



Bioequivalence Study of Deferiprone In Healthy Pakistani Volunteers

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SUMMARY. The study was conducted to evaluate the bioequivalence of deferiprone 500 mg with innovator drug in Pakistani men. Twenty four healthy volunteers were enrolled in this study. Each volunteer take two tablets of generic and innovator deferiprone with two-week washout period. Blood samples were collected at predetermined time intervals. Plasma deferiprone levels were analyzed using validated HPLC method. Pharmacokinetic parameters computed non-compartmentally after logarithmic transformation of data. The mean relative bioavailability was 104 %. The mean C_{max} , AUC_{0-t} , $AUC_{0-\infty}$ for generic drug were 14.41, 40.49, and 42.84 $\mu\text{g}\cdot\text{h}/\text{mL}$ and for innovator were 12.68, 38.63, and 40.75 $\mu\text{g}\cdot\text{h}/\text{mL}$, respectively. Mean ratio (generic/innovator) of AUC_{0-t} at 90 % CI was 0.9737-1.1150 and for C_{max} was 0.99876-1.2425. Hence, the mean ratio of 90 % confidence interval of AUC_{0-t} and C_{max} lie within the acceptable limit of (0.80-1.25) for bioequivalence. Therefore, it was concluded that Ferinil and Ferriprox was proved to be bioequivalent in healthy Pakistani men.

KEY WORDS: Bioequivalence, Pharmacokinetics, Deferiprone, Pakistani men.

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