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SPECTROPHOTOMETRIC DETERMINATION OF LAMOTRIGINE IN PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

A simple and sensitive spectrophotometric method for the determination of lamotrigine in bulk drug and pharmaceutical dosage forms has been developed. The developed spectrophotometric procedure was based on the reaction of lamotrigine with vanillin under acidic conditions to form yellow coloured chromogen with absorption maxima at 390 nm against reagent blank. Beer's law was obeyed in the concentration range of 40-100 μg/mL of drug. The method was successfully applied to the determination of lamotrigine in tablets.

Key words: Lamotrigine, Spectrophotometric, Pharmaceutical.

INTRODUCTION

Lamotrigine is chemically, 6-(2,3-dichlorophenyl)-1, 2,4-triazine-3,5-diamine. It is a novel antiepileptic drug; chemically unrelated to other anticonvalsants used as an add-on therapy of seizure in children and adults. It has been shown that lamotrigine is effective against partial and secondarily generalized tonic–clonic seizures as monotherapy or adjunctive treatment. There are some analytical methods available for the determination of lamotrigine in bulk drug and in formulations, which include UV spectrophotometry[1,2], HPTLC[3] and HPLC[4].

In the present work, lamotrigine was treated with vanillin under acidic condition to form yellow colour chromogen. The yellow colour chromogen was measured at 390 nm

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against reagent blank. The aim of this study was to develop simple spectrophotomeric method for the estimation of lamotrigine in pharmaceutical dosage forms.

EXPERIMENTAL

Instrumentation

A Milton Roy 1001 plus spectrophotometer with 1 cm quartz cells was used for all measurements. All the chemicals and reagents used were of AR grade. Double distilled water was used throughout the investigation.

Chemicals and reagents

Hydrochloric acid (4 N) was prepared and standardized with standard procedure. Vanillin (1% w/v) solution was prepared.

Standard solution

50 mg of lamotrigine was dissolved in 50 mL methanol. This stock solution was further diluted with methanol to get desired concentrations.

Assay procedure

Aliquots of lamotrigine ranging form 0.4-1 mL were transferred into a series of 10 mL volumetric flask. To each flask, 1.0 mL of 1% vanillin solution and 1.0 mL of 4 N hydrochloric acid solutions were added. The flasks were shaken for 1 min and the volume in each flask was made up to the mark with methanol. The absorbance of the yellow colour chromogen was measured after 15 min at 390 nm against reagent blank. The amount of lamotrigine present in the sample was computed from calibration curve.

Pharmaceutical formulations

Ten tablets of lamotrigine were weighed and powdered. The powder equivalent to 50 mg of lamotrigine was transferred into 50 mL volumetric flask, shaken thoroughly with 30 mL methanol and filtered. The filtrate was diluted to 50 mL with methanol. This stock solution was further diluted to obtain the working concentration of 100 μg/mL. Different aliquots of solutions were taken and analyzed by using the procedure described earlier and the amount of lamotrigine present in sample was computed from calibration curve. The results are tabulated in Table 1.

Table 1: Assay of lamotrigine in tablets

Sample	Labelled amount (mg)	Amount found in mg		C. V.	$^{*}t_{cal}$
		Proposed method ± S.D*	Official method*		
Tablet 1	100	99.6 ± 0.37	99.40	0.3782	0.2366
Tablet 2	150	149.98 ± 0.47	149.93	0.3176	0.0938
Tablet 3	200	200.07 ± 0.29	150.02	0.1487	0.5271

*Average of five determinations based on label claim

RESULTS AND DISCUSSION

The proposed method involves the condensation of lamotrigine with vanillin in acidic medium to form yellow colour chromogen. The absorbance of yellow colour chromogen was measured at 390 nm against reagent blank. Beer's law was obeyed in the concentration range of 40-100 μg/mL of lamotrigine**.** The results shown in Table 1 are in good agreement with those obtained with the reported method. The optimum conditions were established by varying one parameter and keeping others fixed and observing the effect produced on the absorbance of the solution. The effect of hydrochloric acid concentration and reagent concentration were studied through controlled experiments and optimum conditions were incorporated in the procedure. The common excipients employed do not interfere in the estimation of lamotrigine. The statistical analysis was studied by proposed method. The standard deviation values were satisfactorily low, indicating the accuracy and reproducibility of the proposed method. The calculated t-values did not exceed the theoretical value indicating that there is no significant difference between proposed method and official method.

The proposed method was found to be simple, sensitive, precise and economical and can be used in the determination of lamotrigine in bulk drug and its pharmaceutical dosage forms in a routine manner.

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