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SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF GLIMEPIRIDE IN BULK AND PHARMACEUTICAL FORMULATIONS

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ABSTRACT

A simple, sensitive and resproducible spectrophotometric method for the analysis of glimepiride in pure form and in pharmaceutical formaulations has been developed. glimepiride is a synthetic oral hypoglycemic agent, which belongs to the class of sulfonylureas used in treatment of type-2 diabetes mellitus. Glimepiride exhibited maximum absorbance at 226.0 nm with an apparent molar absorptivity of 2.94 x 10^6. Beer's law was obeyed in the concentration range of 2-32 μg/mL. Results of the analysis were validated statistically and by recovery studies. This method is successfully employed for the determination of glimepiride in various pharmaceutical preparations.

Key words : Glimepiride, Spectrophotometric method, Beer's law

INTRODUCTION

Glimepiride is an example of synthetic hypoglycemic agent used in the treatment of type-2 diabetes mellitus[1]. It is chemically 3-ethyl-2, 5-dihydro-4-methyl-N-[2-[4-[[[[trans-4-methyl cyclohexyl] amino] carbonyl] amino] sulphonyl] phenyl] ethyl] 2-oxo-1H-pyrrole-1-carbonamide[2,3]. It is official in U. S. Pharmacopoeia. A few analytical methods have been reported for its quantitative estimation in pharmaceutical formulations which include UV methods[4-7] and HPLC methods[8-10]. In view of the above fact, some simple analytical methods are needed for quantitative estimation. The objectives of the present work were to develop a simple spectrophotometric method with greater precision and accuracy that can be used for the routine Q. C. analysis of the formulations containing glimepiride, in which the drug was dissolved in methanol and then the absorbance was measured at 226.0 nm.

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EXPERIMENTAL

Instrumentation

Absorbance of the solutions are made with Systronics UV-Visible spectrophotometer 117 Model with resolution of 0.1 nm, wavelength accuracy of ± 1 nm and spectral band width of ± 2 nm. Alll chemicals and solvents were of analytical grade, procured from Merck speciality Pvt. Ltd., Mumbai.

Standard and sample solution of glimepiride

About 90 mg of glimepiride (bulk or formulation) was weighed accurately and dissolved in 100 mL of methanol in a volumetric flask to give a stock solution having 0.9 mg/mL concentration. Aliquots of stock solution were suitably diluted with methanol to give final concentrations of 2-32 μg/mL. The absorbance of the diluted solutions was measured at 226.0 nm against blank.

Assay procedure

Two commercial brands of glimepiride were procured one brand containing label claim of 1 mg and second brand has 2 mg of glimepiride. 20 tablets of each brand were weighed and ground to fine powder. Tablet powder equivalent to 10 mg of drug was transferred to 100 mL volumetric flask and it was dissolved and made up to mark with methanol. The solution was filtered through Whatmann filter paper No. 41 and it is suitably diluted to obtain a solution having concentration of 10 μg/mL. Now this solution was analyzed by the method described above. The amount of glimepiride was computed from the calibration curve.

Determination of glimepiride in the presence of additives

2 mg of glimepiride USP and starch (tablet additive) were taken in a 100 mL volumetric flask. To this, methanol was added, contents were mixed, filtered and the drug content was estimated, in a similar manner as given in the assay procedure. The same method was adapted for other tablet additives such as lactose, poly vinyl pyrrolidine K 30.

RESULTS AND DISCUSSION

In the proposed method, glimepiride showed absorption maxima at 226.0 nm. The calibration curve was found to be linear in the concentration range of 2.0 to 32.0 μg/mL. The optical characteristics such as absorption maxima, Beer's law limits, molar

absorptivity and Sandell's sensitivity are presented in Table 1. The regression analysis, using method of least squares was made. The slope (a), intercept (b) and correlation coefficient (r) obtained from the different concentrations and the results are summarized in Table 1.

The percent relative standard deviation and standard error were calculated from the six replicates of sample containing known amounts of the drug and the results are also shown in Table 1.

Table 1: Optical characteristics, precision and accuracy of proposed method

Parameter	Method
Absorption maxima (λmax) nm	226.0
Beers law limit (μg/mL)	2-32
Sandell's sensitivity (μg/cm^2/0.001 abs. Units)	0.0166
Molar absorptivity (litre. Mole^{-1}. cm^{-1})	2.944 x 10^6
Correlation coefficient (r)	0.9999
Regression equation (Y)*	Y = 0.0616 + 0.00967 X
Slope (a)	0.00616
Intercept (b)	0.00967
% RSD**	0.6161
Standard Error**	0.8416

*Indicates Y = a + b X when Y is absorbance and X is the concentration of glimepiride (μg/mL).

**Denotes six replicates.

To evaluate the accuracy and reproducibility of the proposed method, known amounts of pure drug were added to the previously analysed pharmaceutical preparations and the mixtures were analysed by the proposed method. The percent recoveries are given in Table 2.

Studies undertaken using tablet additives such as lactose, starch and PVP K 30 indicate that they did not interfere with estimation of glimepiride by the proposed method.

Table 2 : Estimation of glimepiride in pharmaceutical formulations

Name of the tablet	Claim as per label (mg)	Amount estimated (mg)	% label claim ± S. D.	S. E.
Glypride - 1	1	0.982	100 ± 1.9	2.595
	1	1.02		
	1	0.998		
Glimep - 2	2	1.982	101 ± 3.79	5.177
	2	1.996		
	2	2.12		

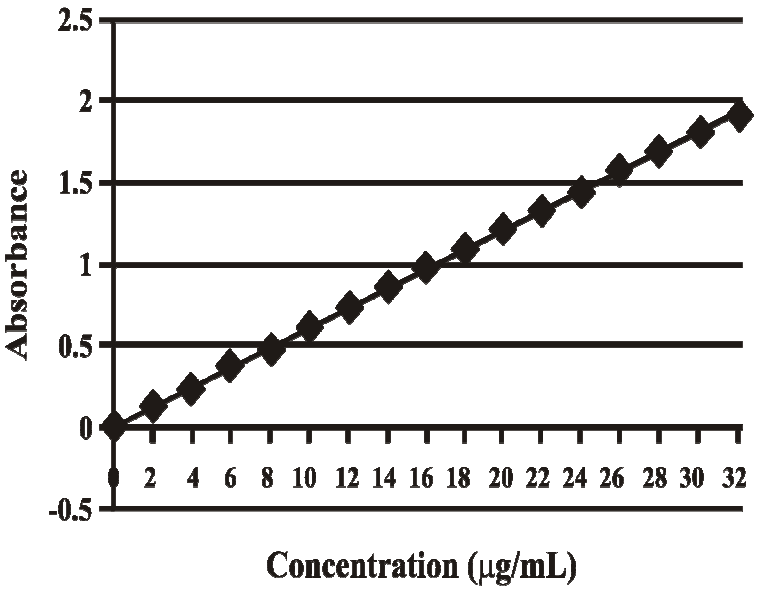

Fig. 1

Table 3 : Recovery studies

Amount of drug taken from tablets (mg)	Amount of standard drug added (mg)	Amount found* (mg)	% Recovery ± S. D.	Standard error
2	0.5	2.42	96.8 ± 2.27	3.101

Cont…

Amount of drug taken from tablets (mg)	Amount of standard drug added (mg)	Amount found* (mg)	% Recovery ± S. D.	Standard error
2	1	2.89	96.33 ± 2.26	3.087
2	2.0	3.91	97.75 ± 1.01	1.3797

*Mean of five replicates

Thus the proposed method is simple and sensitive with reasonable precision and accuracy. This can be used for the routine determination of glimepiride in Q. C. analysis.

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