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Visible Spectrophotometric Method for the Estimation of Gliclazide in Tablets.

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ABSTRACT

The present work describes a simple, sensitive and precise visible spectrophotometric method for the estimation of Gliclazide in bulk drug as well as in pharmaceutical dosage form. This method is based on the formation of orange-red chromogen (λ_{max} at 512nm) by complexation of Gliclazide with 1,10-phenanthroline in presence of ferric chloride. The proposed method is statistically validated and found to be useful for the routine determination of Gliclazide in tablets.

Keywords: Gliclazide, Visible spectrophotometry, Tablets, Validation.

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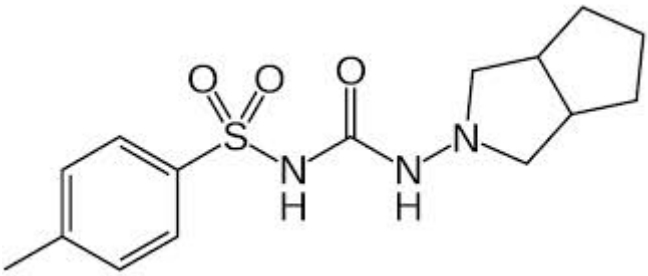
INTRODUCTION

Gliclazide (GCZ) is a specific type of an anti-diabetic drug most commonly used for type 2 diabetes mellitus [1]. Chemically it is 1-(1-azabicyclo (3,3,0) octyl)-3-(p-tolylsulphonylurea) [2]. Literature review revealed very few analytical methods including Radioimmunoassay [3], Gas chromatography[4] ,HPLC[5,6], Evaporative Light Scattering [7], Mass spectroscopy [8] and LC-MS [9] for quantification of GCZ in pharmaceutical dosage forms. The present work deals with the estimation of GCZ in tablets by formation of coloured complex with 1,10-phenanthroline and ferric chloride having λ_{max} at 512nm (Figure 1). Spectrophotometric parameters are established for standardization of the method including statistical analysis of data.



Gliclazide

EXPERIMENTAL

Instrumentation

All spectral and absorbance measurement was made on Shimadzu UV-VIS spectrophotometer-1650.

Reagents

1,10-phenanthroline(0.1%w/v), Ferric chloride(5%w/v).All reagents used were of analytical grade .

Standard solution and Calibration curve

A 1mg/ml stock solution of GCZ was prepared by dissolving 50 mg of drug in 50 ml of methanol. Aliquots of GCZ were pipetted out into a series of 10ml volumetric flasks so as to get a concentration of 100-600 µg/ml. To each flask 1ml of ferric chloride and 1ml of 1,10-phenanthroline were added and made up to volume with methanol. The absorbance of the orange-red coloured chromogen was measured at 512nm against the reagent blank. The calibration curve was obtained by plotting concentration versus absorbance.

Sample Preparation

Twenty tablets were weighed. A quantity equivalent to 50 mg of GCZ was weighed accurately, transferred to a beaker, dissolved in methanol, filtered through whatmann filter

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paper No.1 into a 50ml volumetric flask and made up to volume with methanol to get a concentration of 1 mg/ml. Appropriate aliquots were subjected to the above method and the amount of GCZ was determined from the calibration curve. The results of sample analysis are furnished in Table-2.

RESULTS AND DISCUSSION

The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and Sandell's sensitivity are furnished in Table-1.The regression characteristics like slope(m),intercept(c),correlation co-efficient(r),percent relative standard deviation(% RSD) and standard error (SE) obtained from different concentration were calculated and the results are summarised in Table 1.

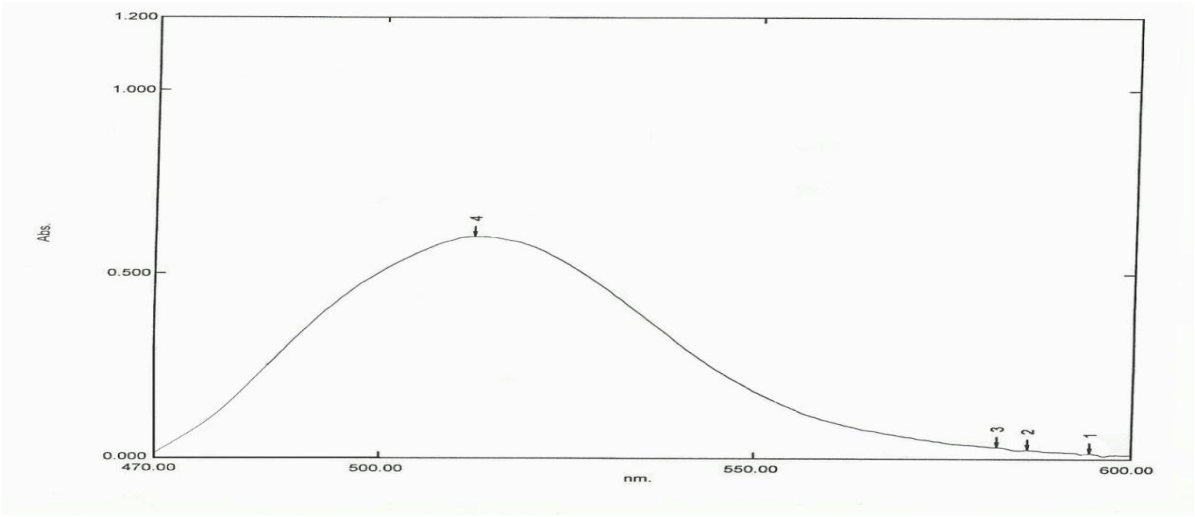

Figure 1: λ_{max} of GCZ at 512nm

Table 1: Optical and statistical characteristics

Parameter	Results
λmax(nm) Beer's law limits(µg/ml) Molar absorptivity(Lmol-1 cm-1) Sandell's sensitivity(µg/cm2/0.001absorbance unit)	512 100-600 0.498 x 103 0.0649
Regression equation(y=mx+c)*	y=0.000285x+0.00333
Slope(m) Intercept(c) Correlation coefficient(r)	0.000285 0.00333 0.999
%RSD Standard error(SE)	0.27013 0.0439

*y=mx + c, where c is the concentration of GCZ in µg/ml

Table 2: Assay and recovery of GCZ in tablet dosage form

Drug	Labelled amount (mg)	Amount obtained(mg)*	Percentage recovery**
GCZ	40	39.87	100.03

*Average of six determinations, **Average of three determinations

To study the accuracy and reproducibility of the proposed method, recovery experiments were carried out by adding a known amount of drug to preanalyzed sample and the percentage recovery was calculated. The results are furnished in Table 2.The results indicate that there is no interference of other ingredients present in the formulations. Thus, the proposed method is simple, sensitive, precise, accurate and reproducible and useful for the routine determination of GCZ in bulk drug and its pharmaceutical dosage forms.

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