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Evaluation of the Bioequivalence and Pharmacokinetics of Two Formulations of Gliclazide in Healthy Chinese Volunteers Using Population Pharmacokinetic Approach

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***SUMMARY*. A randomized, two-way, cross-over study was conducted in healthy Chinese volunteers to compare two formulations of gliclazide 80 mg tablets. The data were analyzed using population compartmental pharmacokinetic analysis, as well as non-compartmental method, which is a standard approach to the bioequivalence test data using model-independent parameters. Simulated data were also analyzed to graphically evaluate the model and the pharmacokinetic characteristics of these two gliclazide formulations. Results indicate that the rate and extent of bioavailability of gliclazide did not differ between the test and reference products. The pharmacokinetics of gliclazide was defined robustly in healthy volunteers using population pharmacokinetic approach and the precise parameters calculated will also enable clinicians to optimize the dosing regimen of gliclazide. The methodology presented here can provide more precise parameters and information for the evaluation of the bioequivalence and pharmacokinetics of gliclazide and may be applicable for bioequivalence evaluation of other compounds.**

KEY WORDS: Bioequivalence, Gliclazide, Pharmacokinetics, Population pharmacokinetics.

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