P2 THE BIOEQUIVALENCE STUDY OF ORAL GABAPENTIN 300 MG CAPSULE

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Gabapentin is an antiepileptic drug with the structure similarity to GABA. Gabapentin provides notable benefit, reducing seizure frequency in patients with partial seizures. A new product of gabapentin 300 mg has been developed. The bioequivalent data compared with the innovator's product is required in order to assure the quality and performance of the new generic product.

To compare the bioavailability of new generic product of oral gabapentin capsule manufactured by Unison Laboratories Co.,Ltd. with the innovator's product. The pharmacokinetic parameters of gabapentin in Thai subjects have been studied. Randomized, two-treatment, two-period, two-sequence, single dose crossover design. The study was performed in 14 Thai healthy male volunteers. Each received a single oral dose of 300 mg gabapentin. Double blind randomized two way crossover design was used with two weeks washout period between treatments. After drug administration, serial blood sample was collected over a period of 32 hours. Gabapentin plasma level was determined by the automated High Performance Liquid Chromatography (HPLC) with fluorescence detection after deproteinized with acetonitrile and derivatization with o-phthaldehyde (OPA) reagent containing 2-mercaptoethanol. The difference of phamacokinetic parameters, C_{max} and $AUC_{(0\text{-}inf)}$, were analyzed by Two Way Analysis of Variance (ANOVA) and 90% confidence interval. The maximum concentration (C_{max}, μg/ml) of gabapentin was 3.04±0.55 (range 2.16-4.04) and 3.26±0.62 (range 2.48-4.52) μg/ml for generic and innovator' s product, respectively. The time to peak plasma gabapentin concentration (T_{max}, hr) of generic and innovator's product was 3.00±0.68 (2.00-4.00) and 3.18±0.80 (2.00-5.00), respectively. The area under the plasma concentration-time curve ($AUC_{(0\text{-}inf)}$, μg.hr/ml) was 28.48±7.14 (15.03-42.98) and 29.81±6.33 (20.88-44.15), respectively. The 90 % confidence interval of mean difference of C_{max} and $AUC_{(0\text{-}inf)}$ in term of log transformed data of generic to innovator's product were 82.80-104.61% and 85.57-104.36%, respectively. They were within the range of the acceptance criteria 80-125%.

Conclusions : Gabapentin from the two formulations were bioequivalent.

Keywords: gabapentin, bioequivalence, HPLC