Int. J. Chem. Sci.: 6(2), 2008, 688-692

NEW SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF LAMIVUDINE IN BULK AND PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

A simple sensitive, rapid, accurate and precise spectrophotometric method has been developed for estimation of lamivudine in bulk and pharmaceutical dosage forms. Lamivudine shows maximum absorbance (λ_{max}) at 274 nm with molar abosrptivity of 1.117×10^3 lit. $mol^{-1}cm.^{-1}$ Beer's law was obeyed in the concentration range of 2.5 to 25 µg/mL. The results obtained with the proposed method are in good agreement with labeled amount, when marketed pharmaceutical preparations were analyzed. Results obtained were validated statistically and by recovery studies and found to be reproducible.

Key words: Lamivudine, Spectrophotometric method.

INTRODUCTION

Lamivudine, a potent reverse transcriptase inhibitor of the class, nucleoside, analog reverse transcriptase inhibitor (NARTI), is chemically, L-2, 3'-dideoxy-3'- thiacytidine (3TC) [1]. This compound is having solubility of approximately 70 mg/mL in water at 200°C. Few analytical methods like spectrophotometric[2,3] and HPLC[4,5] are reported. Although a spectrophotometric method is reported but to develop simple and sensitive method with minimum wastage of organic solvents for the estimation of lamivudine is still need of today.

Based on the above objective, the authors attempted to design precise and inexpensive spectrophotometric method of estimation, which could be applied to analyze lamivudine in bulk and pharmaceutical dosage forms and will be useful to the

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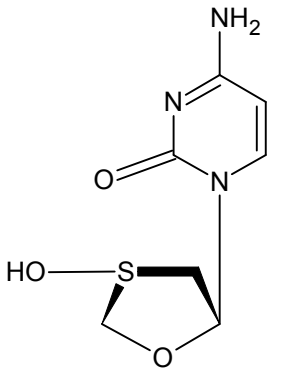
pharmaceutical industry.

Structure



EXPERIMENTAL

A Shimadzu model No. 1700, double beam UV-Spectrophotometer, with 1 cm matched cuvettes was used to measure the absorbance of the resulting solution.

Pure drug sample of lamivudine

A gift sample of pure lamivudine was obtained from Nicholas Piramal Ind. Ltd., Mahad.

Preparation of standard solution

Standard solution of lamivudine was prepared by taking 10 mg of pure drug in 100 mL volumetric flask. Then to this, about 10 mL of double distilled water was added and the resulting mixture solution was shaken for complete dissolution of the pure drug in water and finally volume was adjusted to 100 mL with double distilled water.

Selection of wavelength of maximum absorption (λ_{max})

2 mL of standard solution was transferred to 10 mL volumetric flask and then the volume was adjusted to 10 mL by using doubled distilled water. After thorough shaking, the flask was kept aside for 2 min for reaction to complete. The absorbance was measured in the range of 200-400 nm against blank.

The stability study was carried out and results were plotted by using absorbance versus time in minutes.

Calibration curve

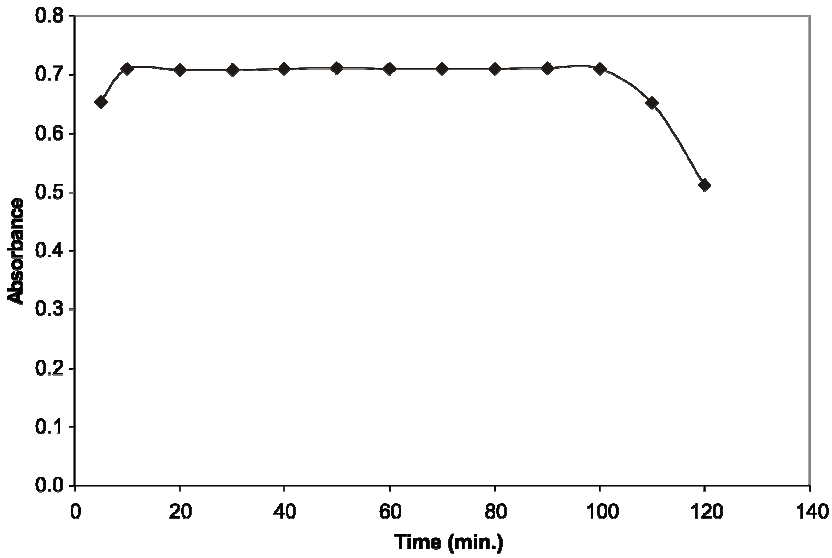


Fig. 1 : Stability study of lamivudine

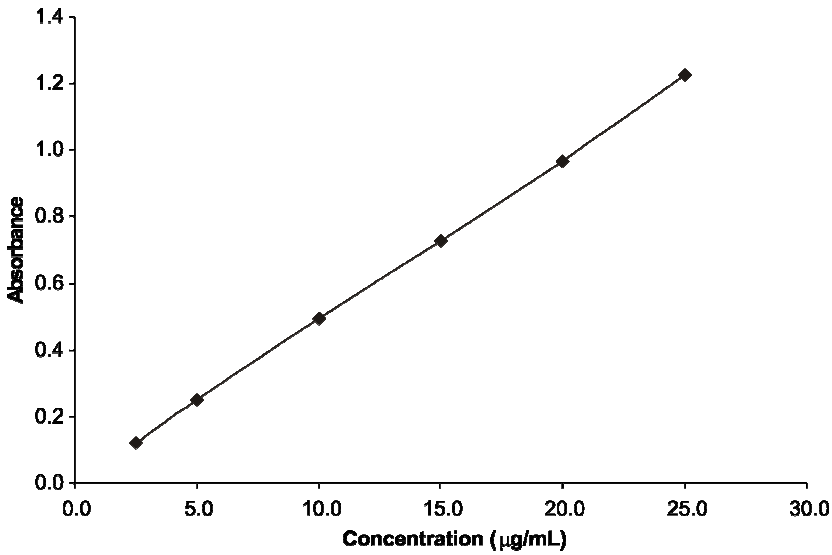


Fig. 2 : Calibration curve of lamivudine

Aliquots of standard solution ranging from 0.25 mL to 2.5 mL were transferred to a series of 10 mL volumetric flasks. To each flask, volume was adjusted up to 10 mL with

distilled water. After thorough shaking, the flasks were kept aside for 2 min. Absorbance of solution was measured at 274 nm against blank.

Analysis of formulation

Pharmaceutical formulations lamivir HBV and lamuvid respectively were taken for analysis. Tablet powder equivalent to 10 mg of lamivudine was dissolved in distilled water. This solution was filtered through Whatman filter paper No. 42 and volume was made up to 100 mL with the distilled water. The sample was analyzed in the same way as that of calibration curve. The content of lamivudine from tablets was computed from calibration curve.

RESULTS AND DISCUSSION

The proposed method of determination of Lamivudine showed molar absorptivity of 1.117×10^3 lit. mol^{-1} cm^{-1} and Sandell's sensitivity 0.0205 $g/cm^2/0.001$ absorbance units. Linear regression of absorbance on concentration gave equation $y = 0.0487x + 0.0019$ with a correlation coefficient of 0.9998. Standard deviations for lamivir HBV and lamuvid were found to be 0.9521 and 1.0043, respectively indicating precision and reproducibility of results.

Table 1. Optical characteristics and precision Data

Parameter	Value obtained
Absorption maxima	274
Beer's law limit μg/mL	2.5 – 25
Correlation coefficient	0.9998
Molar absorptivity (lit/mole/cm)	1.117×10^3
Sandell's sensitivity (mcg/sq.cm/0.001)	0.0205
Regression equation	
Slope (m)	0.0487
Intercept	0.0019
% COV	0.0590
Confidence limit with 0.05 level	0.0014

Lamivudine exhibits its maximum absorption (λ_{max}) at 274 nm and obeyed Beer's

law in the range of 2.5 to 25 μg/mL. The results of analysis and recovery studies are presented in Tables 1 and 2.

Table 2.

Formulation	Label claim (mg)	% Estimated	% Recovery	S.D.
Lamivir HBV	100	100.9562	98.0962	0.9521
Lamuvid	100	101.1044	98.0961	1.0043

CONCLUSION

The developed method was found to be sensitive, accurate, precise and reproducible. This method proved to be economical due to use of water as a solvent. It is also found useful for the routine quality control analysis of lamivudine in bulk drugs and formulations.

ACKNOWLEDGMENTS

The authors are thankful to Nicholas Piramal Pvt. Ltd. Mahad for providing the gift sample of pure drug of lamivudine for research work. The authors are grateful to the Principal, Govt. College Pharmacy, Karad for providing laboratory facilities and constant encouragement.

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Accepted : 17.03.2008