

汉防己甲素眼用凝胶剂的制备及质量控制

赵文明

辽宁医学院 药学院, 辽宁 锦州 121001

收稿日期 2009-6-25 修回日期 2009-6-30 网络版发布日期 2009-7-30 接受日期 2009-6-25

摘要

目的 制备汉防己甲素眼用凝胶剂并建立质量控制方法。方法 采用羟丙基甲基纤维素 (HPMC) 作基质制备眼用凝胶剂, 采用HPLC法测定汉防己甲素的含量, 并建立制剂其他的质量控制指标。结果 汉防己甲素眼用凝胶剂外观为无色澄明黏稠胶体。汉防己甲素又名粉防己碱 (tetrandrine, TET) 在5~40 mg/L-1的浓度内线性关系良好 ($r=0.9999$)。平均回收率为99.3% (RSD=0.16%)。结论 该眼用凝胶剂处方可用于工业化大生产。

关键词 [药剂学](#) [眼用凝胶剂](#) [汉防己甲素](#) [高效液相色谱法](#)

分类号 [R94](#)

Preparation and quality control of tetrandrine ophthalmic gels

ZHAO Wen-ming

Department of Pharmacy, Liaoning College of Medicine, Jinzhou 121001, China

Abstract

Objective To prepare tetrandrine ophthalmic gels and establish quality control method. Methods HPMC K4M was used as the matrix to prepare ophthalmic gels. The quality control method was explored. The content of tetrandrine was determined by HPLC. The stability of the gels at different conditions was studied. Results The ophthalmic gels were colorless and viscous. There was a good linear relationship between peak area and drug concentration in the concentration range of 5-40 mg/L-1 ($r=0.9999$). The recovery of tetrandrine was 99.3% (RSD=0.16%). Conclusion The procedure of preparing ophthalmic gels is reliable and the prepared ophthalmic gels are stable.

Key words [pharmaceutics](#) [ophthalmic gel](#) [tetrandrine](#) [HPLC](#)

DOI:

通讯作者 赵文明 zhaowenming1957@163.com。

作者个人主页 赵文明

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