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Pharmacokinetic bioequivalence between generic and branded Ciprofloxacin formulations available in UAE market

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Background & Aim: There are concerns about the quality of generic drugs in the post-marketing settings. Introducing generic products from multiple sources into health care systems exist in many countries in an approach aiming to improving the overall healthcare system. However, this has been accompanied by a variety of problems, the most critical of which is the widespread distribution of counterfeit or substandard products. The aim of this study was to investigate whether locally marketed ciprofloxacin tablets have the required chemical and physical attributes and to establish whether two generic formulations of ciprofloxacin, available on the UAE market, fulfill the criteria for *in vitro* dissolution test and pharmacokinetic bioequivalence.

Method: The ciprofloxacin generic products were compared to the reference as per weight variation, friability, etc. and determination of similarity and difference to assess *in vitro* bioequivalence requirements. The bioequivalence study was conducted according to a single dose, randomized, 2-treatment, 2-sequence, 2-period crossover study design. The pharmacokinetic parameters, C_{max} and T_{max}, were obtained directly from plasma data, ke was estimated by log-linear regression and the area under the curve (AUC) was calculated by the linear trapezoidal rule. The parameters, $AUC_{0-\infty}$ and C_{max}, were tested for bioequivalence after log transformation of data, while the differences of T_{max} were evaluated non-parametrically.

Result & Conclusion: All values were within the bioequivalence acceptance range of 80-125%. The results of this study suggest that the two preparations, the test formulation of ciprofloxacin tablets were bioequivalent to the marketed reference tablet in these healthy male volunteers, based on the USFDA's regulatory definition and UAE guidelines.

Biography

Golnaz Adel Lashkari is currently a Graduate Student at Dubai Pharmacy College, Dubai. He is very much interested on Generic Drugs, Drug Design, and Drug Discovery etc

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