

论文

尼卡地平血药浓度测定及其人体药代动力学

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摘要:

目的 建立人血浆中尼卡地平(Nic)浓度测定的毛细管柱气相色谱法, 并以此法研究健康受试者po Nic缓释胶囊后的药代动力学。方法 样品经甲苯提取, 过无水硫酸钠小柱后, 用HP-1 25 m×0.32 mm ID毛细管柱分离, 采用无分流进样方式, 以巴尼地平作为内标, ⁶³Ni电子捕获检测器检测。结果 该法在0.5~100 ng.mL⁻¹浓度范围内呈线性关系, 最低定量浓度为0.5 ng.mL⁻¹, 日内、日间RSD分别小于4%和7%, 低、中、高浓度(0.5, 10, 50 ng.mL⁻¹)的平均回收率分别为86.0%, 95.7%和91.2%。用此法测定了12名健康受试者单剂量及多剂量po Nic缓释胶囊后的血药浓度经时变化过程。结论 此法提取率高、重现性好、操作简便、检测灵敏度高, 适用于临床药代动力学研究及血药浓度监测。

关键词: 尼卡地平; 气相色谱法; 药代动力学

DETERMINATION OF NICARDIPINE IN PLASMA BY GC-ECD AND STUDY ON ITS PHARMACOKINETICS IN HEALTHY VOLUNTEERS

CHEN Hui; GU Shi-fen; XIAO Zhou; ZENG Fan-dian;WU Wen-zhong; ZHANG Qing-hua

Abstract:

AIM A gas chromatographic method was developed for the determination of nicardipine in human plasma and its pharmacokinetics in healthy volunteers. METHODS Nicardipine in plasma was extracted with toluene and barnidipine was used as internal standard. Chromatography was performed on a 25 m×0.32 mm ID fused-silica capillary column by splitless injection with an electron-capture detector. RESULTS The calibration curve was linear in the range of 0.5~100 ng.mL⁻¹, the minimal detectable concentration in plasma was 0.5 ng.mL⁻¹. The precisions (RSD) of within-day and between-days were less than 4% and 7% respectively. The extraction recoveries for the concentrations of 0.5, 10 and 50 ng.mL⁻¹ were 86.0%, 95.7% and 91.2%, respectively. The plasma concentration-time curves and the pharmacokinetic characteristics of nicardipine sustained release capsules after a single and multiple oral doses in 12 healthy volunteers were studied by the GC-ECD method. CONCLUSION The established method was shown to be sensitive, accurate and simple for the determination of nicardipine levels in human plasma. It is suitable for its pharmacokinetic study and therapeutic drug monitoring.

Keywords: GC-ECD pharmacokinetics nicardipine

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