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A Pharmacokinetic Comparison of Metformin/gliclazide Combined-tablet versus the Same Two Drugs Given Concurrently in Healthy Male Volunteers

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Background/Aims: Metformin hydrocloride and gliclazide have been frequently used with the different action mechanisms for the glycemic control of type 2 diabetic patients. This study was conducted to compare the pharmacokinetic properties of a fixed-dose combined-formulation tablet (metformin hydrochloride 500 mg/gliclazide 80 mg) with coadministration of metformin hydrochloride and gliclazide as separate tablets in healthy male subjects.

Methods: An open-label, randomized, single-dose, two-treatment, two-way crossover study was carried out in 32 healthy subjects with 7-day washout period between each treatment. Blood samples were collected for 32 hours after dosing. Plasma concentrations of both drugs were measured using HPLC method. Evaluation of pharmacokinetic parameters by the noncompartmental analysis was performed, followed by statistical comparisons to assess bioequivalence. Treatments were considered bioequivalent if 90% confidence intervals for the geometric mean ratios (GMR) (combined-formaulation/coadministration) of Cmax and AUC(0-last) fell within the prespecified bounds of (0.80, 1.25). Safety profiles were also assessed.

Results: The GMRs of the Cmax, AUC(0-last), and AUC(0-inf) (90% confidence intervals) between combination tablet and coadministered separate tablets were 0.99 (0.93～1.05), 1.01 (0.93～1.09), and 1.00 (0.93～1.08), respectively, for metformin hydrochloride and 1.05 (1.01～1.08), 1.04 (1.01～1.07), and 1.05 (1.02～1.08), respectively, for gliclazide, indicating that both treatments were equivalent each other in terms of rate and extent of absorption after drug administration.

Conclusion: These results suggest that the fixed-dose metformin/gliclazide combined-tablet is pharmacokinetically equivalent to coadministration of both drugs separately.