International Journal of PharmTech Research
CODEN (USA): IJPRIF ISSN : 0974-4304
Vol.3, No.1, pp 356-359, Jan-Mar 2011

Visible Spectrophotometric determination of Abacavir Sulphate in Bulk Drug and Tablet Dosage Form

VENKATAMAHESH R*, DHACHINAMOORTHI D

Department of Pharmaceutical Analysis, QIS College of Pharmacy,

vegamukkapalem,prakasam (District), Andhra pradesh, India

Corres.author: venkatamahesh.pharma@gmail.com ,Phone no: 08880148814

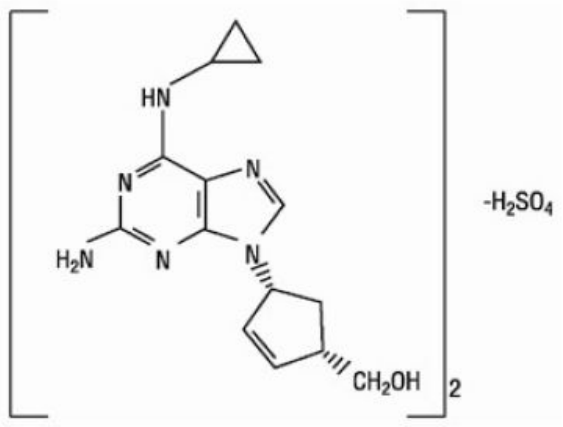
Abstract: A simple visible[1,2] spectrophotometric method has been developed for the estimation of abacavir sulphate in bulk and tablet dosage form. This method is based on the diazotization of abacavir sulphate with nitrous acid to form diazotized abacavir sulphate, followed by its coupling with β-naphthol to form a red coloured chromogen which shows maximum absorption at 574.0nm and obeys Beer's law in the concentration range of 5-20mcg/ml. This method was validated for precision, accuracy, ruggedness and robustness. Statistical analysis proves that the method is reproducible and selective for the estimation of said drug.
Key words: Visible spectrophotometry; Abacavir sulphate; β-naphthol; Validation.

1.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[2-4] and some other spectrophotometric methods. The present study describes simple, sensitive, accurate, rapid and economical visible spectrophotometric method for the estimation of abacavir sulphate in bulk & its tablet dosage forms.

2.MATERIALS AND METHODS

An analytical UV/Vis double beam spectrophotometer (model T 60) with 1 cm matched quartz cells was used for all spectral measurements. All the chemicals used in the investigation were of analytical grade. Authentic drug sample of abacavir sulphate was given as a gift sample by Hetero drugs Ltd., Hyderabad. Tablets of abacavir are procured from local market.



Chemical Structure of abacavir sulphate

2.1 Working Standard Solution of abacavir sulphate

Pure abacavir sulphate powder equivalent to 100 mg was accurately weighed and dissolved in 50 ml of methanol in a 100 ml volumetric flask and the volume was made up to 100 ml with distilled water (1 mg/ml). From this, a working standard solution containing 100 mcg/ml was prepared with distilled water.

2.2 Sample Preparation of abacavir sulphate

Twenty tablets of abacavir sulphate each containing 300 mg were accurately weighed, average weight was determined and crushed into fine powder. An accurately weighed quantity of powder equivalent to 50 mg of abacavir sulphate was transferred into 50 ml volumetric flask and dissolved in 25 ml of methanol and sonicated for 5 mins. The solution was filtered through Whatmann filter paper no.41. The residue was washed with 5 ml portions of distilled water two times and the total volume of the filtrate was made up to 50 ml with distilled water (1 mg/ml). The final concentration was brought 100 mcg/ml with distilled water.

2.3 Method development

Aliquots of standard solution of abacavir sulphate ranging from 0.5 to 2.0 ml (1 ml = 100 mcg) were transferred into a series of 10 ml volumetric flasks. To each flask, 1.0 ml of hydrochloric acid (2 N) and 1.0 ml of sodium nitrite (0.1% w/v) was added and a reaction time of 10 min at 0-5°C was given for the completion of reaction. Then 1.0 ml of alkaline β-naphthol solution (0.1% w/v in 2% aqueous NaOH) was added to each flask with gently shaking and after 10 min, the volume in each flask was made up to 10 ml with distilled water. The absorbances of red colored chromogen were measured at 574 nm against the reagent blank. The colored chromogen was stable for 3 h. The amount of abacavir sulphate present in the sample solution was computed from the respective calibration curve.

Table 1: Optimum conditions, optical characteristics and statistical data of the regression equation in the proposed method

Parameter	Values
λ_{max} (nm)	574
Beer's law limits (mcg/ml)	5-20
Molar extinction coefficient (mol^{-1} cm^{-1})	0.0465 $X10^4$
Sandell's sensitivity (mcg/cm^2-0.001 absorbance units)	0.021
Regression equation (Y*)	Y=0.0092C + 0.0006
Slope (b)	0.0092
Intercept (a)	0.0006
Correlation coefficient(r^2)	0.9995
% RSD**	0.648
Limit of detection (mcg/ml)	0.130
Limit of quantitation (mcg/ml)	0.422

*Y= bC + a where C is the concentration of abacavir sulphate in mcg/ml and Y is the absorbance at the respective $\lambda_{max.}$

**Average of five determinations.

Table 2: summary of validation parameters:

Parameters	Tablet A	Tablet B
Label claim, mg	300	300
% label claim*	99.77	99.56
Amount found ±% RSD*	299.31±0.86	298.68±1.18
Precision (% RSD)*	1.237	1.121
% Recovery ± % RSD*	99.80±1.130	99.88±1.158
Ruggedness % RSD*	99.38±1.235	99.21±1.193

*Mean of five determinations, A and B represents brands of abacavir sulphate tablet, RSD indicates relative standard deviation

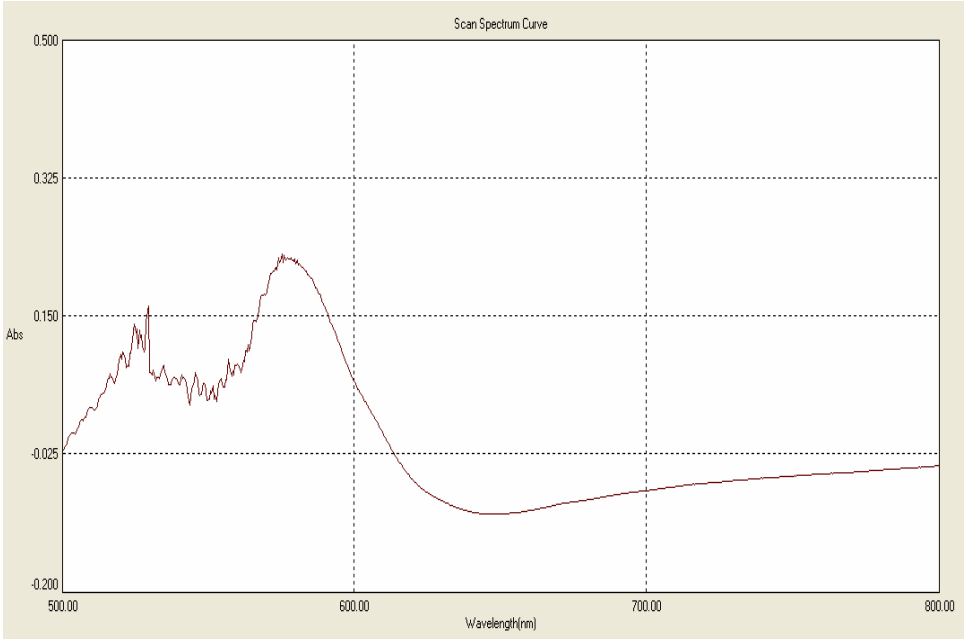


Fig. 01- Absorption spectrum of abacavir sulphate with β-naphthol λ_{max} (nm)at 574

.

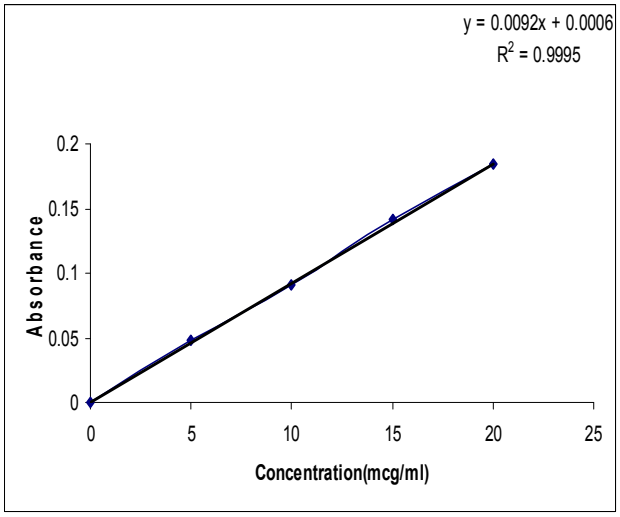


Fig. 02- Calibration curve of abacavir sulphate with β-naphthol.

3.RESULTS AND DISCUSSION

The method was validated according to the ICH guidelines with respect to linearity, accuracy, precision and ruggedness. [8,9, 10,]

Appropriate dilutions were prepared for drug from the standard stock solution and the solutions were scanned in the wavelength range of 200-400 nm. The Abacavir sulphate shows absorption maxima at 574 nm. The linearity was found in the concentration range of 5-20 mcg / ml was shown in **Fig:02.** The Correlation coefficient was 0.9995. The regression equation was found to be Y = 0.0092C + 0.0006 were shown in **Table: 1.** The method was validated for accuracy and precision. All the Characteristic parameters were shown in **Table: 2.**

4.CONCLUSION

The proposed method is validated and found to be simple, sensitive, accurate, precise, reproducible, rugged and relatively inexpensive. The developed method can be easily applied for the routine Quality Control analysis of Flupentixol dihydrochloride in bulk and pharmaceutical preparations.

5. ACKNOWLEDGEMENT

We would like thank to Hetero drugs Ltd., Hyderabad for providing reference sample of Abacavir sulphate to facilitate this work and also to the Principle, Qis College of Pharmacy, ongole for providing facilities

6.REFERENCES

1. http://en.wikipedia.org/wiki/Abacavir
2. http://www.rxlist.com/ziagen-drug.htm
3. Joshua R Ravitch and Caroline G Moseley. High-performance liquid chromatographic assay for abacavir and its two major metabolites in human urine and cerebrospinal fluid. J Chromatogr Biomed Appl 2001;762(2):165-173.
4. CPWGM Verweij-van Wissen, R E Aarnoutse and D M Burger. Simultaneous determination of the HIV nucleoside analogue reverse transcriptase inhibitors lamivudine, didanosine, stavudine, zidovudine and abacavir in human plasma by reversed phase high performance liquid chromatography. J chrom b 2005;816(1-2):121-129.
5. D Anantha Kumar, G Srinivasa Rao, J V L N Seshagiri Rao. Simultaneous Determination of Lamivudine, Zidovudine and Abacavir in Tablet Dosage Forms by RP HPLC Method. E.j.chem 2010;7(1):180-184.
6. Mirza Shahed, Palaskar Pallavi S, MHG Dehghan and SN Mokale . Simultaneous Spectrophotometric Estimation of Abacavir sulfate and Lamivudine in Tablet Dosage Form. asian j chem 2009;2(04):461-463
7. Edmund V Capparelli, Scott L Letendre, Ronald J. Ellis, Parul Patel, Diane Holland, J Allen McCutchan. Population Pharmacokinetics of Abacavir in Plasma and Cerebrospinal Fluid. Antimicrob Agents Chemother 2005;49(6): 2504–2506.
8. International Conference on Harmonization (ICH), Validation of Analytical Procedures: Text on Validation of Analytical Procedures Q2A, 1994.
9. International Conference on Harmonization (ICH), Validation of Analytical Procedures: Methodology Q2B, 1996.
10. International Conference on Harmonization (ICH), Validation of Analytical Procedures: Text and Methodology Q2 (R1), 2005

*****