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芦丁亚微乳剂的制备及其理化性质的考察

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摘要

目的 优化静脉注射芦丁亚微乳剂的处方工艺，并考察其理化性质及溶血性试验。方法 用正交试验设计优化芦丁亚微乳处方，并在其基础上考查制备工艺因素对乳剂的影响。通过对粒径、zeta电位、含量、包封率等的测定研究芦丁亚微乳的理化性质。紫外分光光度法判断制剂是否发生溶血作用。结果 采用油相（MCT-LCT 质量比1:1）100 g·L-1、大豆磷脂18 g·L-1 、泊洛沙姆F-68 8 g·L-1、油酸 5 g·L-1、VE 4 g·L-1、甘油22.5 g·L-1，在室温下100 MPa均质6次，制备的芦丁亚微乳剂平均粒径为143 nm，zeta电位为-27.4 mV，pH值为5.0～6.0，含量在90%以上，包封率在90%以上，试管溶血试验阴性。结论 利用该处方和工艺制备的芦丁亚微乳性质稳定，不产生溶血作用。

关键词 药剂学 亚微乳 高压匀质法 芦丁 性质

分类号 R94

Preparation and characterization of rutin submicron emulsion

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Abstract

Objective To optimize the formulation and preparation procedure of rutin submicron emulsion for injection and investigate its physico-chemical properties and hemolysis potential. Methods Orthogonal experiment was designed to optimize the formulation of rutin submicron emulsion. The content and entrapment efficiency of the preparation were determined by HPLC, and its properties such as particle size, zeta potential and hemolysis were studied. Results The optimized formulation was composed of rutin 2 g·L-1, oil phase 100 g·L-1 with MCT-LCT (m:m=1:1), SPC 18 g·L-1 , Poloxamer F-68 8 g·L-1 , sodium oleate 5 g·L-1, vitamin E 4 g·L-1, and glycerin 22.5 g·L-1. Homogenizing the sample for 6 times at 100 MPa at room temperature was optimal. Both drug content and mean entrapment efficiency of rutin submicron emulsions were above 90.0 % , with the pH value between 5 and 6, mean particle size of 143 nm, and ζpotential of -27.4 mV Conclusion By using this optimized formulation and preparation technique, stable rutin submicron emulsion can be obtained without hemolysis.

Key words pharmaceutices submicron emulsion homogenization rutin properties

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