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论文

LC-MS/MS 法测定人血浆中倍他米松

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摘要：

建立测定人血浆中倍他米松的LC-MS/MS方法。采用Venusil XBP C_8 (200 mm×3.9 mm ID, 5 μm)色谱柱，流动相为甲醇-水(含甲酸铵5 mmol·L^{-1})(80∶20)，流速0.4 mL·min^{-1}；质谱仪离子源为电喷雾离子源(ESI)，正离子模式检测，监测离子为393.3→355.2(倍他米松)和361.3→343.2(泼尼松龙,内标)。血浆样本用乙酸乙酯处理。倍他米松在0.5~80.0 ng·mL^{-1}线性关系良好(r=0.999 2)， 血浆低、 中、 高3种浓度(1.0， 10.0， 60.0 ng·mL^{-1})平均提取回收率为88.24%，定量限为0.5 ng·mL^{-1}。本方法操作简便、准确、灵敏，适用于复方倍他米松注射液人体药代动力学研究。

关键词： 倍他米松 LC-MS/MS 药代动力学 复方倍他米松注射液

Determination of betamethasone in human plasma by liquid chromatography with tandem mass

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Abstract:

A sensitive and selective liquid chromatography-tandem mass spectrometric (LC-MS/MS) method was developed and validated for the determination of betamethasone in human plasma. The analyte was isocratically eluted on a Venusil XBP C_8 column (200 mm×3.9 mm ID, 5 μm) with methanol-water (containing 5 mmol·L^{-1} ammonium formate) (80∶20) at a flow rate of 0.4 mL·min^{-1}, and detected with a triple quad LC-MS/MS using ESI with positive ionization. Ions monitored in the multiple reaction monitoring (MRM) mode were m/z 393.3→355.2 for betamethasone and m/z 361.3→343.2 for prednisolone (IS). Betamethasone was extracted from 0.5 mL human plasma with ethyl acetate. The average recovery is 88.24% and the low limit of quantitation (LLOQ) was 0.5 ng·mL^{-1}. The 3-day validation study demonstrated excellent precision and accuracy across the calibration range of 0.5-80.0 ng·mL^{-1}. The method was successfully applied to the pharmacokinetic study of compound betamethason injection in healthy Chinese volunteers.

Keywords: LC-MS/MS pharmacokinetics compound betamethasone injection betamethasone

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