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Bioequivalence Evaluation of Two Different Controlled Release Matrix Formulations of Ketoprofen Tablets in Healthy Malaysian Volunteers

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***SUMMARY*. The aim of this study was to evaluate the *in vivo* behavior of matrix tablets formulated with ketoprofen as a model drug after oral administrations in healthy Malaysian male volunteers and to compare its rate and extent of absorption with the commercially available tablet Apo-Keto SR® as a reference product. The test formulation containing 20 % HPC (GXF) as release retardant was selected in this regards. The bioequivalence study was conducted according to a single dose, randomized, 2-treatment, 2-sequence, 2-period crossover study design on six healthy non-smoking Malaysian adult male volunteers. Plasma concentrations of ketoprofen were determined by a high-performance liquid chromatographic method with UV detection. The pharmacokinetic parameters, T_{max}, C_{max}, $AUC_{0-\infty}$, K_e, and $T_{1/2}$ were determined. The 90 % confidence intervals of the mean values for the test/reference ratios were 96.89-107.03 % for $AUC_{0-\infty}$ and 99.64-104.62 % for C_{max}, respectively. The results of this study suggest that the two preparations, the test formulation of ketoprofen 200 mg tablets were bioequivalent to the marketed reference tablet of Apo-Keto SR® 200 mg in these healthy Malaysian male volunteers. However, this study results are to be further confirmed by carrying out a pivotal biostudy using more number of subjects.**

KEY WORDS: Bioequivalence, Controlled-release, Ketoprofen, Malaysian volunteers.

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