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论文

LC-MS/MS法测定人血浆中的氨溴索和克仑特罗

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摘要：

建立了快速、灵敏的LC-MS/MS法测定人血浆中的氨溴索和克仑特罗的浓度，并用于氨溴特罗口服液的药代动力学研究。分别采用不同的流动相系统和离子源测定氨溴索和克仑特罗。血浆样品经液-液萃取后以甲醇-水-甲酸(80∶20∶0.2，*v*/*v*/*v*)为流动相，采用APCI源以SRM方式对血浆样品中的氨溴索进行定量分析。采用ESI源，以乙腈-水-甲酸(40∶60∶0.05，*v*/*v*/*v*)为流动相测定克仑特罗的血浆浓度。结果表明，氨溴索血浆浓度测定方法的线性范围为0.080～400 μg·L^{-1}，日内、日间精密度(RSD)均小于6.7%，准确度(RE)在±1.9%之内。克仑特罗血浆浓度测定方法的线性范围为5.00～5 000 ng·L^{-1}，日内、日间精密度(RSD)均小于7.5%，准确度(RE)在±2.5%之内。本方法专属性强、灵敏度高，血浆用量少，适用于复方制剂中氨溴索和克仑特罗的药代动力学研究。

关键词： 氨溴索 克仑特罗 液相色谱-串联质谱法 药代动力学

Determination of ambroxol and clenbuterol in human plasma by LC-MS/MS method

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Abstract:

Ambroxol and clenbuterol were extracted from human plasma samples by liquid-liquid extraction, ambroxol was separated on a Zorbax XDB-C_{18} column and detected by tandem mass spectrometry with an atmospheric pressure chemical ionization interface after oral administration of a compound preparation. Clenbuterol was separated on a Zorbax XDB-C_8 column and detected by tandem mass spectrometry with an electrospray ionization interface. Diphenhydramine is used as the internal standard. The linear concentration ranges of the calibration curves for ambroxol and clenbuterol were 0.080-400 μg·L^{-1} and 5.0-5 000 ng·L^{-1}, respectively. The lower limits of quantification were 0.080 μg·L^{-1} for ambroxol and 5.0 ng·L^{-1} for clenbuterol, individually. The inter-day and intra-day precision (RSD) across three validation run over the entire concentration range was below 7.5%, and the accuracy (RE) was within ±2.5% for both ambroxol and clenbuterol. The methods were used to determine the pharmacokinetic parameters of ambroxol and clenbuterol in human plasma after oral administration of a compound preparation containing 60 mg ambroxol hydrochloride and 40 μg clenbuterol hydrochloride. The method was proved to be highly sensitive, selective and suitable for the pharmacokinetic study of different compound preparations containing ambroxol and clenbuterol.

Keywords: clenbuterol LC-MS/MS pharmacokinetics ambroxol

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