

UV-SPECTROPHOTOMETRIC DETERMINATION OF α -TOCOPHEROL ACETATE IN PHARMACEUTICAL PREPARATIONS

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ABSTRACT

UV-spectrophotometric method has been developed to estimate α -tocopherol acetate in tablets and soft capsules. The λ_{max} was found to be 285 nm in ethanol and isopropanol. The percentage error was found to be 2 to 7 in α -tocopherol acetate preparations whilst this increases in multivitamin preparations.

Introduction

The development of reliable assay method for the tocopherol has been an evolutionary process and much work has been done for its estimation in single ingredient preparation. There exists little literature for determination of tocopherol amount accurately in mixtures of other vitamins and pharmaceutical preparations. The direct measurement of vitamin E acetate in drug is preferred over long development of colours and estimations by colorimetric methods because it eliminates the use of hazardous chemicals (Tsen, 1961; Whittle and Pennock, 1967; Shepperd and Hubbard, 1969; Adeniyi and Juselskis, 1980; Labadie and Bedford, 1987). The British Pharmacopoeia (1980) method for determining vitamin E is time consuming and difficult. Barary *et. al.* (1985) have reported the direct measurement of tocopherol acetate with chloroform from soft capsules and suggested the method reproducible.

In the present paper attempts have been made to develop a spectrophotometric method for the analysis of α -tocopherol acetate in tablets and soft capsules, by dissolving in ethylalcohol and isopropanol solvents. The spectrophotometric assay method has also been studied for α -tocopherol preparations in presence of glucose, sucrose, lactose, gum arabica and gelatin.

Material and Methods

Materials and Apparatus

α -Tocopherol acetate, n-hexane, chloroform, lactose, sucrose and glucose used in this study were of analytical grade, supplied by E. Merck and Fluka. These chemicals were used as such without further purification. The vitamin preparations used in this study were collected from different pharmaceutical companies, for example Theragran-M

(Squibb), Evian tablets and capsules E-Merck, Ephynai and Rovigon (Roche) and centrism (Lederle).

The spectra were recorded with Hitachi 220 double beam spectrophotometer. The spectra were recorded in the UV region between 241- 340 nm with scan of 30 nm/min.

Preparations of standard solution and UV-spectra

Accurately weighed amount of 100mg α -tocopherol acetate was transferred to 100 ml volumetric flask and diluted with ethanol/isopropanol up to the mark. UV-spectra of standard solutions were recorded (Fig. 1 and 2).

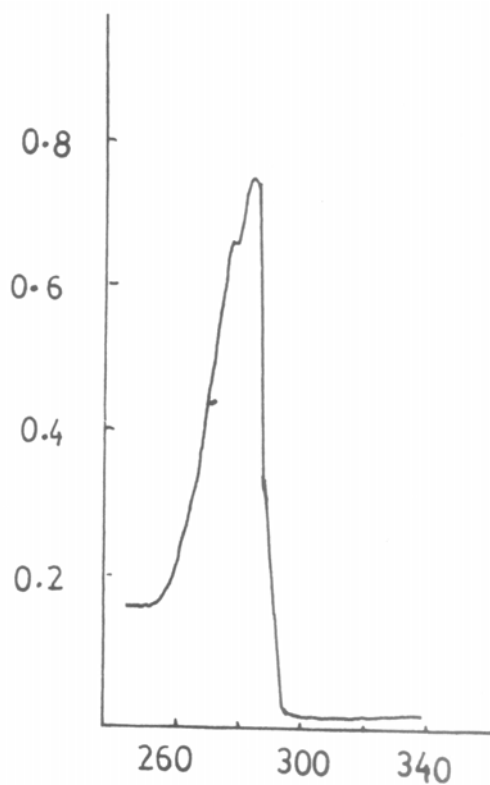


Fig. 1: Ultraviolet spectra of α -tocopherol acetate in ethanol.

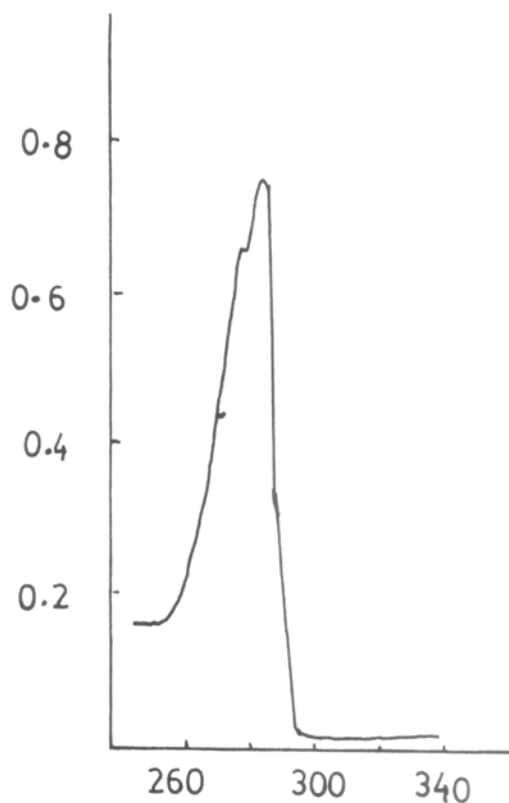


Fig-2: Ultraviolet spectra of α -tocopherol acetate in isopropanol. α -Tocopherol acetate concentration (mg/ml)

Preparations of standard dilutions and calibration graph

Serial dilutions of standard solutions are prepared by pipetting out 1.0 to 5.0 ml solutions into 10 ml volumetric flask and brought the volume upto mark with ethanol and isopropanol. The absorbance of each dilution was recorded on spectrophotometer at 285 nm and calibration graphs were prepared by plotting absorbance against concentration (Fig. 3).

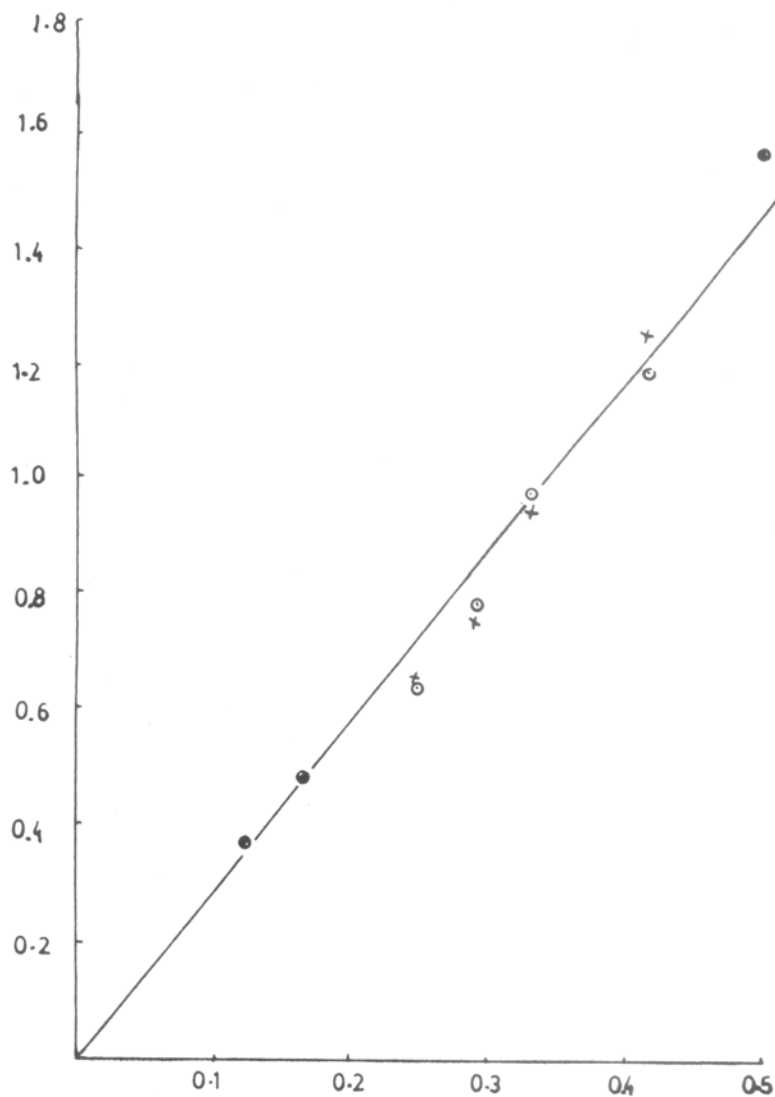


Fig. 3: Standard curve of α -tocopherol acetate in ethanol (O—O) and isopropanol.

Analysis of α -tocopherol acetate from pharmaceutical preparation

An accurate weight as shown in Table 1 and 2, equivalent to α -tocopherol acetate was taken from the mixed content of 10 tablets and was dissolved in ethanol and

isopropanol. The solution was filtered using sintered glass funnel and the nitrate was transferred to 100 ml volumetric flask and diluted with ethanol and isopropanol upto mark. Whereas 10 capsules were cut and their contents were mixed. An accurate volume of 1.0 and 2.0 ml from stock solution of tablets and capsules were diluted to 10 ml with ethanol and isopropanol and the absorbance values were recorded against ethanol and isopropanol.

Preparation of mixture samples

100mg of α -tocopherol acetate was mixed with 100mg of glucose/lactose/sucrose/gelatin and gum arabic and the mixture was dissolved in 100 ml ethanol/isopropanol. An accurate volume 1.0 and 2.0 ml was transferred from the mixture solution to 10 ml volumetric flask and diluted with ethanol/isopropanol upto the mark (Table-3).

Table-1

Determination of α -tocopherol acetate in pharmaceutical preparations in ethylalcohol at 285nm.

Pharmaceutical preparations	Amount used (mg)	Amount found* (mg)	Recovery (%)	S.D.	C.V. (%)
Evion Tab.	61.83	65.33	105.66	1.5	2.33
Evion Cap.	200.00	204.00	102.00	1.0	0.49
Theragran-M	60.00	267.80	445.00	13.86	5.17
Centrum	30.00	103.00	343.33	8.98	8.72
Ephynal	55.31	55.04	99.51	1.06	1.92
Rovigon	103.24	111.21	107.70	1.32	1.19

* Based on a total of three determination.

S.D. = Standard deviation

C.V.% Coefficient of variation percentage

Table-2
Determination of α -tocopherol acetate in pharmaceutical preparations in ethylalcohol at 285nm.

Pharmaceutical preparations	Amount used (mg)	Amount found*	Recovery (mg)	S.D.	C.V. (%)
Evion Tab.	90.12	89.00	98.75	1.55	1.78
Evion Cap.	230.00	236.00	102.60	2.00	0.84
Theragran-M	45.14	94.96	210.36	7.13	7.50
Centrum	44.33	107.00	343.62	3.56	3.33
Ephynal	80.88	78.17	96.52	0.94	1.23
Rovigon	79.57	202.00	253.80	8.48	4.20

* Based on a total of three determinations.

Table-3
Determination of α -tocopherol acetate in other preparations

Other preparations	Amount of α -tocopherol acetate			
	In Ethylalcohol solvent		In isopropanol solvent	
	Amount used** (mg)	Amount found*** (mg)	Amount used** (mg)	Amount found*** (mg)
α -Tocopherol acetate	100	101.28	100	101.00
α -Tocopherol acetate	100	147.60	100	103.10
+ Glucose*				
α -Tocopherol acetate	100	103.62	100	102.20
+ Sucrose*				
α -Tocopherol acetate	100	114.36	100	101.35
+ Lactose*				
α -Tocopherol acetate	100	110.44	100	100.50
+ Gum Arabica*				
α -Tocopherol acetate	100	102.00	100	100.90
+ Gelatin*				

* The amount of other substances used (100mg)

** α -Tocopherol acetate used (100mg)

*** Estimation of α -Tocopherol acetate based on a total of three determinations.

Results and Discussion

The UV-spectra of α -tocopherol acetate in ethanol and isopropanol were recorded and max 285nm was observed in both solvents for α -tocopherol as shown in Fig. 1 and 2, hence all measurements were carried out at this wavelength.

It can be seen from the standard curve (Fig: 3) that α -tocopherol acetate in ethanol and isopropanol in the range of 0.1 to 0.5 mg/ml obey the Beer's Lambert law quite nicely.

For checking the reliability of the present method the pure solution of α -tocopherol acetate was analyzed and the results shown that quite good determinations of α -tocopherol acetate from tablets and capsules in ethanol and isopropanol are shown in Table 1 and 2. The results obtained from tablets and capsules containing only α -tocopherol acetate shows good correlation between expected and observed level of α -tocopherol acetate in ethanol and isopropanol. However multivitamin preparations shows higher observed values of α -tocopherol acetate in both solvents than calculated values.

The effect of interfering substances such as glucose, sucrose, lactose, gelatin and gum Arabic were investigated. As seen in Table-3 that glucose, lactose and gum Arabic interfere the recovery percentage but sucrose and gelatin in the same range did not interfere in the determination of α -tocopherol acetate in ethanol. However all these interfering components do not interfere when isopropanol was used as a solvent.

Conclusions

It is concluded from the percentage recovery determination that this method could be used safely in the determination of α -tocopherol acetate in tablets and capsules. The time involved is considerably shorter in the proposed procedure than that required for the chemical method. Thus the developed spectrophotometric method is useful as a routine analysis for α -tocopherol acetate estimation in tablets and capsules.

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