P4 BIOEQUIVALENCE TEST OF THE GENERIC GLICLAZIDE (DIANID®) AND THE INNOVATOR (DIAMICRON®) IN HEALTHY THAI MALE VOLUNTEERS

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ABSTRACT

The purpose of this study was to compare the bioequivalence of 80 mg oral hypoglycemic gliclazide preparations between a generic (Dianid® The Biolab Company, Thailand), and the inovator (Diamicron® Les laboratories, Servier Industrie, France). The pharmacokinetics and bioequivalence test were studied in 12 healthy male subjects. A single oral dose of each preparation was given to the subjects in a randomized double-blind, two period crossover design with 2 weeks washout period. Blood samples were collected before and at 1, 3, 5, 6, 7, 8, 9, 10, 11, 12, 13, 15, 24, 30, 36, 48, 60 hours after drug administration. Serum gliclazide concentrations were determined by using high - performance liquid chromatography. Individual concentration time profiles were depicted and the pharmacokinetic parameters were analyzed by noncompartmental pharmacokinetic method with the use of TOPFIT, a pharmacokinetic data analysis program. Statistical analysis comparing the parameters between the test and reference preparations was performed by three-way ANOVA. No significant differences in area under the serum concentration-time curves at time 0 to infinity ($AUC_{0-\infty}$), maximal gliclazide concentrations (Cmax) and time to the Cmax (Tmax) were observed between the test and reference preparations. The means and 90% confidence intervals (90% CI) of the Dianid®/Diamicron® ratios of $AUC_{0-\infty}$ and the Cmax were 1.08 (0.98-1.18) and 1.09 (0.89-1.34), respectively. These values were well within the acceptable bioequivalence ranges of 0.8-1.25 proposed by the United States Food and Drug Administration (USFDA) and 0.70-1.43 proposed by the commission of the European Community of Food and Drug Administration (ECFDA), respectively. The means and 90% CI of the difference in Tmax between Dianid® and Diamicron® were 0.08 [(-1.44) -1.61] hour. This value was within the stipulated bioequivalence range of $\pm$ 2.30 hours ($\pm$ 20 % of the Tmax of the reference formulation). Thus, the test product Dianid® was considered bioequivalent to the reference Diamicron® regarding the rate of absorption (Cmax and Tmax) and the extent of absorption (AUC).