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论著

星点设计-效应面法优化柘树提取物片剂处方

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摘要
目的 通过星点设计-效应面法优化柘树提取物片剂处方。方法 以微晶纤维素（MCC）的用量、乳糖的用量和黏合剂聚维酮（PVP）的浓度为考察因素，以崩解时间和3个有效成分的溶出度为考察指标，分别用多元线性模型、二次多项式模型描述考察指标和3个考察因素之间的数学关系，绘制效应面和等高线图，确定较优处方并进行验证试验。结果 根据二次多项式模型，发现3个考察因素和4个考察指标之间存在可信的定量关系；优选的最佳处方为MCC的用量40 mg，乳糖的用量为70 mg，PVP浓度为4 %，优化处方各设定的预测值和测定值非常接近。结论 采用星点设计-效应面法，得到了基于二次多项式模型的柘树提取物片剂处方优化模型，实现了该片剂的处方优化。

关键词 柘树提取物片；星点设计；效应面法

分类号

Optimization of Cudrania extractum tablets formulation by central composite design-response surface methodology

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Abstract
Objective To optimize the formulation of Cudrania extractum tablets by the central composite design-response surface methodology. Methods In the formulation design using response surface methodology plus central composite design，independent variables were the amounts of MCC，lactose，and the PVP content in 95% EtOH，disintegration time of tablets and dissolution of three active components in the extractum at 45 minutes were taken as dependent variables. Multilinear and quadratic models were used to estimate the relationship between the dependent and the independent variables，and to delineate RSM and overlay contour plots in order to select the optimal formulations. Finally，predicted responses were verified. Results The quantitative relationships between three factors and four evaluation indexes were characterized. Optimal formulation was proposed to contain MCC 40 mg，lactose 70 mg，and 4 % PVP. Dissolution test of the selected optimal formulation indicated that there existed high approximation between the observed and estimated values. Conclusions The muti-objective simultaneous optimization of Cudrania extractum tablets formulation could be achieved by the central composite design and response surface methodology.

Key words Cudrania extractum tablets；central composite design；response surface methodology

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