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A NEW SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF EFAVIRENZ

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ABSTRACT

A simple and reproducible spectrophotometric method has been developed for the estimation of efavirenz in pure form. The method is based on the reaction of the drug with ferric chloride and potassium ferricyanide, which forms a green chromogen exhibiting maximum absorption at 737 nm.

Key word : Efavirenz, Spectrophotometric method.

INTRODUCTION

Efavirenz[1], one of the recent anti–HIV agents, is a non–nucleoside reverse transcriptase inhibitor. Chemically, it is [(S)–6–chloro–4–(cyclopropyl ethynyl)–1, 4–dihydro–4–(trifluoromethyl)–2H–3, 1–benzoxazin–2–one]. A few analytical methods[2–7] based on HPLC and spectrophotometry have been reported earlier for the determination of efavirenz. The authors now report the development of a simple and reproducible spectrophotometric method for its estimation in pure form. Spectrophotometric parameters were established for standardization of the method by statistical analysis of the data. This method can be successfully extended to the pharmaceutical preparations containing efaverinz.

EXPERIMENTAL

All the chemicals used were of analytical grade. Solutions of ferric chloride (0.1M) and potassium ferricyanide (0.1% w/v), were prepared using double distilled water. Spectral and absorbance measurements were made on a Systronics UV–Vis spectrophotometer (Model 117) with 10 mm–matched quartz cells.

Preparation of standard solution

100 mg of pure efavirenz was dissolved in 5.0 mL of 0.3 M sodium hydroxide and kept aside for 10 hours to undergo hydrolysis. This solution was filtered and diluted to 100 mL with

water in a volumetric flask. This solution was further diluted with water to get a working standard solution of 250 µg/mL.

Method

Aliquots ranging from 0.2 to 0.8 mL of the working standard solution of efavirenz (250 µg/mL) were transferred into a series of 10 mL graduated test tubes. To each of these tubes, 2.5 mL of ferric chloride and 3.0 mL of potassium ferricynide were successively added and the final volume was brought to 10.0 mL with distilled water. The absorbances were measured at 737 nm against a reagent blank. The coloured compound was stable upto 90 min.

RESULTS AND DISCUSSION

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar extinction coefficient, percent relative standard deviation and percent range of error were calculated for the method and the results are summarized in Table 1. The values obtained for the determination of efaverinz in the sample by the proposed method are compared with those of a reference method (Table 2). To evaluate the validity and reproducibility of the method, known amounts of pure drug were added to the solution and the mixtures were analyzed by the proposed method. The percent recoveries thus obtained are given in Table 2.

Table 1. Optical characteristics and precision data

Parameters	
Beer's law limit (µg/mL)	5–20
Sandell's sensitivity (µg/cm^2/0.001 absorbance unit)	0.0278
Molar extinction coefficient (mole^{-1} . cm^{-1})	1.161 x 10^4
% Relative standard deviation	0.6754
% Range of error	
0.05 confidence limits	± 0.5648
0.01 confidence limits	± 0.6356
Correlation coefficient	0.9996
Regression equation (Y = b + aC)*	
Slope (a)	0.0375
Intercept (b)	0.0085

* Where C is concentration in µg/mL and Y is absorbance unit.

Table 2. Assay of Efaverinz in pure samples

Sample	Labelled amount (mg)	Amount obtained (mg)		Percent recovery by the proposed method
		Reference method*	Proposed method	
1.	20	19.4	19.86	99.30
2.	10	10.2	9.97	99.70
3.	20	19.8	19.87	99.35

* UV method developed by authors

The drug after hydrolysis reduces ferric chloride to ferrous form, which in turn couples with potassium ferricyanide to give a green coloured potassium ferro–ferrous complex.

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