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# 中心复合设计-效应面法优化阿魏酸哌嗪缓释片处方

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摘要
目的 制备阿魏酸哌嗪缓释片。方法 以羟丙甲纤维素（HPMC）联合羧甲基纤维素钠（CMC-Na）为骨架材料制备阿魏酸哌嗪缓释片，并对影响药物释放的因素进行考察。在此基础上运用中心复合设计-效应面法（central composite design-response surface methodology，CCD-RSM）对处方进行优化。结果 HPMC K15M及CMC-Na用量是影响药物释放的主要因素，当HPMC K15M与CMC-Na各占片质量分数的20.5%和18.6%时所得缓释片各时间点累计释放率接近合格标准，即25%(2 h)、60%(6 h)、90%(12 h)。结论 HPMC K15M与CMC-Na以一定比例联合使用可以抑制水溶性药物的前期突释，优化处方制备的阿魏酸哌嗪缓释片体外累积释放度符合要求，拟合方程预测性良好。

关键词 药剂学 缓释片 中心复合设计-效应面优化法 阿魏酸哌嗪 羟丙甲纤维素 羧甲基纤维素钠

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# Formulation optimization of piperazine ferulate sustained- release tablets by central composite design-response surface methodology

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Abstract
Objective To prepare piperazine ferulate (PF) sustained-release tablets. Methods The PF sustained-release tablets were prepared by employing the mixture of HPMC K15M and CMC-Na as the basic matrix materials. Factors that affected drug release were investigated. Thereafter, a central composite design-response surface methodology (CCD-RSM) was applied to optimize the formulation of the PF sustained-release tablets. Results The content of HPMC K15M and CMC-Na were the main factors that affected the drug release. The optimized formulation contained 20.5% of HPMC K15M and 18.6% of CMC-Na of the total weight and the accumulative release percentages at 2 h、6 h、12 h were consistent with the criterion, that is 25%、60%、90% ,respectively. Conclusions The initial burst release of water-soluble drugs from matrix sustained-release tablets could be restrained by using HPMC combined with a certain proportion of CMC-Na. The optimized PF sustained-release tablets have an ideal cumulative release profile and the fitting equation has a good predictability.

Key words pharmaceutics sustained-release tablet central composite design-response surface methodology piperazine ferulate HPMC CMC-Na

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