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Bioequivalence study of trimetazidine modified release tablet formulations in indonesian healthy subjects

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Abstract

This study was conducted in order to compare the bioavailability of two modified release tablets containing 35 mg of trimetazidine. Twenty-four subjects were enrolled in a single center, randomized, single dose, open label, two-way crossover study with a one-week washout period. Plasma samples were collected up 48 hours following drug administration and trimetazidine was determined by liquid chromatography-tandem mass spectrometry (LC-MS/MS) method with turboionspray mode. Pharmacokinetic parameters used for bioequivalence assessment were AUC_{0-t}, $AUC_{0-\infty}$ and C_{max}. The 90% confidence intervals obtained by analysis of variance for $AUC_{0-t,}$ $AUC_{0-\infty}$ and C_{max} were 94.89-105.15%, 94.85-105.23%, 93.31-107.36%, respectively. These result 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 ten worked as Head of Public Service Center at Department of Pharmacy, University of Indonesia. Now she is Dean of Faculty of Pharmacy 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.