

论文

液相色谱-电喷雾串联质谱法测定人血浆中班布特罗:在药代动力学研究中的应用

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摘要:

目的 建立液相色谱 串联质谱法测定人血浆中班布特罗浓度,研究中国受试者口服该药的药代动力学特点。方法 血浆样品经液 液萃取后,采用液相色谱电喷雾串联质谱法以选择离子反应监测(SRM)方式进行检测。结果班布特罗的线性范围为0.05 - 4.0ng·mL⁻¹,最低定量浓度为0.05ng·mL⁻¹,该法的日内及日间精密度(RSD)小于8%,准确度(RE)在±9%范围内。18名中国健康受试者单剂量口服班布特罗10 mg后,主要药代动力学参数T_{max},C_{max},T_{1/2}和AUC_{0-t}分别为(2.3±1.3)h,(3.95±2.20)ng·mL⁻¹,(11.4±6.1)h和(26.85±11.77)ng·h·mL⁻¹。结论 该法灵敏度高,操作简便、快速,适用于临床药代动力学研究

关键词: 班布特罗 液相色谱-电喷雾串联质谱法 血浆药物浓度 药代动力学

DETERMINATION OF BAMBUTEROL IN HUMAN PLASMA BY LIQUID CHROMATOGRAPHY-ELECTROSPRAY TANDEM MASS SPECTROMETRY: APPLICATION TO PHARMACOKINETIC STUDY

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Abstract:

AIM To develop a sensitive, specific and accurate method for quantifying bambuterol in human plasma and to study pharmacokinetics of bambuterol in male healthy Chinese. METHODS Plasma samples were prepared based on a simple liquid liquid extraction. The extracted samples were analyzed on liquid chromatography using a Zorbax SB C₁₈ column interfaced with a triple quadrupole tandem mass spectrometer and detected by use of selected reaction monitoring mode. RESULTS The linear calibration curves were obtained in the concentration range of 0.05-4.0 ng·mL⁻¹. The limit of quantification was 0.05 ng·mL⁻¹. The intra- and inter-run precision was measured to be below 7%. The inter-run accuracy was less than 8% for the analyte. After an oral administration of 10 mg bambuterol hydrochloride to 18 healthy Chinese volunteers the main pharmacokinetic parameters of bambuterol were as follows: T_{max} was (2.3±1.3) h; C_{max} was (3.95±2.20) ng·mL⁻¹; T_{1/2} was (11.4±6.1) h and AUC_{0-t} was (26.85±11.77) ng·h·mL⁻¹. CONCLUSION The method is shown to be accurate, robust and convenient, and suitable for pharmacokinetic studies of bambuterol. It was found that there was marked inter-individual difference in the pharmacokinetics of bambuterol in Chinese volunteers after a single oral dose, which may be attributed to the difference of activity of cholinesterase, an enzyme catalyzing bambuterol metabolism.

Keywords: liquid chromatography-electrospray tandem mass spectrometry plasma concentration pharmacokinetics bambuterol

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