عنوان مقاله:

Bioequivalence Study of Two Formulations of Tramadol Capsules in Healthy Myanmar Volunteers

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خلاصه مقاله:

Background: Tramadol is one of the most commonly used analgesics, thanks to its efficacy and safety. It is widely used in Myanmar for postoperative and cancer pain control. The use of generic drugs has been steadily increasing worldwide, mostly in developing countries. Generic drugs should have efficacy and safety comparable to their innovators or other approved generic products. Objectives: This study aims to compare the bioequivalence of locally producing, Tramadol BPI® capsule (test product) with the Tramazac® capsule (reference product) in healthy Myanmar volunteers. Methods: The bioequivalence was determined in ۱۶ healthy Myanmar volunteers after a single oral administration of ۱۰۰ mg tramadol (under fasting condition) in a randomized, open-label, two-period, and two-treatment crossover study with a two-week washout period. Blood samples were collected at specified times, and plasma tramadol concentrations were measured with a validated high-performance liquid chromatography method with a fluorescence detector. Pharmacokinetic parameters were determined using the plasma concentration-time data in a non-compartmental model. Results: The analysis of variance of the logarithmically transformed parameters (maximum plasma concentration (Cmax), area under the concentration-time curve from the time of administration to the last measured concentration (AUC_{0-t}), and to infinity ($AUC_{0-\infty}$) revealed no sequence, period, and formulation effects between the test and reference products. Significant differences were found between the subjects within the sequence for both AUC_{0-t}, and $AUC_{0-\infty}$, indicating a substantial inter-subject variation. The geometric mean ratio of test/reference and their ۹۰% confidence intervals were within the ASEAN (Association of Southeast Asian Nations) bioequivalence acceptance interval of ۸۰% to ۱۲۵%. Conclusion: Tramadol BPI® and Tramazac® capsules, after a single oral administration of ۱۰۰ mg, were bioequivalent in respect of their rate and extent of absorption under fasting condition.

کلمات کلیدی:
(Bioequivalence, Bioavailability, Tramadol, Pharmacokinetics, High-performance liquid chromatography (HPLC