastatin tablets formulation, Zolotin, was shown to be bioequivalent to the ZOCOR® tablets.