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Bioequivalence Assesment of Tiropramide in Korean Male Volunteers

Young-Jin Park[1°], Youn-Bok Chung[2] and Oh-Seung Kwon[1]

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

ABSTRACT

Two formulations of tiropramide {(±) α-(benzoylamino)-4-[2-(diethylamino)-ethoxy]-N,N-dipropyl-benzenepropanamide hydrochloride}, an antispasmodic agent, were orally administered to 16 healthy Korean male volunteers by the Latin crossover design with the purpose of evaluating bioeqivalence and pharmacokinetics of tiropramide. Tiropramide in human plasma was determined by a gas chromatography/nitrogen phosphorus detector. Detection limit of tiropramide was 5 ng/ml. C_{max} values in test and reference formulations were 93.9 ± 54.3 and 96.4 ± 51.6 ng/ml, respectively. $AUC_{0\rightarrow last}$ and $AUC_{0\rightarrow inf}$ were, respectively, 330.7 ± 193.9 and 349.5 ± 205.3 ng.hr/ml for test formulation, 348.9 ± 207.7 and 380.8 ± 239.0 ng.hr/ml for reference formulation. Terminal half-life was 2.3-2.6 hr. Bioavailability differences for C_{max} and $AUC_{0\rightarrow last}$ were 2.48% and 5.22%, respectively. Minimum detection differences were less than 20 % in both C_{max} and AUC. Based on this results, two formulations of tiropramide were considered to be bioequivalent.