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SPECTROPHOTOMETRIC DETERMINATION OF ABACAVIR SULPHATE IN PHARMACEUTICAL FORMULATIONS

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ABSTRACT

A simple and sensitive spectrophotometric method has been developed for determination of abacavir sulphate in pharmaceutical dosage forms. The method is based on the condensation of amino group containing drugs with vanillin under acidic conditions to produce yellow coloured schiff's base. The absorbance of the coloured species is measured at 395 nm against the reagent blank, prepared in a similar manner devoid of drug solution, and the amount of the drug is made through the calibration curve. The method was simple rapid accurate, precise and can be used successfully to assay abacavir sulphate in pharmaceutical dosage forms. The authors attempted to design a precise, inexpensive colorimetric method for estimation, which could be applied to analyze abacavir sulphate in pharmaceutical dosage form and will be helpful to the pharmaceutical industry.

KEYWORDS: Spectrophotometry, abacavir sulphate, Vanillin, Pharmaceutical and Formulation.

INTRODUCTION

The chemical name of the abacavir is (1S, cis)-4-[2-amino-6-(cyclopropylamino)-9Hpurin- 9-yl]-2-cyclopentene-1-methanol sulfate and is a novel nucleoside reverse transcriptase inhibitor (NRTI) that is potent in vivo and in vitro inhibitor of HIV-1, the causative agent of the acquired immunodeficiency syndrome (AIDS). The molecular formula is (C14H18N6O) 2•H2SO4 and is soluble in water, methanol and buffers, fine crystal form with white in color. The literature suggested and reported which includes, spectrophotometric method1-12 HPLC

ethod13-14 and RP-HPLC15-21, techniques for the quantitative estimation of abacavir ulphate in formulations.

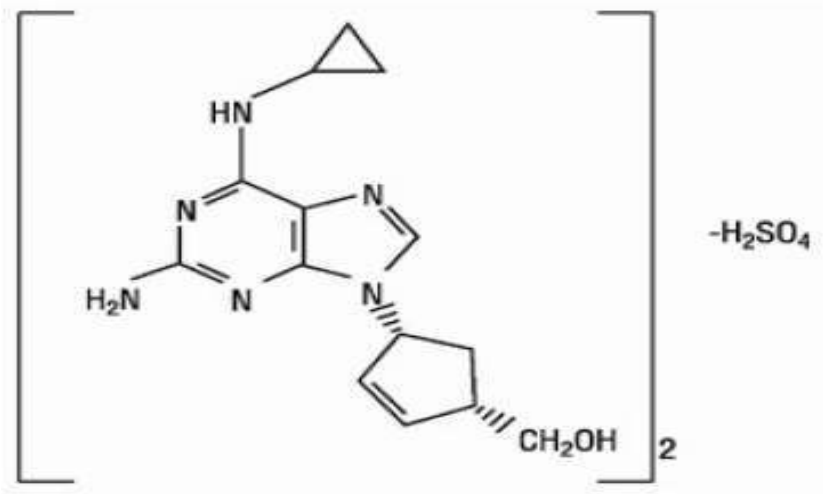

Figure 1: Chemical structure of abacavir sulphate

MATERIALS AND METHODS

Instrument

All measurement were done on Milton Roy 1001spectrophotometer by using 10 mm matched quartz cuvettes.

Materials

All chemicals used are of A.R. grade and were purchased from S.D. fine chemicals and LOBA-Chemi, Mumbai. Doubled distilled water were used for preparation of solutions.

Vanillin solution (1% w/v): Accurately weighed 1 gm of vanillin is dissolved in double distilled water and the volume made up to 100 ml with double distilled water.

Hydrochloric acid (4N): Hydrochloric acid solution (4N) is prepared by diluting the requisite volume of concentrated AR hydrochloric acid with distilled water and standardized by usual procedure.

Preparation of standard stock solution: Standard solution of abacavir sulphate was prepared by dissolving 100 mg of abacavir sulphate in 100 mL of distilled water. From this a working concentration of 100 µg/ml was prepared for the proposed method.

Determination Of Working Wavelength (λmax)

Preparation of standard stock solution of abacavir 50 mg of abacavir was weighed and transferred in to 50ml volumetric flask and dissolved in methanol and then make up to the mark with methanol and from this a working concentration of 100 µg/ml was prepared for the proposed method. The wavelength of maximum absorption (λmax) of the drug, 100 µg/ml solution of the drug in methanol were scanned using UV-Visible spectrophotometer within the wavelength region of 250–460 nm against methanol as blank. The resulting spectra are shown in the fig. 2 and the absorption curve shows characteristic absorption maxima at 395 nm for abacavir.

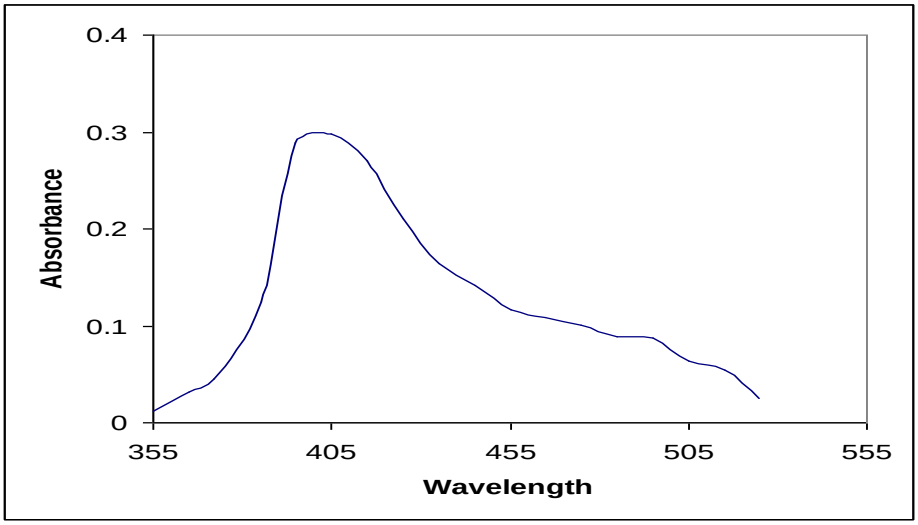

Fig 2: Overlain spectrum of abacavir sulphate treated with vanillin

Assay procedures

Various aliquots of the standard drug solution ranging from 0.5-2.5 ml are transferred into a series of 10 ml volumetric flasks. To each flask, 0.5 ml of 4 N hydrochloric acid solution and 1.0 ml of 1% vanillin solution are added. The contents are shaken well and the volume in each flask is adjusted to 10 ml with distilled water. The absorbance of the yellow colour schiff's base is measured after five minutes at 395 nm, against the reagent blank, prepared in the same manner but devoid of the drug solution. Calibration graph is obtained by plotting absorbance values and concentrations of drug solution. The amount of the drug is computed from calibration curve. The calibration curve is found to be linear over a concentration of 50 to 250 µg/ml of abacavir sulphate. The results are presented in fig.3.

Assay of pharmaceutical Formulations

For analysis of tablet formulations from the powdered tablets, 50 mg of the drug is weighted accurately and transferred into a 50 ml beaker and mixed well with 30 ml of methanol. The solution is filtered and transferred into a 50 ml volumetric flask and the volume is made up to the mark with methanol. The concentration of the drug solution is now 1mg/mL. This stock solution is further diluted to obtain the working concentration and treated as per the procedure of the calibration curve. Amount of the drug present in sample is computed from respective calibration curve. The concentration of the resulting solution was found to be 1 mg/ml. The sample solution was analyzed in the same way as mentioned in the calibration curve.

Validation

Accuracy of the proposed methods was carried as on the basis of recovery studies. It is performed by the standard addition method. Recovery studies were performed by adding standard drug at different levels to the pre-analyzed tablets powder and the proposed method was followed. From the amount of the drug estimated, the percentage recovery was calculated. The results of the analysis are shown in table1.

RESULTS AND DISCUSSION

The method was based on the condensation of abacavir sulphate with vanillin in acidic medium to produce yellow coloured schiff's base. The absorbance of the yellow color is measured at 395 nm against reagent blank. The colour of the product is stable for more than 6 hours. The calibration curve (concentration vs absorbance) is linear over the range of 50-250 µg/ml of abacavir sulphate. The % RSD is less than 2, which indicates that the method has good reproducibility. The values of standard deviation values are low, indicates high accuracy and reproducibility of the method. The't' calculated value compares well with the theoretical value of 2.78 there by indicating that the precision of the method is good. There no effect of additives and excipients such starch, calcium lactose and glucose in the concentrations those present in general pharmaceutical preparations.

The optimum conditions for color development have been established by varying the parameters one at a time and keeping the other parameters fixed and observing the effect of product on the absorbance of the colored species. These studies revealed that the common excipients and other additives such as starch, talc, lactose and magnesium stearate, that are

usually present in tablet dosage forms, did not interfere at their regularly added levels orated in the procedure.

Table 2: Assay And Recovery Of Abacavir Sulphate In Tablet Formulations

Formulations	Labeled amount	*Amount found (mg±S.D)	% Recovery	% RSD	*t value
Tablet 1	300	300.02±0.37	99.9	0.1255	0.3563
Tablet 2	300	299.94±0.29	100.14	0.0988	1.3065

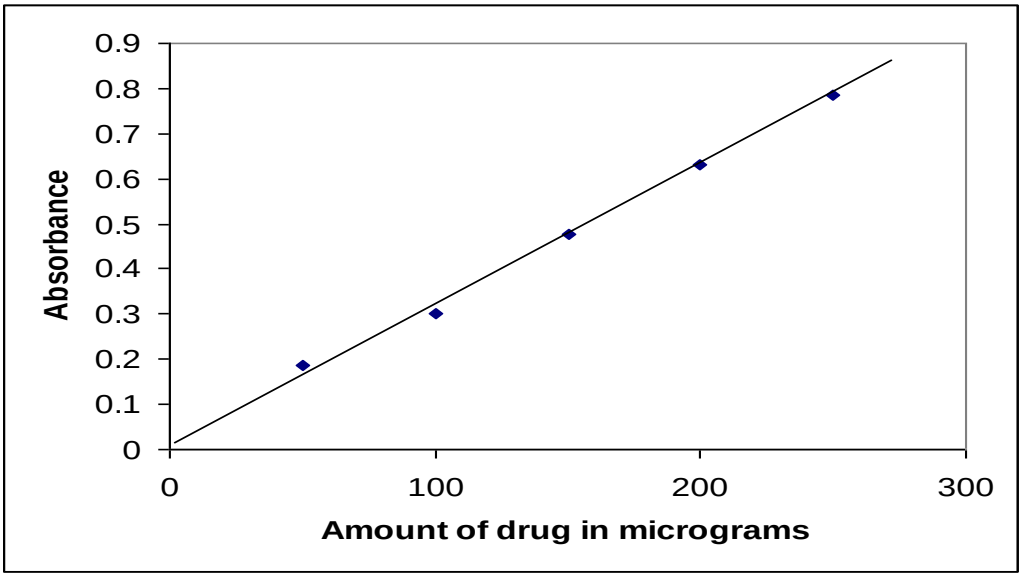

Fig.3: Calibration curve of abacavir sulphate

CONCLUSION

It could be concluded that the developed method for estimation of abacavir sulphate in pharmaceutical dosage forms and in bulk is simple, sensitive, relatively precise and economical. The proposed methods are used for the routine analysis of the drugs in the quality control.

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