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Spectrophotometric determination of Cilastazol using p-dimethylaminobenzaldehyde

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ABSTRACT

A simple accurate and reproducible spectrophotometric method was established for the estimation of Cilastazol based on the formation of condensation product. The method is based on the formation of yellow colored chromogen, when the drug reacts with p-Dimethylaminobenzaldehyde (PDAB). The colored species has an absorption maximum at 425 nm and obeys Beer's law in the concentration range of 6-10 mg/ml.The optimum experimental parameters for the experiment has been studied. Statistical analysis of the results has been carried out revealing high accuracy and good precision.

Keywords: Cilastazol, Spectrophotometry, PDAB.

INTRODUCTION

Cilastazol (CTZ), 6-[4-(1-cyclohexyl-1H-tetrazol-5-yl) butoxy]-3,4-dihydro-2(1H)-quinoline, is a quinoline derivative that inhibits cellular phosphodiesterase III, and is used for inhibition of platelet aggregation and a vasodilator.1 Cilastazol has been reported to undergo extensive metabolism2. Earlier reports reveal that CTZ in plasma, urine and microsomal incubation samples was estimated by HPLC technique.3-6 The aim of this present work was to develop a simple, validated, and rapid visible spectrophotometric method for the routine analysis of cilastazol in tablet preparations

EXPERIMENTAL

Materials and Methods

All spectral and absorbance measurements were made on an ELICO-SL164 UV/VIS double beam spectrophotometer with 10mm matched quartz cells.

All chemicals and reagents were of analytical grade. A 1mg/ml stock solution was prepared by dissolving 100 mg of CTZ in 100 ml of ethanol. Ethanolic PDAB was prepared by dissolving 1g of PDAB in 30 ml of ethanol (95%) ,180 ml of 1-butanol and 30 ml of HCl.

To each 25 ml volumetric flasks, aliquots 6-10ml (1mg/ml), of ethanolic standard drug solution and 3ml of ethanolic PDAB solution were added and placed in water bath for 10 min. Then the flasks were cooled and made upto mark with ethanol and the absorbance was measured at 425 nm against the reagent blank. The concentration of the drug sample was computed from Beer's law plot.

RESULTS AND DISCUSSION

Chemical reaction of the method

The amino group in quinolinone moiety of

CTZ undergoes condensation with PDAB to form colored species, azomethine.

Validation of method

The optimum condition for the color development was established by varying the concentration of PDAB, heating time and observing the effect produced on the absorbance of the colored species.

The optical characteristics such as Beer's law limits, molar absorptivity and sandell's sensitivity were given in Table-1. The precision of the method was found by measuring the absorbance of 6 separate samples containing known amounts of drug and the results obtained are incorporated in Table-1. Regression analysis using the method of least squares was made to evaluate the slope (b), intercept (a) and correlation coefficient (r).

The accuracy of the method was ascertained by comparing the results by proposed and reference methods. The comparison shows that there is no significant difference between the results of studied methods and those of reference. The similarity of the results is obvious evidence that during the application of these methods the excipients present in formulation do not interfere in the assay of proposed method. As an additional check of accuracy of the proposed method recovery studies were carried out. The recovery of the added amounts of standard drug was studied at 3 different levels. Each level was repeated 6 times. From the amount of drug found, the percentage recovery was calculated.

Table 1: Optical and regression characteristics of the proposed method for CTZ

Parameters	
λmax, nm	425
Beer's law limits mg/ml	6^{-10}
Molar absorptivity,L/mol.cm	$1.915x10^{-1}$
Sandell's sensitivity, mcg/cm2/0.001 absorbance unit	$8x10^{-3}$
Regression equationY=a+bc	
Slope(b)	$1.023x10^{-3}$
Intercept(a)	$5.264x10^{-2}$
Correlation coefficient(r)	0.9987

Table 2: Analysis of tablet formulation

Label claim	**%Amount found ± S.D [n=5]**	**% R.S.D**	**%Recovery [n=5]**
50mg	99.65±0.280	0.784	99.61
100mg	99.78±0.213	0.633	99.85

CONCLUSIONS

The proposed visible spectrophotometric method is simple and sensitive with reasonable precision, accuracy and constitute better alternative to the existing ones for the routine determination of CTZ in bulk and pharmaceutical formulations.

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