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A bioequivalence study of two Azithromycin tablet formulations in Indonesian healthy subjects

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Aim: To compare the bioavailability of two azithromycin tablet formulations 500 mg Azivol® tablets as test formulation and 500 mg Zithromax® tablets as reference formulation.

Methods: A single-dosed, open-label randomized two-way crossover design under fasting period with two weeks wash-out period was evaluated in 24 subjects. For the analysis of pharmacokinetic properties, the blood samples were drawn taken up to 120 hours after dosing. Plasma concentration of azithromycin was determined using liquid chromatography–tandem mass spectrometry method with TurboIon Spray mode. Pharmacokinetic parameters AUC0-t, AUC0-∞ and C_{max} were tested for bioequivalence after log-transformation of data and ratios of tmax were evaluated non-parametrically.

Results: The point estimates and 90% confidence intervals (CI) for AUC0-t, AUC0-∞, and C_{max} for azithromycin were 94.63% (86.27-103.81%), 95.35% (87.15-104.31%), and 94.16% (80.31-110.41%) respectively.

Conclusion: These results indicated that the two formulations of Azithromycin were bioequivalent and thus may be prescribed interchangeably.

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