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Study of Comparative Bioavailability Among Two Formulations Containing Hydroxyzine Hydrochloride in Healthy Volunteers After a Single Dose Administration

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***SUMMARY*. The study was performed to compare the bioavailability of two hydroxyzine hydrochloride 25 mg tablet formulation in 16 volunteers of both sexes. The study was conducted open with randomized two period crossover design and a two weeks wash out period. Plasma samples were obtained over a 96 h interval. Hydroxyzine concentrations were analyzed by Liquid Chromatography with Tandem Mass Spectrometry (LC-MS/MS). Bioequivalence between the products was determined by calculating 90 % confidence intervals (90 % I.C) for the ratio of AUC_{0-t}, AUC_{0-inf} and C_{max} values for the test and reference products, using logarithmic transformed data. The 90 % confidence intervals were 81.89–105.85 %, 84.61–105.30 %, and 84.04–108.66 %, respectively. Since the 90 % confidence intervals for C_{max}, AUC_{0-t} and AUC_{0-inf} were within the 80–125 % interval proposed by the Food and Drug Administration, it was concluded that the two hydroxyzine hydrochloride formulations are bioequivalent in their rate and extent of absorption.**

KEY WORDS: Bioequivalence, Hydroxyzine hydrochloride, LC-MS/MS, Pharmacokinetics.

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