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论文

液相色谱-串联质谱法测定犬血浆中布地奈德

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摘要：

建立液相色谱-串联质谱法测定犬血浆中布地奈德。血浆样品碱化后，经乙酸乙酯液-液萃取，以乙腈-5 mmol·L^{-1}醋酸铵(60∶40，*v*/*v*)为流动相，Capcell Pak C_{18} MG柱分离；采用电喷雾电离源，以多反应监测(MRM)方式进行负离子检测，用于定量分析的离子反应分别为*m*/*z* 489→*m*/*z* 357(布地奈德)和*m*/*z* 493→*m*/*z* 413(内标，曲安奈德)。测定血浆中布地奈德方法的线性范围为25.0～2 000 pg·mL^{-1}，定量下限为25.0 pg·mL^{-1}，日内、日间精密度(RSD)均小于15%，准确度(RE)在-8.1%～-1.7%。应用本法研究6只比格犬单次和多次给予布地奈德缓释胶囊9 mg后的药代动力学结果显示：单次给药后T_{max}为(3.5±3.3) h，C_{max}为(786±498) pg·mL^{-1}；多次给药后C_{max}为(2 142±1 515) pg·mL^{-1}。该法选择性强、灵敏度高、操作简便，适用于布地奈德缓释制剂的药代动力学研究。

关键词： 布地奈德 缓释制剂 液相色谱-串联质谱法 药代动力学

LC-MS/MS determination of budesonide in dog plasma

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Abstract:

A liquid chromatographic-tandem mass spectrometric (LC-MS/MS) method was developed for the determination of budesonide in dog plasma. Budesonide and the internal standard triamcinolone acetonide were separated from plasma by alkalinized liquid-liquid extraction with ethyl acetate. Chromatographic separation was performed on a Capcell Pak C_{18} MG column with the mobile phase consisted of acetonitrile - 5 mmol·L^{-1} ammonium acetate (60∶40, *v*/*v*) at a flow-rate of 0.50 mL·min^{-1}. A tandem mass spectrometer equipped with electrospray ionization source was used as detector and operated in the negative ion mode. Quantification was performed using multiple reaction monitoring (MRM) of the transitions *m*/*z* 489 → *m*/*z* 357 and *m*/*z* 493 → *m*/*z* 413 for budesonide and the internal standard, respectively. The linear calibration curves were obtained in the concentration range of 25.0-2 000 pg·mL^{-1}. The lower limit of quantification was 25.0 pg·mL^{-1}. The intra- and inter-day relative standard deviation over the entire concentration range was less than 15%. The accuracy was in the range of -8.1% to -1.7% in terms of relative error. The method was applied to a pharmacokinetic study of budesonide controlled-release capsules in Beagle dogs. Maximal budesonide plasma level was observed after (3.5±3.3) h and the C_{max} was (786±498) pg·mL^{-1} after a single oral administration of 9 mg budesonide capsules, C_{max} was increased to (2 142±1 515) pg·mL^{-1} after multiple oral administration (9 mg×5 d) of budesonide capsules. This method was selective and rapid, and the sensitivity was sufficient for the purpose of the pharmacokinetic study of budesonide controlled-release formulation.

Keywords: controlled-release formulation LC-MS/MS pharmacokinetics budesonide

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