B were not different and accepted by KP disintegration test criteria.
So, the disintegration test in soft capsules is applicable in present KP disintegration test.

Poster Presentations - Field E2. Pharmacokinetics

[PE2-1] [04/19/2001 (Thr) 15:30 - 16:30 / Hall 4]

HPLC, BLOOD PARTITION AND PROTEIN BINDING OF A NEW REVERSIBLE PROTON PUMP INHIBITOR, DBM-819

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A high-performance liquid chromatographic method was developed for the determination of a new proton pump inhibitor, DBM-819, in human plasma and urine, and rat tissue homogenates using KR-60461 as an internal standard. A 100-ml aliquot of acetonitrile (containing 0.5 mg/ml of the internal standard) and a 200-ml aliquot of 0.1 M Na2HPO4 (adjusted pH 11 with 1 N NaOH) were added to a 100-ml aliquot of biological sample. After vortex-mixing, the mixture was extracted with 1 ml of ethylacetate. After centrifugation at 12,000 g for 3 min, the organic layer was collected and evaporated under nitrogen gas. The residue was then reconstituted with a 100-ml aliquot of mobile phase, and a 40-ml aliquot was injected onto the HPLC column. The mobile phase, 0.02 M phosphate buffer (pH 5) : acetonitrile : methanol (46:44:10, v/v/v), was run at a flow rate of 0.5 ml/min and the column effluent was monitored by the fluorescence detector set at an excitation wavelength of 340 nm and an emission wavelength of 470 nm. The retention times for DBM-819 and the internal standard were approximately 10.5 and 12 min, respectively. The detection limits of DBM-819 in human plasma and urine, and rat tissue homogenates (including blood) were 0.01, 0.02 and 0.02 mg/ml, respectively. The coefficients of variation of the assay (within-day and between-day) were below 10.6% for human plasma and urine, and rat tissue homogenates. No interferences from endogenous substances were found.
The blood partition of DBM-819 between plasma and blood cells, and the factors influencing the binding of DBM-819 to 4% human serum albumin (HSA) were also evaluated. DBM-819 reached equilibrium rapidly between plasma and blood cells of rabbit blood. The equilibrium plasma/blood cells partition ratios were independent of initial rabbit blood concentrations of DBM-819, 0.5, 2, and 10 mg/ml; the values were in the range of 0.376 ?2.30. Binding of DBM-819 to 4% HSA was dependent on HSA concentrations, DBM-819 concentrations, incubation temperature, 뫁he buffer?pHs, alpha-1-acid glycoprotein concentrations, and addition of acetylsalicylic acid. However, the binding of DBM-819 was independent of heparin concentration and buffers containing various concentrations of chloride ion.

[PE2-2] [04/19/2001 (Thr) 15:30 - 16:30 / Hall 4]

HIGH-PERFORMANCE LIQUID CHROMATOGRAPHIC ANALYSIS, BLOOD PARTITION AND PROTEIN BINDING OF OF A NEW NEUROPROTECTIVE AGENT FOR ISCHEMIA-REPERFUSION DAMAGE, KR-31378