

Bioequivalence Study with Comparative Antibacterial Activity of a Generic Meropenem

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ABSTRACT

Bioequivalence with antibacterial activity was comparatively studied with a generic meropenem (Enem¹) and an original Meronem¹, employing a randomized, open-label, crossover study, in twenty-six healthy males recruited at Siriraj Hospital, Thailand. The duration of one-gram intravenous infusion was 30 minutes, and the washout period was one week. Fourteen blood samples were collected before and at prescheduled intervals after meropenem infusion. Blood samples were coded and separated into plasma and serum samples for blind analyses. Plasma concentrations were determined by validated method using high-pressure liquid chromatography-ultraviolet (HPLC-UV) detector. Serum inhibition test was used to indicate antibacterial activity using *Escherichia coli* ATCC 25922, and the results were measured in term of the inhibitory zone size. The statistical analysis of the means and 90-percent confidence interval of geometric mean ratio of peak concentration (C_{max}), area under concentration curve (AUC_{0-t}), and AUC_{0-inf} were 95.1401 (88.7502-101.9902%), 97.8434 (94.1017-101.7340%), and 97.3817 (93.6596-101.2517%), respectively. The results were within the standard range of bioequivalence acceptance criteria (80-125%). Serum inhibitory zone sizes of both generic and original meropenems were similar with respect to the times of blood collections and their widths, and exhibited a curvature relation with the corresponding plasma levels. We concluded from this study that the generic meropenem (Enem¹) exhibited similar antibacterial activity and pharmacokinetic equivalence, compared to the original meropenem. (*J Infect Dis Antimicrob Agents* 2008;25:63-72.)

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