Thesis Title Pharmacokinetic Studies of Oral Cephalexin in Healthy Thai Volunteers and Comparative Bioequivalence of Two Brands of Oral Cephalexin

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ABSTRACT

The present study aims to evaluate the pharmacokinetic of a single oral dose of cephalexin in healthy Thais and to compare the bioavailability of cephalexin capsules produced by two manufacturers. A single blind randomized crossover design with seven days wash-out period was used in this study. A 500 mg (one capsule) dose of cephalexin was randomly given orally to each subject. There were ten healthy subjects, six males and four females who ingested oral cephalexin in the morning after an overnight fasting. Blood samples were drawn at 0, 0.5, 1, 1.5, 2 and 4 hours after ingestions of the drug. The serum concentration of each sample was determined by HPLC. The present results indicate that the serum peak concentration (C_{max}) of cephalexin from two brands, imported and local made, are 16.11 ± 1.94 ug/ml. and 14.66 ± 1.71 ug/ml. The elimination half-life (t 1/2) are 0.869 ± 0.07 and 0.876 ± 0.06 hours. The time to peak concentration (T_{max}) are 57.00 ± 7.00 and 54.00 ± 6.00 mins

respectively. Final parameter in the present study is the area under the concentration-time curve (AUC), from time zero to four hours ($AUC_{0-4\ hrs}$), are 1955.80 ± 212.73 and 1791.45 ± 213.58 µg. mins per ml. The comparison of bioequivalence of two tested brands shows no statistical difference in all pharmacokinetic parameters at significant level of p value = 0.05 by student t test. The local manufactured product tested can be used interchangeably with this original manufactured product.