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### 星点设计-效应面法优化硝酸布康唑缓释乳膏的制备

### Optimized Preparation of Butoconazole Nitrate Sustained-release Cream by Central Composite Design and Response Surface Method

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英文关键词: [butoconazole nitrate](#) [sustained-release cream](#) [central composite design](#) [response surface methodology](#)

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中文摘要:

**目的** 采用星点设计-效应面法对硝酸布康唑缓释乳膏的处方进行优化。**方法** 以液体石蜡用量( $X_1$ )、乳化剂用量( $X_2$ )、助乳化剂占乳化剂比例( $X_3$ )为考察因素, 以24, 48, 72 h的累积释放度为考察指标, 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, 根据模型绘制效应面图和等高线图, 通过重叠等高线图确定优化处方, 最后进行验证。**结果** 二次多项式模型比多元线性模型置信度高; 根据二次多项式模型, 发现3个考察因素和3个考察指标之间存在可信的定量关系; 优化处方各设定指标的预测值和实际值非常接近。**结论** 星点设计-效应面法可用于硝酸布康唑缓释乳膏的处方优化, 所建模型具有良好的预测能力。

英文摘要:

**OBJECTIVE** To optimize the formulation of butoconazole nitrate sustained-release cream by the central composite design-response surface method (CCD-RSM). **METHODS** In the formulation design using CCD-RSM, independent variables were the amounts of liquid paraffin and emulsifier, the ratio of auxiliary emulsifier in the emulsifiers. The percentages of *in vitro* cumulative releases at 24, 48, 72 h were 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. **RESULTS** Quadratic model showed better prediction capability than multilinear model. The quantitative relationships between three factors and three evaluation indexes were characterized. Moreover, *in vitro* release test of one selected optimal formulation indicated that were high approximation between the observed and estimated values. **CONCLUSION** The CCD-RSM can be applied to optimize the formulation of butoconazole nitrate sustained-release cream and the established model is of satisfactory predictive value.

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