

方药纵横

天仁安眠颗粒的质量标准研究^{*}

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摘 要: **目的** 建立天仁安眠颗粒的质量标准。 **方法** 采用薄层色谱法对天仁安眠颗粒中的天麻和酸枣仁进行定性鉴别; 采用高效液相色谱法对本品中的天麻素进行含量测定, 流动相条件为 HYPERSIL C18 色谱柱, 流动相乙腈-0.05% 磷酸溶液(3:97), 流速 0.5 ml/min, 柱温 25℃, 检测波长 220 nm。 **结果** 薄层鉴别斑点清晰、分离较好; 天麻素的质量浓度在 0.05~0.30 mg/mL 范围内与峰面积呈良好的线性关系($r=0.9999$), 天麻素的平均加样回收率为 100.67%, $RSD=1.39\%$ ($n=6$)。 **结论** 本研究所建立的定性与定量方法简便可行, 可用于天仁安眠颗粒的质量控制。

关键词: 天仁安眠颗粒; 天麻素; 薄层色谱法; 高效液相色谱法

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Study on the Quality Standard of Tianren Hypnotic Granules

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Abstract Objective: To establish quality standard for Tianren hypnotic granules. **Method:** gastrodia elata and spine date seed in Tianren hypnotic granules were identified by TLC. The content of gastrodin in the product was determined by high performance liquid chromatography. The mobile phase conditions were HYPERSIL C18 column, mobile phase acetonitrile-0.05% phosphoric acid solution (3:97), flow rate of 0.5 ml/min, column temperature of 25℃, detection wavelength of 220 nm. **Result:** TLC spots were clear and well separated. The mass concentration of gastrodin showed a good linear relationship with the peak area in the range of 0.05~0.30 mg/mL ($r=0.9999$), and the average recovery rate of gastrodin was 100.67%, $RSD=1.39\%$ ($n=6$). **Conclusion:** The qualitative and quantitative methods established in this study are simple and feasible, and can be used for the quality control of Tianren hypnotic granules.

Key words Tianren hypnotic granules; gastrodin; TLC; HPLC

天仁安眠颗粒是由酸枣仁、首乌藤、天麻、黄胆、脾气血阴阳的功效, 临床上用于治疗失眠症。连和肉桂组成的复方中药制剂, 具有调节心、肝、本品对中医辨证为心血虚弱、体内阴阳失和、阴虚

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