measurement of lansoprazole in human plasma, and the application of pharmacokinetic study has been evaluated. Omeprazole was used as an internal standard. After adding methyl tert-butyl ether, samples were stored at -70℃. The extracts were easily obtained only with pouring the organic phase. The mobile phase was prepared using acetonitrile and water at the volume ratio of 38:62. The signals were monitored by UV detector at 285 nm with a flow-rate of 1 ml/min. The retention time of lansoprazole and omeprazole were 6.1 min and 10.2 min, respectively. The limits of lansoprazole in human plasma were 10 ng/ml for detection and 50 ng/ml for quantitation. As a result of the intra-day and inter-day validations, the accuracy of the assay was from 99.51% to 102.24% and the coefficient of variation was less than 9.4%. Moreover, this method was available for pharmacokinetic studies in humans. The maximum plasma concentrations (Cmax), time of maximum plasma concentration (Tmax), and area under the curve ($AUC_{0\rightarrow12hr}$) of lansoprazole were 1.08±0.11 μg/ml, 2.14±0.38 hr, and 2.89±0.36 μg•hr/ml, respectively. This method is suitable for the analysis and pharmacokinetic study of lansoprazole in human subjects.

[PD4-6] [10/18/2002 (Fri) 13:30 - 16:30 / Hall C]

Studies on the Analysis of Anti-impotent Drugs(II) - Rapid analysis of Sildenafil and modified Sildenafils using HPTLC

Choi HyunCheol○, Kang SinJung, Yun MiOk, Park SangAeh, Kim HoJeong, We SaeSeung

Drug Evaluation in Korea Food & Drug Administration

HPTLC(High Performance Thin Layer Choromatography) method was developed for rapid and precise analysis of Sildenafil and modified Sildenafils(Vardenafil, Homosildenafil, Tadanafil). Chromatographic conditions were Optimized for simultaneous analysis of them and each specific UV spectra were obtained. The calibration curve of Sildenafil and modified Sildenafils had a linearity in the range of 1.0 ~ 56.5 μg/mL at 254nm. The Limit of Detection(LOD) and the Limit of Quantification(LOQ) of Sildenafil and modified Sildenafils were 0.8μg/mL and 1.0 μg/mL. The percentage of C.V was not more than 2.3% in precision test. Finally, We rapidly assayed Sildenafil and modified Sildenafils in health supplemental food by this method.

[PD4-7] [10/18/2002 (Fri) 13:30 - 16:30 / Hall C]

Proficiency Test for Pharmaceutical Companies in Analyzing Drug Products (II) - Analysis of Variance of Factors Influencing Test Results

Cho JungHwan○, Choi SeonHee, Sung JunHyun, Lee SeungKyung, Lee HwaJung, Choi YongHoon, Sho YooSub, Moon ByungWoo

Sookmyung Women's University, Kyungin Regional Korea Food & Drug Administration

Analytical results during the proficiency test managed by Kyungin Regional Korea Food & Drug Administration were proposed to be influenced by several factors. Data of several factors were collected along with the test results with ibuprofen and sobrerol formulations. The collected data were the use of internal standard, academic background and career of analytical personnel, production size of the company and location of the participating laboratory. The analytical result itself and deviation from the median value were subject to one-way analysis of variance(ANOVA). The statistical test was performed in a double-blind manner. The use of internal standard gave a significantly different analytical accuracy in the cases of gas chromatographic analysis but not in the cases of liquid chromatographic analysis. The academic background of analytical personnel was influential to the analytical results, that is, analysts with chemistry-related major gave better results. Those with more than 5-year career of pharmaceutical analysis gave better results according to ANOVA. Analytical results from one out of 4 locations of participating laboratories were significantly different from others, which is believed to be an artifact in data. Finally, laboratories of major companies gave more accurate results compared to those of smaller companies.

[PD4-8] [10/18/2002 (Fri) 13:30 - 16:30 / Hall C]

Chiral Separation of Non-Steroidal Inflammatory Drugs and Metabolites by Achiral Gas Chromatography as O-Trifluoroacetylated (-)-Menthyl Esters