

suppression of antitumor effects by 5-FU was not found in the using tumor-bearing mice as experimental animals, during administration of KH. This results show that KH is useful to recovery of hematopoietic side effects without suppression of anti-tumor effects by 5-FU. This results offers benefit with respect to the potential use of these hemopoiesis-protecting drugs in chemotherapy

Poster Presentations – Field D4. Analytical Chemistry

[PD4-1] [04/19/2002 (Fri) 10:00 – 13:00 / Hall E]

High throughput analysis of metabolic stability of dopamine receptor antagonists and identification of their metabolites by liquid chromatography/tandem mass spectrometry

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An efficient method using high performance liquid chromatography (HPLC) coupled with ion trap mass spectrometry (MS) for simultaneous quantitation of multiple drugs and identification of their metabolites is described. This approach illustrated with analysis of the *in vitro* metabolism of dopamine receptor antagonists. The compounds were separated into three cassette groups by using a computer program. The samples from incubation with rat liver microsomes were pooled into the designed cassette groups and analyzed by HPLC/electrospray (ESI) ion trap MS in full-scan mode. The metabolic stability of the drugs determined by comparing their signals after incubation for 0 and 30 min, respectively. The quantitative results from the cassette analysis procedure agreed well with those obtained from conventional discrete analysis. In addition, the technique allowed simultaneous detection of metabolites formed during the same incubation without having to reanalyze the samples. The metabolites were first characterized by nominal mass measurement of the corresponding protonated molecules. Subsequent multi-stage tandem spectrometry (MSn) on the ion trap instrument allowed confirmation of the detected metabolites.

[PD4-2] [04/19/2002 (Fri) 10:00 – 13:00 / Hall E]

Studies on test method for residual organic solvents in pharmaceuticals

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The headspace-GC/FID(HS-GC/FID) method was performed for test method development of residual organic solvents in pharmaceuticals. Using SPB-5 and DB-WAX column, 28 kinds of solvents in ICH residual solvents guideline class 1, 2 could be individually identified and quantitated. The following residual solvents were not detected by the headspace injection condition : N,N-dimethylacetamide, N,N-dimethylformamide, ethyleneglycol, formamide, 2-methoxyethanol, N-methylpyrrolidone, sulfurane. The effects of the addition of salts, equilibration time, and equilibration temperature on headspace analysis were investigated. The optimum conditions were obtained with addition of Na₂SO₄ 1g as a salt, simultaneously, the time and temperature of equilibration were 30min and 85°C, respectively. The recovery have found between 90.9 and 114.5% except 1,1-dichloroethene(68.3%). Using DB-624 column & HS-GC/ECD method, 9 kinds of residual solvents could be individually identified and quantitated. This HS-GC method can be applied to test the residual organic solvent in the pharmaceuticals.