

Thermal kinetics Study for Prediction of Shelf Life of Drug

F. Xu^{C, S}, L.-X. Sun, L.-N. Yang, J.-G. Liang and H.-T. Zhang

Materials & Thermochemistry Laboratory, Dalian Institute of Chemical Physics, Chinese Academy of Sciences, Dalian, China
lxsun@dicp.ac.cn

The stability of drug and its dosage is of great importance for prediction of its shelf life. In traditional way, the drugs or dosages are normally conserved at room temperature and investigated until they lose their pharmacy effect. Therefore, the traditional method is really time consuming [1,2]. The research efforts of many researchers are mainly focused on finding an easy way for this purpose [3,5]. In the present work, thermal analyses for about 21 drugs (terfenadine dispersible tablets, ganmaotui yaopian tablets, amantadine hydrochloride tablets, aciclovir tablets, aminopyrine caffeine tablets, erythromycin ethylsuccinate tablets, cefradine capsules and so on) were performed. The results obtained show that there is a correlation between pk (i.e. negative logarithm of rate constant of decomposition/evaporation process) and shelf life of the drugs. What this work would like to point out is that the initial thermal decomposition temperature of principal components in drugs should be considered except pk , in order to determine the shelf life of the drugs. It is suggested that the shelf life of the drugs should be classified into the following 3 ranges in terms of their pk values and the initial temperature of thermal decomposition; for range I ($\text{pk} < 7.0$, and initial temperature $T < 450 \text{ K}$), the shelf life of drugs is between 1.5 and 2 years; for range II ($7.0 < \text{pk} < 12.0$, and initial temperature $T > 450 \text{ K}$), the shelf life of drugs is about 3 years; for range III ($\text{pk} > 12.0$, and initial temperature T was not defined at present yet), the shelf life of drugs is between 4 and 5 years. The shelf life for different tablets of vitamin B4, coronary heart disease, ciprofloxacin hydrochloride and vitamin B12 was predicted with the established model as mentioned above, and it is in good agreement with that on its label. Hence, the thermal analysis techniques utilized in the work can be used for prediction of shelf life of drugs.

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