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星点设计-效应面法优化基于纳米CaCO₃的辣椒素缓释漂浮微丸制备工艺的研究

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中文摘要:目的:制备基于纳米CaCO₃的辣椒素缓释漂浮微丸。方法:以海藻酸钠为基质,滴制法制备辣椒素缓释漂浮微丸,采用单因素试验,研究CaCl₂浓度、纳米CaCO₃与海藻酸钠比例、辣椒素与海藻酸钠比例对微丸的影响。在此基础上以微丸的漂浮能力、载药量、体外释放性能作为考察指标,用星点设计-效应面法进一步优化其处方工艺。结果:筛选的最优处方为1.87%的CaCl₂、纳米CaCO₃与海藻酸钠比例为2.16:1,辣椒素与海藻酸钠比例为2.36:1。在该条件下制备的辣椒素缓释微丸外观圆整,粒径大小分布均匀,在人工胃液中能够持续漂浮15 h以上,缓释效果较好,12 h体外累积释放度达89.93%。结论:经星点设计-效应面法优化后制得的辣椒素缓释漂浮微丸具有良好的漂浮能力和缓释效果。

中文关键词:辣椒素 胃漂浮 纳米CaCO₃ 缓释

Optimization of preparation process of floating sustained-release pellets of capsaicin based on nanometer CaCO₃ by central composite design-response surface method

Abstract: Objective: To prepare floating sustained-release pellets of capsaicin based on nanometer CaCO₃. **Method:** The floating sustained-release pellets were prepared by the dropping method with sodium alginate as matrix. The effects of the concentration of sodium alginate, the ratio of capsaicin to sodium alginate and the ratio of nanometer CaCO₃ to sodium alginate on pellets were detected in the single-factor test. On that basis, central composite design-response surface method were used to optimize the formula, with the floating capacity, drug-loading rate and *in vitro* drug release property of pellets as indicators. **Result:** In the optimal formula, CaCl₂ accounted for 1.87%, the ratio of nanometer CaCO₃ to sodium alginate was 2.16:1, and the ratio of capsaicin to sodium alginate was 2.36:1, respectively. Capsaicin sustained-release pellets prepared under the conditions featured round granule, even particle size. It could float on artificial gastric fluid for over 15 hours, showing good sustained-release effect. Its accumulative drug-release percent of pellets *in vitro* at 12 h were 89.93%. **Conclusion:** The floating sustained-release pellets of capsaicin show good floating capacity and sustained-release effect after being optimized with central composite design-response surface method.

keywords: capsaicin gastric floating nanometer CaCO₃ sustained-release

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