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Development of UV spectroscopic method for the estimation of tenofovir in bulk and solid dosage forms

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ABSTRACT

A simple and sensitive spectroscopic method in ultraviolet region was developed for the estimation of Tenofovir in Bulk and pharmaceutical dosage forms. The method is based on Tenofovir, showing absorbance at 260 nm for zero order spectroscopy in distilled water. The method obeys Beers law in the concentration range of 4 to 40µg/ml. The proposed method is precise, accurate, linear, stable and reproducible and can be extended to the analysis of Tenofovir in bulk and pharmaceutical formulations.

KEYWORDS

Tenofovir;
U.V.spectroscopic;
U.V.estimation.

INTRODUCTION

Tenofovir is chemically [(2R)-1-(6-aminopurin-9-yl) propan- 2-yl] oxymethyl phosphonic acid. It is a white crystalline powder used as antiretroviral agents, for the treatment of HIV infection. It has an empirical formula of $C_9H_{14}N_5O_4P$ and molecular weight of 287.2123. Tenofovir belongs to a class of antiretroviral drugs known as nucleotide analogue reverse transcriptase inhibitors (NtRTIs), which block reverse transcriptase, an enzyme crucial to viral production in HIV-infected people[1]. Food and drug administration granted approval to market viread (TENOFOVIR) for the treatment of chronic hepatitis B[2]. Literature survey reveals that very few analytical methods has been established for the estimation of tenofovir and emtricitabine in bulk and in tablet dosage form by spectrophotometric method[3], Simultaneous determination of emtricitabine and Tenofovir by area under curve and dual wavelength spectrophotometric method[4], relevance of a combined UV and single mass spectrometry detection for the determination of tenofovir in human plasma by HPLC in therapeutic drug monitoring[5], segmented polyurethane intravaginal rings for the sustained combined delivery of antiretroviral agents dapivirine and tenofovir[6], simultaneous quantification of a non-nucleoside reverse transcriptase inhibitor efavirenz, a nucleoside reverse transcriptase inhibitor emtricitabine and a nucleotide reverse transcriptase inhibitor tenofovir in plasma by liquid chromatography positive ion electrospray tandem mass spectrometry[7], RPHPLC method for the determination of tenofovir in pharmaceutical formulations and spiked human plasma[8], spectrophotometric determination of tenofovir disoproxil fumarate after complexation with ammonium molybdate and picric acid[9], quantitative analysis of tenofovir by titrimetric, extractive ion-pair spectophotometric and charge-transfer complexation methods[10]. The objective of this work was to develop a new, simple, economic, rapid, precise, and accurate U.V. spectroscopic method for quantitative

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analysis of tenofovir as bulk drug and in pharmaceutical formulations.

MATERIAL AND METHODS

Instrument

Elico SL 164 double beam spectrophotometer was used for all the spectroscopic measurements. The spectral bandwidth was 1 nm.

Prepartion of standrad solution and sample solution

A stock solution of 1mg/ml Tenofovir in water was used. The working solutions were (0.1 mg/ml) prepared by transferring 5.0 ml from respective stock solution to a 50 ml volumetric flask and completing to volume with water.

Determination of tenofovir in tablets

Brand name

Viread (300mg)

Company name

Pure standard of Tenofovir (assigned purity 99.98%) was obtained as a gift sample from Ranbaxy labs Pvt. Ltd. Gurgaon, India.

Procedure

A total of 20 tablets were accurately weighed and powdered in a mortar. An amount equivalent to 100 mg (118.32mg) was taken and dissolved in 50 ml of water and stirred on magnetic stirrer for five minutes. About 10 ml of water was added and stirred for further 5 minutes. Then transferred to a 100 ml volumetric flask through a Whatman No. 40 Filter paper. The residue was washed thrice with water and the combined filtrate was made up to the mark.

Determination of tenofovir

100 mg of pure Tenofovir was taken and dissolved in 50 ml of water and stirred on magnetic stirrer for five minutes, finally make up the volume up to 100 ml with distilled water. An aliquot of this stock solution (10 ml) was diluted to 100 ml with distilled water. The procedure with standard solution of drug has same concentration as test solution. The absorbance of test and standard solutions were measured at 260 nm against reagent blank. The experiment was performed for bulk drug and formulation and we get standard plot at a wavelength of 260 nm given in Figure 1 with optical activity given in TABLE 1.

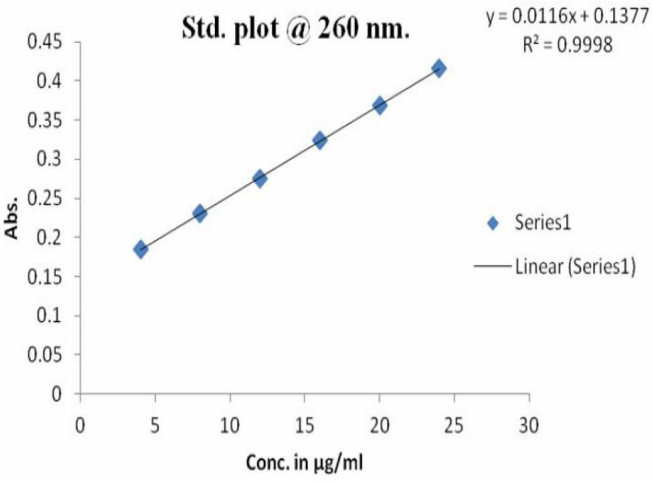

Figure 1 : Standard plot for zero order spectra

TABLE 1 : Optical characteristic of zero order

Sl.NO.	Parameters	Results
1	Absorption maxima (nm)	260
2	Beer's law limits (mcg/ml)	4-40
3	Molar extinction coefficient ($mole^{-1}$ cm^{-1})	0.04634
4	Sandell,s sensitivity (mcg/cm/0.001 absorbance units)	0.02157
5	Regression equation (y)*	0.9998
	Slope (b)	0.0116
	Intercept (a)	0.1377
6	Coefficient of variance	0.009247
7	Standard deviation**	0.003

***y = a + bx; when x is the concentration in µg/ml and y is absorbance unit; **Three replicate samples.**

RESULTS AND DISCUSSION

In the present study attempts shall be made to develop specific spectroscopic method for the estimation of Tenofovir in bulk and in Pharmaceutical formulation (Tablets). The method involves UV spectroscopic estimation of Tenofovir using distilled water as solvent in bulk and in formulation. The absorption maximum was measured at 260 nm and calibration curve was plotted with linearity in the concentration range 4-40µg/ml. The sandells sensitivity was found out to be 0.02157 mcg/

cm/0.001 absorbance units and molar absortivity 0.04634 mol^{-1} cm^{-1}. The regression equation for the proposed method is calculated by Least Square method as Y= a + bx and found to be 0.9998, intercept (a) was found to be 0.1377 and slope (b) was found to be 0.0116 of the line. The standard deviation of 0.003 indicated accuracy and reproducibility of the method. The method was extended for the determination of Tenofovir in tablet formulation. It was observed that the recovery was found to be 99.78 to 101.86% indicating practically no interference of formulation excipients with the proposed method. The accuracy, precision and recovery studies prove that the method is the best for further analysis of the drug. So the developed spectroscopic methods were found to be simple, accurate, economical and reproducible for the estimation of Tenofovir in bulk and in Pharmaceutical formulation (Tablets).

CONCLUSION

The proposed UV spectroscopic method is found to be accurate, precise, linear, stable, specific, and simple, for quantitative estimation of Tenofovir in raw material and pharmaceutical formulations. Hence the present UV spectroscopic method is suitable for routine assay of Tenofovir in raw materials and in pharmaceutical formulations in the quality control laboratories.

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