

正相液相色谱-串联质谱法分离普萘洛尔对映体

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Enantiomeric separation of propranolol by normal phase chiral liquid chromatography coupled with tandem mass spectrometry

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摘要 建立正相液相色谱-串联质谱(LC-MS/MS)分离普萘洛尔对映体的方法,并用于盐酸普萘洛尔片对映体含量测定。样品使用甲醇进行简单提取,采用Chiralcel OD-H手性柱,以正己烷-乙醇-氨水(70:30:0.4, v/v/v)为流动相,流速为0.4 mL/min。在正离子模式下,通过电喷雾离子化(ESI+),采用多反应监测(MRM)方式进行检测,用于定量分析检测的离子对为m/z 260.2→116.0,在20 min内完成普萘洛尔对映体定量分析。盐酸普萘洛尔对映体在2.5~1000 µg/L质量浓度范围内线性关系良好,定量限为2.5 µg/L;日内及日间测定的相对标准偏差小于2.64%。两种对映体的加样回收率范围分别为99.08%~102.58%和100.21%~103.16%。该方法准确、简便、可靠、有效,可用于盐酸普萘洛尔片对映体的质量控制。

关键词: 正相液相色谱-串联质谱 手性分离 测定 普萘洛尔对映体

Abstract: A rapid and sensitive method was developed and validated using a normal phase liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS) for determination of propranolol enantiomers in pharmaceuticals. Sample preparation involved a single extraction step by the addition of methanol. Separation of propranolol enantiomers was achieved on a Chiralcel OD-H chiral column using a mobile phase consisting of n-hexane-ethanol-ammonia (70:30:0.4, v/v/v), and the flow rate was 0.40 mL/min for 20 min. The analyte was monitored by tandem mass spectrometry with electrospray positive ionization in multiple reaction monitoring (MRM) mode, using the transitions of m/z 260.2→116.0. Propranolol enantiomers can be completely separated. The linear range was 2.5~1000 µg/L, and the limit of quantification (LOQ) was 2.5 µg/L. The values for within day and between day precisions and accuracies were well within the generally accepted criteria for analytical methods. The relative standard deviations (RSDs) were less than 2.64%, and the recoveries of the two enantiomers were 99.08%~102.58% and 100.21%~103.16%, respectively. The separation method is accurate, convenient, reliable, efficient, and can be subsequently used for quality control of propranolol enantiomers in pharmaceuticals.

Keywords: normal phase liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS) chiral separation determination propranolol enantiomers

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