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APPLICATION OF UV-SPECTROPHOTOMETRIC METHODS FOR ESTIMATION OF LAMIVUDINE IN TABLETS

S. Shalini[a†], V. P. Shanooja[a], S. Abdul Jameel[a], Basima[a], K. K. Harilal[a], Harish Rajak[b], V. Ravichandran[a*]
[a] *Alshifa College of Pharmacy, Perinthalmanna, Kerala, India.*
[b] *Institute of Pharmaceutical Sciences, Guru Ghasidas University, Bilaspur-495 009 (CG) INDIA.*
† *Present Address: Faculty of Pharmacy, AIMST University, Semeling – 08100, Kedah, Malaysia.*

Two new, simple, cost effective and sensitive spectrophotometric methods (A and B) for the determination of lamivudine in dosage and bulk forms are described. Lamivudine was estimated at 279.6 nm in 0.1 N HCl by method A and at 269.8 nm in 0.1 N NaOH by method B. In both the methods linearity was found to be in the range of 0-6 μg/mL for method A and 0-10 μg/mL for method B. The proposed methods were successfully applied for the determination of lamivudine in pharmaceutical formulations. The results demonstrated that the procedure is accurate, precise and reproducible (relative standard deviation <1%), while being simple, cheap and less time consuming and can be suitably applied for the estimation of lamivudine in different dosage forms.

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Keywords: UV-Spectrophotometry; Estimation; Lamivudine

1. Introduction

Lamivudine is chemically 2′,3’-dideoxy -3′-thiacytidine [3TC]. It is a well known non – nucleoside reverse transcriptase inhibitors used in the treatment of HIV (Human Immunodeficiency Virus) infection and Hepatitis B [1]. Few high performance thin layer chromatography [2], high performance liquid chromatography [3-6] and spectrophotometric [7-8] methods have been reported for its analytical monitoring in formulations. Lamivudine is not yet official in IP and BP. So our aim is to develop some new simple, efficient and reliable spectrophotometric methods for the analysis of lamivudine in formulations.

2. Experimental

Materials

Shimadzu UV/VIS spectrophotometer model 1701(Japan) with 1 cm matched quartz cells was used for spectral and absorbance measurements. Lamivudine (GlaxoSmithkline Pharmaceuticals Ltd, Mumbai), and all the chemicals were of analytical grade.

Reagents

* Corresponding author: Phravi75@rediffmail.com

a) 0.1 N HCL b) 0.1 N NaOH

Preparation of standard stock solution

Standard stock solution containing 100 µg/mL of lamivudine was prepared in 0.1N HCl and 0.1 N NaOH. From the each stock, different aliquots were taken and diluted to 10 mL mark with respective solvent to obtain series of concentrations. The solutions were scanned on spectrophotometer in the UV range 200-380 nm. Lamivudine in 0.1 N HCl showed absorbance maxima at 279.6 nm and in 0.1 N NaOH showed absorbance maxima at 269.8 nm.

Sample preparation for analysis (Method A and B)

Twenty tablets of each formulation T_1 and T_2 containing 100 and 150 mg of lamivudine were accurately weighed and powdered. Weight of powder equivalent to 100 mg of drug was taken in a 100 mL volumetric flask with 50 mL of 0.1 N HCl for method A, shaken for 30 min and volume adjusted with 0.1 N HCl then filtered using whatmann filter paper. For method B the tablet powder equivalent to 100 mg of drug was dissolved in 0.1 N NaOH. Further 1 mL of each solution was diluted to 10 mL with respective solvent.

Analytical procedure for method A

Pipette out 0.1 to 0.6 mL of working standard drug solution (100 µg/mL) into a series of 10 mL volumetric flask and adjusted to volume with 0.1 N HCl. The absorbance of solution was measured at 279.6 nm against the reagent blank. The calibration curve is shown in Fig.1. Each sample preparation of T_1 and T_2 was taken into 10 mL volumetric flask (final concentration is 6 µg/mL) and the above procedure was subsequently followed.

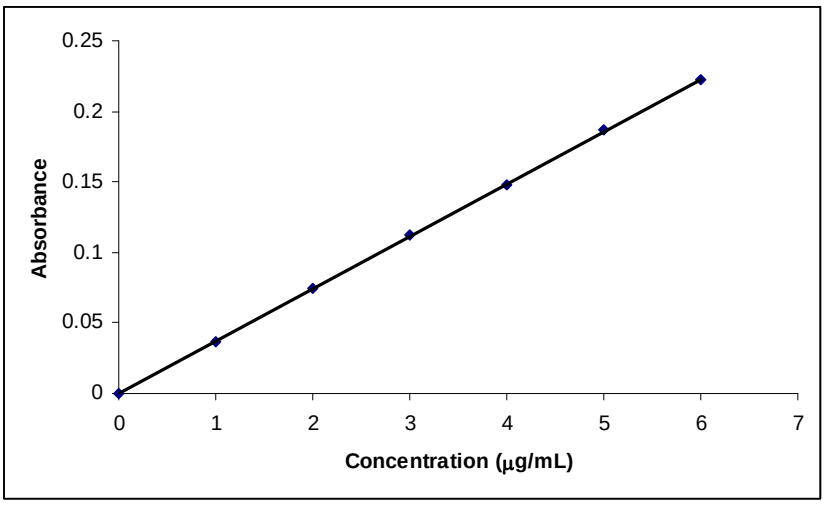

Fig.1. Calibration curve of Lamivudine in 0.1N HCl (279.6 nm).

Analytical procedure for method B

Pipette out 0.2, 0.4 to 1 mL of working standard drug solution (100 µg/mL) into a series of 10 mL volumetric flask and adjusted to volume with 0.1 N NaOH. The absorbance of solution was measured at 269.8 nm against the reagent blank. The calibration curve is shown in Fig.2. Each sample preparation of T_1 and T_2 was taken into 10 mL volumetric flask (final concentration is 6 µg/mL) and the above procedure was subsequently followed.

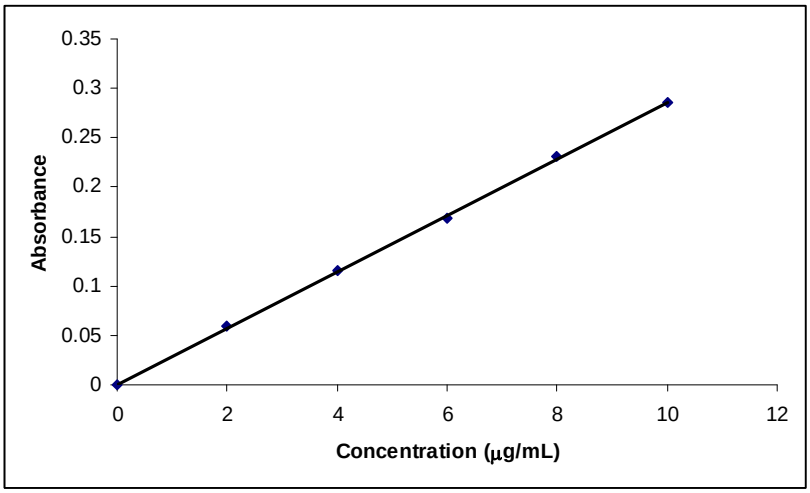

Fig.2. Calibration curve of Lamivudine in 0.1N NaOH (269.8 nm).

3. Results

The optical characteristics such as Beer's law limits, molar extinction coefficient, Sandell's sensitivity, correlation coefficient, slope and intercept data from linear least squares treatment and percent relative standard deviation were summarized in Table 1. In order to justify the reliability and suitability of the proposed methods, known quantities (1 mg/mL) of pure drug were added to its pre analyzed dosage forms and the mixtures were analyzed by the proposed methods and the values are listed in Table 2. There was no interference from other ingredients present in formulations, in these assay methods. Both the solutions are stable up to 30 min at room temperature (37 ± 1^0C).

4. Discussion

Method A is based on spectrophotometric determination of lamivudine in UV region using 0.1 N HCl as solvent and the absorbance spectral analysis showed the maximum absorption at 279.6 nm. Beer's law obeyed in the concentration range 0-6 µg/mL. The tablet assay result showed low co-efficient of variation 0.6772. The percentage recovery value in the range of 99.99-100.45 and it indicated the non-interference of the excipients in the tablet formulation.

Table 1. Optical Characteristics Data

Parameters	Method A	Method B
λ_{max} (nm)	279.6	269.8
Beer's law limits (µg/mL)	0 – 6	0-10
Molar absorptivity (L/mol/cm)	11.1×10^4	8.4×10^4
Sandell's sensitivity (µg/cm^2/0.001 A.U.)	2.70×10^{-2}	3.571×10^{-2}
Regression equation (Y = a + bc)		
Slope (b)	3.75×10^{-2}	2.85×10^{-2}
Intercept (a)	-2.1×10^{-3}	1.095×10^{-3}
Correlation coefficient (r)	0.9992	0.9993
Relative standard deviation (%)*	0.67	0.57

* Calculated from six determinations. A.U. indicates absorbance unit.

Method B is based on spectrophotometric determination of lamivudine in UV region using 0.1NaOH as solvent and the absorbance spectral analysis showed the maximum absorbance at 269.8 nm. Beer's law obeyed in the concentration range 0-10 μg/mL. The tablet assay result showed low co-efficient of variation 0.5693. The percentage recovery value in the range of 100.62-101.12 and it indicated the non-interference of the excipients in the tablet formulation.

Table 2. Assay of Lamivudine in Pharmaceutical Formulations

Pharma-ceutical Formulations*	**Labeled amount (mg)**	**Amount found by proposed method** (mg)**		**% recovery by proposed method *****	
		Method A	**Method B**	**Method A**	**Method B**
T_1	100	100.09 ± 0.68	99.92 ± 0.56	100.22 ± 0.57	100.69 ± 0.47
T_2	150	150.42 ± 0.69	149.98 ± 0.58	100.87 ± 0.37	100.38 ± 0.45

* T_1, T_2 – Various brands of lamivudine tablets. ** Average ± standard deviation of five determinations. *** Recovery of (1 mg/mL) of pure lamivudine added to the previously analyzed pharmaceutical formulations (average of five determinations).

The low value of standard deviation and percentage relative standard deviation of the both method A and method B indicated that the proposed methods are very precise and accurate.

The proposed methods are simple and sensitive with good precision and accuracy, employing inexpensive and prevalent chemicals compared to the reported methods, can be used for the routine analysis of lamivudine in pure form as well as in pharmaceutical formulations.

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