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Simplistic Spectroscopic Method for Determination of α-Tocopherylacetate in Bulk and Formulated Microemulsion.

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Subject: Pharmaceutical Analysis

Abstract

Simplistic UV spectrophotometric method develops for determination and identification of analysis Tocopherylacetate (TOP) in bulk and formulated Microemulsion. Tocopherylacetate freely soluble in ethanol show λ max at 286nm. Analysis carried out by Absorption Maximum Method using Shimadzu 1800 spectrophotometer. Beer's law obeyed in concentration range of 1 to 12 µg/ mL. Limit of detection is 0.093µg/ml and limit of quantification was found to be 0.236µg/ml calculated from calibration graph. The results obtained are reproducible with a coefficient of variation less than 2%. The method was validated for Precision, Specificity, Reproducibility, Linearity and Accuracy as per ICH guidelines.

Keywords: *Tocopherylacetate, Beer's law, LOD, LOQ, Validation ICH guidelines.*

Introduction

α-Tocopherylacetate (TOP) is a derivative of Vitamin E are the most active and widely distributed in nature; other naturally occurring tocopherols include beta, gamma, and delta tocopherols, but these are not used in therapeutics. α-Tocopherylacetate chemically (+) -2,5,7,8-Tetramethyl-2- (4,8,12-trimethyltridecyl) chroman - 6-ol[1]. It has anti-oxidant properties and used in number of life threatening human diseases such as anti-cancer, atherosclerosis, diabetes, cancer and aging [2,3,4]. Several methods are reported for determination and quantification of α-Tocopherolacetate in pharmaceutical formulation, Plant and fruits extract and biological sample includes Chromatography [5,6,7,8], spectrophotometry [9,10]. In present study novel pharmaceutical formulation developed as Microencapsulation for this UV-Spectrophotometric method design for identification and quantification. The method was simple, accurate, precise and reliable for routine analysis of α-Tocopherolacetate. Develop method also validated according to ICH guideline and % RSD less than 2% means method is reliable and use for routine analysis.

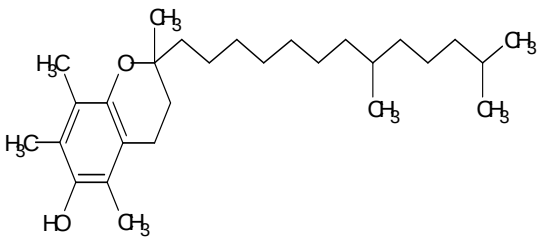

Fig. 1: Chemical Structure TOP

Material and Method

Shimadzu 1800 spectrophotometer with 1.0 cm quartz cuvettes attach with computer loaded with Shimadzu UV PC software (UV probe) version 2.31. Instrumental conditions were: wavelength range 200- 600 nm; scan rate 1000 nm/min;

slit 1.0 nm. All weighing were done on single pan balance (Shimadzu). Bath sonicator (Ultrasonic Bath UCB-70).

Reagent and Chemical

Analytically pure sample of TOP was gifted by Vijay Chemicals (Aurangabad, India) batch no. AF9A590270 containing ≥ 96% of TOP and used as such without further purification. IR Spectra of Pure drug sample shown in figure no. 2. Pharmaceutical formulation of TOP Microemulsion formulated in house by factorial design less than 2% contain 150 mg of TOP. All chemicals are of AR grade and were purchased from Qualigens fine Chemicals, Mumbai, India.

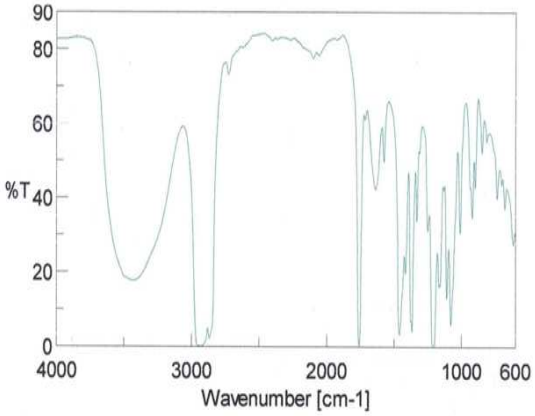

Fig. 2: IR Spectra of TOP

Preparation of Standard Stock Solutions

Standard stock solutions were prepared by dissolving separately 10 mg of drug in 100 mL of ethanol to get concentration of 0.1 mg mL-1. 1 mL of the stock solution was further diluted to 10 mL with ethanol to get a working standard solution of concentration 10 µg mL-1 of TOP and scanned in the wavelength range of 200-400 nm shown in figure no. 3.

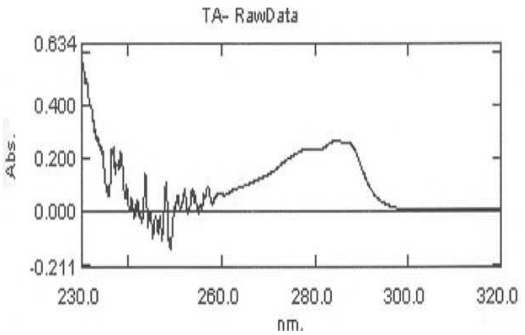

Fig. 3: UV-Spectra of TOP

Preparation of Sample Stock Solution

For determination of drug Contents, about 1 gm of the Microemulsion Gel weighed in 100 ml volumetric flask and dissolved in ethanol, it was diluted appropriately and drug content was determine by UV Spectrophotometer at 286 nm.

Absorption Maxima Method

For selection of analytical wavelength, 10 µg/mL solution of TOP was prepared by appropriate dilution of standard stock solution and scanned in the spectrum mode from 400 nm to 200 nm figure 3. From the spectra of drugs λ max TOP 286 nm was selected for the analysis. The calibration curve was prepared in the concentration range of 1-12 µg/mL at 286 nm. By using the calibration curve, the concentration of the sample solution determined.

Results and Discussions

Linearity and range

A standard stock solution of TOP was prepared; they were diluted to yield five standard solutions. For UV Spectrophotometric method, linearity was obtained in concentration range of 1 – 12 µg/mL shown in figure no. 4, with regression 0.997, intercept 0.024 and slope 0.006 and 0.0391 for TOP. The results are depicted in Table 1.

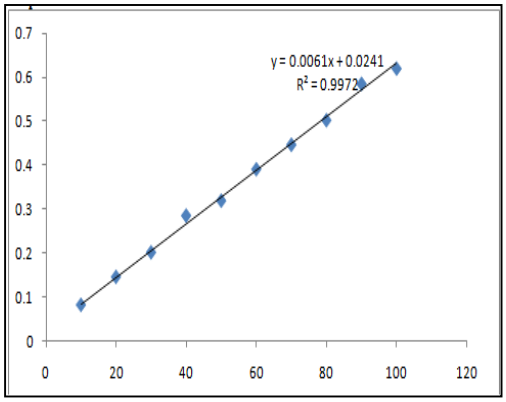

Fig. 4: Linearity of TOP in Concentration Range 1-12 µg/ml

Table No. 1: Optical Characteristics of TOP

λ max (nm)	286 nm
Linearity (µg/ml)	1-12µg/mL
Regression	0.997
Slope(m)	0.024
LOD (µg/ml)	0.093
LOQ (µg/ml)	0.236

Accuracy and precision

The accuracy of the proposed methods was checked by recovery studies, by addition of standard drug solution to pre analysed sample solution at three different concentration levels within the range of linearity. Results of recovery studies are shown in Table 2. The accuracy and reproducibility is evident from the data as results are close to 100 % and the value of standard deviation and % R.S.D. were found to be < 2 %; shows the high precision of the method. Similarly for precision was carried out between intraday and interday and result shown in table no 3. The proposed method is simple, economical, rapid, precise and accurate. Hence it can be used for routine analysis of TOP in formulated formulation.

Specificity

The proposed method was found to be specific as there is no interference from other excipients shown in figure 5.

Conclusion

Analysis of formulated Microemulsion was carried out and the amount recovered was expressed as percentage. The percentage recovery for TOP is 99.98±0.645. The proposed methods was evaluated by the assay (n = 6) of TOP.

UV method developed for TOP does not require special reagents, equipments and process, and only needs to dissolve TOP in ethanol and then to measure the absorbance, which saves much time and money. The authors therefore recommend this method for the routine determination of TOP in its granule and tablet formulations.

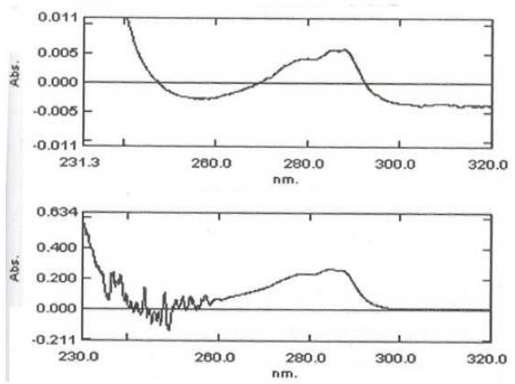

Fig. 5: Specificity of method

Table 2: Recovery data of TOP

Amount of drug in formulation(µg/ml)	Level of addition (%)	Amount added(µg/ml)	Drug found	% Recovery	Mean % recovery
10	80	8	17.85	99.71	
10	100	10	19.75	99.51	99.76
10	120	12	22.15	100.07	

Table 3: Intraday and Interday Precision

Concentration (µg/ml)	Intraday Precision		Interday Precision	
	Standard Deviation	Relative Standard Deviation	Standard Deviation	Relative Standard Deviation
10	0.0428	1.113	0.0461	1.150
20	0.0399	1.008	0.0483	1.171
30	0.0418	1.029	0.0410	1.147

Table 4: Stability Data

Sr. No.	Absorbance (nm)	Time (hr)	% Assay	% RSD
1		1	99.77	0.79
2	286	5	99.15	0.34
3		10	99.23	1.26
4		24	98.67	0.63

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