

双氯芬酸钠脂质微球注射液的制备及其理化性质

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摘要

目的 使用长链脂肪酸甘油酯(long-chain triglycerides, LCT)及中链脂肪酸甘油酯(middle-chain triglycerides, MCT)作为双氯芬酸钠的载体制备脂质微球注射液。方法 以脂质微球物理性质、粒径及粒度分布、 ζ -电位和包封率为指标,通过单因素考察的方法对双氯芬酸钠脂质微球的处方及制备工艺进行了筛选。对方剂中油相的组成和比例、乳化剂的种类和用量进行了研究。对药物的加入方法、均质、灭菌和pH值对脂质微球稳定性的影响进行了考察。结果 采用质量分数为4.00%的长链脂肪酸甘油酯、质量分数为16.00%的中链脂肪酸甘油酯混合作为油相、质量分数为3.00%的豆磷脂、质量分数为0.40%的Tween-80、质量分数为0.40%的泊洛沙姆F-68、质量分数为0.06%的油酸和质量分数为2.50%的甘油,均质压力70 MPa,均质8次,氮气保护下灌装,100 °C灭菌30 min。平均粒径小于140 nm, pH值在6.0-6.5之间, ζ -电位的绝对值大于20 mV。制剂的包封率在85%以上。双氯芬酸钠脂质微球注射液至少在6个月内稳定。结论 双氯芬酸钠脂质微球注射液理化性质稳定,易于实现工业生产。

关键词 [药剂学](#) [双氯芬酸钠](#) [脂质微球注射液](#) [处方](#) [稳定性](#)

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Preparation and characterization of diclofenac sodium lipid microsphere injection

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Abstract

Objective To prepare diclofenac sodium lipid microsphere injection by using long-chain triglycerides (LCT) and middle-chain triglycerides (MCT) as the carriers. Methods According to the physical property, particle size and size distribution, ζ -potential and entrapment efficacy, formulations and preparation procedures were investigated by single factor method. The composition of oil phase was studied. Meanwhile, influence of the sort and amount of emulsifiers were also investigated. In addition, influence of drug incorporation method, homogenization method, sterilization and pH on the stability of the lipid microsphere injection were tested. Results The lipid microsphere injection was prepared with LCT 4.00%, MCT 16.00%, lethicin 3.00%, Tween-80 0.40%, F-68 0.40%, oleic acid 0.06% and glycol 2.50%. The coarse lipid microsphere was homogenized for 8 times under 70 MPa, followed by filling in 10 mL-vials under nitrogen protection and sterilized at 100°C for 30 min. The mean particle size of the final product was less than 140 nm, pH value was between 6.0 and 6.5. The absolute value of ζ -potential was above 20 mV. The entrapment efficacy of the preparation was higher than 85%. Meanwhile, the preparation was stable for at least 6 months. Conclusion The diclofenac sodium lipid microsphere injection is stable and could be produced in industrial scale.

Key words [pharmaceutics](#) [diclofenac sodium](#) [lipid microsphere injection](#) [formulation](#) [stability](#)

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