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Bioequivalence Assessment of Two Brands (Dong-Kwang Tramcinolone® *vs.* Wyeth Korea Ledercoat® 4 mg Tablets) of Triamcinolone in Healthy Male Human Volunteers

Oh-Seung Kwon [o], Heesoo Pyoa, Moon-Sun Jang, and Youn-Bok Chung[a]

Toxicology Lab., Bioanalysis and Biotransformation Research Center, Korea Institute of Science and Technology, Seoul 136-790, Korea
[a]College of Pharmacy, Chungbuk National University, Cheongju 361-763, Korea

ABSTRACT

The bioequivalence of two 4 mg triamcinolone tablets (Dong-Kwang Triamcinolone® *vs.* Wyeth Korea Ledercoat®) was assessed in healthy male Korean volunteers after oral administration of 16 mg triamcinolone in a randomized crossover study. Blood samples were collected at specified time intervals, and plasma was analyzed for triamcinolone using a validated HPLC method. The pharmacokinetic parameters of T_{max}, C_{max}, $AUC_{0\rightarrow last}$, $AUC_{0\rightarrow inf}$, and $T_{1/2,\beta}$ were determined from plasma concentration-time profile of two formulations. The pharmacokinetic parameters were statistically compared to evaluate bioequivalence between two formulations, according to the United State or Korea Food and Drug Administration Guidelines. The analysis of variance did not show any significant difference between the two formulations and 90% confidence limits fell within the acceptable range (80-120%) for bioequivalence. Based on these data it was concluded that the two products showed comparable pharmacokinetic profiles and that the Dong-Kwang triamcinolone® tablet is bioequivalent to the Ledercoat® tablet produced by Wyeth Korea.