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Spectrophotometric estimation of abacavir sulphate in pharmaceutical formulations

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ABSTRACT

Visible spectrophotometric methods [I and II] have been developed for the estimation of Abacavir sulphate in bulk drug and pharmaceutical formulation. Method [I] based on the reaction between FC reagent with the drug in alkaline condition to give a blue colour chromogen with absorption maximum at 754.6nm and obeyed beers law in the concentration range of 20 -120 µg/ml. Method [II] based on the reduction of ferric ions to ferrous ions by abacavir which further in presence of potassium ferricyanide produce green chromogen with absorption maximum at 712.3nm and obeyed beers law in the concentration range of 2 -12 µg/ml.

Keywords: Abacavir sulphate, FC Reagent, Pottasium ferricyanide, Spectrophotometric method.

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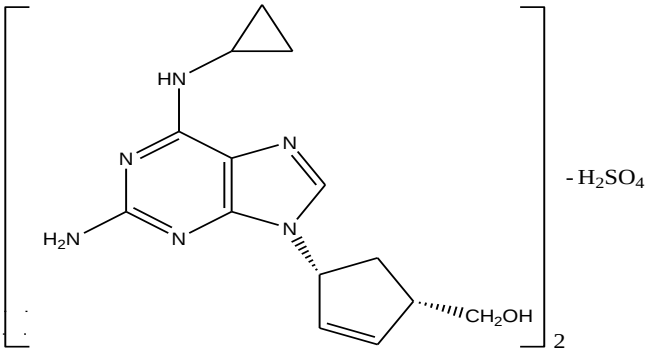
INTRODUCTION

Abacavir sulphate is chemically [(1*S*,4*R*)-4-[amino-6-(cyclo propylamino)-9*H*-purin-9yl]cyclopent-2-en-1-yl]methanol and is a nucleoside reverse trancriptase inhibitor [NRTI] with activity against Human immunodeficiency virus Type-1(HIV-1). ABR is available as salt form as Abacavir sulphate. A few analytical mehods have been reported for its quantitative estimation in pharmaceutical formulations,which include UV, HPLC, LC-MS/MS methods. In view of the above fact, some simple analytical methods are in need for its quantitative estimation. In present work, two simple sensitive economical and accurate spectrophotometric methods have been developed for the quantitative estimation of ABR in bulk and pharmaceutical formulations[(Abamune 300 mg, Ziagen 300mg) tablets].



Abacavir sulphate

MATERIALS AND METHODS

Chemicals and reagents

Abacavir pure drug was obtained from Hetero Drugs Pvt Ltd, Hyderabad, India. All chemicals used were of analytical reagent grade purchased from S. D. Fine chemicals, Mumbai, India. Folin-Ciocalteu (FC) reagent (1 part diluted with 4 parts of water), Sodium carbonate solution (20%), Potassium ferricyanide (0.1%), ferric chloride (0.02M) and Double distilled water was used throughout the analysis.

Instrumentation

A Perkin Elmer UV/VIS double beam spectrophotometer (model Lambda 25) with 1cm matched quartz cells and UV WinLamb 2.8 software used for all spectral measurements.

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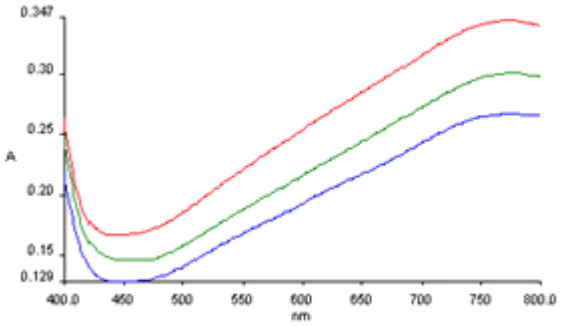
Experimental procedures

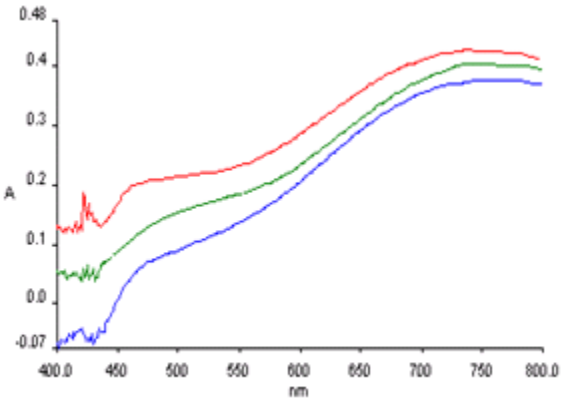
The standard ABR (100mg) was weighed accurately and transferred to volumetric flask (100ml). It was dissolved properly and diluted with distilled water to obtain the final concentration of 1mg/ml and the resulting solution was used as working standard solution. For the sample solution, each tablet containing 300mg of ABR, 20 tablets were accurately weighed and average weight per tablet was determined. The tablets were powdered and powders equivalent to 100mg of drug was taken and treated in similar manner as that of standard.

Fig.1: Assay of Abacavir using FC reagent at 754.6 nm



For Method I [Fig 1], aliquots of 0.2-1.2ml (1ml=100µg) were transferred into a series of 10ml volumetric flasks. To each flask,1ml of Sodium carbonate solution (20%) with 1ml FC reagent were added. After thoroughly shaking, the flask set aside for 10 min for the reaction to complete. The volumes of each flask were adjusted to 10ml with distilled water. The absorbance of blue chromogen was measured at 754.6nm against reagent blank. Calibration curve was prepared by plotting concentration versus absorbance and found to be linear in the concentration range of 20-120µg/ml. Similarly absorbance of sample solution was measured and amount of ABR was determined from standard calibration curve.

Fig.2: Assay of Abacavir using Potassium ferricyanide at 712.3nm



Method II [Fig 2], aliquots of 0.2-1.2ml (1ml=10µg) were transferred into a series of 100ml volumetric flasks. To each flask, 1ml of Ferric chloride (0.02M), and 0.5ml of Potassium

ferricyanide (0.1%) were added. After thoroughly shaking the flask set aside for few min for the reaction to complete. The volumes of each flask were adjusted to 100ml with distilled water. The absorbance of dark green chromogen was measured at 712.3nm against reagent blank. Calibration curve was prepared by plotting concentration versus absorbance and found to be linear in the concentration range of 2.0-12.0µg/ml. Similarly absorbance of sample solution was measured and the amount of ABR was determined from standard calibration curve. The recovery experiments were performed by adding known amounts of the drug to the pre-analysed formulation and reanalysing the mixture by proposed methods.

RESULTS AND DISCUSSION

In the first method, the quantitative reaction of the drug with FC reagent was proposed. The reaction was based on the reduction reaction of FC reagent by ABR in presence of 20% sodium carbonate solution, thereby producing reduced species having characteristic blue colour with the maximum absorbance at 754.6nm.The second method based on reduction of ferric ions to ferrous ion, which further in presence of oxidising agent potassium ferricyanide produced green chromogen at 712.3nm. Coloured chromogen was found to be stable for more than 1 hour at room temperature for both the methods.

The linearity were found in the concentration range 20-120µg/ml (r=0.9999) and 2-12µg/ml (r=0.9987), Molar absorptivity (L/m/cm) $0.0102x10^2$ and $0.157x10^2$, Sandell's sensitivity (µg/ml/cm^2) $1.403x10^3$ and $1.088x10^2$ for methods I and II respectively. The results of analysis of marketed formulations are shown in Table 1.

Table 1: Optical characteristics, precision and accuracy of Abacavir sulphate

Parameters	Method I	Method II
Detection Limit (nm)	754.6	712.3
Beers Limit (µg/ml)	20-120	2-12
Molar absorptivity (L/m/cm)	$0.0102x10^2$	$0.157x10^2$
Correlation coefficient (r)	0.9999	0.9987
Slope (B)	0.0035	0.051
Intercept (A)	0.0019	0.012
Sandell's sensitivity(µg/ml/cm^2)	$1.403x10^3$	$1.088x10^2$
LOD (µg/ml)	0.9	0.06
LOQ (µg/ml)	2.8	0.2

The accuracy of the method was studied by recovery experiments .The recovery experiments were performed by adding known amounts of the drug to the placebo. The recovery was determined at three levels, viz. 50%, 100% and 150% of the selected concentrations. Three samples were prepared for each recovery level. The recovery values for method I and II ranged from 98.5-102.5% and 99.5-101.0% respectively. The reproducibility and

accuracy of the methods were found to be good which was evidenced by the low values of standard deviation. The percent recovery was close to 100% suggests the non–interference in the estimation. All the Validated parameters are summarised in Table 2.

Table 2: Analysis of marketed formulation for ABR using proposed methods

Formulations	Labelled claim (mg)	Amount estimated (mg)		%RSD	Standard deviation	% of label claim estimated*		% Recovered**	
		I	I			I	II	I	II
Abamune	300	303.6	303.4	0.0098	0.28	101.2	100.3	100.5	100.2
Ziagen	300	301	302.6	0.0066	0.22	100.9	100.5	100.2	100.5

*Average of five determinations

**Average of recovery studies at three different levels of concentrations.

CONCLUSION

The proposed method is simple, sensitive, accurate and precise and can be successfully employed for the routine analysis of the abacavir sulphate in Pharmaceutical formulations.

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