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

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Dalfampridine is a medication that is approved by the US FDA to improve walking impairments in patients with multiple sclerosis (MS). The branded dalfampridine is enormously expensive; hence, the availability of generic dalfampridine will provide better access to the medication, especially for non-insured patients with MS. Bioequivalence studies are demanded by the regulatory authorities to allow the marketing of new generics of dalfampridine. The aim of this study is to assess the bioavailability of the generic (test) and branded (reference) formulations of 10 mg dalfampridine of extended release (ER) 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. 27 subjects were given a single dose of the test dalfampridine 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 dalfampridine 100.96 (97.09-104.97%) and 99.77 (95.81-103.87%) for Cmax and AUC0→∞, respectively, were within the allowed limit specified by the regulatory authorities (80-125%). Hence, clinically, the test tablet can be prescribed as an alternative to the reference for the indication of improving walking impairments in patients with MS.

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.

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