

论文

光和热对硫酸罗通定注射液稳定性的影响

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摘要:

目的:研究硫酸罗通定注射液同时对光和热的稳定性。方法:采用在高温下进行光照的试验方法。结果:该药物在恒温加速试验或高温下光照试验中的降解均遵从零级动力学规律。在高温和光照同时作用下的降解速率常数k由两部分构成: $k = k_{\text{dark}} + k_{\text{light}}$, k_{dark} 和 k_{light} 分别为无光照射时热反应的降解速率常数及光化反应的降解速率常数,且 $k_{\text{light}} = A_{\text{light}} \cdot \exp(-E_{\text{a,light}}/RT) \cdot E$ 。其中E为光源的照度, A_{light} 是与光源种类有关的试验常数, $E_{\text{a,light}}$ 亦为一常数。结论:由于该 k_{light} 表达式与Arrhenius方程形式类似,式中 $E_{\text{a,light}}$ 可能为光化反应后继过程的表现活化能,由 $E_{\text{a,light}}$ 值几乎与光源种类无关而支持了这一观点;根据光和热同时对硫酸罗通定注射液稳定性的影响规律,预测了该药物在室室内自然光照射下的贮存期约为20-2 d,与留样观察结果一致。

关键词: 光和热稳定性 优选法 硫酸罗通定注射液

EFFECT OF LIGHT AND HEAT ON THE STABILITY OF ROTUNDINE SULFATE INJECTION

Abstract:

AIM: To study the effect of light and heat on the stability of rotundine sulfate injection. METHODS: Accelerated tests upon exposure to light at high temperatures were employed. RESULTS: The degradation of rotundine sulfate injection in isothermal heating experiments and the exposure experiments to light at high temperatures obeys zero order kinetics. The total degradation rate constant k caused by both light and heat can be divided into two parts: $k = k_{\text{dark}} + k_{\text{light}}$, where k_{dark} and k_{light} are the degradation rate constant caused by heat and light, respectively. The k_{light} can be expressed as $k_{\text{light}} = A_{\text{light}} \cdot \exp(-E_{\text{a,light}}/RT) \cdot E$, where E is the illuminance of light; A_{light} an experimental constant related to the light source; $E_{\text{a,light}}$ an experimental constant independent of light sources. CONCLUSION: Since the form of k_{light} is similar to the Arrhenius equation, it is suggested that $E_{\text{a,light}}$ might be the observed activation energy of the subsequent processes of the photochemical reaction. This viewpoint can be supported by the fact that the $E_{\text{a,light}}$ is independent of light sources. Based on the effect of both light and heat on the degradation, the shelf life of rotundine sulfate injection under indoor daylight at room temperature was predicted, and the result was comparable to that determined by a long-term storage test.

Keywords: optimization rotundine sulfate injection drug stability caused by both light and heat

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