Bioequivalence of two prolonged release Diclofenac sodium formulations in healthy volunteers

Alejandro Saúl Padrón Yaquis¹, Daise Jiménez Rodríguez¹, Carlos Alberto González Delgado¹, Dunia Cazonave Guarnaluce¹, Pedro Lázaro Alejandro Cisneros¹, Tatiana Festary Casanovas¹, Maydel Barrios Sarmiento¹, Alina Díaz Machado¹, Sonia Pérez Rodríguez², Alís Martín Trujillo², Laura Barrero Viera² and Idrian García¹

¹Center for Drug Research and Development, Cuba
²National Center for Toxicology, Cuba

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®.

alejandro.padron@cidem.cu.