AUC_{0-24} increased 1:5.3:7.4 fold and 1:13:42 fold in males and 1:3.3:5.0 fold and 1:8.9:32 fold in females, respectively. On Day 28, C_{max} and AUC_{0-24} increased 1:6.4:11 fold and 1:13:37 fold in males and 1:1.6:3.6 fold and 1:2.5:10 fold in females, respectively. Conclusion: CJ-11555 is dose-dependent in systemic exposure and show better absorption in female with minimum accumulation after multidosing.

[PE2-15] [2003-10-11 09:00 - 12:30 / Grand Ballroom Pre-function]

Bioavailability of Clonazepam in human plasma using a simple HPLC

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We aimed at determining bioavailability of clonazepam, an anxiolytic drug, and developing a simple analysis in human blood using HPLC. A rapid and sensitive HPLC method was developed and validated using reverse-phase C18 column with retension time and limit of quantification of clonazepam being 2.58 min and 5ng/ml, respectively. Quantification was performed at 235 nm with p-hydroxybenzoic acid ethyl ester as internal standard. The method involved a simple extraction. In order to study blood level profile in time, eight volunteers were enrolled and orally took 6 mg clonazepam once. The blood samples were collected from 0 to 120 h after the drug administration. Mean AUC and Cmax value were 1028.17 ±568.165 (ng/ml.hr) and 41.2487 ±10.8180 (ng/ml), respectively. And Mean Tmax and T1/2 value were 1.08375 ±0.42604 (hr) and 30.7823 ±3.26003 (hr). From the results we determine the bioavailability of clonazepam using a newly developed and useful HPLC method

[PE2-16] [2003-10-11 09:00 - 12:30 / Grand Ballroom Pre-function]

Pharmacokinetic disposition of apicidin possessing histone deacetylase inhibiting activities

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The objective of this study was to characterize the absorption and pharmacokinetic disposition of a novel cyclic tetrapeptide, apicidin, in rats. Apicidin was administered to SD rats by i.v. bolus injection (1, 2 or 4 mg/kg) and oral gavages (10 mg/kg). Serum levels of apicidin were monitored by LC/MS over 8 hours following each administration. Upon i.v. injection, serum levels of apicidin were best fit by a multi-exponential equation. The $t_{1/2}$, Cl_s and V_{ss} ranged from 0.9-1.1 hr, 52.8-56.5 ml/min/kg, and 2.6-2.7 L/kg, respectively. No significant difference was found in these parameters as a function of the administered doses. The mean absolute oral bioavailability was 8.1±3.4%. The fraction of unchanged drug excreted in urine was low (<0.1%).

[PE2-17] [2003-10-11 09:00 - 12:30 / Grand Ballroom Pre-function]

Bioequivalence of Enalace™ Tablet to Renitec™ Tablet(Enalapril maleate 10 mg)

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ABSTRACT-The purpose of the present study was to evaluate the bioequivalence of two enalapril maleate tablets, Renitec™(MSD Korea Ltd.) and Enalace™(Welfide Korea Ltd.), according to the guidelines of Korea Food and Drug Administration (KFDA). Twenty-four normal male volunteers, 22.33 ± 2.55 year in age and 66.54 ± 8.30 kg in body weight, were divided into two groups and a randomized 2×2 cross-over study was employed. After two tablets containing 10 mg of enalapril maleate per tablet were orally administered, blood was taken at predetermined time intervals and concentrations of enalapril in plasma were determined using LC-MS-MS. Pharmacokinetic parameters such as AUCt, Cmax and Tmax were calculated and ANOVA test was utilized for the statistical analysis of the parameters using logarithmically transformed AUCt, and Cmax, untransformed Tmax.