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