

[1]张亚红,林凤云,邱妍川,等.蒿甲醚自微乳化释药系统的制备及体外评价[J].第三军医大学学报,2013,35(21):2348-2351.

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Title: Preparation and evaluation of self-microemulsifying drug delivery system for artemether *in vitro*

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摘要: 目的 研究蒿甲醚自微乳化释药系统处方组成和体外特性。 方法 通过溶解度实验、伪三元相图绘制和正交实验设计筛选优化蒿甲醚自微乳化处方。以自乳化速率、粒径、稳定性和体外溶出度为指标评价自乳化微乳系统体外特性。 结果 蒿甲醚自微乳化释药系统的最佳处方选择Lauroglycol 90为油相, Cremophor RH 40为乳化剂, Gelucire 44/14为助乳化剂, 最佳配比为4:4:2, 其中蒿甲醚的载药量为80 mg/g。自制的ARM-SMEDDS均在2 min以内完成自微乳化, 粒径为(61.50±8.66) nm, 常温下3个月基本保持稳定, 体外溶出度结果显示120 min即能达到>99.5%的溶出率, 累积溶出百分率为原料药的7倍。 结论 所制备的ARM-SMEDDS外观和稳定性良好, 能显著提高体外溶出度。

Abstract: Objective To prepare and evaluate the self-microemulsifying drug delivery system (SMEDDS) of artemether (ARM) *in vitro*. Methods The preparation process of ARM-SMEDDS was optimized by solubility study, pseudo ternary phase diagrams and orthogonal design. Self-microemulsifying time, average particle size, stability and dissolution *in vitro* were evaluated. Results The optimized formation of ARM-SMEDDS were composed of ARM 80 mg/g, lauroglycol 90 as oil, cremophor RH 40 as surfactant and gelucire 44/14 as co-surfactant with a weight ratio of 4:4:2. The ARM-SMEDDS prepared above could self-microemulsify within 2 min, with a particle size of 61.50±8.66 nm. ARM-SMEDDS was found to be stable up to 3 months at room temperature. The percentage of accumulated dissolution was more than 99.5% within 120 min which was 7 fold compared to ARM. Conclusion ARM-SMEDDS has good appearance and stability, and its

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dissolution *in vitro* is improved significantly.

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