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萘普生钠缓释微丸的制备及包衣液处方优化

薛晓柏,邹梅娟,王悦,黎苏,李颖,程刚

沈阳药科大学 药学院，辽宁 沈阳 110016

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摘要
目的 采用乙基纤维素水分散体包衣液苏丽丝（Surelease?）对萘普生钠微丸进行缓释包衣，制备日服1次的萘普生钠缓释微丸。方法 通过单因素实验考察影响药物释放的主要因素，采用中心复合设计试验对包衣液处方进行优化，确定处方组成。结果 包衣增质量和致孔剂用量是影响药物释放的主要因素，当包衣增质量分数为51.3%，致孔剂用量质量分数为2.97%时所制得的微丸在2、6、10 h的累积释放度最接近拟定标准，综合评分值最小。结论 采用中心复合设计优化处方的体外释放度预测性良好，制得萘普生钠缓释微丸符合实验设计要求。

关键词 药剂学 缓释微丸 中心复合设计 萘普生钠 苏丽丝

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Preparation of naproxen sodium sustained-release pellets and optimization of the coating film formulation

XUE Xiao-bai,ZOU Mei-juan,WANG Yue,LI Su,LI Ying,CHENG Gang

School of Pharmacy，Shenyang Pharmaceutical University，Shenyang 110016，China

Abstract
Objective To prepare naproxen sodium sustained-release pellets using ethylcellulose aqueous dispersion (Surelease?) as the coating film. Methods The formulation was developed based on single-factor tests, which were carried out to screen the critical factors influencing drug release.The optimal formulation was obtained by using central composite design. Result The coating levels and the porogenic agent levels were the main factors influencing the release rate.The NPS pellets provided a rather good sustained-release behavior when the coating level and the porogenic agent level were 51.3% and 2.97%, respectively. Conclusions Central composite design is successfully used to optimize the preparation process of sustained-release pellets of naproxen sodium. The pellets comply with the requirements of the experimental design.

Key words pharmaceutics sustained-release pellet central composite design naproxen sodium Surelease?

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通讯作者 程刚 chenggang63@hotmail.com

作者个人主页 薛晓柏;邹梅娟;王悦;黎苏;李颖;程刚