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注射用尼莫地平亚微乳的处方筛选及性质考察

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摘要

目的 制备稳定的注射用尼莫地平亚微乳剂。方法 以离心稳定常数（Ke）为指标，用正交设计法筛选尼莫地平注射用亚微乳的处方和工艺，测定制剂的zeta电位、粒径、pH值和相变温度。结果 所制备的注射亚微乳外观为乳白色，略带蓝色乳光。3批样品的Ke值分别为3.4、3.6 、3.4；zeta电位分别为-33.2、-33.0、-35.8 mV；平均粒径分别为153、154 、150 nm；pH值分别为7.24、7.19、7.23；相变温度为83 ℃。结论 制备工艺可行，制剂物理稳定性较好，pH值符合静脉注射的要求。

关键词 药剂学 亚微乳剂 正交试验 尼莫地平 制备工艺 物理常数

分类号 R94

Formulation optimization and characterization of nimodipine submicron emulsion for intravenous injection

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Abstract

Objective To prepare stable nimodipine (NMD) submicron emulsion for i.v. injection by optimizing formulation and preparation process and determining the physical constants. Methods Submicron emulsion was prepared using high pressure homogenization method. Taking centrifugal stability constant Ke as an index, orthogonal design was employed to optimize the formulation and preparation method of nimodipine submicron emulsion for i v. injection. Physical parameters such as Ke, zeta potential, particle size, pH value and phase transition temperature were determined. Results The appearance of the submicron emulsion prepared was ivory with a little bluish opalescence. The Ke values of three batches were 3.4, 3.6 and 3.4, zeta potential -33.2, -33.0 and -35.8 mV, mean particle size 153nm, 154 nm and 150nm, and the pH values were 7.24, 7.19 and 7.23, respectively. The phase transition temperature was 83 ℃. Conclusions The preparation process is feasible to prepare submicron emulsion with good physical stability. The pH value met the requirement of iv injection.

Key words pharmaceutics submicron emulsion orthogonal test nimodipine preparation process physical constant

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