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., log1.02~log1.14 and log1.03~log1.19 for AUCt and Cmax, respectively). The major parameters, AUCt and Cmax, met the criteria of KFDA for bioequivalence indicating that Enalace™ tablet is bioequivalent to Renitec™ tablet.

[PE2-18] [2003-10-11 09:00 - 12:30 / Grand Ballroom Pre-function]

Pharmacokinetics of DA-8159, a new PDE5 inhibitor, after single and 1-week repeated oral administrations in mice

Park Kyung-jin°, Ahn Gook-jun, Kim Dong-hwan, Shim Hyun-joo, Ahn Byung-ok, Kim Soon-hoe, Kim Won-bae

Dong-A Pharmaceutical Co. LTD., 47-5, Sanggal-ri, Kiheung-up, Yongin-si, Kyunggi-do, 449-905, Korea

DA-8159 is a new PDEV (Phosphodiesterase V) inhibitor, synthesized by Dong-A Pharm., as an oral agent to treat male erectile dysfunction. To make a selection of the dosage of oral administration in carcinogenic studies, we studied preliminarily the pharmacokinetics of DA-8159 after single (at the 1st day) and 1-week (at the 7th day) oral administrations of the drug at doses of 15, 50 and 150 mg/kg/day, to male ICR mice. In 15mg/kg single and 1-week repeated oral administration groups, the concentrations of DA-8159 and DA-8164(the main metabolite of DA-8159) were below the limit of quantitation(LOQ:50ng/ml). The AUC of DA-8159 was not significantly different between single and 1-week oral administration at 50mg/kg/day. But the AUC of DA-8159 150mg/kg/day 1-week oral administration group was two times higher than that of single administration group. The metabolic ratios (AUC of DA-8164 divided by AUC of DA-8159) of 1-week oral administration at 50mg/kg/day and 150mg/kg/day were increased than those of single oral administration groups. And the metabolic ratios of DA-8159 in mice were very high(over 100%). The metabolic ratio from DA-8159 to DA-8164 of mice was more than those of rats(48.9%), dogs(10.0%) and humans(59.4%).

[PE2-19] [2003-10-11 09:00 - 12:30 / Grand Ballroom Pre-function]

Determination of Prazosin in Human Plasma Using a Validated HPLC Method and Bioavaliability of a Tablet Formulation

Oh JungHyun°, Cho YoungAh, Gwak HyeSun, Noh EunSun, Lee NaYoung, Chun InKoo

Chosun University, College of Pharmacy, Dongduk Women's University, College of Pharmacy

A rapid and reproducible high performance liquid chromatographic assay of prazosin in human plasma was developed. After addition of internal standard (IS, terazosin hydrochloride) and alkalization of the plasma, the drug and IS were extracted into t-butylmethylether. The organic phase was back-extracted with 0.05% phosphoric acid and 50 μl of the acid solution was injected into a reverse-phase C18 column with a mobile phase consisting of water : acetonitrile : triethylamine = 75 : 25 : 0.1 (pH 5.0). The samples were detected utilizing a fluorescence detector. Prazosin and IS showed good resolutions and an excellent linear relationship was (r^2 = 1) was obtained between the peak area ratios and the corresponding concentrations in the ranges of 0.5-50 ng/ml. The applicability of the method was demonstrated by analysis of plasma after oral administration of a single 2-mg dose to 16 healthy subjects. From the plasma prazosin concentration vs. time curves, the mean $AUC_{0\rightarrow12}$ was 108.4 ± 74.2 ng · h/ml and Cmax of 23.1 ng/ml reached 2.1 h after administration. The mean biological half-life of prazosin was 2.5 ± 0.6 h. (This study was supported by a grant from Korea Food and Drug Administration; KFDA-03142-EQI-519)

[PE2-20] [2003-10-11 09:00 - 12:30 / Grand Ballroom Pre-function]

The Effect of Quercetin on the Pharmacokinetics of Paclitaxel in Rats

Choi Jun Shik°, Li Xiuguo

College of Pharmacy, Chosun Uncversity, Guangju 501-759, Korea

The purpose of this study was to investigate the effect of quercetin(2.0, 10, 20 mg/kg; combined or pretreated) on the