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HPLC-ELSD测定多西他赛注射用浓溶液中溶血磷脂酰乙醇胺、溶血磷脂酰胆碱的含量

Determination of Lyso-phosphatidylethanolamine and Lyso-phosphatidylcholine in Docetaxel Concentrated Solution for Injection

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中文关键词: [多西他赛注射用浓溶液](#) [溶血磷脂酰乙醇胺](#) [溶血磷脂酰胆碱](#) [高效液相色谱-蒸发光散射法](#) [含量测定](#)

英文关键词: [Docetaxel Concentrated Solution for Injection](#) [lyso-phosphatidylethanolamine](#) [lyso-phosphatidylcholine](#) [HPLC-ELSD](#) [content determination](#)

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中文摘要:

目的 建立同时测定多西他赛注射用浓溶液中的溶血磷脂酰乙醇胺(LPE)、溶血磷脂酰胆碱(LPC)含量的HPLC-ELSD。方法 采用YMC Pack PVA-Sil(150 mm×2 mm, 5 μm)色谱柱, 以三氯甲烷为流动相A、甲醇-水(93.5:6.5)为流动相B, 梯度洗脱, 流速为0.4 mL·min<sup>-1</sup>, 柱温为25 °C, 蒸发光散射检测器检测, 检测器漂移管温度: 100 °C, 雾化气: 空气, 气体流量为2.0 L·min<sup>-1</sup>。结果 LPE和LPC峰面积的对数与相应的浓度的对数呈良好的线性关系, 线性范围分别为0.203~0.811 μg( $r=0.999\ 0$ )和0.407~6.102 μg( $r=0.999\ 6$ ), LPE 3个浓度的平均加样回收率分别为104.1%, 95.1%, 101.6%, RSD分别为3.8%, 0.3%, 2.4%, LPC 3个浓度的平均回收率分别为108.7%, 104.5%, 105.5%, RSD分别为1.0%, 3.0%, 2.6%。结论 该法简单、准确、重复性好, 可用于多西他赛注射用浓溶液中大豆磷脂分解产物的质量控制。

英文摘要:

OBJECTIVE To develop an HPLC-ELSD method for the determination of lyso-phosphatidylcholine(LPC) and lyso-phosphatidylethanolamine(LPE) in Docetaxel Concentrated Solution for Injection. METHODS It was separated with YMC Pack PVA-Sil (150 mm×2 mm, 5 μm) by gradient elution with chloroform as mobile phase A and methanol-water (93.5:6.5) as mobile phase B at a flow rate of 0.4 mL·min<sup>-1</sup>. The column temperature was kept at 25 °C for separation. The detector was ELSD, of which the drift tube temperature was maintained at 100 °C and the flow rate of carrier gas

air was kept at  $2.0 \text{ L} \cdot \text{min}^{-1}$ . RESULTS The linear response was calculated by logarithm. The calibration curves were linear in the range of  $0.203\text{--}0.811 \mu\text{g}$  ( $r=0.9990$ ) for LPE and  $0.407\text{--}6.102 \mu\text{g}$  ( $r=0.9996$ ) for LPC. The average recovery for LPE was 104.1%, 95.1%, 101.6%, RSD=4.6%; and the average recovery for LPC was 108.7%, 104.5%, 105.5%, RSD=2.7%. CONCLUSION The established method is simple, accurate and reproducible, which can be used for the quality control of Docetaxel Concentrated Solution for Injection.

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