



Comparative Bioavailability of Two Digoxin Formulations: Determination in Human Plasma by Microparticle Enzyme Immunoassay

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SUMMARY. The present study was performed to compare the bioavailability of two digoxin 0.25 mg tablet formulation in 30 volunteers of both sexes. The study was conducted open with randomized two period crossover design and a three-week washout period. Plasma samples were obtained over a 144 h interval. Digoxin concentrations were analyzed by a validated microparticle enzyme immunoassay with optical detection by fluorescence. Bioequivalence between the products was determined by calculating 90 % confidence intervals (90 % I.C) for the ratio of AUC_{0-72h} and C_{max} values for the test and reference products, using logarithmic transformed data. The 90 % confidence intervals were 86.98–118.33 %, and 84.52–98.76 %, respectively. Since the 90 % confidence intervals for C_{max} and AUC_{0-72h} were within the 80–125 % interval proposed by Food and Drug Administration, it was concluded that the two Digoxin formulations are bioequivalent in their rate and extent of absorption.

KEY WORDS: Bioequivalence, Digoxin, Pharmacokinetics, Volunteers.

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