International Journal of ChemTech Research
CODEN(USA): IJCRGG ISSN : 0974-4290
Vol.3, No.1, pp 90-93, Jan-Mar 2011

Simple Spectrophotometric Estimation of Lamivudine in Bulk Drug and Tablet Formulation

Prasada Rao CH[1]*, Seshagiri Rao JVLN[2], Dhachinamoorthi D[1], Lakshmi Aswini G[3], Ashok K[1]

[1]Dept. of Pharmaceutical Analysis, QIS College of Pharmacy, Ongole -523272, India.

[2]Dept. of Pharmaceutical Analysis, University College of Pharmaceutical sciences, Andhra University, Vishakapatnam -530003, India.

[3]Dept. of Pharmaceutical Analysis, Vagdevi College of Pharmacy, Gurazala -522415, India.

Corres.author: prasadpharmach@gmail.com

Abstract: A simple, accurate and economic UV spectrophotometric method has been developed for the estimation of Lamivudine in bulk and tablet formulation. Lamivudine has maximum absorbance at 270 nm in distilled water. Beer's law is obeyed in the concentration range of 5-25 µg/ml with correlation coefficient 0.9999. The developed method was applied for the estimation of Lamivudine in bulk and tablet formulation and gave satisfactory results. The proposed method was validated statistically as per ICH guidelines and the low values of %RSD indicate high precision of the method.

Keywords: Lamivudine, distilled water, spectrophotometric method.

INTRODUCTION

Lamivudine is chemically, (1R, cis)-4-amino-1-(1-hydroxy methyl-1,3-oxathiolan-5-yl)- (1H)-pyrimidine-1-one. It is a nucleoside reverse transcriptase inhibitor and antiretroviral used in the treatment of AIDS [1]. Lamivudine is soluble in distilled water. The chemical structure of Lamivudine is shown in Fig. 1. Literature survey reveals that there are HPLC [2-8] and HPTLC [9] methods for the quantitation of Lamivudine in its formulation. The main objective of the work was to develop simple, fast, inexpensive, sensitive and accurate method which could be applied to analyse Lamivudine in pure form and in pharmaceutical dosage form.

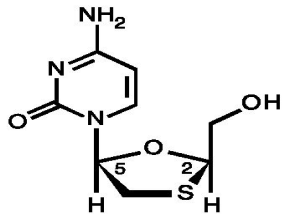

Fig. 1: Structure of Lamivudine

MATERIALS & METHODS

A Systronics 2201 UV/VIS spectrophotometer with 1cm matched quartz cells was used for absorbance measurements. Lamivudine was obtained as a gift sample from Hetero Drugs Limited, Hyderabad. All reagents used were of analytical grade.

Preparation of standard solution

Standard stock solution was prepared by dissolving accurately weighed, 100 mg of Lamivudine in distilled water and the volume was made up to 100 ml with distilled water (stock solution-I,1000 µg/ml). 10 ml of stock solution-I was diluted to 100 ml with distilled water. (stock solution-II, 100 µg/ml). This stock solution-II was used to prepare further standard solutions of drug. Aliquots (0.5-2.5ml) of stock solution of Lamivudine were transferred into a series of 10 ml volumetric flasks and the volume was made upto the mark with distilled water to give the concentration range from 5-25 µg/ml. The absorbance was measured at 270 nm against the reagent blank. The absorption spectrum of Lamivudine is shown in Fig. 2. The optical characteristics such as Beer's law limit, Molar extinction coefficient and Sandell's sensitivity are expressed in Table 1.

Preparation of sample solution

The Lamivudine content in marketed brand of Lamivudine tablet was determined.The tablet powder equivalent to 100 mg of Lamivudine was accurately weighed and transffered to 100 ml volumetric flask. About 40ml distilled water was added to the flask and sonicated for 15 min.The solution was filtered through whatmann filter paper No.41.The filter paper was washed with distilled water. The washings were added to the filtrate and the final volume was made upto 100ml with distilled water. After suitable dilution, the absorbance of the sample solution was recorded at 270 nm. The drug content in the sample was calculated from the calibration curve. The results are expressed in Table 2.

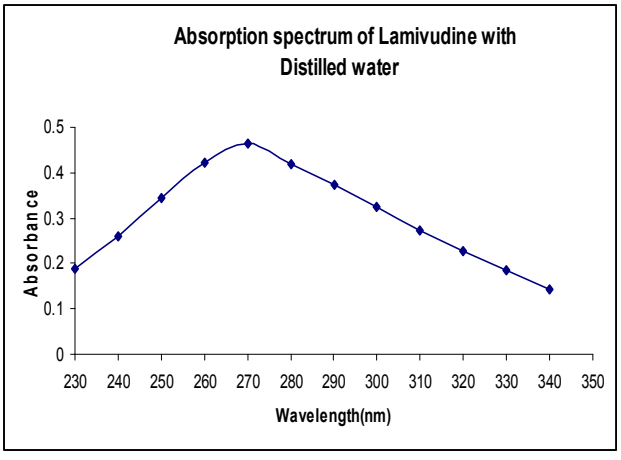

Fig. 2: Absorption spectrum of Lamivudine with Distilled water

A linear curve was constructed between the absorbance and concentration and the equation of line was obtained which is Y=0.046C + 0.0014 with correlation coefficient of 0.9999.The calibration curve of Lamivudine is shown in Fig.3. This indicates a good linearity between absorbance and concentration.

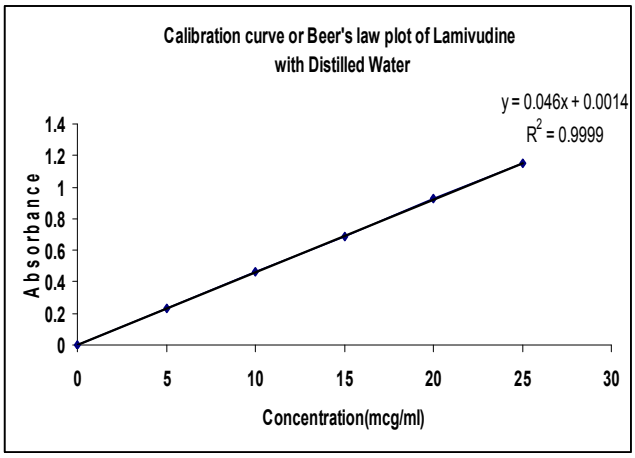

Fig. 3: Calibration curve of Lamivudine with Distilled water

VALIDATION OF PROPOSED METHOD

Linearity study

Under optimized working conditions, standard calibration curve was plotted over the concentration range of 5-25 µg/ml for Lamivudine, with the linear regression equation Y=0.046C + 0.0014 (Correlation coefficient r^2 = 0.9999).Results shows good correlation between the absorbance and concentration of Lamivudine.

Recovery studies

To study validity and reproducibility of the method, recovery studies were carried out by adding a known amount of drug to pre analysed sample at two different levels and the % recoveries were calculated. The results are expressed in Table 3.

Repeatability

Repeatability is given by intra and inter-day precision. Intra-day precision was determined by analyzing the same concentration of drug for five times in the same day. Inter-day precision was determined by analyzing the same concentration of the drug for three days in a week. The results are summarized in Tables 4 & 5. The precision of the assay was determined and found to be lower than 1.261%.

Ruggedness

Ruggedness of the proposed method is determined by analysis of aliquots from homogenous slot in different laboratories by different analysts, using same operational and environmental conditions and the data is summarized in Table 6.

RESULTS OF ANALYSIS

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

Parameter	UV Method
λ_{max} (nm)	270
Beer's law limits (µg/ml)	5-25
Molar extinction coefficient (mol^{-1} cm^{-1})	0.0465 $X10^4$
Sandell's sensitivity (µg /cm^2-0.001 absorbance units)	0.021
Regression equation (Y*)	Y=0.046C + 0.0014
Slope (b)	0.046
Intercept (a)	0.0014
Correlation coefficient(r^2)	0.9999
% RSD**	0.648
Limit of detection (µg/ml)	0.130
Limit of quantitation (µg/ml)	0.422

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

**Average of five determinations.

Table 2: Results of analysis

Brand used	Label claimed(mg)	Amount found by proposed method(mg)	% label claim	% RSD*
Tab-a	100	99.77	99.77	0.86
Tab-b	100	99.56	99.56	1.18

*Average of five determinations.

Table 3: Results of recovery studies

Brand used	Label claimed(mg)	Mean assay value	Known amount of Lamivudine added	Mean % recovery ±%RSD*
Tab-a	100	99.77	10mg	99.80±1.130
			20mg	99.95±1.586
Tab-b	100	99.56	10mg	99.88±1.158
			20mg	99.74±1.479

*Average of five determinations.

Table 4:Results of intra day precision studies

Brand used	Label claimed(mg)	Amount found by proposed method(mg)	% label claim	% RSD*
Tab-a	100	99.70	99.70	1.261
Tab-b	100	99.52	99.52	1.188

*Average of five determinations.

Table 5: Results of inter day precision studies

Brand used	Label claimed(mg)	Amount found by proposed method(mg)	% label claim	% RSD*
Tab-a	100	99.17	99.17	1.237
Tab-b	100	99.04	99.04	1.121

*Average of five determinations.

Table 6: Results of ruggedness studies

Brand used	Label claimed(mg)	Normal condition (Mean assay value)	Changed condition (Mean assay value) ±%RSD*
Tab-a	100	99.77	99.38±1.235
Tab-b	100	99.56	99.21±1.193

*Average of five determinations.

RESULTS AND DISCUSSION

The λmax of the Lamivudine in distilled water was found to be 270 nm. Lamivudine follows linearity in the concentration range of 5- 25 µg/ml. Two brands of tablets were analyzed and amount of drug were determined by proposed method; it was in good agreement with the label claim. The proposed method was validated as per the ICH guidelines. The recovery studies were carried out by adding a known amount of drug to pre analysed sample at two different levels and the % recoveries were ranges from 99.74-99.95%, which shows the accuracy of method. Intra-day and Inter-day precision of the assay was determined by analyzing the drug sample using same concentration. The intra-day and inter-day % RSD values were calculated and lying in the range of 1.121-1.261%. Ruggedness of proposed method was studied with the help of two different analysts and results were evaluated by calculating the % RSD values; lying within the range of 1.193-1.235%.

CONCLUSION

The proposed method is economic, sensitive, accurate, reproducible and useful for the routine determination of Lamivudine in tablet formulation.

ACKNOWLEDGEMENTS

Hetero Drugs Limited, Hyderabad for providing standard drug and to the Principal, and faculty of pharmacy department and management of QIS College of Pharmacy for providing facilities to carry out the work.

REFERENCES

1. Indian Pharmacopoeia 1996: Addendum 2002. New Delhi: The controller of publications; 2002. p. 918-20.
2. Hari Krishnan N, Gunasekaran V, Roosewelt C, Vijaya Kumar M, Kalaivani K, Ravichandiran V. Asian J Chem 2008;20(4):2551-56.
3. Mangaonkar K, Desai AD. Indian drugs 2008;45(2):119-122.
4. Pai N, Desai AD. Indian J Pharm Sci 2007;69(1):118-120.
5. Namita K, Sateesh K, Ramesh P. J Pharm Biomed Anal 2006;41(3):761-5.
6. Namita K, Sateesh K, Ramesh P. Anal Chim Acta 2006;570(1):41-5.
7. Pai N, Desai AD. Indian drugs 2003;40(2):111-4.
8. Pai N, Desai AD. Indian drugs 2005;42(10):681-4.
9. Wankhede SB, Gupta KR, Wadodkar SG. Indian J Pharm Sci 2005:96-7.

*****