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Research Article

A FACILE SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF CARBAMAZEPINE IN TABLETS

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ABSTRACT

A simple spectrophotometric method was developed and validated for the quantification determination of carbamazepine in tablet formulation. The method is based on formation of nitrosamine by a specific reaction of carbamazepine with nitrite under acid condition. Carbamazepine undergoes nitrosation forming greenish yellow product and the absorbance measured at 417 nm. All the optimum conditions are established. The calibration graphs are rectilinear in the concentration ranges 0.2 – 10 µg / ml in the final measured solution. The Sandell sensitivity (S), molar absorptivity, correlation coefficient, regression equations are calculated. The proposed method is applied for the assay of drug in pharmaceutical dosage forms. The results are in good agreement with the label claim.

KEY WORDS: Spectrophotometry, carbamazepine, nitrosation, tablets.

INTRODUCTION

Carbamazepine (CBZ) is widely used in the treatment of epilepsy, frequently in combination with other anticonvulsants. Its metabolite, carbamazepine-10,11-epoxide, is pharmacologically active and is increased with concurrent use of valproate and other anticonvulsants. It is also used for the treatment of schizophrenia, paroxysmal extreme pain disorder, phantom limb syndrome and post-traumatic stress disorder. The methods available for the determination of carbamazepine drug in pharmaceuticals are HPLC (Walker 1988, Yuan et al. 2003, Demirkaya and Kadioglu; 2005, Tatar 2006, Dzodic et al. 2009, Najma et al. 2013), gas chromatography (Liu et al. 1991, Kadioglu and Demirkaya; 2007), flow injection - spectrophotometry (Comoglu 2006), flow injection - spectrofluorimetry (Huang et al. 2002), chemiluminescence - spectrometry (Lee et al. 2003), flow injection - chemiluminescence spectrometry (Xiong 2009), electrolysis - fluorescence spectrometry (Pan et al. 1998), polarography (Panchagnula et al. 1998), visible spectrophotometry (Rao et al. 1992, Agarwal et al. 1989, Sameer et al. 2010). The aim of the present work is to develop simple and accurate method for the determination of carbamazepine in pharmaceutical formulation. The proposed method is applied successfully to the determination of carbamazepine either in pure or in dosage forms, with good accuracy and precision. The results were compared with those given by the official methods. The proposed methods stands atop over the reported method with respect to

simplicity, cost effectiveness and the method neither requires extraction nor prior separation of the drug.

MATERIALS AND METHODS

Apparatus

UV-visible Spectrophotometer of Systronics Model 117 with 10 mm matched quartz cells were used for absorbance measurement.

Materials and Reagents

Carbamazepine was received from pharmaceutical company. Tablets, Zeptol-100 of Sun pharmaceuticals, Mumbai, India and Tegretol-100 of Novartis India Ltd., were purchased from local market. Sodium nitrite (BDH) and sulfuric acid (S.D. Fine Chem, Mumbai, India, Sp. gr. 1.84) were used for the experiment. All other chemicals and solvents were of analytical grade.

Standard Solutions

Standard stock solution of carbamazepine (100 µg / ml) was prepared by dissolving 10 mg of carbamazepine in methanol and diluted to 100 ml with distilled water. The working standard solution was prepared by further dilution. 0.5% solutions of phenol and sodium nitrite and 2% sulfuric acid solutions were used. All other chemicals and solvents used were of analytical grade.

General procedure

Different aliquots of the standard carbamazepine (0.2 – 10 µg / ml) were transferred into a series of 10 ml volumetric flasks. 1.0 ml of 0.5 % sodium nitrite was added, cooled in an ice bath and 1 ml of 2 % sulfuric acid, cooled. 2ml of 0.01 % of lamotrigine was added to the solutions of the drug. Solutions were mixed thoroughly and heated on a water bath for 5 minutes. After cooling solutions to the room temperature and were diluted to the mark with 1:1 H_2SO_4 and mixed thoroughly. Absorbance was measured at 417 nm against reagent blank.

Table 1. Optical characteristics of the proposed procedure

Parameters	Method A
Color $\lambda_{max,}$ nm	Greenish 417
Stability Beer's limit (µg/ml)	16 hours 0.2 - 10
Molar absorptivity (L $mol^{-1}cm^{-1}$)	2.1450 x 10^4
Sandelsensitivity (µg cm^{-2}/0.001A)	0.01101
Correlation coefficient	0.98315
Regression equation Slope(b) Intercept(a)	0.02044 0.05371
Standard deviation	0.03978

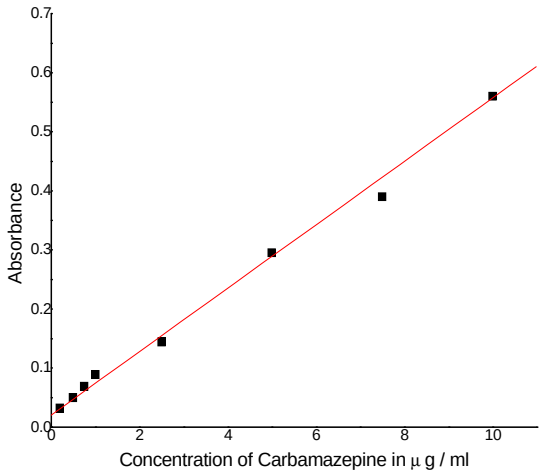
Procedure for the determination of carbamazepine in commercial samples

Ten tablets of carbamazepine were powdered and mixed thoroughly. The powder equivalent to 10 mg was weighed precisely and dissolved in methanol. The residue was filtered into 100 ml volumetric flask. The residue was washed repeatedly with distilled water and rinses were added to the filtrate. Final volume of filtrate was made up to the mark with distilled water.

RESULT AND DISCUSSION

Calibration curve

The calibration curve was prepared by recommended procedure as shown in fig.1. Linear relationships between absorbance and concentration held over range of 0.2 to 10 µg / ml and other parameters are given in Table 1.



Carbamazepine + 1 ml of H2SO4 (2%) + Cool + 1 ml of NaNO2 (0.5%) + Cool + 2 ml lamotrigine (0.01%) + warm on a water bath + cooled to room temperature + diluted with 1:1 H2SO4.

Optimum reagents concentration

It was found that a 0.5 % solution of sodium nitrite (1.0 ml), 2 % solution of sulfuric acid in the range of 0.5 - 1.5 ml and 2 ml of 0.01 % lamotrigine were necessary to get the maximum color intensity. The dilution of the colored solution with different solvents and acids has been tested. 1:1 H2SO4 gives the maximum intensity.

Quantification and reaction sequence

Beer's law is obeyed over the carbamazepine concentration range of 0.2-10 µg / ml. The optical characteristics and precise data are given in table 2. Nitrosation of amines is an important and well established reaction in organic synthesis.1 The most general reagent is nitrous acid, generated from sodium nitrite and mineral acid in water. Carbamazepine undergo nitrosation forming greenish yellow product.

Side reactions were prevented by adding lamotrigine. Under these conditions lamotrigine does not undergo diazotization.

Table 2. Analysis of pharmaceutical formulations

Amount found[a] in mg			
Pharmaceutical formulation	Label Claim(mg)	Proposed Method	Reference Method (Sameer et al. 2010)
Zeptol-100	100	99.90 ± 0.15	97.78± 2.06
Tegretol-100	100	99.70 ± 0.35	-----

[a] *An average of three determinations ± % R.S.D.*

Stability

The proposed reaction procedure completes in 30 minutes. Nitrosation of carbamazepine impart greenish yellow color and is stable for only 15 minutes but addition of lamotrigine inhibits side reactions and can causes color stable for more than 16 hours at room temperature.

Interferences

The effect of excipients was observed by determining 05 µg / ml of carbamazepine in presence of different excipients such as starch, glucose, cellulose, lactose and talc at different concentrations present in tablet formulation. The results specify that there is no hindrance from any excipients.

Applications

The applicability of the method for the determination of pharmaceutical preparations was examined. The results of assay of availability of carbamazepine are given in table 2. The results are highly reproducible and concur very well with label claimed. The sturdiness of the methods is that does not require any extraction and co precipitation.

CONCLUSION

The developed methods were found to be simple and accurate. Statistical comparison of the results for the carbamazepine in tablet formulation by these methods indicated has no significant differences. The excipients present in the tablet dosage form do not interfere with the determination of carbamazepine. The methods neither require expensive instruments nor pH maintenance. Hence the proposed methods can be used lucratively for the determination of carbamazepine in tablet formulation.

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