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Spectrophotometric Method for Estimation of Tenofovir Disoproxil Fumarate in Tablets

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Short Communication

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ABSTRACT

A new, simple and cost effective UV-spectrophotometric method has been developed for estimation of tenofovir disoproxil fumarate in bulk and tablets. Tenofovir disoproxil fumarate was estimated at 260 nm in water after dissolving in methanol. The linearity was found to be in the range of 10 - 50 µg/ml. (Y=0.024X-0.037; r =1.00004). The results of analysis were validated statistically and by recovery studies and they demonstrated that the procedure is accurate, precise and reproducible (relative standard deviation <2%), while being simple, cheap and less time consuming. The proposed methods were successfully applied for the determination of tenofovir disoproxil fumarate in pharmaceutical formulations.

INTRODUCTION

Tenofovir disoproxil fumarate (TDF) is an antiretroviral drug and acts by blocking reverse transcriptase[1]. Chemically TDF is 9-[(R)-2-[[bis[[(isopropoxycarbonyl) oxy] methoxy]phosphinyl]methoxy]propyl]adenine fumarate (1:1)[2]. The dose of TDF is 300 mg per day [3]. Several combinations of tenofovir with other antiretroviral drugs are available in the market for treatment of HIV infected Patients [4]. Literature survey revealed that analytical methods which include liquid chromatography with tandem mass spectrometry[5], simultaneous quantification of emtricitabine and tenofovir in human plasma using high- performance liquid chromatography after solid phase extraction[6]. Sensitive determination of tenofovir in human plasma samples using reversed-phase liquid chromatography [7]. TDF is official in IP [8]. The present work deals with the estimation of TDF by UV-spectrophotometry [9,10,11].

MATERIALS AND METHODS

Instruments

UV-visible spectrophotometer (2450 Shimadzu with UV probe 2.21 software), 10 mm quartz cell and spectral bandwidth 1nm

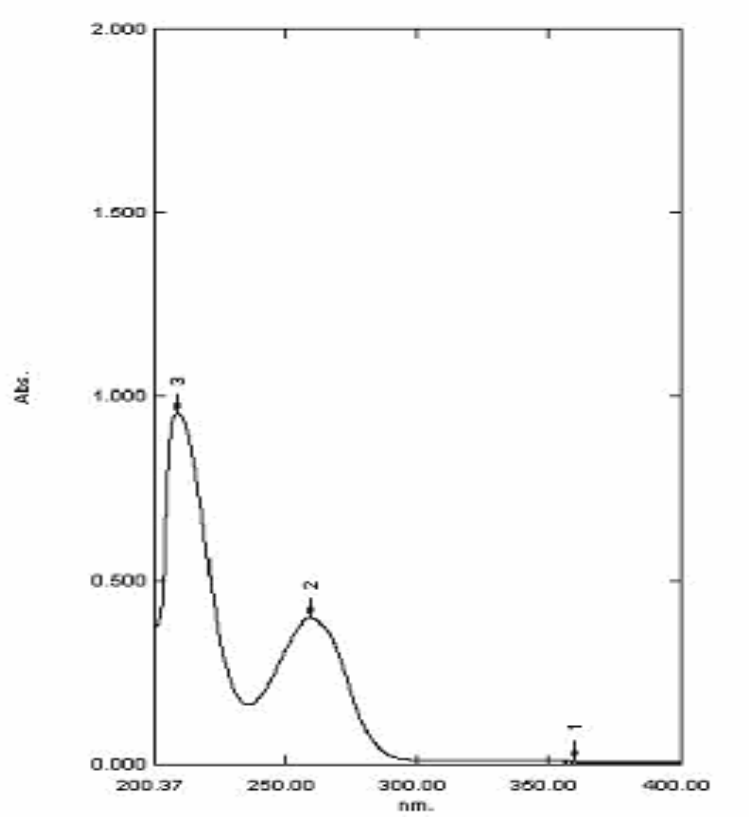
Reagents

a) Methanol
b) Distilled water

Preparation of Standard Stock Solution

Standard stock solution containing 100 µg/ml of TDF was prepared by dissolving in 1ml methanol and the volume was made up to 100 ml with distilled water. From the stock, different aliquots were taken and diluted to 10 ml mark with same solvent to obtain series of concentrations. The solutions were scanned on spectrophotometer in the UV range 200-400 nm.TDF showed absorption maxima at 260 nm (fig 1). In the method, drug follows linearity in the concentration range of 10 – 50 µg/ml (Y= 0.024 X-0.037, r = 1.00004).calibration curve for TDF was shown in fig 2.

Figure 1: UV Spectrum of Tenofovir



Preparation of Sample Solution

For analysis of commercial formulation; twenty tablets were weighed, average weight was determined and crushed into fine powder. An accurately weighed quantity of powder equivalent to 100 mg of tenofovir was transferred into 100 ml volumetric flask. The powder was dissolved in 1 ml methanol and volume was made up with distilled water. This solution was brought into a concentration of 100 µg/ml with distilled water. An appropriate aliquot was transferred to 10 ml volumetric flask, volume was adjusted to the mark and absorbance was recorded at 260 nm.

Recovery studies were carried out by adding a known quantity of pure drug to the pre -analyzed formulation and the proposed method was followed. From the amount of drug found, percentage recovery was calculated (table 1). The results from validation studies were shown in table 2.The proposed method of determination of Tenofovir showed molar absorptivity of 1.31273×10^4 lit mol^{-1} cm^{-1} and sandell's sensitivity of 0.04841 µg /cm^2 0.001absorbance unit.

Linear regression of absorbance on concentration gave the equation y = 0.024x-0.037 with a correlation coefficient of 1.00004.

The percentage recovery value 99.34% indicates that there is no interference from the excipients present in the formulation.

Table 1: Results of Assay and Recovery Studies

Pharmaceutical formulation	Label claim	Amount found* (mg)	Amount found* %	% recovery*
Tavin (Emcure)	300 mg	298	99.55	98.85
Tenof (Hetro)	300 mg	296.5	98.83	98.93
Tentide (Ranbaxy)	300 mg	299	99.66	99.01

*Mean of five determinations

Figure 2: Calibration Curve for TDF

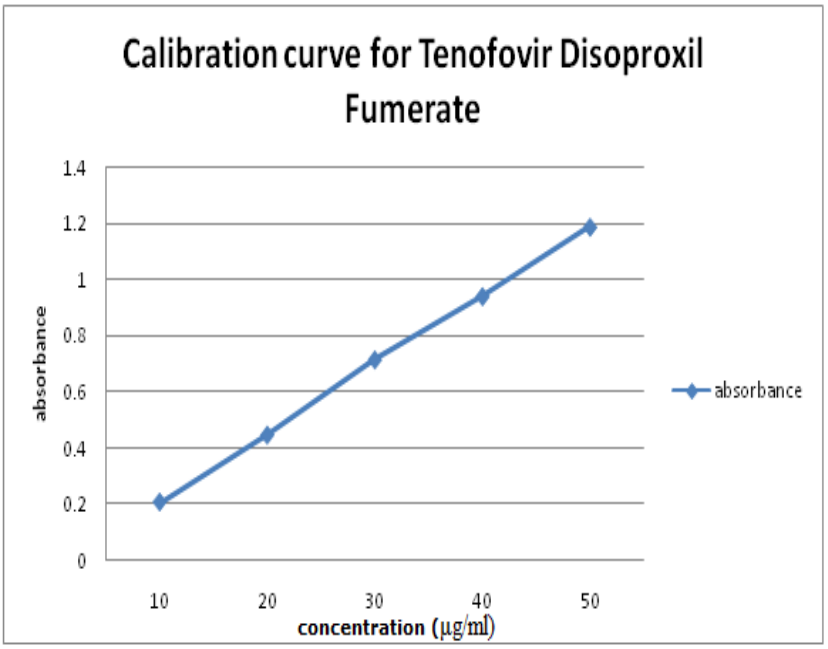


Table 2: Summary of Validation Parameters

Parameters	UV-Spectrophotometric values
Linearity (µg/ml)	10 – 50 µg/ml
LOD	0.0144
Accuracy (% Recovery) (n =5)	98.85
Precision (%RSD)	0.0023
Sandell's Sensitivity	0.04841µg/cm^2 0.001 absorbance unit
Confidence limit (95%)	0.3033
Confidence limit (99%)	0.3014

RESULT AND DISCUSSION

The UV spectrum of TDF in Methanol and Distilled Water has showed maximum absorbance at 260 nm. The amount of drug determined was in the good agreement with the label claim as shown in table 1. The methods were validated for accuracy, precision,

Sandells Sensitivity. Confidence limit 95% and 99% were also determined. The precision of the methods were studied. The % RSD values less than 2 indicate the methods are accurate and precise.

CONCLUSION

The method is simple, rapid , accurate and precise and can be used for routine analysis of tenofovir from tablet formulations

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