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A bioequivalence study of quetiapine film coated tablets in Indonesian volunteers

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This study was conducted in order to compare the bioavailability of two film coated tablets containing 25 mg of quetiapine. Twenty-four subjects were enrolled and completed in a single center, randomized, single dose, open label, two-way crossover study with a one-week washout period. Plasma samples were collected up 24 hours following drug administration and quetiapine was determined by liquid chromatography-tandem mass spectrometry (LC-MS/MS) method with turbo ion spray mode. Pharmacokinetic parameters used for bioequivalence assessment were AUC0-t, AUC0-∞ and Cmax. The 90% confidence intervals obtained by analysis of variance for AUC0-t, AUC0-∞ and Cmax were 80.39-99.64%, 80.26-99.51% and 83.23-109.20%, respectively. These results were all within the range of 80.00-125.00%. Bioequivalence between formulations was concluded both in terms of rate and extent of absorption.

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 Mathematics and Natural Sciences Institute Technology Bandung. She then worked as Head of Public Service Center at Department of Pharmacy, University of Indonesia. Now she is a part of Bioavailability and Bioequivalence Laboratory, Faculty of Pharmacy, University of Indonesia and member of BA/BE working group Indonesia, also as the Bioequivalence expert at National Agency of Drug and Food Control Republic of Indonesia.

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