

Quantitation of Mevinolic acid in human plasma by HPLC

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Simple and precise high-performance liquid chromatographic(HPLC) assay developed and validated for the determination of a HMG-Co A reductase inhibitor, lovastatinTM and its active metabolite(Mevinolinic acid) in human plasma. The internal standard and analyte were extracted solid phase extraction using Sep-Pak Cartridge. Samples were analyzed by reversed-phase HPLC using Capcell-Pak C18 column with ultraviolet detection at 238 nm. The quantitation limit of mevinolinic acid was 2ng/ml and the calibration curve was linear over range of 0.002-0.05 µg/ml ($r^2 > 0.99$). In human plasma, intra- and inter-assay accuracy ranged from 97.07 to 103.33% and 98.72 to 104.53%, respectively. The average recoveries were similar(80%) for mevinolinic acid and methylmevinolinic acid. The method described has been successfully applied to the quantification of mevinolinic acid in about 1000 human plasma samples over six-month period.

[PD4-6] [10/19/2000 (Thr) 15:00 - 16:00 / [Hall B]]

MICROBORE HIGH PERFORMANCE LIQUID CHROMATOGRAPHIC ANALYSIS OF LOVASTATINIC ACID IN HUMAN SERUM WITH COLUMN -SWITCHING

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A fully automated semi-microbore high performance liquid chromatographic method using triple column switching was developed for the analysis of lovastatinic acid, an active metabolite of lovastatin from human serum samples obtained after oral administration of lovastatin tablet. Serum samples (120 µl) were directly injected onto a Capcell pak MF ph-1 column (20 x 4.0 mm I.D.) where lovastatinic acid was separated from serum components and lovastatinic acid fraction was transferred into an intermediate column (35 x 2.0 mm I.D.) using 5 % acetonitrile in phosphate buffer (30 mM, pH 6.86) for deproteinization and concentration. The main separation was performed on a semi-microbore C18 column (250 x 1.5 mm I.D.) using linear gradient elution with solvent A (5 % acetonitrile in phosphate buffer (30 mM, pH 6.86)) and solution B (70 % acetonitrile in 0.2 % phosphoric acid). The method showed excellent sensitivity (limit of quantitation : 2 ng/ml) and good precision(C.V. 8.2 %), and shortened total analysis time per serum sample (55 min). The calibration curve was linear (r^2 0.999) over the concentration range 2-100 ng/ml. The applicability of the assay method was proved in the bioequivalence test of two commercial lovastatin tablets.

[PD4-7] [10/19/2000 (Thr) 15:00 - 16:00 / [Hall B]]

The Contents of Preservations in Commercial Drugs

Myoung NH^o, Chae YZ, Song YM, Hwang IS, Lee GM and Shin JY

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This study was performed to analyze the content of preservatives in commercial drugs. 159 of drugs kinds were collected from 1998. 1 to 1999. 12 in Seoul area.

The results were as follows :