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论著

高效液相色谱法测定吡美拉唑血药浓度及其药代动力学

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摘要 目的 建立测定吡美拉唑血药浓度的高效液相色谱(HPLC)方法, 并初步考察其在人体内的药代动力学特性。方法 受试者口服吡美拉唑10 mg后, 分别于给药前, 给药后0.5, 1, 1.5, 2, 4, 8, 12, 21, 36, 48, 60和72 h采集血样, 通过HPLC吡美拉唑的血药浓度, 并应用3P87软件拟合并计算药代动力学参数。结果 吡美拉唑的线性范围为25~4000 μg·L^{-1}, 最低检测浓度为25 μg·L^{-1}, 回收率95.2%~107.7%, 日内精密度均<6.9%, 日间精密度<10.2%。吡美拉唑的主要药代动力学参数: $t_{1/2}$为(22.58±1.59)h, AUC_{0-72}为(29 089±8886)μg·h·L^{-1}, CI/F为(338.9±114.0)L·h^{-1}, t_{max}为(2.67±1.54)h, c_{max}为(1585±469)μg·L^{-1}。结论 吡美拉唑在人体内吸收快, 半衰期较长, 有效作用时间长, 疗效好。

关键词 吡美拉唑 高效液相色谱法 药代动力学

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Determination of pymeprazole in human plasma by RP-HPLC and its pharmacokinetics

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Abstract

OBJECTIVE To establish a high performance liquid chromatography (HPLC) method for pymeprazole in humans, and to explore its pharmacokinetics. **METHODS** HPLC column was Diamond C_{18} (5 μm, 250 mm×4.6 mm) column, the mobile phase was 0.05 mol·L^{-1} phosphatic buffer (pH=6.50)-acetonitrile (64:36, *V/V*), flow rate was 1.0 ml·min^{-1}, and UV detection wavelength was set at 305 nm. Subjects were given pymeprazole 10 mg (*po*) before blood samples were collected at 0, 0.5, 1, 1.5,2, 4, 8, 12, 24, 36, 48, 60 and 72 h after administration. Concentrations of pymeprazole in plasma were determined by HPLC, and parameters were calculated with 3P87 software. **RESULTS** The calibration curve of pymeprazole in plasma samples was linear over the range of 25-4000 μg·L^{-1}(r=0.99998). The lower limit of quantification for pymeprazole in plasma was 25 μg·L^{-1}. The recovery of the method was from 95.2% to 107.7%. The intra-day RSD and inter-day RSD were less than 6.9% and 10.2%, respectively. The main pharmacokinetic parameters of pymeprazole were $t_{1/2}$ (22.58±1.59)h, AUC_{0-72} (29 089±8886)μg·h·L^{-1}, Cl/F (338.9±114.0)L·h^{-1}, t_{max} (2.67±1.54)h, and c_{max} was (1585±469)μg·L^{-1}. **CONCLUSION** S HPLC method is simple, quick, sensitive and accurate. Pymeprazole is rapidly absorbed, and its $t_{1/2}$ is longer than that of other proton inhibitors in subjects.

Key words pymeprazole HPLC pharmacokinetics

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