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Bioequivalence of clopidogrel hydrogen sulfate tablets in healthy Chinese volunteers

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ABSTRACT. We aimed to evaluate the bioequivalence of clopidogrel in healthy Chinese volunteers after administration of a single oral dose. We administered a single oral dose of 75 mg clopidogrel (test and reference) to 32 healthy Chinese volunteers according to an open, randomized, crossover design. The concentration of clopidogrel acid (carboxylic metabolite of clopidogrel) in the plasma was determined using liquid chromatography-tandem mass spectrometry (LC-MS/MS). Bioequivalence of the test and reference preparations were calculated using analysis of variance and one-sided *t*-test by using the DAS 2.0 software. The pharmacokinetic parameters of the test and reference preparations were as follows: peak plasma concentration (C_{max}), 1351.101 ± 654.955 ng/mL and 1184.652 ± 607.713 ng/mL; area under the curve, 2642.017 ± 1093.848 ng·h/mL and 2780.666 ± 1283.100 ng·h/mL; and time to reach C_{max} (T_{max}), 0.789 ± 0.318 h and 0.953 ± 0.633 h, respectively. The relative bioavailability of the formulation was 101.7 ± 35.3%, which indicated that the test preparation was bioequivalent to the reference drug.

Key words: Clopidogrel; Clopidogrel acid; Bioequivalence

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