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Research Article

APPLICATION OF UV SPECTROPHOTOMETRIC METHOD FOR ANALYSIS OF GLICLAZIDE IN PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

A simple and sensitive spectrophotometric method has been described for the assay of gliclazide either in pure form or in pharmaceutical solid dosage form. An absorption maximum of gliclazide in dichloromethane was found to be at 232 nm. Beer's law is obeyed in the range 0.25-80 µg mL^{-1}. Result of percentage recovery and placebo interference shows that the method was not affected by the presence of common excipients. The percentages assay of gliclazide in tablet was more than 99%. The method was validated by determining its sensitivity, accuracy and precision which proves suitability of the developed method for the routine estimation of gliclazide in bulk and solid dosage form.

Keywords: Gliclazide, UV Spectrophotometer

INTRODUCTION

Gliclazide is N-(4-methylbenzene sulfonyl) -N'-(3-azabicyclo [3.3.0] oct-3-yl) urea or 1-(3-azabicyclo[3.3.0] oct-3-yl) -3-p-tolylsulfonyl[1], Molecular weight 323.4, is a white or almost white crystalline powder, odorless, tasteless, m.p., 165-170° C[2]. It is official in British Pharmacopoeia 2007[3]. Gliclazide (Glz) is a second-generation sulphonylurea oral hypoglycemic agent used in the treatment of non-insulin dependent diabetes mellitus. It stimulates insulin secretion by pancreatic beta cells. In the long-term, it reduces hepatic gluconeogenesis, and increases insulin effects by acting at receptor or post-receptor sites. It also inhibits platelet aggregation and increases fibrinolysis[4,5]. A survey of literature has revealed few U V spectrophotometric methods for simultaneous estimations of gliclazide in pharmaceutical formulation[6,7] and for estimation of gliclazide and metformin in combined tablet dosage form[8]. Few HPLC determations are available for the estimation of drug in human serum [9-16] and pharmaceutical formulation[17]. But to the best of our knowledge, there is no work in the literature reported about the UV spectrophotometric method for the analysis of gliclazide in pharmaceutical formulations using dichloromethane as solvent.

There is a need for develop new, simple, economic and rapid method for the estimation of gliclazide alone in bulk and solid dosage forms and can be used for routine analysis. Hence, the authors have made an attempt to develop a simple and rapid UV spectrophotometric method for the estimation of gliclazide in tablet dosage form by taking dichloromethane as solvent.

MATERIAL AND METHODS

Instrument and apparatus

Perkin Elmer UV-Visible Spectrophotometer Lambda 25 model was used for spectral measurements with spectral band width 1 nm, wavelength accuracy is 0.5 nm and 1 cm matched quartz cells. Glassware used in each procedure were soaked overnight in a mixture of chromic acid and sulphuric acid rinsed thoroughly with double distilled water and dried in hot air oven.

Reagents and Materials

All chemicals were of analytical grade.

Standard drug solution

Pharmaceutical grade Gliclazide was kindly provided by Panacea Biotech Ltd., India. A stock standard solution equivalent to 1mg/mL Gliclazide was prepared by dissolving 100 mg of pure drug in dichloromethane and diluting to 100 mL in calibrated flask with dichloromethane.

Method

Different aliquots (0.0, 0.25 0.5, 1.0,..... , 8.0 mL) of 1 mg mL^{-1} Gliclazide solution were accurately measured and transferred into a series of 100 mL volumetric flasks and volume made up to the mark with dichloromethane. Then all dilutions were scanned between 200-400 nm against blank which shows the maximum absorbance at 232 nm (Fig. 1).

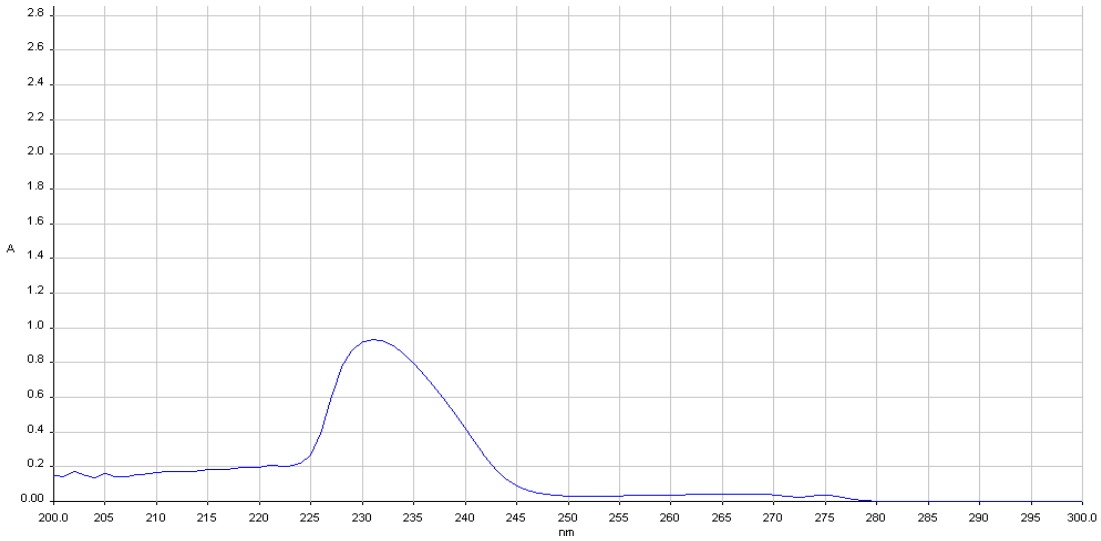

Fig. 1: UV spectra of Gliclazide

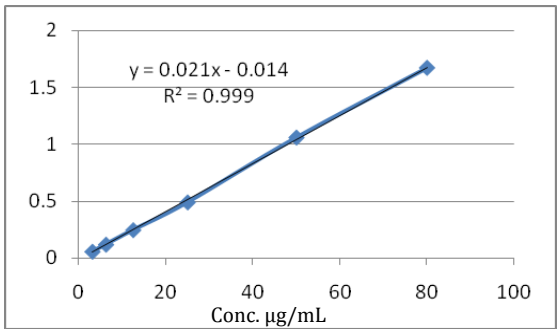

Fig. 2: Standard plot for Gliclazide

The same λ max was used for further measurement of drug. A calibration curve for absorbance vs. concentration was plotted (Fig. 2).

Assay of pharmaceutical Formulations

Twenty tablets were weighed accurately and ground into a fine powder. Powder equivalent to 100 mg of Gliclazide was weighed accurately and transferred into a 100 mL volumetric flask with 60 mL dichloromethane. The content was shaken for 15-20 min, diluted to volume with dichloromethane and filtered using a Whatman No. 42 filter paper. First 10 mL portion of filtrate was discarded and subsequent portions were subjected to analysis.

RESULTS AND DISCUSSION

The absorption spectrum of Gliclazide was measured in the range 200–400 nm against the blank solution dichloromethane similarly prepared. The standard solution show maximum absorbance at λ max for each three systems as recorded in Table 1. And the method was validated by studying the following parameters:

Table 1: Parameters for determination of Gliclazide against dichloromethane

Parameters	Values
λ max, nm	232
Beer's law limit, µg mL^{-1}	0.25- 80
Molar absorptivity, L mol^{-1} cm-1	$1.58x10^4$
Regression equation:	
Slope (m)	0.021
Intercept (c)	-0.014
Correlation coefficient	0.999

The accuracy of the above method was ascertained by comparing the results obtained with the proposed and reference methods in the case of formulation are presented in Table 2.

Table 2: Assay and Recovery of Gliclazide in Pharmaceutical Formulations

Formulation	Label Claim (mg)	Amount Found (mg)	% Recovery Proposed method #	% Recovery Reference method*
I	40	39.61	99.03	98.52
II	40	39.65	99.12	99.23

I and II are tablets from different batches (Glizid-40, Panacea Biotec Ltd)

* Reference method [7]; # Recovery amount was the average of six determinants.

As an additional check on the accuracy of these methods, recovery experiments were performed by adding known amounts of pure drug to pre-analyzed formulation and percent recovery experiments were also done. Recovery experiments indicated the absence of interferences from the commonly encountered pharmaceutical additives and excipients.

CONCLUSION

It could be concluded that the developed method for estimation of Gliclazide in pharmaceutical dosage forms and in bulk is simple, sensitive, relatively precise and economical. The proposed methods are used for the routine analysis of the drugs in the quality control.

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