P16 BIOEQUIVALENCE STUDY OF THE GENERIC CEFOTAXIME (CEFTARAN®) AND THE INNOVATOR PREPARATION (CLAFORAN®) IN HEALTHY THAI MALE VOLUNTEERS

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ABSTRACT

Cefotaxime is one of the most commonly used third generation cephalosporins against many gram negative aerobic bacteria. Recently, generic preparations of cefotaxime have been introduced into markets. Bioequivalence of the generic preparations and the innovator preparation has been questioned by medical doctors and the Food and Drug Administration(FDA) of Thailand. Therefore, the objective of this study was to investigate the bioequivalence of a generic preparation of cefotaxime(Ceftaran®), manufactured by the Thai Nakorn Patana Co. Ltd. (Bangkok, Thailand) and the innovator preparation (Claforan®), manufactured by the Hoechst AG, Frankfurt am Main, Germany in 12 healthy Thai male volunteers. The study was a randomised, double blind, two-period crossover study with a washout period of 7 days. Each volunteer received a single intramuscular dose(1 g.) of either the generic or innovator preparation during each visit. Serum concentrations of cefotaxime were determined by HPLC. No statistically significant difference was found in the AUC, C_{max} and T_{max} of both preparations. Both preparations fulfilled the bioequivalence criteria based on the 90% confidence intervals. In conclusion, the two preparations could be considered to be bioequivalent both the rate and extent of drug absorption into systemic circulation, suggesting that they would produce the same therapeutic results. However, comparative clinical studies should also be carried out further.

Acknowledgement : This study was supported by a grant from the Thai Nakorn Patana Co., Ltd., Bangkok, Thailand.

References :

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