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Development and Validation of Spectrophotometric Methods for Quantification of Gliclazide in Tablets.

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ABSTRACT

Two simple and precise spectrophotometric methods (A and B) were developed for the estimation of Gliclazide in bulk drug as well as in pharmaceutical dosage form. Method A is Area Under Curve (AUC) method which involves the calculation of integrated value of absorbance with respect to the wavelength between two selected wavelengths. Method B is First derivative spectroscopy method. The First derivative spectrum is a plot of the rate of change of absorbance with wavelength against wavelength (dA/dλ versus λ).It is characterized by a maximum, minimum and a cross-over point at the λ_{max} of the absorption band. Beer's law was obeyed in the concentration range of 4-24µg/ml for both the methods A and B respectively. The proposed methods were statistically validated and found to be useful for the routine determination of Gliclazide in tablets.

Keywords: Gliclazide, 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 Detection[7], LC-MS[8] and Mass spectroscopy[9] for quantification GCZ in pharmaceutical dosage forms. In the present work, two simple and sensitive spectrophotometric methods (A and B) have been developed. for the estimation of GCZ in bulk drug and pharmaceutical dosage form. Method A is Area Under Curve method. Method B is First derivative spectroscopic method. Spectrophotometric parameters are established for of standardization of the methods including statistical analysis of data.

MATERIALS AND METHODS

Instrument

All spectral and absorbance measurements were made on Shimadzu UV-Vis spectrophotometer-1650.

Standard solution of GCZ

A 1mg/ml stock solution of GCZ was prepared by dissolving 50 mg of drug in 50 ml of methanol.

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 paper No.1 into a 50ml volumetric flask and made up to volume with methanol to get a concentration of 1 mg/ml.

Assay

Method A

Area Under Curve (AUC) method involves calculation of integrated value of absorbance with respect to the wavelength between two selected wavelengths 220 nm and 235nm.The area under curve between 220 nm and 235 nm was calculated by inbuilt software. Aliquots of stock solution of GCZ were suitably diluted with methanol to give varying concentrations ranging from 4-24µg/ml. The solutions were scanned in the spectrum mode in the wavelength range of 200-400nm and AUC was recorded as shown in fig -1. The calibration curve was obtained by plotting concentration versus AUC. The amount of GCZ was computed from the calibration curve.

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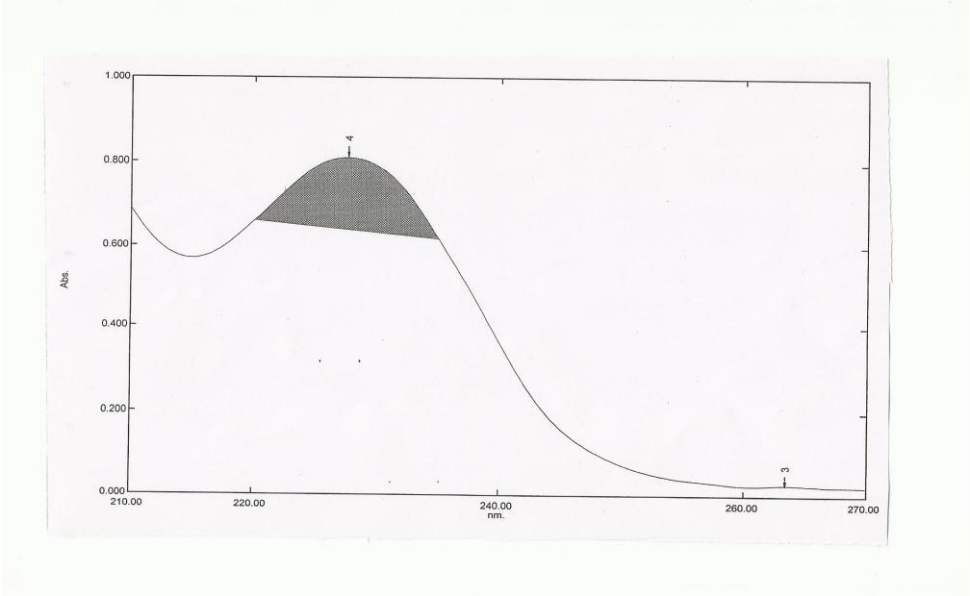

Figure 1: AUC of GCZ by Method A

Method B

The stock solution was diluted suitably with methanol to give a series of concentration ranging from 4-24µg/ml of GCZ. The above solutions were scanned in the range of 200-400nm and the resultant spectra were derivatised to get the first order derivative spectra as shown in fig-2. The calibration curve was constructed by plotting absorbance versus concentration. The amount of GCZ was computed from calibration curve.

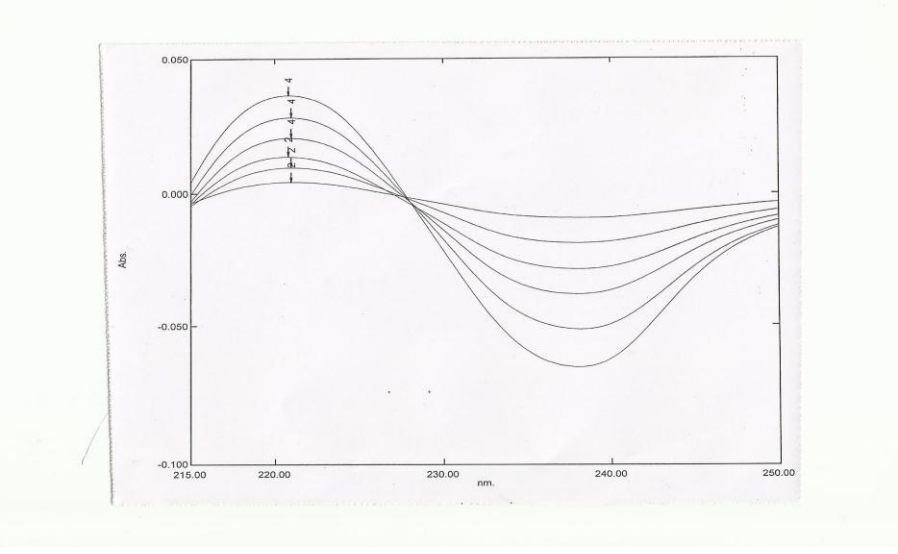

Figure 2: First derivative overlain spectra of GCZ by Method B

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Sample Analysis

Pharmaceutical formulation of GCZ was successfully analyzed by the proposed methods. Appropriate aliquots were subjected to the above methods and the amount of GCZ was determined from the calibration curve.

RESULTS AND DISCUSSION

The optical characteristics like absorption maxima and the regression characteristics like slope (b), intercept (c),correlation coefficient(r), percent relative standard deviation (%RSD) and standard error (SE) were calculated and the results are summarized in Table-1.The results of sample analysis are furnished in Table-2.The results of sample analysis showed that the drug determined by the proposed methods was in good agreement with the label claim proving the accuracy of the proposed methods.

Table 1: Optical and statistical parameters by methods A and B.

Parameter	Method A	Method B
Absorption maximum/wavelength range(nm)	220-235	227
Linearity range(µg/ml)	4-24	4-24
Limit of detection[LOD](µg/ml)	2	2
Limit of quantification [LOQ](µg/ml)	4	4
Correlation coefficient(r)	0.99	0.9952
Standard deviation	0.2454	0.2702
Standard error	0.01097	0.1208
%Relative standard deviation	0.6165	0.6768
Slope(m)	0.1007	0.0010
Intercept(c)	-0.01026	-0.0004
Regression equation y=mx+c	0.1007x--0.01026	0.0010x -0.0004

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

Method	Labelled amount (mg)	Amount obtained(mg)*	Percentage recovery**
A	40	39.80	100.03
B	40	39.81	100.01

*Average of six determinations
**Average of three determinations

To study the accuracy and reproducibility of the proposed methods, recovery experiments were carried out by adding a known amount of drug to preanalyzed sample and the percentage recovery calculated. The results are furnished in Table-2.The results indicate that there is no interference of other ingredients present in the formulation. Thus the proposed

methods are simple, sensitive, economical, accurate and reproducible and useful for the routine determination of GCZ in bulk drug and its pharmaceutical dosage forms.

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