



丹参注射液生产中一次醇沉上清液浓缩工艺质控指标研究

投稿时间: 2011-03-30 责任编辑: 马超一 [点此下载全文](#)

引用本文: 张寒,闫安忆,龚行楚,瞿海斌.丹参注射液生产中一次醇沉上清液浓缩工艺质控指标研究[J].中国中药杂志,2011,36(11):1436.

DOI: 10.4268/cjmm20111106

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基金项目:中国博士后科学基金项目(20090461360);浙江省教育厅科研项目(Y200907556)

中文摘要:目的:研究丹参注射液生产时一次醇沉上清液浓缩工艺的质控指标。方法:在相同条件下,对溶剂相同但固形物化学组成不同的一回流进行二次醇沉实验;用逐步回归法分析实验数据,寻找一回流中影响二次醇沉上清液内酚酸类成分保留率变化的主要因素。结果:二次醇沉上清液中酚酸类成分含量主要受一回流pH和咖啡酸含量影响。结论:丹参注射液生产中一次醇沉上清液浓缩工艺应将pH和咖啡酸含量作为质控指标并进行严格控制。

中文关键词:丹参注射液 醇沉工艺 浓缩工艺 质量指标 制药过程质量控制

Study on quality indicators for concentration process of supernatant obtained in first ethanol precipitation in production of Danshen injection

Abstract:According to the effect of second ethanol precipitation (SEP) in the production of Danshen injection, the indicators for controlling the quality of a concentration process of the supernatant obtained in the first ethanol precipitation (FEP) were investigated. The concentrated supernatants of FEP with different constituents were prepared and treated with the same amount of ethanol. The parameters which affect phenolic compound retention ratios in SEP supernatant were found using a stepwise regression method. Phenolic compound contents in SEP supernatant were mainly affected by pH and caffeic acid content of the concentrated supernatant of FEP. Caffeic acid content and pH should be set as quality indicators and strictly controlled in concentrating the supernatant of FEP.

keywords:[Danshen injection](#) [ethanol precipitation technics](#) [concentration technics](#) [quality indicators](#) [quality control of pharmaceutical process](#)

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