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DEVELOPMENT OF NEW SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF GLICLAZIDE

Rajeshree Panigrahi[1]*, Saiprasanna Behera[1], Prasanta Kumar Choudhury[1], Gitanjali Mishra[2]

Lecturer in Royal College of Pharmacy and Health Sciences[1]
Principal in St. Ann's College of Pharmacy[2]
HOD in Dept. of Zoology, Berhampur University[3]

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***Corresponding author:** ranuroyal@gmail.com*
Phone No. - 09438251715

ABSTRACT

Simple, sensitive and specific Spectrophotometric method was developed and validated for quantification of Gliclazide in tablet dosage form. Drug showed the absorption maxima at 227 nm and was linear for a range of 5-30 mcg/ml with a correlation coefficient of 0.9997. The validation of the above method was done by carrying out precision and accuracy studies. The percentage recovery was found to be 99% and showed good repeatability with relative standard deviation less than 2. So, the proposed method can be applied for the routine analysis of Gliclazide from formulations.

Keywords: Spectrophotometric estimation, Gliclazide.

INTRODUCTION

Gliclazide, [1-(3-azabicyclo (3, 3, 0) oct-3-yl)-3-p-tolylsulfonylurea] is a second generation hypoglycaemic sulfonylurea which is useful in the treatment of non-insulin dependent diabetes mellitus (NIDDM) [1]. Prior reports reveal that the drug shows good tolerability, low incidence of hypoglycaemia, and a low rate secondary failure [2]. In addition, it has a potential for slowing the progression of diabetic retinopathy. For the reasons stated Gliclazide appears to be a drug of choice in long term sulfonylurea therapy for the control of NIDDM[2, 3]. Gliclazide is a white crystalline powder, relatively insoluble in water. The pKa of Gliclazide is 5.8. Gliclazide exhibits slow GI absorption rate and inter individual variations of its bioavailability[3]. The slow absorption rate of drug usually originates from either poor dissolution of drug from the formulation or poor permeability of drug across GI membrane. Gliclazide causes hypoglycemia by stimulating insulin release from pancreatic ß cells. Simple and reproducible Spectrophotometric method has been developed for the estimation of Gliclazide in pure and its pharmaceutical

formulations using 0.1N NaOH. The maximum absorbance was observed at 227 nm. Beer's law was obeyed in the concentration range of 5-30 µg/ml. The standard graph values are summarized and standard graph is plotted.

MATERIALS AND METHODS

Instrumentation and Materials:

All the spectral and absorbance measurements were made on an ELICO SL-59 UV-VIS spectrophotometer by using 1 cm quartz cells. Gliclazide used in the present investigation was purchased from Aurovindopharma, Hyderabad. Sodium Hydroxide used was of analytical grade.

Scanning and determination of maximum wavelength:

In order to ascertain the wavelength of maximum absorbance (λmax) of the drug, solution of drug concentration 10µg/ml and 20µg/ml in 0.1N NaOH were scanned using spectrophotometer within the wavelength range of 200-350 nm against 0.1N NaOH as blank. The absorbance curve showed characteristics absorbance maximum at 227nm as shown in Figure – 1 and Figure – 2.

Figure: 1 It shows the scanning report for 10mcg/ml for gliclazide using 0.1n NaOH solution having λmax as 227.2 and absorbance as 0.304nm

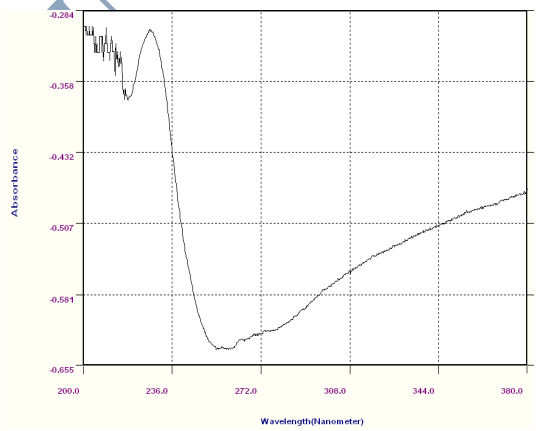
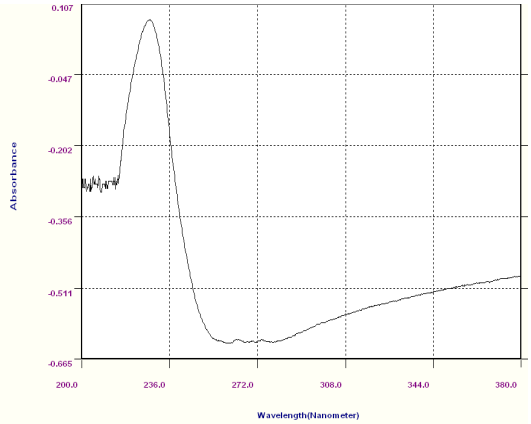


Figure: 2 It shows the scanning report for 20mcg/ml for gliclazide using 0.1n naoh solution having λmax as 227.7 and absorbance as 0.070 nm respectively



Preparation of standard solution

Stock solution of 1mg/ml (Pure drug) was prepared by dissolving 25 mg of Gliclazide in 25 ml of 0.1N NaOH. Further dilutions were made with 0.1N NaOH to get working standard stock solution of 100µg/ml.

Assay of Gliclazide in pharmaceutical dosage forms

Aliquots of working standard Gliclazide solution (0.5-5 ml: 1 ml = 100 µg) were transferred into a series of 10 ml graduated test tubes. Then the final volume was made up to 10 ml with 0.1N NaOH and absorbance was measured at 227 nm against a reagent blank. Requisite amount between 5-30 µg/ml of drug solution was taken and the absorbance was measured at 227 nm. The drug content in pharmaceutical dosage form was calculated using the standard curve. Results are reported in Table – 1 and calibration curve is plotted as shown in Figure- 3.

Validation [4, 5]:

The methods were validated with respect to Linearity, Accuracy and Precision.

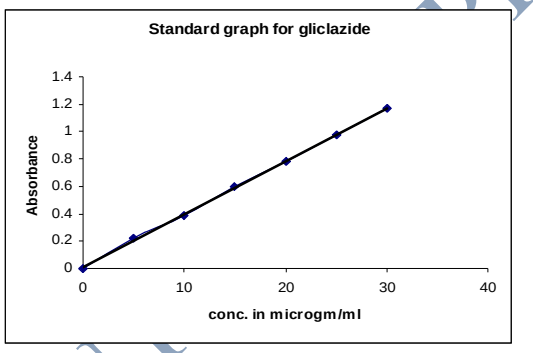
Accuracy[6, 7]

To determine the accuracy of drug, recovery studies were carried out by adding different amounts (80%, 100% & 120%) of bulk samples of Gliclazide within the linearity range were taken and added to the pre-analyzed formulation of conc. 10µg/ml. From that percentage recovery values were calculated. The results were shown in Table – 2.

Table 1. Calibration Curve of Gliclazide It shows the absorbance for different concentrations of drug solution

Sl. no	Concentration (µg/ml)	Absorbances (λmax=227nm)
1	0	0
2	5	0.22
3	10	0.39
4	15	0.601
5	20	0.781
6	25	0.997
7	30	1.174

Figure 3. It shows the statistical evaluation of the calibration plot



Y = 0.0388x + 0.0104
R^2 = 0.9995
R = 0.9997

Precision

The precision of the method was ascertained by actual determination of eight replicates of fixed concentration of the drug within the Beer's range and finding out the absorbance by the proposed method. From these absorbance mean, standard deviation (S.D), % relative standard deviation (%RSD) and percentage range of errors (at 0.005 and 0.01 confidence limits) was calculated. The reading was shown in Table – 3. Further optical characteristics and precision was calculated and reported in Table – 4.

Table 2. Accuracy- It shows the accuracy and % recovery studies of gliclazide

S1:80%	8	10	99.23	Mean = 99.14
S2:80%	8	10	98.46	S.D = 0.6443
S3:80%	8	10	99.74	%RSD=0.64%
S4:100%	10	10	98.46	Mean = 98.80
S5:100%	10	10	99.48	S.D= 0.588
S6:100%	10	10	98.46	%RSD=0.59%
S7:120%	12	10	99.48	Mean = 99.31
S8:120%	12	10	99.48	S.D= 0.2944
S9:120%	12	10	98.97	%RSD=0.29%

Table 3. Precision- It shows the precision studies of gliclazide

Sl.no	Concentration (µg/ml)	Absorbance (227 nm)	Statistical analysis
1	10	0.389	Mean = 0.387 SD= 0.0027% RSD = 0.693
2	10	0.390	
3	10	0.388	
4	10	0.387	
5	10	0.390	
6	10	0.382	
7	10	0.386	
8	10	0.390	

Table 4. Optical characteristics - It shows the optical characteristics of gliclazide

Parameters	Values
Absorption maxima (nm)	227nm
Beer's law limit (µg/ml)	5-30
Molar Absorptivity (L mol $^{-1}$ cm $^{-1}$)	14.19x10^{6}
Sandell's Sensitivity	0.022 (µg/cm^{2}/0.001 absorbance unit)
% Relative standard deviation	0.481
Correlation coefficient	0.9998
Regression Equation (Y*) Slope(a)	0.0388
Intercept(b)	0.0104

Y* = a X +b where 'X' is Concentration in µg/ml. and Y* is absorbance unit

RESULTS AND DISCUSSION

A UV-Spectrophotometric method was developed for Gliclazide determination. The analytical method is simple, sensitive, rapid and specific accurate, precise and reproducible and could be used for the routine estimation of quality control of Gliclazide in bulk and pharmaceutical dosage forms. Linear regression of absorbance on concentration gave the equation Y = 0.0388X + 0.0104 where X is the concentration in µg/ml and Y is the absorbance at 227nm with correlation coefficient R = 0.9997.This indicates a good linear relationship.

The proposed method shows absorption maxima at 227 nm obeyed beer's law in concentration range of 5-30 µg/ml. the percentage recovery value (99%) indicates that there is no interference of the excipients in the formulation. The low value of standard deviation and co-efficient of variations indicates that the proposed method was precise. All statistical data prove validity of the proposed method, which can be applied in industries for routine analysis of this drug from tablets.

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