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#### 论文

HPLC-MS/MS法测定血浆中十肽化合物LXT-101及Beagle犬药代动力学研究

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摘要:

建立HPLC-MS/MS法测定血浆中十肽化合物(LXT-101)的浓度,并应用于Beagle犬的药代动力学研究。血浆样品采用乙腈直接沉淀蛋白的方法,内标(IS)选用 $^{127}$ I-LXT-101,采用ESI-MS/MS二极质谱,选择反应监测(SRM)方式进行检测。LXT-101的线性范围为0.5~500.0  $ng\cdot mL^{-1}$  ( $r^2>0.993$  0),绝对回收率为85.2%~90.7%,日内、日间精密度(RSD%)均小于10.9%,准确度(RE)在±1.8%之内。血浆中的最低检测限(LOQ)为0.5  $ng\cdot mL^{-1}$ 。该法操作简便、快速、灵敏度高。可检测出低剂量肌注(im)给药后犬体内的血药浓度,适于临床前药代动力学研究。

关键词: 十肽 HPLC-MS/MS 药代动力学

Determination of decapeptide LXT-101 in plasma by HPLC-MS/MS and its pharmacokinetics in Beagle dogs

KONG Ai-ying; ZHANG Zhen-qing; QIAO Jian-zhong; ZHANG Fan; ZHOU Wen-xia; LIU Ke-liang; RUAN Jin-xiu

#### Abstract:

This paper developed a sensitive and specific liquid chromatography-electrospray ionization mass spectrometry (HPLC-MS/MS) method for the determination of decapeptide LXT-101 in Beagle dog plasma. Plasma samples spiked with internal standard (IS) were treated with acetonitrile to precipitate the protein. Selected reaction monitoring (SRM) using the precursor  $\rightarrow$  product ion combinations of m/z 472.1 $\rightarrow$ 587.9 and m/z 502.8 $\rightarrow$ 633.8 were used to quantify LXT-101 and IS, respectively. The linear calibration curves were obtained in the concentration range of 0.5-500.0 ng·mL<sup>-1</sup>. The limit of quantification (LOQ) was 0.5 ng·mL<sup>-1</sup>. The inter-day and intra-day precision (RSD) across three validation run over the entire concentration range was below 10.9%, and the accuracy (RE) was within  $\pm$ 1.8%. The main pharmacokinetic parameters of LXT-101 after muscle injection of 20  $\mu$ g·kg<sup>-1</sup> were as follows, AUC<sub>0-t</sub>: (176.8 $\pm$ 116.7)  $\mu$ g·h·L<sup>-1</sup>, MRT<sub>0-t</sub>: (2.52 $\pm$ 0.53) h,  $T_{1/2}$ : (1.4 $\pm$ 0.3) h; CL: (0.16 $\pm$ 0.09) L·h<sup>-1</sup>·kg<sup>-1</sup>, and  $V_{\rm d}$ : (0.30 $\pm$ 0.16) L·kg<sup>-1</sup>, respectively. The method is proved to be specific, sensitive and suitable for the investigation of LXT-101 pharmacokinetics in Beagle dog.

Keywords: HPLC-MS/MS pharmacokinetics decapeptide

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