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World Congress on

BIOAVAILABILITY & BIOEQUIVALENCE: BA/BE STUDIES SUMMIT

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International Conference on

FOOD & BEVERAGES

August 06-07, 2018 | Tokyo, Japan

Yahdiana Harahap et al., J Pharm Sci Emerg Drugs 2018, Volume: 6
DOI: DOI: 10.4172/2380-9477-C5-017

A bioequivalence study of two memantine hydrochloride film coated tablets formulations assessed in healthy Indonesian subjects

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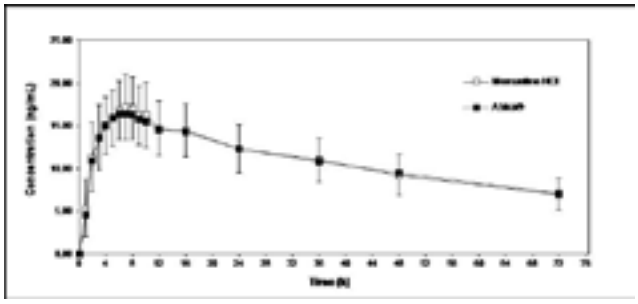
Statement of the problem: Memantine hydrochloride is an N-Methyl-D-aspartate (NMDA) receptor antagonist and approved for treatment of moderate to severe Alzheimer's disease. It is compulsory for the generic product of memantine hydrochloride to conduct the bioequivalence study. Bioequivalence studies are important to compare the systemic exposure profile of a test product to that of a reference product. This study was performed to investigate the pharmacokinetics and bioavailability of two memantine hydrochloride film coated tablet formulations in order to prove bioequivalence between the two formulations.

Methods: The study was a single dose, open label, randomized; two ways cross over in 19 healthy subjects under fasting condition. The wash out period was five weeks. Blood samples were obtained prior to dosing and at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 12, 16, 24, 36, 48 and 72 hours after drug administration. Plasma concentration of memantine HCl was monitored using liquid chromatography tandem mass spectrometry. The pharmacokinetics parameter AUC 0-24 h and Cmax were tested for bioequivalence after log transformation of data and ratios of Tmax were evaluated non-parametrically. Result: the point estimates and 90% confidence interval for AUC 0-72 h and Cmax were 97.43 to 104.13% and 97.15 to 105.96% respectively. Conclusion: The results indicate that two formulations of memantine HCl were bioequivalent thus may be prescribed interchangeably



Biography

Yahdiana Harahap is a Professor in the field of Pharmaceutical Chemistry especially Bioanaysis related to bioequivalence study and DNA Adduct. She received her Master Degree in 1994 and Doctoral degree in 2003 from Department of Pharmacy, Faculty of Mathematics and Natural Sciences, Institute Teknologi Bandung. She has been the Head of Bioavailability-Bioequivalence Laboratory Faculty of Pharmacy University of Indonesia since 2008. She serves as member of Expert Council Indonesian Pharmacist Association, reviewer in several international journals, President elected on Asian Federation of Pharmaceutical Science, Head of Sub Collegium Indonesia Pharmaceutical Industry and as the Head of Pharmacy Division in Indonesian Accreditation Agency for Higher Education in Health (LAM PT-Kes). She has generated more than 80 scientific works published in international and national journals, thus presented them in national and international conferences.

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