

Sophoricoside was isolated as the inhibitor of IL-5 bioactivity from *Sophora japonica* (Leguminosae). To develop as a novel anti-allergic drug, kinetic study was performed in rats. Serum concentration of sophoricoside was measured by gas chromatography-mass spectrometry (GC/MS) in male Sprague-Dawley rat (250 ± 10 g, $n=5$) after oral administration of sophoricoside (100mg/kg). The recovery of sophoricoside after extraction and concentration was above 95 % from rat serum. Between-day precision (relative standard deviation 2.2-2.8%) and within-day precision (2.0-12.1%) were determined from replicate analysis of a spiked control and incurred serum sample. The detection limits of sophoricoside in this serum was approximately 0.1 ng/mL. The Pharmacokinetic parameters were derived from the noncompartmental analysis. The C_{max} ($3.56 \pm 0.34 \mu\text{g/mL}$) value for sophoricoside in male rat was observed at 7.6 h. The elimination half-life ($t_{1/2}$) of sophoricoside was approximately 4.47 h, the mean residence time (MRT) averaged 10.75 h, the total body clearance (Cl) averaged 0.0042 mL/min/kg. and the area under the serum concentration-time curve ($AUC_{0-\infty}$) was 24.93 $\mu\text{g}\cdot\text{hr/mL}$.

[PE2-23] [04/18/2003 (Fri) 09:30 - 12:30 / Hall P]

Studies on the Standard Protocols of Bioequivalence Test

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After beginning the new medical system separating the prescription from the drug dispensary, the demand of bioequivalence test significantly increases to show the equivalence between the test and reference drugs as a result of amendment of the pharmaceutical affairs law which allows a generic substitution. Accordingly the standard protocols provided by the government are required for reducing the period and the cost to perform the bioequivalence study. As a result of the requirement, this paper provides standard protocols of bioequivalence tests for 11 drugs, composed of 6 protocols based on the documents submitted to KFDA and 5 protocols based on the US pharmacopeia. Standard protocols which are completed by this study are Nabumetone, Doxazosin mesylate, Azelastine hydrochloride, Eperisone hydrochloride, Terazosin hydrochloride, Terbinafine hydrochloride, Dichlofenac sodium, Diltiazem hydrochloride, Captopril, Piroxicam, and Hydroxychloroquine sulfate.

Poster Presentations - Field E3. Physical Pharmacy

[PE3-1] [04/18/2003 (Fri) 09:30 - 12:30 / Hall P]

Synthesis and characterization of transferrin-polyethylenimine conjugate for targeted gene delivery

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