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Research Article

SIMPLE UV SPECTROPHOTOMETRIC DETERMINATION OF EMTRICITABINE IN PURE FORM AND IN PHARMACEUTICAL FORMULATIONS

C.M. Bhaskar Reddy[1]*, G.V. Subba Reddy[2]

[1]Research Scholar, Rayalaseema University, Kurnool - 518002 A. P., India

[2]Associate Professor of Chemistry, Dept of Chemistry, JNTU College of Engineering, Pulivendula, Kadapa (DT) A. P., India

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*E-mail: cmbr2008@gmail.com

ABSTRACT

A new, simple and sensitive spectrophotometric method in ultraviolet region has been developed for the determination of Emtricitabine in bulk and in pharmaceutical formulations. Emtricitabine exhibits absorption maxima at 240 nm with apparent molar absorptivity of 7.2345 x10^4 L/mol.cm in methanol. Beer's law was found to be obeyed in the concentration range of 2-18 µg/mL. The method is accurate, precise and economical. This method is extended to pharmaceutical preparations. In this method, there is no interference from any common pharmaceutical additives and diluents. Results of the analysis were validated statistically and by recovery studies.

KEYWORDS: Spectrophotometric determination, methanol , Emtricitabine, Validated

INTRODUCTION

Emtricitabine is 4-amino-5-fluoro-1-[(2R,5S)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-2-(1H)-pyrimidone and A non-nucleoside reverse transcriptase inhibitor used as part ofcombination therapy for a treatment of HIV- 1 infection[1-3] mtricitabine (FTC), with trade name Emtriva (formerly Coviracil), is a nucleoside reverse transcriptase inhibitor (NRTI) for the treatment of HIV infection in adults and children.Emtricitabine is also marketed in a fixed-dose combination with tenofovir (Viread) under the brand name Truvada. A fixed-dose triple combination of emtricitabine, tenofovir and efavirenz (Sustiva, marketed by Bristol-Myers Squibb) was approved by the U.S. Food and Drug Administration (FDA) on July 12, 2006 under the brand name Atripala[4] Emtricitabine was discovered by Dr. Dennis C. Liotta, Dr. Raymond Schinazi and Dr. Woo-Baeg Choi of Emory University and licensed to Triangle Pharmaceuticals by Emory in 1996[5] Emtricitabine exhibits clinical activity against the hepatitis B virus (HBV). Among individuals with chronic HBV infection, emtricitabine treatment results in significant histologic, virologic, and biochemical improvement. The safety profile of emtricitabine during treatment is similar to that of a placebo. Emtricitabine, however, cures neither HIV nor HBV infection. In a study involving individuals with HBV infection, symptoms of infection returned in 23% of emtricitabine-treated individuals who were taken off therapy[6] In studies involving individuals with chronic HIV infection, viral replication also resumes when study subjects are taken of therapy[7] Emtricitabine is not approved by the FDA for treatment of HBV infection. As with drugs used to treat HIV infection, drugs used to treat HBV infection may have to be used in combination to prevent the evolution of drug resistant strains. Lamivudine is also active against HBV virus and commercially available. Like emtricitabine, lamivudine, when used on its own, does not completely suppress viral replication. This allows drug resistant strains to Emerge[8] It is used as antiviral drug. Emtricitabine is nucleoside reverse transcriptase inhibitors[9]. Literature survey reveals few chromatographic methods in biological fluids reported along with other antiretroviral drugs[10]. Literature survey revealed that rapid method for the quantitative determination of Emtricitabine in human plasma[2] and HPLC[11] method are available for estimation of Emtricitabine alone and in Combinations with other drugs[12-13]. Therefore, an attempt was made to develop simple, accurate and reliable spectrophotometric method for estimation of Emtricitabine in bulk and in capsule dosage form.

EXPERIMENTAL

Apparatus

A GBC Cintra-10 double beam UV-Visible spectrophotometer (Australia) equipped with 10 mm matched quartz cells was used in the present investigation. A sartorius analytical balance was used.

Chemicals and reagents

Methanol (AR) (Qualigens) was used in the present study. Pure Emtricitabine obtained from ATRIPLA TABLETS, (GILEAD SCIENCES LTD, UK) & TRUVADA TABLETS (CIPLA INDIA LTD, HYDERABAD) was used as such without further purification.

Recommended procedure and calibration curve

Emtricitabine (100 mg) was accurately weighed and dissolved in 100 mL methanol to form a stock solution (1000 µg/mL). The stock solution was further diluted suitably with methanol to get a working standard solution of concentration 100 µg/mL. This working standard solution was suitably diluted to give a concentration of 14 µg/mL and this was then scanned in UV range. This showed an absorption maximum at 240 nm Aliquots (0.2,0.4……1.8) mL of working standard solution corresponding to 2-18 µg were taken in a series of 10 Ml volumetric flask and volume made up with methanol. The absorbance measurements of these solutions were carried out against methanol as blank at 240 nm. A calibration curve of EMTRICITABINE was plotted. The concentration of the unknown was read from the calibration graph or computed from the regression equation.

Procedure for tablets

Two commercial formulation, ATRIPLA TABLETS (GILEAD SCIENCES LTD, UK) and TRUVADA TABLETS (CIPLA INDIA LTD, HYDERABAD) were purchased from local market. The average weight of each tablet (before and after removing coating) was calculated by weighing 20 tablets. Ten tablets were powdered finely in a

glass mortar. Powder equivalent to 50 mg of Emtricitabine was successively extracted with methanol (4 x 20 mL) and the extracts transferred quantitatively into 100 mL volumetric flask after filtering through Whatman No. 1 filter paper. The volume was then made up with methanol (500 µg/mL). Then this solution was further diluted with methanol to get working standard solution of 50 µg/mL. Suitable volume of this solution was taken in 10 mL volumetric flask and volume was made up with methanol. Absorbances were read and concentrations of Emtricitabine determined using the calibration curve. Calculations were then made with the dilution factor to find out the concentration of the drug in tablets. The experiments were repeated six times to check its reproducibility

RESULTS AND DISCUSSION

The proposed method for determination of Emtricitabine showed molar absorptivity of 7.2345 x 10^4 L/mol.cm. Linear regression of absorbance on concentration gave the equation y = 0.0726x + 0.001 with a correlation coefficient (r) of 0.9978 (Table 1). Statistical analysis of commercial formulations has been shown in Table 2. To evaluate the validity and reproducibility of the method, known amount of pure drug was added to the analyzed sample of tablet powder and the mixture was analyzed for the drug content using the proposed method. The percentage recovery was found to be within range (Table 3). mtricitabine exhibited maximum absorption at 240 nm and obeyed Beer's Law in the concentration range of 2-18 µg/mL. The recovery experiments indicated the absence of interference from the commonly encountered pharmaceutical additives and excipients Thus it can be said that the proposed method is precise, accurate and economical which can be very well applied to the marketed samples.

CONCLUSION

The developed method was found to be simple, sensitive, accurate, precise, economic and can be used for routine quality control analysis of Emtricitabine in bulk as well as in pharmaceutical dosage form.

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Table 1. OPTICAL CHARACTERISTICS OF EMTRICITABINE

Parameters	Values
lmax nm	240
Beer's Law Limit, µg/mL	2-18
Molar absorptivity, L/mol.cm	7.2646 x 104
Sandell's sensitivity (µg/cm2 x 0.001 absorbance unit)	0.0137
Regression equation	y = ax + b
Slope (a)	0.0726
Intercept (b)	0.001
Correlation coefficient (r)	0.9978

Table 2. STATISTICAL ANALYSIS OF EMTRICITABINE

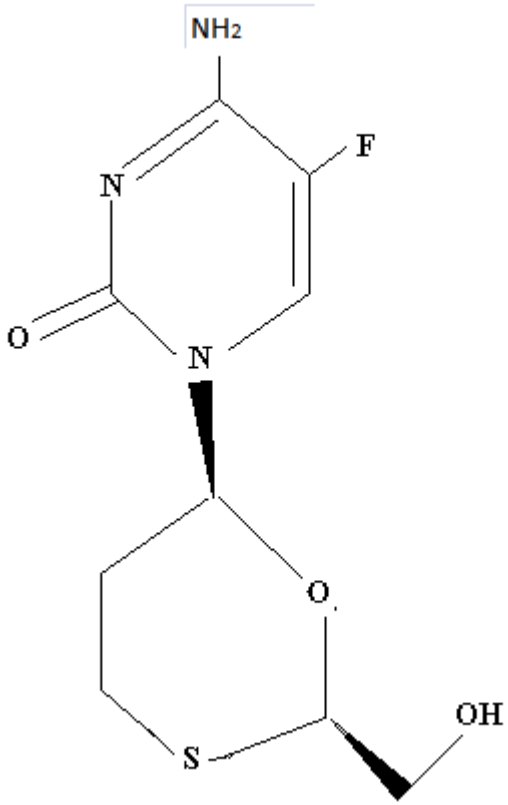
S.N	Brand	Label claim mg/tab	Amount found mg/tab*	% Label claim±SD*	SE*
1	ATRIPLA	100	9.9904	9.99±0.0140	0.0057
2	TRUVADA	100	9.9892	9.98±0.0108	0.0044

*Average of six determinations

Table 3. RECOVERY STUDIES OF. EMTRICITABINE TABLETS

S.N	Brand	Amount added (mg)	Amount found (mg)	% Recovery ±S.D.*
1	ATRIPLA	100	59.9976	99.99±0.0766
2	TRUVADA	100	59.9563	99.92±0.0658

FIG: 1 THE STRUCTURE OF EMTRICITABINE



Systematic (IUPAC) name
4-amino-5-fluoro-1-[(2*S*,5*R*)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-1,2-dihydropyrimidin-2-one

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