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Simple high-performance liquid chromatographic determination of nizatidine in human serum

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Introduction

Nizatidine is used to treat and prevent the recurrence of ulcers and to treat other conditions where the stomach makes too much acid. Nizatidine also is used to treat or prevent occasional heartburn, acid indigestion, or sour stomach. It decreases the amount of acid made in the stomach.

Purpose

To characterize the precise pharmacokinetic properties of Nizatidine, we have developed a new method for the determination of nizatidine in human serum.

Method

Isocratic reverse-phase HPLC was employed for the quantitative analysis by using ranitidine as an internal standard. Solid-phase extraction was performed on an Oasis^{TM} HLB cartridge. The HPLC assay was carried out using a Capcell pak C18 MG (5 ㎛ particle size, 3.0*150 mm I.D.) column. The mobile phase was 5mM Hexanesulfonate soln(0.1% *o*-phosphoric acid) - Acetonitrile, 85:15 (v/v %). The flow rate was 0.5 mL/min and the detection wavelength was set at 320nm. **Result** Calibration of the overall analytical procedure gave a linear signal over concentration range 0.1 - 5 ㎍/mL of nizatidine in serum(r^2 = 0.9956). The

detection limit was 100 ng/mL in serum. Retention time of Nizatidine is 4.2 min, Ranitidine is 5.5 min and is clearly separated from other serum proteins. CVs were assayed by measuring 6 replicate of each pool plasma over 4 days. CVs of the between-day assays and of the average within-day imprecision of the 12 assays ranged between 3.01 and 12.66. Average recovery for Nizatidine was 101.31 %, ranging between 97.37 % and 107.14 %.