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甘草酸二铵磷脂复合物注射液的初步稳定性研究

Preliminary Stability Study of Diammonium Glycyrrhizinate Phospholipid Complex Injection

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英文关键词: [diammonium glycyrrhizinate phospholipid complex injection](#) [formulation](#) [initial stability](#)

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中文摘要:

目的 制备合适的甘草酸二铵磷脂复合物注射液, 并考察其初步稳定性。方法 以粒径、过氧化值、pH为指标, 分别考察了不同种类溶媒和pH值对注射液稳定性的影响。通过影响因素实验的结果确定最佳处方, 并对最适处方进行加速实验。结果 以5%葡萄糖注射液为溶媒的处方在高温60 °C和强度4 500 Lx光照下放置10 d理化性质没有发生明显变化, 且初步加速实验也显示出良好的稳定性。结论 甘草酸二铵磷脂复合物葡萄糖注射液质量稳定, 粒径符合肝脏靶向性要求。

英文摘要:

OBJECTIVE To prepare an appropriate diammonium glycyrrhizinate phospholipid complex injection, and examine its initial stability. METHODS The influence of different solvents and pH values were investigated, using particle size, peroxide value and pH as indicators. The optimal formulation was determined by factor experiment, and undergone acceleration experiment. RESULTS The physical and chemical properties of 5% gluconse formulation did not change significantly under 10 days of high temperature and illumination, as well as under acceleration experiment. CONCLUSION The diammonium glycyrrhizinate phospholipid complex 5% gluconse injection was stable. It meets the requirements of liver targeting.

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