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KINETIC STUDIES AND PREDICTION OF SHELF LIVES OF COMMERCIAL TABLETS OF ASCORBIC ACID UNDER DIFFERENT CONDITIONS

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A detailed kinetic study has been undertaken on seven different commmercial samples of ascorbic acid tablets stored at 25°, 40° and 45° in the absence of humidity to determine the shelf lives and activation energies. The shelf lives of these samples have also been evaluated at 40° and 45° in the presence of humidity.

INTRODUCTION

Kinetic studies on degradation of ascorbic acid have been reported in literature, [1,2]. The rate of degradation of ascorbic acid in solution is affected by many factors like pH, temperature, vehicle, presence and absence of oxygen. The prediction of stability under such conditions has also been made [3,4,5]. The degradation patterns of multivitamin solutions containing thiamine hydrochloride and ascorbic acid prepared in syrup, glucose, sorbitol or sucrose solutions adjusted to pH 3.2, 4.5 or 7.0 and kept 30 hr at different temperatures have been studied by a number of workers. The ascorbic acid was found stable at pH 7.0 [6].

Recently a detailed investigation has been carried out on the kinetics and physical studies for ascorbic acid in solution [7]. The rate constant has been reported which is of first order kinetics.

Examination of literature shows that less work has been done on the kinetic studies of ascorbic acid in solid dosage forms. Stability test for multivitamins including ascorbic acid in tablet forms at elevated temperatures has been studied [8]. The effect of ascorbic acid in powder preparations was investigated by storing the samples at 37° and 100 % relative humidity [9]. The stability of ascorbate salt was reported in the order as Ca> Mg> Na> K. The shelf lives of ascorbic acid tablets have also been predicted by quantitative changes in their colour during storage [10]. Present communication deals with detailed kinetic study on seven different commercial samples of ascorbic acid. The shelf life of these samples has also been studied at 40° and 45°.

EXPERIMENTAL

Commercially prepared tablets were procured from seven different manufacturers original packs.

These were marked 1,2,3,. . . .7, and these stored in their original packs at 25°, 40° 45° with and without humidity for a period of six months.

Assay Procedure: At the end of every month, the samples were withdrawn and an iodometric assay was carried out on twenty tablets of each sample to determine the first order rate constant of ascorbic acid.

RESULTS AND DISCUSSION

In the present work an attempt has been made to evaluate the kinetics of degradation of ascorbic acid in commercial samples under different storage conditions. It is assumed that ascorbic acid degrades as a one step reaction. This is in agreement with Garrett's view [11] that vitamins in solid dosage multivitamin formulations exhibit zero order or first order.

Using the kinetic data the apparent shelf lives of the samples stored at various temperatures in the absence and presence of humidity have been calculated by the equation:

$$t = \frac{2.303}{K} \times \log \frac{100}{90} \qquad (1)$$

Where t is the shelf life (period for the loss of 10 % of initial potency)

K is the rate constant for a first order reaction.

It is suggested that since in different commercial tablets the factors affecting the stability of ascorbic acid and the

Table 1. First order rate constants (K), shelf lives (Ts) and activation energies (K.cal/mole) of commercial tablets of ascorbic acid.

Sample No	25° and normal Humidity (R.H 75-80 %)		40° Without humidity		40° With humidity (R.H. 75% ± 1)		45° Without humidity		45° With humidity (R.H. 100%)		Activation energies (K.cal/mole)
	K (day^{-1})	Ts (months)	K (day^{-1})	Ts (months)	K (day^{-1})	Ts (months)	K (day^{-1})	Ts (months)	K (day^{-1})	Ts (months)	
1	0.000624	5.659	0.00212	1.666	0.00276	1.279	0.003380	1.045	—	—	15 80
2	0.000368	9.598	0.00072	4.906	0.00088	4.023	0.00109	3.241	0.001100	3.210	16.22
3	0.000292	12.010	0.00126	2.803	0.00139	2.541	0.00205	1.723	0.00273	1.293	19.14
4	0.000164	21.540	0.00145	2.435	0.00176	2.006	0.00272	1.298	0.00230	1.536	27.03
5	0.003840	0.920	0.00959	0.368	0.01944	0.182	0.01469	0.2403	0.04350	0.081	12.61
6	0.000191	18.49	0.00027	12.845	0.00044	8.026	0.000734	4.811	0.000790	4.471	13.16
7	0.000059	59.85	0.00023	15.36	0.00029	12.140	0.000482	9.226	0.000630	5.607	19.85

— = Rate constant and shelf lives could not be determined due to spoilage of tablets.

physical characteristics of the tablets are not similar due to variations in the nature and composition of excipients and the amount of ascorbic acid present in a tablet, the determined shelf lives are only a measure of the true shelf lives. The shelf lives (period for loss of 10 % of the initial potency) of the various commercial samples of ascorbic acid therefore give an indication of their relative stability under different storage conditions.

The shelf lives for various commercially available tablets are shown in the Table 1. Among 500 mg ascorbic acid tablets stored at 25°, 40° and 45° with and without humidity the decreasing order of stability is in the order of 1, 2 and 3, while among 100 mg tablets is 5, 6 and 4.

It is also apparent from the Table 1, that the shelf lives for all the samples under various storage conditions of temperature and humidity decrease in the order of 25° > 40° without humidity, > 40° with humidity, > 45° without humidity, 45° with humidity. It is evident from the results that an increase in temperature may alter the physical characteristics of the tablets so as to decrease the shelf lives in comparison to those at room temperature.

It is also noted that at 45° the rate of degradation of ascorbic acid in all the samples is higher than that at 40° both in the absence and presence of humidity and the rate of degradation of ascorbic acid at 40° with and without humidity is higher than at 25° and normal humidity.

The activation energies for the degradation of ascorbic acid tablets from the velocity constants determined at different temperatures under only normal humidity using Arrhenius equation have also been calculated for all the samples. The Arrhenius equation can be applied for the prediction of stability of ascorbic acid and other vitamins in such preparations.

$$K = Ae^{-E/RT} \quad (2)$$

Where E is the energy of activation, R the gas constant, T the absolute temperature and A the frequency factor. The activation energies in K. cal/mole are given in Table 1 and it is apparent that for a sample with higher shelf life (increased stability) the greater activation energy is calculated. Among the 500 mg. ascorbic acid tablets the activation energies decrease in the order of 1,2 and 3, and among 100 mg samples as 5, 6 and 4. The activation energy for 50 mg ascorbic acid tablet (sample 7) is 19.85 K. cal/mole. The typical energy for ascorbic acid has been reported as 16 K. cal/mole [12]. This is more or less of the same order as determined for most of the samples.

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