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Comparative randomized, single dose, two-way crossover open label study to determine the bioequivalence of two formulations of Alfuzosin tablets

Abdel Qader Al Bawab
Al-Zaytoonah University of Jordan, Jordon

Alfuzosin is an α1 blocking medication that is approved by the US FDA to treat Benign Prostate Hyperplasia (BPH) by relaxing the muscles in the prostate and bladder neck, making it easier to urinate. The branded alfuzosin is an expensive option; hence, the availability of generic alfuzosin will provide better access to the medication, especially for non-insured patients with BPH. Bioequivalence studies are demanded by the regulatory authorities to allow the marketing of new generics of alfuzosin. The aim of this study is to assess the bioavailability of the generic (test) and branded (reference) formulations of 10 mg alfuzosin of extended release (XR) tablets after oral administration to healthy adults under fed conditions. The current report methodology was based on a comparative, randomized, single dose, two-way crossover open label study design. Thirty three subjects were given a single dose of the test alfuzosin tablet and completed the clinical study. The pharmacokinetic parameters Cmax and AUC0→t, Kel, AUC0→∞, tmax, t1/2el were estimated to prove bioequivalence. The confidence intervals for the log-transformed Test/Reference Ratios for alfuzosin 110.65 (98.01-124.93) % and 111.98 (101.87-123.10) % for Cmax and AUC0→∞, respectively, were within the allowed limit specified by the regulatory authorities (75-133% for Cmax and 80-125% for AUC0→∞). Hence, clinically, the test tablet can be prescribed as an alternative to the reference for the indication of trewting patients with BPH.

Biography

Abdel Qader Al Bawab is a Pharmacist from Jordan. He has completed his Master's degree in Biopharmaceutical from University of New South Wales, Australia in 2006 and in 2012 he attained a PhD degree in Clinical Pharmacy from Queens's University Belfast. He is interested in clinical pharmacokinetics, population pharmacokinetic and bioequivalence studies.

abdelqader.albawab@zuj.edu.jo

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