Study of Pharmacokinetics and Bioequivalence of 250 mg Clarithromycin Tablet in Health Thai Volunteers

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ABSTRACT

Pharmacokinetics and bioequivalence of clarithromycin were evaluated. Eighteen healthy Thai volunteers participated in this research which had a crossover design with a one week washout period. A single dose of 250 mg clarithromycin was given orally to each subject after 8 hrs overnight fasting. The sequential blood samples were collected and analyzed for clarithromycin by high performance liquid chromatography. The pharmacokinetic parameters (mean ± SD) of the test and the reference preparations were as follows, the maximum plasma concentration (C_{max}) was 1.0112 ± 0.3113 and 0.8718 ± 0.2589 µg/mL, time to reach maximum plasma concentration (T_{max}) was 1.2670 ± 0.7362 and 2.0296 ± 0.7907 hr, area under the plasma concentration time-curve from time zero to infinity ($AUC_{0-\infty}$) was 6.1247 ± 1.7666 and 5.8169 ± 1.7484 µg·hr/mL, elimination half life ($T_{1/2}$) was 2.9964 ± 0.7796 and 2.8050 ± 0.9822 hr, The bioequivalence of the two preparations was not significantly different as measured by ANOVA. The ninety percent confidence interval for the means of the ratio of the maximum plasma concentration and the area under the plasma concentration time-curve from time zero to infinity, of the test preparation to the reference preparation, was within the range of 0.80-1.25.

It is concluded that the test preparation was bioequivalent to the reference preparation in terms of the maximum plasma concentration and area under the plasma concentration time-curve from time zero to infinity.

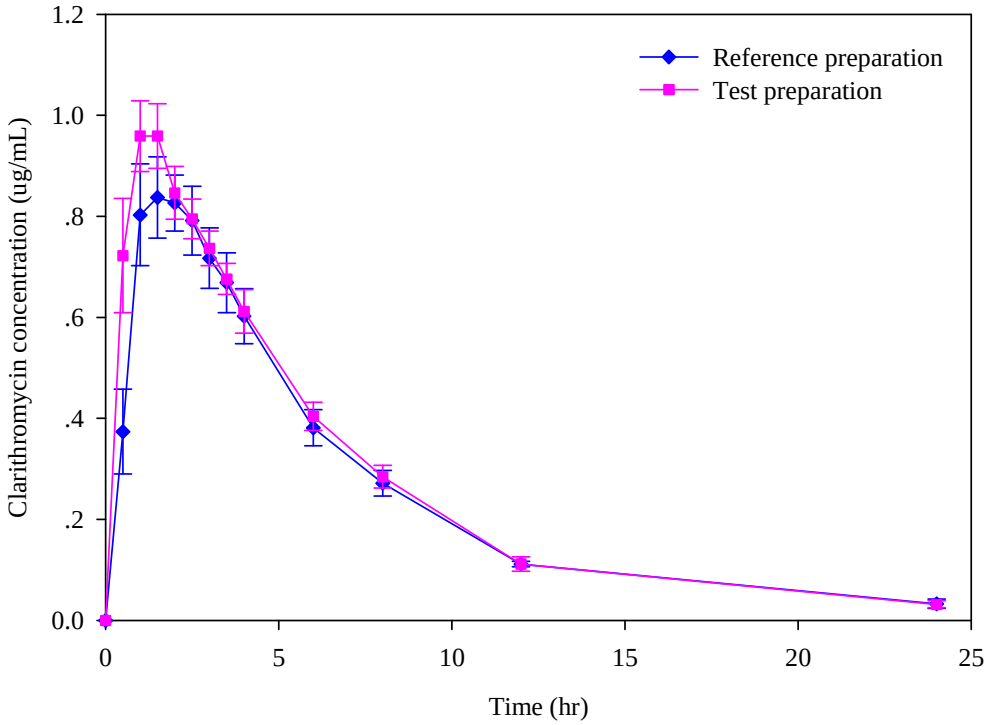

Figure 1 Concentration-time curve (mean ± SEM) of 250 mg clarithromycin after a single oral dose in the test and the reference preparation to healthy Thai volunteers