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大蒜素亚微乳注射液的制备与质量评价

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中文摘要:采用高压匀质机对大蒜素亚微乳的初乳进行均质化，并以0.22 μm微孔滤膜过滤除菌，无菌分装，制成大蒜素亚微乳注射液。采用HPLC法测定大蒜素的含量，以外观、pH、粒径及其分布、包封率、有关物质限度、含量为指标考察大蒜素亚微乳的稳定性。优选的处方外观质量较好，粒径在100-150 nm，包封率达96.5%，在加速及长期试验条件下留样12个月，各项检查指标基本无变化。结果表明所制得大蒜素亚微乳注射液的理化性质较稳定，此制剂为提高难溶性大蒜素药物的稳定性及降低其血管刺激性奠定了基础，并改善了临床使用时患者的顺应性。

中文关键词:大蒜素 亚微乳 制备 包封率 稳定性 刺激性

Preparation and quality evaluation of allitride submicron emulsion injection

Abstract: The aim of this study was to prepare and evaluate allitride submicron emulsion injection.The submicron emulsion injection was prepared by high-pressure homogenizer,sterilized by 0.22 μm filter membrane and subsequent sterile-packing.Allitride was determined by HPLC.The physical appearance,pH value,particle size distribution,entrapment efficacy,impurities and the allitride content were used as the indexes to evaluate the stability of allitride submicron emulsion injection.It was shown that the optimized formulation of allitride submicron emulsion injection had stable physical appearance,with mean particle size of 100-150 nm,and the entrapment efficacy of 96.5%.All the indexes kept unchanged after the accelerated stability test and long-time stability test. These results demonstrated the stability of allitride submicron emulsion injection，which established the foundation for improving insoluble allitride stability,reducing the vascular stimulation,and subsequently improving the patient compliance during the clinical use.

keywords:allitride submicron emulsion preparation entrapment efficacy stability irritation

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