

论文

台阶型变温加速试验——药物稳定性预测的新方法

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摘要:

本文提出一个药物稳定型预测的变温动力学新方法——台阶型变温法。它比其它七十年代的变温动力学方法,设备简单易行;比经典恒温动力学方法,则大大减少人力和时间。本法数据处理简单,可以计算,也可以图解,结果精度也高。文中以蔗糖酸催化水解、抗坏血酸水溶液的氧化及阿糖胞苷水解脱氨反应实验结果为例,说明在工作量大为减轻的情况下,对于活化能、指数前因子(频率因素)、以及常温速度常数或贮存期的预测,台阶法与经典法的差别无显著性意义。

关键词:

THE STAIRCASE NONISOTHERMAL ACCELERATED TEST——A NEW METHOD FOR STABILITY PREDICTION

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Abstract:

In the present paper, a new kinetic technique is established for prediction of stability of pharmaceuticals, named staircase nonisothermal kinetic method, which is simpler in equipment and easier in operation than any other nonisothermal kinetic method in the 70's. The experimental data obtained may be treated either by computation or by charts. Acid catalytic hydrolysis of sugar, oxidation of ascorbic acid and deamination of arabinosylcytosine are taken as examples in comparing the staircase nonisothermal method with the conventional isothermal kinetic method. Results show that there is no significant difference between these two methods for the value of activation energy, pre-exponential factor (frequency factor), rate constant and shelflife prediction. Furthermore, this method requires much less time and labour than other methods.

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