Available online at http://www.journalijdr.com

IJDR

International Journal of
DEVELOPMENT RESEARCH

ISSN: 2230-9926

International Journal of Development Research
Vol. 06, Issue, 04, pp. 7464-7467, April, 2016

Full Length Research Article

SPECTROPHOTOMETRIC DETERMINATION OF AN ANTIDIABETIC DRUG GLIMEPIRIDE BULK AND PHARMACEUTICAL FORMULATIONS

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ARTICLE INFO

Article History:

Received 29th January, 2016
Received in revised form
02nd February, 2016
Accepted 30th March, 2016
Published online 27th April, 2016

Key Words:

Glimepiride,
Spectrophotometric method,
Diabetes1, 10-phenanthroline (O-PHEN),
Glimstar-1 Marketed formulation.

ABSTRACT

A new, simple, precise, sensitive, accurate, and reproducible spectrophotometric method have been developed for the determination of Glimepiride in pure and dosage forms. Method is based on oxidation of the drug with 1,10 phenanthroline producing orange colored chromogen which is measured at 470 nm. Beer's law is obeyed in the concentration range of 0.8-8.0 µg/mL for the developed method.The molar absorptivity and Sandell's Sensitivity are found to be9199.14 L $mol^{-1}cm^{-1}$and 0.053 µg/cm^2 respectively. The regression equation for Glimepiride as found to bey= 0.0184X - 0.0013and the correlation coefficient for the regression line was 0.9943. Different experimental parameters affecting the color development and stability of colored product are carefully studied and optimized. The developed method could be successfully applied to pharmaceutical formulations. The results obtained are in good agreement with those obtained using standard method.

INTRODUCTION

Glimepiride is an oral anti diabetic belongs to the class of sulfonylurea. It is chemically describe as 1-[[p-[2-(3- ethyl-4 methyl-2-oxo-3-pyrroline-1carboxamido)ethyl] phenyl] sulfonyl] -3-(trans-4- methylcyclohexyl) urea (C24H34N4O5S) with a molecular weight of 490.62. (Khedekar*et al*., 2010; Lakshmi*et al*., 2009). Glimepiride is a white to yellowish-white, odorless, crystalline powder and is practically insoluble in water.Glimepiride acts as an insulinsecretagogue (Lakshmi and Damm*et al*., 1990). It lowers blood sugar by stimulating the release of insulin by pancreatic beta cells and by inducing increased activity of intracellular insulin receptors. Literature survey reveals that several methods have been developed for the quantitative determination of Glimepride in plasma and urine.These include HPLC (Lehr and Damm, 1990; Sane*et al*., 2004; Rabbaa-Khabbaz*et al*., 2005) and LC (Khan*et al*., 2004), UV spectrophotometry (Altinöz and Tekeli, 2001) and HPTLC (Sane*et al*., 2004). The aim of the present work is to develop simple accurate, precise and validated method for determination of Glimepiride in tablets, which therefore serves as a tool for the quality control of pharmaceutical dosage forms.

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Experimental

Instrumentation

An ELICO SL-159 model, 2nm high resolution, double beam, 1cm length quartz coated optics; Wavelength range190-1100nm; High stability, linearity, precision instrument is used for all the spectral measurements. All chemicals and reagents used in the analysis are of analytical grade and doubly distilled water is used for the preparation of all the solutions.

MATERIALS AND METHODS

Preparation of Standard solution of drug

An accurately weighed 2 mg of Glimepiride is dissolved in methanol.The final volume is adjusted with methanol (1:1)to 100ml in standard flask. Working solution prepapared by suitable dilution of this solution.

Preparation of Reagents

0.241%(w/v)Fe (III) solution is prepared by dissolving 241mg of anhydrous ferric ammonium sulphate in 100mL of double distilled water, 0.991% (w/v) o-phenanthroline is prepared by dissolving 991mg of the reagent in 100mL of alcohol and 0.15% (v/v) O-phosphoric acid solution is prepared by diluting

1.5 mL of laboratory reagent (AR Grade) of o-phosphoric acid to 1000mL with distilled water.

Experimental Procedure

Different portions (1.0- 10.0 mL, 0.8 µg/mL) of standard Glimepiride solution is delivered into a series of 25mL calibrated standard flask and then 1.0 mL of $5.0x10^{-3}$M of Fe (III) solution, 1.0mL of $5.0x10^{-2}$M o-phenanthroline are added successively. The total volume in each flask is brought to 16mL with distilled water. The flasks are kept on a boiling water bath for 30minutes. The flasks are removed and cooled to room temperature.2.0mL of $2.0x10^{-2}$M of o-phosphoric acid is added and volume in each flask is made up to the mark with distilled water. The absorbance of the colored complex solution is measured after 5minute against a reagent blank prepared under the identical conditions at 470nm (Fig.1A). The amount of the Glimepiride is computed from the appropriate calibration graph (Fig.2).

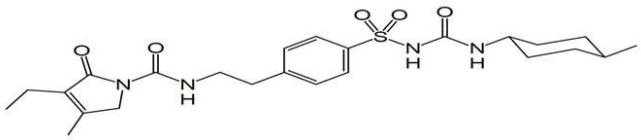

Figure 1. Chemical Structure of Glimepiride

Analysis of pharmaceutical sample

Tablets powdered equivalent to 2 mg of the drug is weighed accurately and transferred into 250ml beaker and shaken with 25 ml methanol and filtered into 100ml standard flask,wash with methanol (1:1) and volume is adjusted with methanol (1:1). Suitable aliquots of this solution used for the determination of Glimepiride contents by procedure describe earlier.

Absorption spectra

The absorbance of the colored complex solution is measured against a reagent blank prepared under identical conditions from 395 to 510 nm and maximum absorbance is found to be at 470 nm

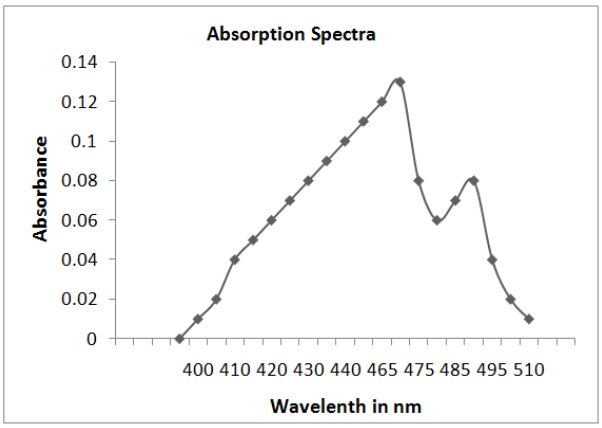

Fig. 1A. Absorption spectra glimepiride with Fe (III)/O-PHEN

Calibration curve

The calibration curve is plotted between absorbance values and amount of drug (concentration of drug). The calibration curve is found to be linear over a concentration range of 0.8 to 8.0 µg/ml of Glimepiride.

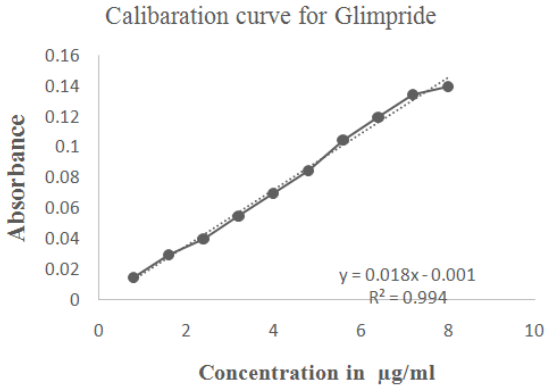

Fig. 2.Linear plot of Glimepiride with Fe (III)/O-PHEN

Effect of heating time

It is observed that 25 minutes are sufficient for full colour development hence 30 minutes time is selected for further studies.

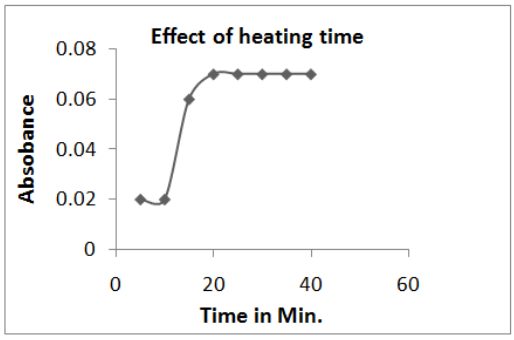

Fig.3. Effect of heating time

Effect of concentration of H_3PO_4

It is observed that there is no change in absorbance for varing concentration of H_3PO_4.Hence 0.02M H_3PO_4 is used for colour development and further studies.

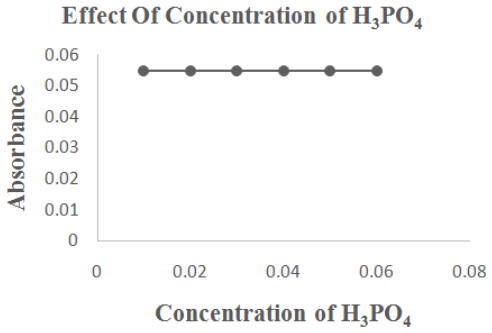

Fig.4. Effect of concentration of H_3PO_4

Effect of concentration of 1,10 phenanthroline

It is observed that absorbance remains constant after 0.02 M concentration of 1,10 phenanthroline.Hence we have used 0.05 M for colour development and further studies.

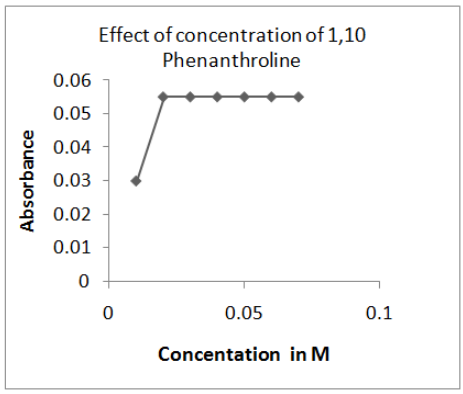

Fig.5. Effect of concentration of 1,10 phenanthroline on absorbance of developed system

RESULTS AND DISCUSSION

In order to test whether the colored product formed in this method adhere to Beer's law, the absorbance at maximum wavelength of a series of ten concentrations are plotted against concentration of the drug in µg/mL (Fig2). Beer's law is obeyed within the limits 0.8-8.0 µg/mL of Glimepiride, molar absorptivity and Sandell `s sensitivity is found to be9199.14L $mol^{-1}cm^{-1}$and 0.053 µg/cm^2 .Regression analysis of the Beer's law plots at λ_{max} reveals a good correlation. The graphs show negligible intercept and are described by the regression equation y = 0.0184X - 0.0013 and the correlation coefficient for the regression line was 0.9943.(where Y is the absorbance of 1 cm layer, b is the slope, a is the intercept and C is the concentration of the measured solution in µg/mL). The high molar absorptivity of the resulting colored complex indicate the high sensitivity of the method.Precision of the developed method is ascertained from the absorbance values obtained by actual determination of ten replicates of a fixed amount of the test in total solution.

linearity limits are prepared and analyzed by the developed method. The percent recoveries of the drug by this method is found to be within the range which indicates that the developed method is accurate. Optical characteristics, linear regression parameters, precision and accuracy of the proposed method is shown in Table-1.

The method have been successfully applied for the determination of Glimepiride in pharmaceutical preparations.[a]Regression equation Y=a+bC , Where Y stands for absorbance and C is concentration in µg/mL [b]%Relative standard deviation is calculated for ten determination. The proposed method has been used for the analysis of Glimepiride.The result obtained are comparable with stanadard method(Table- 2).

Scheme of coloured product

Ferric salt converts into a ferrous salt upon oxidation and can be easily detected by the usual reagent o-phenanthroline. The reduction product is tris complex of Fe (II), well known as ferroin. The colored prodct of the reaction is given below.

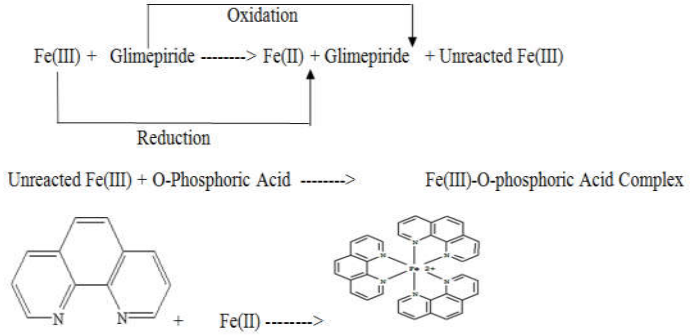

Table 1. Optical characteristics, Regression parameters, Precision and Accuracy of the proposed method

Parameters	Results
Maximum Wavelength λ_{max}	470 nm
Beer's Law Limits µg/mL	0.8-8.0 µg/mL
Sandell's Sensitivity (µg/cm^2 /0.0001 Absorbance)	0.053 µg/cm^2
Molar Absorptivity L $mol^{-1}cm^{-1}$	9199.14 L $mol^{-1}cm^{-1}$
Slope(b)[a]	0.0184
Intercept(a)[a]	-0.0013
Standard Deviation on intercept(S_a)	0.003079
Standard Deviation on slope (S_b)	0.000552
Correlation Coefficient (r)	0.9943
Standard Deviation (S)	1.449
%RSD	1.832
Variation from mean at 95% level confidence limit	±1.0356
Limit of Detection (LOD)µg/mL	0.5707
Limit of Quantification (LOQ)µg/mL	1.7295

Table 2. Analysis of Pharmaceutical Formulations of Glimepiride

Drug	Manufacturing company	Labelled amount(mg)	*Amount found by Proposed Method(mg)	*Amount found by Referrence Method(mg)
Glimepiride	Glimstar-1 Marketed formulation	1	0.988	0.991

* Average of three determinations

The percent of relative standard deviation and Variation from mean at 95% level confidence limit percent are calculated for the developed method. To determine the accuracy of the method, three different amounts of drug sample within the

Conclusions

The developed method is simple, sensitive, accurate and reproducible. This method can be successfully applied for the analysis of pharmaceutical formulations in any laboratory.

Acknowledgements

The authors are thankful to Principal VES College of Arts Science and commerce, Chembur for providing laboratory facilities.

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