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论文

药物稳定性预测方法的简化——初均速法

庞贻慧;鲁纯素

北京医学院药学系物理化学教研室

摘要:

初均速法预测药物贮存期系以药物分解初阶段的平均速度V_0的对数,代替反应速度常数k的对数对开尔文温度(Kelvin *T*)的倒数回归,得到符合Arrhenius指数规律的直线方程,由此计算活化能及室温贮存期。因为不必求k,所以不必知道反应级数。此法简便,在每个加速稳定性试验温度下,只需在反应初阶段取样分析一次,实验工作量及数据处理工作量均大大减少。本文分别用初均速法与经典法测定了抗坏血酸溶液的稳定性,得到抗坏血酸氧化的活化能分别为18.32及18.49 kcal·mol^{-1}。20℃贮存期分别为119天及110天,结果符合很好。本文并应用初均速法测定了阿糖胞苷溶液及硫酸链霉素溶液的稳定性,得到活化能数值与文献值符合。

关键词: 药物贮存期 抗坏血酸 阿糖胞苷 硫酸链霉素 反应速度常数 活化能 经典恒温动力学法 初均速法

A SIMPLIFIED METHOD FOR PREDICTING THE STABILITY OF PHARMACEUTICALS——THE INITIAL AVERAGE RATE METHOD

PANG Yi-hui and LU Chun-su

Abstract:

The initial average rate method for predicting the shelflife of pharmaceuticals is established by using the logarithm of the average rate of the initial stage of reaction (lg V0) instead of the logarithm of the rate constant (lg k) in the Arrhenius equation. It was found that the regression curve of lg V0 by plotting against the reciprocal of Kelvin temperature (1/T)is a contended well straight line. The linear equation so obtained is in accordance with Arrhenius' exponential equation and can be used to calculate the activation energy and shelflife at room temperature. Since k is not needed here, the calculation can be made without knowledge of the order of reaction. Thus this method is simple and convenient. Under each testing temperature only one analysis of initial stage sample is needed, so laboratory work and data treatment are greatly reduced.We applied this initial average rate method and also classical isothermal kinetic method to determine the stability of ascorbic acid solution, the activation energies of oxidation of ascorbic acid obtained were 18.60 and 18.50 kcal mol^{-1} respectively; the shelflives at 20℃ were 125 and 111 days. The results agreed satisfactorily.This method was also used to determine the stabilities of solutions of arabinosylcytosine and streptomycin sulfate. The activation energies obtained were comparable to published values.

Keywords: shelflife Ascorbie acid Arabinosylcytosine Streptomycin sulfate Rate constant Activation energy Classical isothermal, kinetic method Initial average rate method Pharmaceutical

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