

宋玉乔 北京市海淀区复兴路28号 解放军总医院医学实验测试中心 100853

廖杰 北京市海淀区复兴路28号 解放军总医院医学实验测试中心 100853

陶忠华 解放军总医院科技开发中心 100853

等

摘要: 目的: 采用高效液相对银杏内酯B注射液在生理盐水中的稳定性进行研究, 又采用HPLC-MS法对银杏内酯B注射液在生理盐水中经加热后所生成的降解产物进行研究。方法: 高效液相条件为: 色谱柱: Venusil XBP-C 18 (5 μ m, 4.6 \times 250mm), 柱温: 25 $^{\circ}$ C, 流动相[DK(): [DK)]甲醇[DK(): [DK)]水(40 [DK(): [DK)]60), 流速: 1.0mL/min, 检测波长: 220nm。结果: 在上述色谱条件下, 本品在0.1~2mg/mL范围呈线性关系, 回归方程为: $Y=313.95X+0.8054$, $r=0.9999$; 精密度良好, RSD: 0.86%; 主峰与其它杂质峰分离良好。结论: 银杏内酯B注射液在生理盐水中至少可放置3个月。

关键词: 银杏内酯B, 银杏内酯B注射液, HPLC HPLC-MS, 有关物质

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Study on stability of Ginkgolide B injection in the chloride sodium injection

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Abstract: Objective To study the stability of Ginkgolide B injection in the chloride sodium injection by HPLC and its degradation after heating by HPLC-MS. Method Chromatographic condition: the column: Venusil XBP-C 18 (5 μ m, 4.6mm \times 250mm); column temperature: 25 $^{\circ}$ C; the mobile phase: methanol:water(40/60, V/V); the flow rate: 1.0mL/min; the detection wavelength: 220nm. Result The relationship between amount of Ginkgolide B and peak areas can be described by the linear equation: $Y=313.95X+0.8054$ ($r=0.9999$). The precision was good with RSD of 0.86%. A good separation was achieved from Ginkgolide B and its related substances. Conclusion Ginkgolide B injection can keep stable at least three years in the chloride sodium injection.

Key words: Ginkgolide B, Ginkgolide B injection, HPLC HPLC-MS, Related substances

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