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Bioequivalence study of Quetiapine 25 mg tablets under fasting conditions

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Quetiapine is an atypical antipsychotic which is indicated for the treatment of schizophrenia, bipolar depression and mania. A generic product of Quetiapine has been developed with lower price by the Government Pharmaceutical Organization (GPO) to be an alternative of related physicians and patients who will gain access to the lower price medicines at the same quality and safety as the reference product. A comparative randomized, single dose, two-way crossover, open-label bioequivalence study of a generic Quetiapine 25 mg tablets formulations, Quetiapine of GPO, Thailand and the reference product, Seroquel of AstraZeneca Pharmaceutical Co., Ltd. in healthy Thai volunteers under fasting conditions was conducted with 7 days wash-out period between the treatments to compare the rate and extent of absorption and evaluate the safety of the formulations. Blood samples were collected at predefined time points up to 48 hours and centrifuged to separate the plasma. Plasma samples were analyzed using a validated liquid chromatography-tandem mass spectrometry (LC-MS/MS) method. Non-compartmental model was used for pharmacokinetic analysis and statistical analysis. The 90% parametric confidence intervals for the ln-transformed test/reference ratios of primary pharmacokinetic parameter, $AUC_{0\text{-}tlast}$, $AUC_{0\text{-}\infty}$ and C_{max} were 102.0 (96.08-108.33), 102.1 (96.21-108.31) and 108.1 (96.52-121.09), respectively for Quetiapine. These values were within the acceptable range of 80.00-125.00. These results showed that both formulations were bioequivalent in terms of rate and extent of absorption. Therefore, this study confirmed that both formulations can be used interchangeably.

Biography

Chutima Manamuti is currently working as a Researcher of Bioequivalence Study Group, Research and Development Institute, the Government Pharmaceutical Organization, Bangkok, Thailand, responsible for method development, method validation and bioanalysis in biological fluids.

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