



Pharmacokinetics and Bioequivalence Evaluation of Metronidazole Tablets in Healthy Malaysian Volunteers

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SUMMARY. The objective of this study was to investigate the pharmacokinetics and to compare the bioavailability of two metronidazole products, Frotin and Flagyl, in healthy Malay ethnic male volunteers in Malaysia. A single dose, randomized, fasting, two-period, two-treatment, two-sequence crossover, open label bioequivalence study was conducted in 18 healthy Malay adult male volunteers, with one week washout period. The drug concentration in the sample was analyzed using high performance liquid chromatography. The mean (SD) pharmacokinetic parameter results of Flagyl were, AUC_{0-36} , 84.41 (13.15) $\mu\text{g}/\text{mL}\cdot\text{h}$; $AUC_{0-\infty}$, 94.75 (16.65) $\mu\text{g}/\text{mL}\cdot\text{h}$; while, those of Frotin were AUC_{0-36} , 83.51 (15.05) $\mu\text{g}/\text{mL}\cdot\text{h}$; $AUC_{0-\infty}$, 93.89 (20.08) $\mu\text{g}/\text{mL}\cdot\text{h}$. The 90 % confidence intervals for the logarithmic transformed C_{max} , AUC_{0-36} and $AUC_{0-\infty}$, of Frotin over Flagyl were between 0.88 to 1.00, 0.96 to 1.04 and 0.96 to 1.05. Both C_{max} and AUC met the predetermined criteria for assuming bioequivalence. Both formulations were well tolerated.

KEY WORDS: Bioequivalence, Frotin, Malay ethnic, Metronidazole, Pharmacokinetics.

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