derivatization with MSTFA, using 1 ml of serum obtained from volunteers orally taken 50 mg MT. MT showed good resolutions in this conditions and no significant interfering peaks were observed. The detection limit is less than 5 ng/ml. A good linearity (r >0.9996) was obtained in the range of 5-250 ng/ml MT. Intra-day accuracy bias and precision (CV%) were 0.39-8.01% and 2.76-12.56% and inter-day accuracy bias and precision were 0.42-7.99% and 2.29-17.69%, respectively. The developed method was applied on the pharmacokinetic study of MT after oral administration (50 mg MT) to 8 healthy human volunteers. The principal pharmacokinetic parameters resulted in 275.2 ± 126.5 ng.hr/ml of $AUC_{0\rightarrow 24hr}$, 95.9 ± 67.1 ng/ml of C_{max}, 1.13 ± 0.79 hr of T_{max}, 0.164 ± 0.034 hr^{-1} of K_e, and 4.39 ± 0.90 hr of $t_{1/2}$. This data indicate that the method is suitable for the studies of clnical pharmacokinetics of methyltestosterone and its analogues (This work was supported by the Korea Food and Drug Administration Grant, KFDA-03142-EQI-504).

[PE2-10] [2003-10-11 09:00 - 12:30 / Grand Ballroom Pre-function]

Bioequivalence Assessment of Shinpoong "Dompil?" Tablets Containing Domperidone Maleate in Healthy Korean Volunteers

Yoo Anna°, Kim Sung Chull, Lee Kyung Hee, Park Jong Min, Nam Doo Hyun
College of Pharmacy, Yeungnam University, Department of Internal Medicine, Yeungnam Medical Center, Department of Pharmacy, Yeungnam Medical Center

The bioequivalence of two tablet formulations of 12.72 mg domperidone maleate (Shinpoong "Dompil?" tablets vs. Janssen Korea "Motilium-M?" tablets) was assessed in healthy Korean volunteers after oral administration in a randomized crossover study. Blood samples were collected at specified time intervals, and plasma concentration was measured as the amount of domperidone base using a validated HPLC method. The pharmacokinetic parameters of $AUC_{0\rightarrow 48}$, C_{max}, T_{max} and $t_{1/2}$ were determined from plasma concentration-time profile of two formulations. Any significant statistical differences were not observed between these two formulations. On the evaluation of bioequivalence according to Korea Food and Drug Administration Guideline, 90% confidence limits after logarithmic transformation fell within the acceptable range (log 0.8 ~ log 1.25). Based on these data, it can be concluded that two domperidone maleate tablets showed comparable pharmacokinetic profiles, which means that the Shinpoong "Dompil?" tablet is bioequivalent to the Janssen Korea "Motirium-M?".

[PE2-11] [2003-10-11 09:00 - 12:30 / Grand Ballroom Pre-function]

Bioequivalence of Ersteine™ Capsule to Erdos™ Capsule(Erdosteine 300 mg)

Ha Yong Hwa°, Cho Sung Hee, Hong Sung Je, Lee Heon Woo, Seo Seong Hoon, Rew Jae Hwan, Lee Kyung Tae
College of Pharmacy,Kyung Hee University, Medical Center, Kyung Hee University

The purpose of the present study was to evaluate the bioequivalence of two Erdosteine capsules, Erdos™(Dae Woong Pharmaceutical Co., Ltd.) and Ersteine™(Dae Won Pharmaceutical Co., Ltd.), according to the guidelines of Korea Food and Drug Administration (KFDA). Twenty-four normal male volunteers, 23.88 ± 2.89 year in age and 68.50 ± 7.71 kg in body weight, were divided into two groups and a randomized 2×2 cross-over study was employed. After three capsules containing 300 mg of erdosteine per capsule were orally administered, blood was taken at predetermined time intervals and concentrations of erdosteine in plasma were determined using HPLC. Pharmacokinetic parameters such as AUC_t, C_{max} and T_{max} were calculated and ANOVA test was utilized for the 7statistical analysis of the parameters using logarithmically transformed AUC_t, and C_{max}, untransformed T_{max}. There were no sequence effects between two formulations in these parameters. The 90% confidence intervals for the log transformed data were acceptance range of log0.8 to log1.25(e.g., log0.9062~log1.0758 and log0.8918~log1.0938 for AUC_t and C_{max}, respectively). The major parameters, $AUC_t$and C_{max}, met the criteria of KFDA for bioequivalence indicating that Erdos™ capsule is bioequivalent to Ersteine™ capsule.

[PE2-12] [2003-10-11 09:00 - 12:30 / Grand Ballroom Pre-function]

Study on the Protein Binding of Anti-cancer Agent, 2"-O-benzoylcinnamaldehyde, using Ultrafilteration and Flurescence Spectrometry