论文

# 指数程序升温药物稳定性试验

詹先成;殷恭宽;马宝忠

华西医科大学药学院，成都 610044

摘要：

介绍了一种新的程序升温(指数程序升温)药物稳定性预测加速试验方法及计算方法。在这一新的程序升温方法中,温度每升高10℃,升温速率将增大2～4倍:$dT/dt=a^{(T-T_0)/10}\cdot(dT/dt)_0$,使药物在高温和低温范围内的降解程度尽可能一致,提高了试验准确度。采用单因素优选法和数值积分法处理试验数据,避免了任何近似处理,使计算结果准确可靠。与线性升温、倒数升温和对数升温加速试验进行了对比,结果表明,指数程序升温法的准确性优于其它3种升温法。

关键词： 指数程序升温法　药物稳定性

# EXPONENTIAL PROGRAMMED FOR DRUG STABILITY EXPERIMENT

XC Zhan; GK Yin and BZ Ma

Abstract:

A new programmed heating model(exponential heating model)for drug stabilityexperiment is intreduced.In this heating model,the temperature rising rate $dT/dt$ is increased 2～4 times when the temperature increases by every 10℃ to fit most chemical reactions:$dT/dt=a^{(T-T_0)/10}\cdot(dT/dt)_0$.A comparison of the new heating model and the linear,reciprocal,andlogarithmic heating models is made and discussed.The results indicate that in the new programmedheating experiment,the degradation of drugs can be more uniform within different temperature rangesand the experimental results can be more accurate than those in the linear,reciprocal,or logarithmicheating experiment.A computation method with optimization and numerical integration for the newprogrammed heating experiment is also introduced.In this computation method, there is no need forapproximation.

Keywords: Drug stabilityFinan cedby National Natural Science Foundatinn of China    Exponential programmed heating

通讯作者：

作者简介：

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