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

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The bioavailability of two 500 mg Azithromycin tablet formulations was compared; using generic tablets (Azivol®) as test formulation and the originator product as reference formulation. Twenty-four subjects were included in this single-dose, open label, randomized two way crossover design following an overnight fasting. Two weeks wash out period was applied. Blood samples were drawn up to 120 h following drug administration. Plasma concentration of azithromycin was determined by liquid-chromatography-tandem mass spectrometry method with TurboIonSpray mode. Pharmacokinetic parameters AUC0-t, AUC0-∞, Cmax and t1/2 were determined and used for bioequivalence evaluation after log-transformation, whereas tmax ratio were evaluated non-parametrically. The estimated point and 90% confidence intervals (CI) for AUC0-t, AUC0-∞ and Cmax were 94.63% (86.27-103.81%), 95.35% (87.15-104.31%), 94.16% (80.31-110.41%), respectively. These result indicated that the two formulations of azithromycin were bioequivalent; therefore they may be prescribed interchangeably.

Biography

Yahdiana Harahap received his education in Indonesia with BSc degree (1987) at Department of Pharmacy Faculty of Mathematics and Natural Sciences University of Indonesia. She obtained her MS (1994) and PhD (2003) in Pharmaceutical Chemistry at Department of Pharmacy Faculty of Mathematic and Natural Sciences Institute Technology Bandung. She ten worked as Head of Public Service Center at Department of Pharmacy, University of Indonesia. Now she is Head of Pharmacy Department University of Indonesia, head of Bioavailability and Bioequivalence Laboratory at University of Indonesia, member of BA/BE working group Indonesia and also as the Bioequivalence expert at National Agency of Drug and Food Control Republic of Indonesia.

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