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Simultaneous Spectrophotometric Estimation of Abacavir sulphate in Tablet Dosage Form

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Abstract

Three simple, precise and economical UV methods have been developed for the estimation of Abacavir sulphate in tablet dosage form. Abacavir sulphate has the absorbance maxima at 285 nm (Method A), and in the first order derivative spectra, showed sharp peak at 275 nm (Method B). Method C applied was area under curve (AUC) in the wavelength range of 280-290 nm. Linearity for detector response was observed in the concentration range of 5-35 µg/mL for Method A and 5- 40 µg/mL for Method B and Method C. The proposed methods were successfully applied for the simultaneous determination of Abacavir sulphate in commercial tablet preparation. The results of the analysis were validated statistically and were found to be satisfactory.

Key words: Abacavir sulphate, UV spectrophotometry, derivative spectroscopy, area under curve.

INTRODUCTION

Abacavir sulphate **[1]** 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 drug is determined by using High Performance Liquid Chromatography only **[2-5]**. No spectrophotometric methods are reported. The present study describes simple, sensitive, accurate, rapid and economical spectrophotometric methods for the estimation of abacavir sulphate in tablet dosage forms.

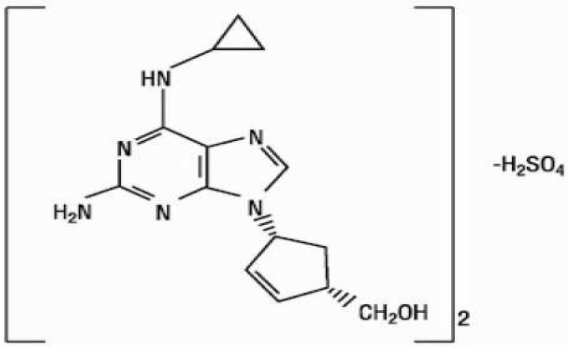

Figure 1 Structure of abacavir sulphate

MATERIALS AND METHODS

Chemicals

Double distilled water used in this study was purchased from Merck Chemicals, India, of analytical grade. Reference standard of abacavir sulphate was purchased from Sigma Aldrich, USA.

Apparatus

The absorbance was measured using UV-VIS double beam spectrophotometer (Lab India, Mumbai).

Preparation of standard solution

A stock solution of abacavir sulphate was prepared by dissolving 50 mg of abacavir sulphate in 50 mL of double distilled water.

Calibration curve

Method A: Absorption Maxima Method:

For the selection of analytical wavelength, 20 µg/mL solution of abacavir sulphate was prepared by appropriate dilution of standard stock solution and scanned in the spectrum mode from 400 nm to 200 nm. From the spectra of drugs (Fig. 2), λ max of abacavir sulphate, 285 nm was selected for the analysis. The calibration curve was prepared in the concentration range of 5-35 µg/mL at 285 nm. By using the calibration curve, the concentration of the sample solution can be determined.

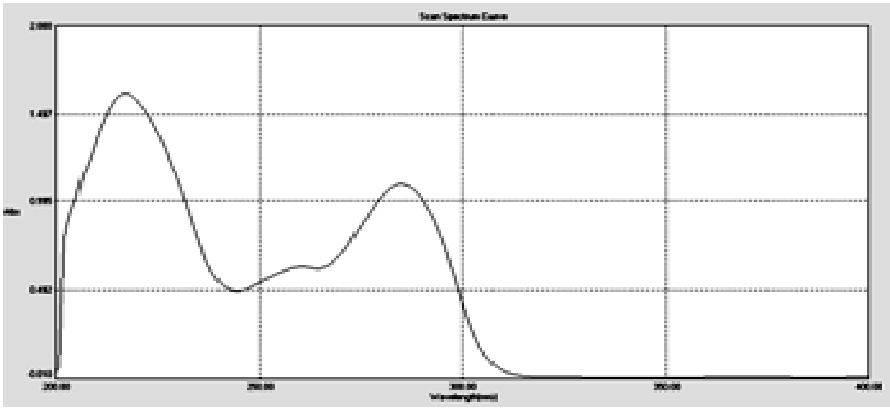

Figure 2 Maximum wavelength of abacavir sulphate (Method A)

Method B: First Order Derivative Spectroscopic method:

In this method, 20 µg/mL solution of abacavir sulphate was prepared by appropriate dilution of standard stock solution and scanned in the spectrum mode from 400 nm to 200 nm. The absorption spectra thus obtained were derivatized from first to fourth order. First order derivative spectra were selected for analysis of both drugs. First order derivative spectra of drug (Fig. 3), showed a sharp peak at 275 nm, which was selected for its quantitation. The calibration curves for abacavir sulphate was plotted in the concentration range of 5-40 µg/mL at wavelength 285 nm The concentration of the drug present in the mixture was determined against the calibration curve in quantitation mode.

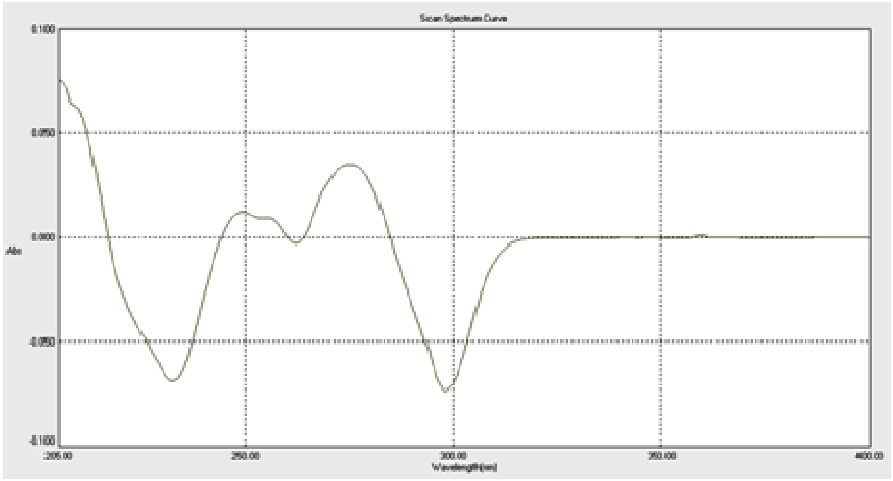

Figure 3 Maximum wavelength of abacavir sulphate (Method B)

Method C: Area under Curve Method:

For the selection of analytical wavelength, 20 µg/mL solution of abacavir sulphate was prepared by appropriate dilution of standard stock solution and scanned in the spectrum mode from 400 nm to 200 nm. From the spectra of drugs, area under the curve in the range of 280 -290 nm was selected for the analysis. The calibration curve was prepared in the concentration range of 5-40 µg/mL at their respective AUC range. By using the calibration curve, the concentration of the sample solution can be determined.

Application of the proposed method for the determination of abacavir sulphate in tablets:

For the estimation of drugs in the commercial formulations, twenty tablets were weighed and average weight was calculated. The tablets were crushed to obtain fine powder. tablet powder equivalent to 50 mg abacavir sulphate was transferred to 100 mL volumetric flask and volume made up to the mark with double distilled water and ultra sonicated for 20 min. The solution was then filtered through a Whatmann filter paper (No. 41). From the filtrate 5 mL was transferred to a 50 mL volumetric flask and diluted to the mark with the same solvent. The solution was further diluted with double distilled water to obtain 15 µg/mL of abacavir sulphate. In Method-A, the concentration of abacavir sulphate was determined by measuring the absorbance of the sample at 285 nm in zero order spectrum modes. By using the calibration curve, the concentration of the sample solution can be determined. Method-B, the concentration of abacavir sulphate was determined by measuring the absorbance of the sample at 275 nm, in first order derivative mode. The results of the tablet analysis were calculated against the calibration curve in quantitation mode. For Method-C, the concentration of abacavir sulphate was determined by measuring area under curve in the range of 280-290 nm. By using the calibration curve, the concentration of the sample solution can be determined. Results of tablet analysis are shown in Table no 1.

Table no 1 Results of Analysis of Tablet Formulation

Method	Drug	Label claim	Amount of drug estimated (mg/tab)	%Label claim ±SD	% Recovery
A	AS	300	298.13	99.38 ± 0.2965	99.34
B	AS	300	299.43	99.81 ± 0.7966	99.52
C	AS	300	299.43	99.81 ± 0.2577	99.29

Validation

The methods were validated with respect to linearity, accuracy, precision and selectivity.

Linearity

The linearity of measurement was evaluated by analyzing different concentration of the standard solution of abacavir sulphate. Beer-Lambert's concentration range were found to be 5-35 µg/ml for Method A and 5-40 µg/ml for Method B and Method C **[6-10]**. The results are in Table no 2.

Precision

The reproducibility of the proposed method was determined by performing tablet assay at different time intervals (morning, afternoon and evening) on same day (Intra-day assay precision) and on three different days (Inter-day precision). Results of intra-day and inter-day precision are expressed in % RSD **[6-10]**. The results are in Table no 2.

Accuracy

To ascertain the accuracy of the proposed methods, recovery studies were carried out by standard addition method at three different levels (80%, 100% &120%). Percent recovery for abacavir sulphate was determined by all the methods and they where found to be under acceptance criteria which is 98% to 102 % according to ICH guidelines **[6-10]**. The results are in Table no 2.

Table no 2 Summary of validation parameters of abacavir sulphate

Parameters	**Results**		
	Method A	**Method B**	**Method C**
Linearity			
Range	5-35 µg/mL	5-40 µg/mL	5-40 µg/mL
Linear equation	Y = mx + C	Y = mx + C	Y = mx + C
Slope (m)	0.053	0.0151	2.166
Intercept (C)	0.015	0.0004	0.7
Correlation coefficient (r^2)	0.999	0.9994	0.999
Standard deviation (SD)	0.041	0.012	0.132
Precision (% RSD)			
Intraday precision (n=3)	0.274	0.234	0.117
Interday precision (n=3)	0.406	0.592	0.156
Accuracy	98.26%	98.75%	100.48%
Limit of Detection (LOD)	0.112 µg/mL	1.25 µg/mL	0.458 µg/mL
Limit of Quantification (LOQ)	0.336 µg/mL	3.75 µg/mL	1.374 µg/mL

Sensitivity

Limit of Detection (LOD) and Limit of Quantification (LOQ) were determined by kSD/s where k is a constant (3 for LOD and 10 for LOQ), SD is the standard deviation of the analytical signal, and s is the slope of the concentration /response graph **[6-10]**. The results are in Table no 2.

RESULTS AND DISCUSSION

The methods discussed in the present work provide a convenient and accurate way for simultaneous analysis of abacavir sulphate in its pharmaceutical dosage form. Absorbance maxima of abacavir sulphate were found to be 285 nm (Method A) and in the first order derivative spectroscopic method, sharp peak at 275 nm (Method B) were selected for the analysis. The wavelength range for quantitation for area under curve (Method C) was 280-290 nm. Linearity for detector response was observed in the concentration range of 5-35 µg/ml for Method A and 5-40 µg/ml for Method B and Method C. Standard deviation and coefficient of variance for six determinations of tablet sample using all the methods was found to be less than ± 2.0 indicating the good precision of both the methods. Accuracy of the proposed methods was ascertained by recovery studies and the results are expressed as % recovery. Percent label claim for abacavir sulphate in tablet analysis was determined by all the three methods including 99.34% for Method A, 99.52% for Method B and 99.29% for Method C. Based on the results obtained, it is found that the proposed methods are accurate, precise, reproducible & economical and can be employed for routine quality control of abacavir sulphate tablet dosage forms.

CONCLUSION

The most striking feature of all the three methods are its simplicity and rapidity, non- requiring-consuming sample preparations such as extraction of solvents, heating, degassing which are needed for HPLC procedure. It can be concluded that the proposed methods are fully validated and found to be simple, sensitive, accurate, precise, reproducible, rugged and robust and relatively inexpensive. So, the developed methods can be easily applied for the routine Quality Control analysis of abacavir sulphate in pharmaceutical preparations.

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