concentration-time curve from time zero to time infinity (AUC) of OH-CZX was significantly greater (733 versus 1900 □g • min/mL), AUCOH-CZX/AUCCZX ratio was considerably greater (24.5 versus 105%), Cmax of OH-CZX was significantly higher (6.20 versus 20.6 □g/mL), Vmax (0.923 versus 1.83 nmol/min/mg protein), and CLint (0.0240 versus 0.0337 mL/min/mg protein) were significantly faster than those in control rats. It could also be expected that increased formation of OH-CZX in rats with dehydration could decrease in rats with glucose supplementation. This was also proven in the following results. In rats with glucose supplementation, AUC of OH-CZX was significantly smaller (1900 versus 1050 □g • min/mL), AUCOH-CZX/AUCCZX ratio was significantly smaller (105 versus 34.3%), Cmax was significantly smaller (20.6 versus 8.08 □g/mL), total amount excreted in 24-h urine as unchanged OH-CZX was significantly smaller (62.3 versus 42,7%), Vmax (1.83 versus 1.04 nmol/min/mg protein), CLint (0.0337 versus 0.0204 mL/min/mg protein) were significantly slower than those in rat with dehydration.

[PE2-11] [04/18/2003 (Fri) 09:30 - 12:30 / Hall P]

BIOEQUIVALENCE EVALUATION OF RISPERIDONE 2 MG TABLETS IN HEALTHY MALE KOREAN VOLUNTEERS

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The purposes of this study were to evaluate bioequivalence (BE) using ln-transformed pharmacokinetic parameters obtained from two risperidone products and to develop the analytical methods for the quantitative determination of risperidone in human serum. In addition, the in vitro dissolution profiles of the two risperidone products in various dissolution media: pH 1.2, 4.0, 6.8 and water (KP Ⅶ Apparatus Ⅱ method) were assessed. BE was evaluated in 24 healthy male Korean volunteers in randomized crossover study. Single oral dose of 2 mg of each product was administered after overnight fasting. Blood samples were collected at predetermined time intervals and the concentrations of risperidone in serum were determined using HPLC method with UV detection. The dissolution profiles of two risperidone tablets were very similar at all dissolution media. Besides, the 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, Cmax and untransformed Tmax. The results showed that the differences in AUCt, Cmax and Tmax between two tablets based on the Risperdal® were -0.22%, 4.91% and -0.68%, respectively. And also, the 90% confidence intervals were within the acceptance range of log(0.8) to log(1.25) (e.g., 0.95~1.15 and 0.99~1.18 for AUCt and Cmax, respectively). Consequently, all parameters met the criteria of KFDA guideline for bioequivalence, indicating that Riperidone tablet is bioequivalent to Risperdal® tablet.

[PE2-12] [04/18/2003 (Fri) 09:30 - 12:30 / Hall P]

Effect of Intravenous Infusion Time on the Pharmacokinetics and Pharmacodynamics of the Same Total Dose of Torasemide in Rabbits

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The pharmacokinetics and pharmacodynamics of torasemide were evaluated after an intravenous