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论文

硫酸链霉素注射液变色规律的探讨和贮存期预测

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摘要:

本文探讨了硫酸链霉素注射液(500,000 u/2 ml)在不同温度下两种处方降解的变色规律。由实验数据归纳出,注射液的变色规律可表示为回归方程:$(A-A_0)=a+bt^{1,5}$注射液的变色速率方程为:$dA/dt=k(A-A_0-a)^{1/3}$,注射液的变色不是一个简单级数的反应。用经典恒温法和初均速法进行了稳定性加速试验,结合Weibull分布拟合法计算了注射液的贮存期,均为20个月。

关键词: 硫酸链霉素 稳定性 变色速率常数 贮存期 Weibull概率纸 变色反应活化能

STUDY ON THE RULE OF DISCOLORATION AND PREDICTION OF SHELF-LIFE OF STREPTOMYCIN SULFATE INJECTION

YX Guo; P He; L Tu and DF Wang

Abstract:

The present paper explores the rule of discoloration of streptomycin sulfate injection (500,000 u/2 ml) of two formulations with different stability agent at various temperatures. Experimental data indicate that the rule of discoloration of the injection may be represented by the following regression equation: $(A-A_0) = a + bt^{1、5}$ where A_0 is the initial absorbance of the injection, A is the absorbance at time t, a, b are the regression coefficients. The rate equation of discoloration of the streptomycin sulfate injection is $dA/dt = k(A-A_0-a^{1/3}$ where k is the rate constant of discoloration of the injection. It is seen from the equation that the discoloration of the injection is not a simple order reaction.According to the rule of discoloration of streptomycin sulfate injection and Arrhenius exponent equation, the accelerated analysis for stabilization of the injection was made by classical isothermal mehtod and initial mean velocity method. Shelf-life of the injection was calculated by classical isothermal method, initial mean velocity method and the Weibull probability paper method. Shelf-life was about 20 months, and also fundamentally coincident with the value obtained from the samples reserved for observation at room temperature. The activation energy of discoloration reaction of the injection obtained from the above three methodsappeared to be the same.

Keywords: Stability Rate constant of the discoloration Shelf-life Weibull probability paper Activation energy for the discoloration rcaction Streptomycin sulfate

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