



中国中药杂志

China Journal of Chinese Materia Medica

 中文标题 检索 跨刊检索

复方苦参注射液关键工艺研究

投稿时间: 2011-02-28 责任编辑: 马超 [点此下载全文](#)

引用本文: 刘晓谦,王碧玉,全燕,王瑞珍,张彦霞,王智民,张启伟.复方苦参注射液关键工艺研究[J].中国中药杂志,2011,36(6):666.

DOI: 10.4268/cjmm20110602

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基金项目:国家“重大新药创制”科技重大专项(2009ZX09308-003,2009ZX09301-005,2008ZX09202-009)

中文摘要:目的:为实现中药大品种的技术升级,进行复方苦参注射液关键生产工艺的优化和示范性研究。方法:以总生物碱(苦参碱、氧化苦参碱、槐定碱、氧化槐果碱)和大洋米苷含量为指标,采用正交试验设计对关键工艺(渗透及活性炭脱色工序)进行优化,采用单因素法对影响醇沉的参数进行优化研究。结果:复方苦参注射液液液提取的最佳工艺为0.8%醋酸4倍量浸泡,流速5 mL·min⁻¹·kg⁻¹,浸泡时间9 h;醇沉工艺为醇沉3次,醇沉浓度依次为60%、80%、90%;活性炭用量为6%,于60℃加热20 min。结论:优化的复方苦参注射液渗透工艺简单,不仅缩短了生产周期,减少了二次污染的潜在风险,而且降低了醋酸的用量,保证了成品的酸不溶性灰分不超标,同时还更好地保留了有效成分。

中文关键词:复方苦参注射液 渗透工艺 醇沉工艺 脱色 正交设计 生物碱 大洋米苷 HPLC

Studies on key processes of Fufang Kushen injection

Abstract:Objective : To study the key processes of Fufang Kushen injection for technical upgrading. Method : Total alkaloids (sum of matrine, oxymatrine, sophoridine and oxysophoridine) and macrozamin were selected as quality evaluation markers. The key processes of percolation with acetic acid and discoloration with activated carbon were optimized by orthogonal experiment design, and process of purification with alcohol was investigated by single factor method. Result : The optimal condition of percolation process is as follows: the medicinal materials are soaked for 9 h with 4 times water containing 0.8% acetic acid, then percolation starts at flowrate of 5 mL·min⁻¹·kg⁻¹ and adding 2 times 0.8% acetic acid solution is added at the same velocity. Purification process is that the concentrated solution is precipitated by 60%, 80% and 90% alcohol in turn. Discoloration process is that 6 activated carbon is added into the solution which is heated at 60℃ for 20 minutes. Conclusion : The optimal extraction process is not only simple, saving the industrial cycle, reducing the potential risk, but also decreasing the acetic acid amount to guarantee the acid-insoluble ash as well as the functional ingredients.

keywords:Fufang Kushen injection percolation process alcohol-purification orthogonal design alkaloids macrozamin HPLC

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