

得生胶囊质量标准提高研究^{*}

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摘 要:**目的** 建立得生胶囊的质量标准。**方法** 采用显微镜对鳖甲进行显微特征鉴别;采用 TLC 法对得生胶囊中人参、郁金进行定性鉴别;采用 2015 年版《中国药典》进行得生胶囊微生物限度检查的方法学验证;采用 HPLC 法测定大黄中大黄素的含量。**结果** 显微特征明显;TLC 鉴别人参、郁金特征斑点清晰,分离度良好;可采用平皿法和直接接种法进行得生胶囊微生物限度检查;含量测定大黄素在 0.02002~0.2002 μg 范围内线性关系良好($r=0.999\ 8$),平均回收率为 98.04%,RSD 为 1.63% ($n=6$)。**结论** 本方法操作简便,专属性高、重复性好,可作为得生胶囊的质量控制方法。

关键词:得生胶囊;质量标准;高效液相色谱法;薄层色谱法;微生物限度检查
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Study on the Improvement of Quality Standard for Desheng Capsule

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Abstract **Objective:**To establish quality standard for Desheng Capsule. **Method:**The microscopic features of the carapax trionycis were identified by microscope. The ginseng and turmeric in Desheng Capsule were qualitatively identified by TLC method, which was verified by the 2015 edition of Chinese Pharmacopoeia. HPLC was used to determine the content of emodin in Rhubarb. **Result:**The microscopic features were obvious; TLC identified ginseng and turmeric characteristic spots were clear and the resolution was good; the microbial limit test of the capsules could be carried out by the plate method and the direct inoculation method; the content of emodin was linear in the range of 0.02002~0.2002 μg ($r=0.999\ 8$), the average recovery was 98.04%, and the RSD was 1.63% ($n=6$). **Conclusion:**The method is simple, highly specific and reproducible, and can be used as a quality control method for Desheng Capsule.

Key words Desheng Capsule; quality standard; HPLC; TLC; microbial limit test

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