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Spectrophotometric Methods for the Determination of Abacavir Sulphate in Pharmaceutical Preparations

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Abstract: Two simple, sensitive, accurate and economic methods A and B have been developed for the quantitative estimation of abacavir sulfate and its formulations.. Method A is based on the diazotization of primary amine group of abacavir sulphate with sodium nitrate and hydrochloric acid followed by coupling with resorcinol to form a orange colored chromogen with a characteristic absorption maximum at 450 nm.. Method B is based on the reaction of the abacavir sulfate with methanolic solution of para dimethyl amino benzaldehyde (PDAB) in acidic condition producing Schiff's base having absorption maximum at 455 nm. Beer's law is obeyed in concentrations ranging from 50-250 µg/ml for both methods.

Key words: Spctrophotometry · Abacavir sulphate · 2,5-dichloro-3,6- dihydroxy-1,4-benzoquinone · Resorcinol

INTRODUCTION

Abacavir sulphate1 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 anti retrovirals. The present study describes simple, sensitive, accurate, rapid and economical spectrophotometric methods for the estimation of abacavir sulphate in bulk & its tablet dosage forms. Literature survey reveals that, several spectrophotometric methods have been reported for the estimation of Abacavir sulphate in pharmaceutical formulations [1-4]. Few analytical methods were reported in literature for the determination of abacavir sulphate and Lamivudine in combinations which includes spectrophotometric method [5], HPTLC [6] and RP-HPLC [7].

Spectrophotometry is the technique of choice even today in the laboratories of research, hospitals and pharmaceutical industries due to its low cost and inherent simplicity. This paper describes two rapid, simple, sensitive and economical spectrophotometeric methods for the determination of abacavir sulphate in commercial dosage forms. Method A is based on the diazotization of primary amine group of abacavir sulphate with sodium nitrate and hydrochloric acid followed by coupling with resorcinol to form a orange colored chromogen. Which is detected at 450 nm? Method B is based on the reaction of the drug with methanolic solution of para dimethyl amino benzaldehyde (PDAB) in acidic condition producing Schiff's base having absorption maximum at 455 nm. These two methods have been extended to the pharmaceutical formulations.

MATERIALS AND METHODS

Instruments: A Spectranoic1001 plus spectrophotometer with 1cm matched quartz cells was used to measure the absorbance of the resulting solution.

Reagents: All chemicals and reagent used were of analytical grade and obtained from s.d. Fine Chemicals. 0.1N hydrochloric acid, 0.1N sulphuric acid, 0.1N sodium nitrate, 1% urea and 1% resorcinol solution was prepared in distilled water and 0.5 % (w/v) of PDAB in methanol was prepared.

Preparation of Standard Drug Solution: 100 mg of the bulk drug was weighed accurately, dissolved in 25 ml distilled water in a 100 ml volumetric flask and the solution

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was made up to 100 ml with distilled water. This stock solution is further diluted with distilled water to obtain the working concentration of 100 µg/ml.

Assay Procedure for Pharmaceutical Tablets

Method A: Aliquots of abacavir sulfate ranging from 0.5-2.5 ml were transferred into series of 10 ml volumetric flask To each of the flask 1.0 ml of 0.1N of hydrochloric acid and 1.5 ml of 0.1N sodium nitrite were added mixed and kept aside for 3 mins, then 1.0 ml of 1% urea was added and the volumetric were kept at room temperature for 3 min for complete neutralization of excess nitrous acid formed in the reaction. Then finally 1.0 ml of sodium hydroxide and 1.0 ml of resorcinol solution was added and mixed well. The volumes were made up to 10 ml with distilled water. The absorbance of the orange colored chromogen was measured at 450 nm against reagent blank. The amount of abacavir sulphate present in the sample was computed from calibration curve.

Method B: Aliquots of abacavir sulfate ranging from 0.5-2.5ml were transferred in a series of 10ml volumetric flask. To each of the flask 2.0 ml of methanolic PDAB and 0.5 ml of 0.1N H_2SO_4 were added and warmed on a water bath for 2 min and kept aside for 15 min. at room temperature, the color development was developed. The volume was made up to mark with methanol. The absorbance of the yellow colored chromogen was measured at 455 nm against reagent blank. The amount of abacavir sulfate present in the sample was computed from calibration curve.

Pharmaceutical Preparations: A total number of twenty tablets of abacavir sulphate accurately weighed and powdered by a mortar and pestle. Tablet powder equivalent to 50 mg of abacavir sulphate was accurately weighed and transferred to 50 ml volumetric flask. Weighed tablet powder is dissolved in 25 ml distilled water and shaken for 15 minutes. Then the volume diluted to 50 ml with distilled water and mix well. The solution was filtered through Whatmann filter paper no 42. This solution was brought to 100µg/ml with distilled water and analyzed as given under the assay procedures for bulk samples. The results are represented in Table 2.

Recovery Studies: To ensure the accuracy and reproducibility of the results obtained, known amounts of pure drug was added to the previously analysed formulated samples and these samples were reanalyzed by the proposed methods and also performed recovery experiments. The percentage recoveries thus obtained were given in Table 2.

RESULTS AND DISCUSSION

The optical characteristics such as absorption maxima, Beer´s law limits, molar absorptivity and Sandell´s sensitivity are presented in Table 1. The regression analysis using method of least squares was made for the slope (b), intercept (a) and correlation (r) obtained from different concentrations and results are summarized. The percent relative standard deviation (0.001level of confidence limits) calculated from the five measurements. The optimum conditions for Method A and the optimum conditions for color development in Method B have been established by varying the parameters one at a time and keeping the other parameters fixed and observing the effects of product on the absorbance and the absorbance of the colored species and incorporated in the procedures.

Table 1: Optical characteristics of proposed method

Statistical parameters	Method A	Method B
λ_{max} nm	450	455
Beer's limits, mcg/ml	50-250	50-250
Sandell's, sensitivity, (µg cm^{-2})	0.174	0.389
Molar absorptivity, (L mol^{-1} cm^{-1})	$1.7x10^3$	$3.8x10^3$
Regression equation, Y*		
Correlation coefficient, (r)	0.9998	0.9996
Intercept (a)	0.0057	0.0025
Slope (b)	0.0032	0.0015

*Y = a+bX, where Y is the absorbance and X concentration in µg / ml

a= Intercept

b= Slope

Table 2: Assay and recovery of abacavir sulphate in tablet formulations

		*Amount found by proposed method		% Recovery by proposed method	
Tablet formulation	Labeled amount (mg/tab)	Method A	Method B	Method A	Method B
ABAVIR	300	299.980	300.012	100.10	99.90
ABAMUNE	300	300.048	299.992	100.06	100.08

*Average of five determination based on label claim

Table 3: Results of statistical analysis of the proposed methods

	*Standard deviation		% Relative standard deviation*		*t value	
Tablet formulation	Method A	Method B	Method A	Method B	Method A	Method B
ABAVIR	0.1637	0.1622	0.0540	0.0559	0.27320	0.1655
ABAMUNE	0.2247	0.0867	0.0748	0.0289	0.0.4761	0.2063

*Average of five determination based on label claim

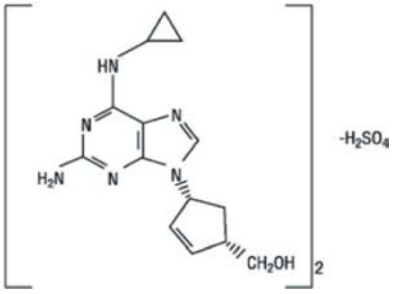

Fig. 1: Abacavir sulphate

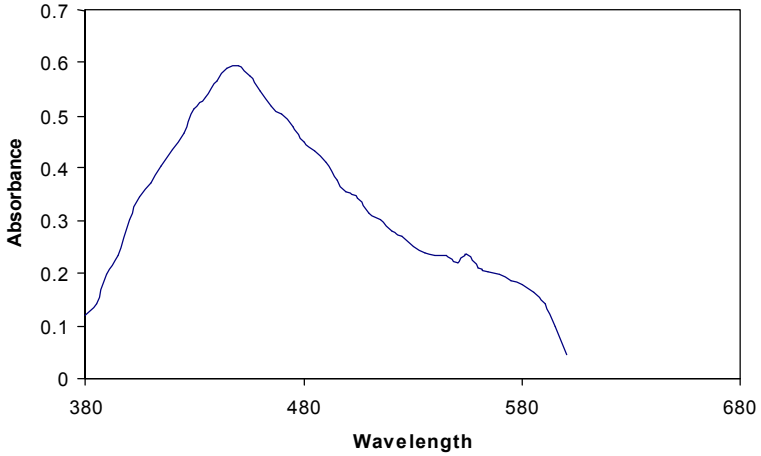

Fig. 2: Absorption spectrum of abacavir sulphate with resorcinol at 450 nm (Method A)

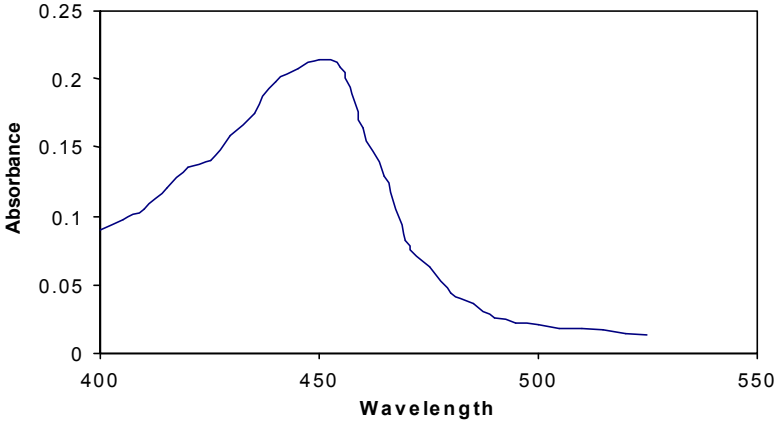

Fig. 3: Absorption spectrum of abacavir sulphate with PDAB at 455 max (Method B)

Comment:

- The discussion of the results are incomplete, you must compare the accuracy and sensitivity of the methods A & B with the previous methods or techniques and supported with the references.
- The letters/words with red color already corrected, while with red color and yellow background need correction/completion of data.

To evaluate the validity and accuracy of the method, known amount of pure drug were added to the previously analyzed pharmaceutical preparations and mixture was analyzed by the proposed method. The percent recoveries are given in Table 2. The percent relative standard deviation, standard deviation and t values were calculated from the five measurements of abacavir sulphate shown in Table 3. The % RSD is less than 2, which indicates that the method has good reproducibility. The values of standard deviation are low, indicates high accuracy and reproducibility of the method. The 't' calculated values are compares well with the theoretical value of 2.78 there by indicating that the precision of the method is good.

CONCLUSION

Proposed methods make use of simple reagents, which an ordinary analytical laboratory can afford. The proposed methods are found to be simple, rapid, sensitive, accurate, precise and economical and canbe used in the determination of abacavir sulphate in its formulations. The commonly used additives such as starch, lactose, titanium dioxide and magnesium stearate do not interfere with the assay procedures.

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