600 ng for DM and 300 ng for DX. Dextromethorphan and dextrorphan concentrations in human urine were quantified after hydrolysis. To compare the effectiveness of hydrolysis by enzyme and acid, specimens were hydrolyzed by two method and quantification was performed. As a result, the yield of dextrorphan by enzyme hydrolysis was higher than acidic hydrolysis.

[PD4-13] [04/18/2003 (Fri) 13:30 - 16:30 / Hall P]

A study of test method for impurities(related compounds) in pharmaceutical products

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The high-performance liquid chromatography method was performed for test method development of related compounds in pharmaceuticals. Using reverse-phase column and gradient elution of 1%acetonitrile-acetonitrile: H2O:triethylamine (70:30:0.5), lansoprazole, 2-hydroxybenzimidazole
, 2-mercaptobenzimidazole, lansoprazole sulfone, lansoprazole sulfide could be individually identified and quantitated. The correction factor by sensitivity was calculated, this test method showed a good repeatability and recovery with the range of 93.2 ~104.7%. Another test method, thin-layer chromatography method has been developed for measurement of lansoprazole and related compounds. Identification and quantitation were performed with silicagel F254 HPTLC plate, using development solvents of ethylacetate-chloroform-methano(12:5:1) & chloroform-methanol(10:1). The absorbance was monitered at 285nm. This HPLC & TLC method can be applied to test related compounds of lansoprazole.

[PD4-14] [04/18/2003 (Fri) 13:30 - 16:30 / Hall P]

Stability of 13C-urea/PEG capsules by LC-APCI-MS

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The applicability of liquid chromatography-atmospheric-pressure chemical-ionization mass spectrometry (LC-APCI-MS) for the determination of 13C-urea in 13C-urea/PEG capsules has been studied. It is essential to assess the stability of a newly developed low-dose (38 mg) 13C-urea/PEG capsule, which will be used for 13C-urea breath test (13C-UBT) to detect Helicobacter pylori infection. Standard curve was linear over the concentration range 10-1000 mg/ml. Intra- and inter-day variations were less than 2.75 % in APCI-MS. The detection limit was 10 pg when selected ion monitoring (SIM) was employed. The content of 13C-urea in capsules was within the acceptable range between 95 and 105 %. Therefore, it was established that 13C-urea/PEG capsules were stable under an accelerated stability condition that was set at 40 ±2℃with relative humidity of 75 ±5 % during 6 months by using LC-APCI-MS.

[PD4-15] [04/18/2003 (Fri) 13:30 - 16:30 / Hall P]

Development of analytical method of DMDM hydantoin, Sorbic acid, Phenoxy ethanol in Cosmetics

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A high-performance liquid chromatographic method for the simultaneous quantitative analysis of DMDM hydantoin, sorbic acid, phenoxy ethanol in cosmetics was studied by using a X-terra C18 column and 0.75mM KH2PO4 in 0.85% sulfuric acid and methanol mixture(7:3) at 214nm. Calibration curves were found to be linear in the 20-100㎍/mL range (DMDM hydantoin), 50-250 ㎍/mL range (sorbic acid) and 10-50㎍/mL range (phenoxy ethanol). The result of recovery test were 96.6% ~ 104.2%. This HPLC method can be applied quality control of cosmetics.

[PD4-16] [04/18/2003 (Fri) 13:30 - 16:30 / Hall P]

DETERMINATION OF SIMVASTATIN IN HUMAN PLASMA BY COLUMN SWITCHING HPLC WITH UV DETECTION

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Purpose. The purpose of this study was to develop and validate sensitive and specific analytical method for determinination of simvastatin in human plasma by the column-switching high-performance liquid chromatography (HPLC) system with UV detection.
Methods. Simvastatin and internal standard were extracted into diethyl ether from plasma. The organic phase containing simvastatin and IS was evaporated to dryness and the residue dissolved in mobile phase of 20 mM phosphate buffer (pH 5.6): acetonitrile (55:45) and injected into the pre-column. The analytes fractionated from pre-column by valve switching step were focused in the top of intermediated column and then separated to the analytical column with a mobile phase of 20 mM phosphate buffer (pH 5.6): acetonitrile (35:65) using the UV detection wavelength of 238nm.
Results. Simvastatin and IS are baseline separated with retention times of 25.5 and 28.3 minutes without disturbance of endogeneous material in plasma. The limit of quantification is 0.5 ng/ml. The method has been validated for a linear range of 0.5-20 ng/ml (R2 = 0.999). Also, inter-and intra-day precisions of this method were less than 15%. The averaged extraction recovery was 81.9 % over the concentration. The assay has been successful in measuring plasma concentrations of simvastatin in volunteers receiving dose of simvastatin (800mg).
Conclusions. The results showed that column switching HPLC method with UV detector could be used for the quantitation of simvastatin in plasma. And this method appears suitable for the pharmacokinetic and pharmacodynamic investigation study of simvastatin.

[PD4-17] [04/18/2003 (Fri) 13:30 - 16:30 / Hall P]

Analysis of opiate alkaloids in seized chinese analgesics, 'bokbanggamchopyeon'

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Recently, 'bokbanggamchopyeon', chinese analgesic which is carried in korea by travelers becomes a problem when they pass customs because it contains opiate alkaloids morphine and