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Journal of Chemical and Pharmaceutical Research

J. Chem. Pharm. Res., 2011, 3(3):119-122

ISSN No: 0975-7384
CODEN(USA): JCPRC5

Difference Spectrophotometric Estimation of Abacavir sulphate in Bulk and Tablet dosage form

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ABSTRACT

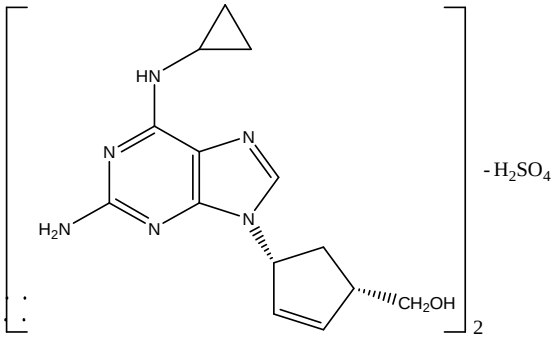
A simple, precise and sensitive UV method have been developed for the estimation of Abacavir sulphate in bulk drug and pharmaceutical dosage form by Difference Spectrophotometric method. Abacavir sulphate has exhibited maximum absorbance at about 248.38 nm and 283.79 nm in acidic and basic solution respectively. Beer's law was obeyed in the concentration range of 2-12mcg/ml in both the cases. The proposed method was successfully applied for the determination of Abacavir sulphate in commercial tablet preparation. As per ICH guidelines the results of the analysis were validated statistically and were found to be satisfactory.

Key words: Abacavir sulphate, Difference spectrophotometry.

INTRODUCTION

Abacavir sulphate is chemically {(1S, 4R)- 4-[2-Amino-6- (cyclopropylamino) -9H - purin-9-yl]-2-cyclopentene-1-methanol}. It is a nucleoside reverse transcriptase inhibitor with antiretroviral activity against HIV. It is administered alone or in combination therapy with other antiretrovirals. Survey of literature reveals that the Quantitative determination of the drug is determined by using UV spectrophotometric [3]-[6] and High Performance Liquid Chromatographic methods [1] - [2]. No difference spectrophotometric method has been reported. Hence the present study describes simple, sensitive, accurate, rapid and economical

spectrophotometric method for the estimation of Abacavir Sulphate in bulk & its tablet dosage form. [(Abamune 300 mg) tablets].



Abacavir sulphate

EXPERIMENTAL SECTION

Abacavir Sulphate [ABR] pure drug was obtained from Hetero Drugs Pvt Ltd, Hyderabad, India.

Chemicals and reagents

All chemicals used were of analytical reagent grade purchased from S.D.Fine chemicals, Mumbai, India. Abacavir sulphate [raw material], Abamune 300mg(CIPLA), 0.1N Sodium hydroxide, 0.1N Hydrochloric acid 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 was used for all spectral measurements.

Preparation of stock solution:

The standard ABR (100mg) was weighed accurately and transferred to volumetric flask (100ml). It was dissolved properly and diluted with with 0.1N NaOH and 0.1N HCl separately to obtain the final concentration of 1mg/ml and the resulting solution was used as working standard solution.

Difference spectroscopy:

The selectivity and accuracy of spectrophotometric analysis of sample containing absorbing interference may be markedly improved by the technique of difference spectrophotometry. The essential feature of difference spectrophotometric assay is that the measured value is the difference in absorbance (ΔA) between two equimolar solutions of the analyte in different chemical forms which exhibit different spectral characteristics.

For the Preparation and Analysis of sample solution, each tablet containing 300 mg 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.

Aliquots of 0.2-1.2ml (1ml=10µg) were transferred into a series of 10ml volumetric flasks. The volumes of each flask were adjusted to 10ml with with 0.1N NaOH and 0.1N HCl separately.

The absorbance was measured at 248.38nm and 283.79 nm in acidic and basic solution respectively against reagent blank. For both the solutions, calibration curve was prepared by plotting concentration versus difference in absorbance and found to be linear in the concentration range of 2.0-12.0µg/ml. (Table 1)

Preparation and Analysis of sample solution

Similarly the difference in absorbance of sample solution was measured and the amount of ABR was determined from standard calibration curve. The differences in absorbance were calculated for the different concentration of the acidic and basic solutions and the concentrations of each component were obtained by analyzing the spectral data of the solutions (Table 2). The recovery experiments were performed by adding known amounts of the drug to the pre-analysed formulation and reanalysing the mixture by proposed methods for both the solutions (Table 3).

Linearity of Abacavir sulphate by Difference spectroscopy

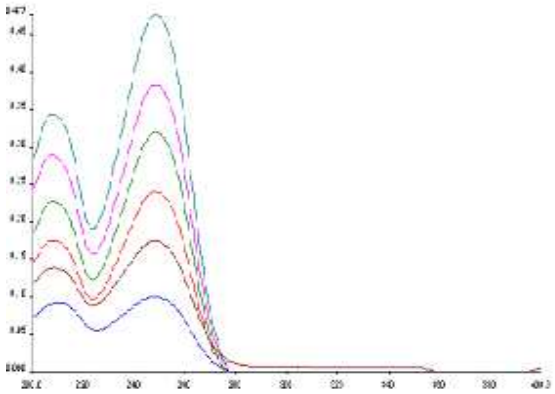


Fig (1): Linearity of ABR with 0.1N HCl at 248.38nm

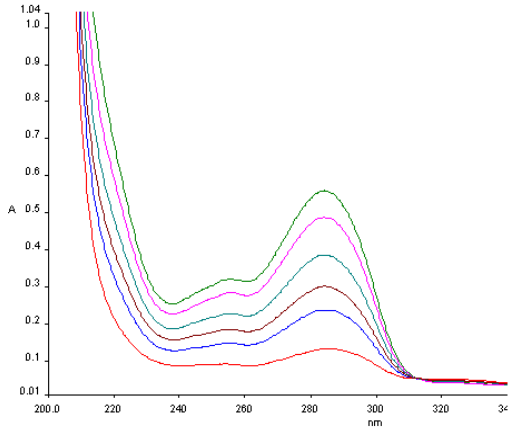


Fig (2): Linearity of ABR with 0.1N NaOH at 283.79nm

Table :1 Linearity of Abacavir sulphate by Difference Spectrophotometry

S. No	Concentration Of Abacavir Sulphate(µg/ml)	Absorbance at 283.79nm (0.1N NaOH)	Absorbance at 248.38nm (0.1N HCl)	Difference in Absorbance
1	2	0.151	0.118	0.033
2	4	0.333	0.269	0.064
3	6	0.521	0.426	0.095
4	8	0.689	0.565	0.124
5	10	0.876	0.718	0.158
6	12	1.084	0.897	0.187

RESULTS AND DISCUSSION

The optical characteristics such as Beer's law limits, percent relative standard deviation and % range of error were found to be within the limits and satisfactory. All of the analytical validation

parameters for the proposed method were determined according to ICH guidelines. The method was found to provide high degree of precision and reproducibility. The recovery studies showed that the results were within the limit indicating no interference. 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.

Table :2 Optical Characteristics Of Abacavir Sulphate By Differential Spectrophotometry

Parameters	Δ A
λ Max (nm)	283.79nm (0.1N NaOH) 248.83nm(O.1N HCL)
Beers Limit (µg/ml)	2-12
Molar absorptivity (Lit/mol/cm)	5.6×10^{-5}
Correlation coefficient (r)	0.9997
Regression Equation* (Y) Slope (m) Intercept (c)	0.015 0.003
Precision (%Relative Standard Deviation)	0.534
LOD (µg/ml)	0.215
LOQ (µg/ml)	0.652

**Y=mx+c, where x is the concentration in* (µg/ml) *and Y is absorbance unit(ΔA)*

Table :3 Analysis of marketed formulation

Method	Label claim(mg)	Amount estimated	%RSD	Standard deviation	% Recovered	Standard error
Abamune (ABR)	300	298.8	0.011	0.035	99.36	0.026

Acknowledgements

The authors are grateful to the management of SRM college of Pharmacy, Kattankulathur for their continuous support and encouragement and for providing the necessary facilities.

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