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Bioequivalence of two prolonged release Diclofenac sodium formulations in healthy volunteers

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Introduction: The implementation of generic drug development programs constitutes a basic component of global health policy. The aim of this work is to determine the existence of bioequivalence between two prolonged release diclofenac sodium formulations in healthy volunteers.

Materials & Methods: A phase I, randomized, crossover, double-blind clinical trial was conducted where Voltaren Retard® (Novartis, Switzerland) and a prolonged release Cuban diclofenac sodium formulation (CIDEM, Havana, Cuba) were compared. The sampling period was 40 hours, with a washout time of 15 days between each period. 36 healthy volunteers of both sexes, aged between 18 and 50, were included. All subjects received orally a single dose of 100 mg (one tablet) of the corresponding formulation in each period.

Results: The quantification of diclofenac sodium in plasma by HPLC demonstrated that both formulations could be considered as bioequivalent. Mean values of the key pharmacokinetic parameters were: AUC (4924.25 vs. 4928.32 µg/mL), Cmax (1046.97 vs. 1042.19 µg/mL); median Tmax was 2 hours for both formulations. The confidence intervals for AUC and Cmax were 98.3-101.7 and 98.75-101.2, respectively. The most frequent adverse events, with both formulations, were headache (11.1%), increase in transaminases values (11.1%), increase in urea (11.1%) and hypertension (8.3%), all of them were mild.

Conclusions: Cuban prolonged release diclofenac sodium formulation was bioequivalent with the international leader formulation Voltaren Retard®.

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