Available online on 15.07.2024 at http://jddtonline.info

Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Full Text Article

Research Article

Method development and validation for estimation of Gliclazide in bulk and tablet form by UV Spectrophotometer

Ravindra Hanwate *[1, 3], Bhupendra Singh [2], Nilesh Khairnar [3], Sushmita Chavan [3]

[1] *Research Scholar, Teerthanker Mahaveer University, Moradabad UP India*

[2] *Professor, Teerthanker Mahaveer University, Moradabad UP India*

[3] *Dept of Pharmaceutics, Valmik Naik College of Pharmacy, Telwadi Kannad Dist Aurangabad 431103*

Article Info:

Article History:

Received 19 April 2024
Reviewed 26 May 2024
Accepted 20 June 2024
Published 15 July 2024

Cite this article as:

Hanwate R, Singh B, Khairnar N, Chavan S, Method development and validation for estimation of Gliclazide in bulk and tablet form by UV Spectrophotometer, Journal of Drug Delivery and Therapeutics. 2024; 14(7):6-9

DOI: http://dx.doi.org/10.22270/jddt.v14i7.6675

*Address for Correspondence:

Hanwate Ravindra, Research Scholar, Teerthanker Mahaveer University, Moradabad UP India

Abstract

UV Spectrophotometric method has been developed to determine Gliclazide in bulk pure and tablet forms. It is a simple, accurate, reproducible, rapid and less time-consuming method. The maximum wavelength of the drug was found to be 232nm. Beer Lamberts' law was obeyed in the concentration range of 2-20 µg/ml. (LOD)The limit of detection and limit of qualification (LOQ) was found to be 0.16 µg/ml and 0.50 µg/ml from this method per cent recovery of the drug was found to be 99.30% which indicates no interaction of the excipients. This method was found accurate, simple, precise and rapid for determination of tablet dosage form.

Keywords: validation, Gliclazide, tablets, UV Spectroscopy, LOD, LOQ

INTRODUCTION

Gliclazide is oral hypoglycemic drug which belong to second generation sulphonylureas. Chemically it is [1-(1-azabicyclo (3, 3, 0) octyl)-3-(p-tolylsulphonylurea)] (Figure 1)

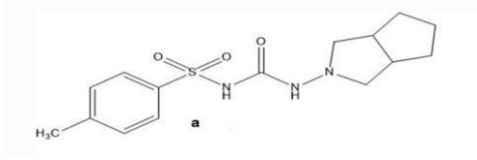

Figure 1: Chemical structure of Gliclazide

The mechanism of action of Gliclazide may reverse insulin resistance in type-II diabetic patients and improve defective insulin secretion. It is readily absorbed from the gastro-intestinal tract with peak concentrations in plasma occurring about 2-4 h and it is highly protein bound [1-3]. Various analytical methods have been reported for the estimation of the drug including HPLC, Gas chromatography, radioimmunoassay, and Evaporative Light Scattering Detection [4-8] However, no UV spectrophotometric method is available for quantitative determination of Gliclazide in its pharmaceutical dosage forms. Some reported analytical methods involve time-consuming and laborious extraction steps [5, 6], lengthy retention time or large volume of biological samples [5, 6], use of mass spectroscopy for detection and identification of drug or solid phase extraction processes [9-11]. The present aim of the study is to develop a simple, rapid, accurate and specific UV spectrophotometric method for the estimation of Gliclazide in pharmaceutical dosage forms. The method was further validated for the parameters like precision, accuracy, sensitivity and linearity. The limit of detection (LOD) and limit of quantification (LOQ) were also determined. The results of the analysis were validated statistically and by recovery studies. The proposed method is recommended for routine analysis since it is simple, accurate, rapid, and sensitive.

MATERIALS AND METHOD

Instruments and Reagents:

Gliclazide was procured as a gift sample from J B Chemicals Thane. All the reagents used in the study were of analytical grade. Distilled water is used throughout the study. Different brands of tablets were procured from local medical shops. These are of brand glycogen by USV Ltd and glycol by Cedilla Pharmaceuticals. UV/VIS 1600 spectrophotometer with 1 cm matched quartz cells was used for the estimation manufactured by A Shimadzu, Japan

Selection of solvent:

The solubility of Gliclazide is determined in a variety of solvents as per pharmacopoeia standard. Solubility test was

carried out in different solvents like methanol, ethanol, and 0.1N sodium hydroxide. From the solubility studies, it was found that Gliclazide is soluble in methanol and 0.1N sodium hydroxide. In this study, methanol was selected as the solvent.

Preparation of standard stock solution of Gliclazide

An accurately weighed 5 mg of Gliclazide was dissolved in 10 ml of methanol in a 50 ml volumetric flask and the volume was adjusted up to the mark with distilled water to obtain a stock solution of 100 µg/ml. The solution was filtered through Whatman's filter paper No. 41.

Determination of λmax:

The standard solution of Gliclazide (10µg/ml) was scanned in the UV region (200-400nm) and the spectrum was recorded. The solvent was used as blank. It was seen that at 232nm maximum absorbance was found, as shown in Figure 2. Therefore, 232nm was selected for this study.

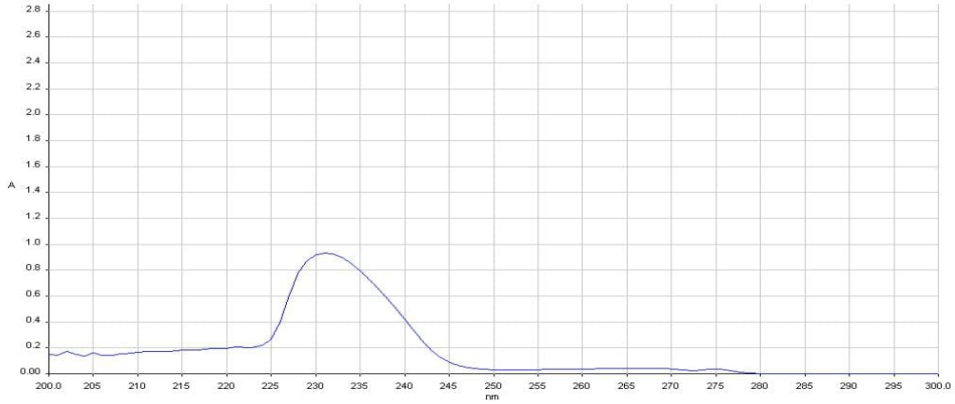

Figure2: absorbance spectra of Gliclazide

RESULTS

Method Validation:

The objective of method validation is to demonstrate that the method is suitable for its intended purpose. The method was validated for linearity, precision, accuracy, robustness, ruggedness, LOD, LOQ, and specificity as per ICH guidelines

Linearity:

Using the standard stock solution, the various dilutions in the concentrations of 2, 4, 6, 8, 10, 12, 14 16, 18, and 20 were prepared. (Table 1) The solutions were scanned at 232 nm and the absorbance was recorded, given in Table 1. From this calibration curve was obtained by plotting absorbance versus concentration of Gliclazide and the linearity graph was represented in Figure 3. The correlation coefficient was found to be 0.997

Table1: linearity parameter

Sr no.	Concentration(µg/ml)	Absorbance
1	2	0.057
2	4	0.1532
3	6	0.2512
4	8	0.3168
5	10	0.4355
6	12	0.501
7	14	0.616
8	16	0.6911
9	18	0.8255
10	20	0.9129

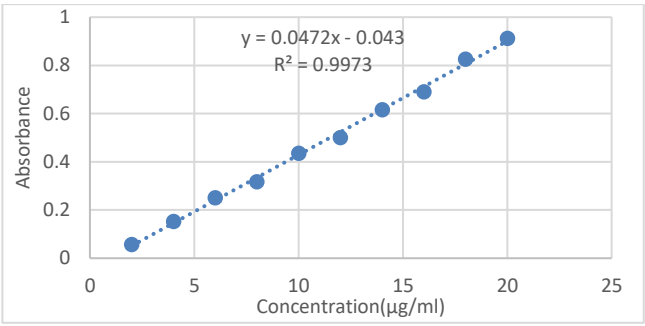

Figure 3: linearity graph of Gliclazide

Precision:

Repeatability of method was checked by scanning 10µg/ml of solution for 6 times. Intra-day precision was determined by checking the absorbance of (10µg/ml) on the same day. Inter-day precision was determined by checking the absorbance of (10µg/ml) on three different days. The %RSD was found to be 0.74% for intra-day and 0.95% inter-day as shown in table 2.

Table2: Precision parameter for Gliclazide

Scan	Intraday	Interday
1	0.4350	0.4320
2	0.4392	0.4395
3	0.4364	0.4360
4	0.4396	0.4384
5	0.4350	0.4306
6	0.4320	0.4326
mean	0.4345	0.4327
SD	0.003212	0.00412
% RSD	0.73	0.92

Accuracy:

The accuracy study was conducted by spiking at three different concentration levels (80%, 100%, and 120%). At each level samples were scanned and from the absorbance recovery percentage was determined.

Limit of detection and Limit of quantification:

Limit of detection is the lowest amount of an analyte in a sample that can be detected, but not necessarily quantified, under the stated experimental conditions. The limit of quantification is the lowest amount of analyze in a sample that can be quantified under stated experimental conditions. The LOD and LOQ for Gliclazide were found to be 0.15µg/ml and 0.50µg/ml.

Assay of Gliclazide tablets:

Two different brands of Gliclazide were analyzed using the validated method. For the analysis, six replicates of each brand were assayed. 20 tablets of Gliclazide were weighed and finely powdered. An accurately weighed quantity of powder equivalent to 50mg of Gliclazide was taken in a 50-volumetric flask. 10ml of methanol was added to it followed by 20ml of solvent. The solution was sonicated for 15 min and then filtered through Whatman's filter paper No.41 and volume was adjusted with the solvent. From this further dilution was made to get a final concentration of 10µg/ml. The absorbance of the sample solution was measured and the amount of Gliclazide was determined by referring to the calibration curve. The results were presented in

table 3.

Table 3: assay of Gliclazide tablets

Sample	Label claim (mg)	Amount found (mg)	% amount found
Glycogen	10	9.80	98.2
Glycol	10	9.95	99.3

DISCUSSION

The method was validated and developed as per ICH guidelines. The method was validated in terms of linearity, precision, accuracy, robustness, ruggedness, LOD, LOQ and specificity. Beer's law is obeyed over the concentration range of 2-20 µg/ml, using regression analysis of the linear equation y = 0.047x-0.043 with a correlation coefficient of r2=0.0997. The precision results show a % RSD of less than 2 at each level, which indicates clearly that the method is precise enough for the analysis of Gliclazide. The accuracy of the method was checked by recovery studies. The high recovery values indicated the accuracy of the developed method. The robustness and ruggedness studies reveal that the method is enough robust and rugged. The LOD and LOQ values indicate the sensitivity of the method. There was no interference observed from the excipients present in the formulation, indicating that the method is specific. Determination of Gliclazide in tablet formulation of two brands showed content of Gliclazide was very close to the labeled amount. The %RSD values in all the parameters were within the acceptable limit. The optical characteristics of the method are represented in Table 4.

Optical characteristics

Table represents the optical characteristics and precision of the proposed method for estimation of Gliclazide.

Table 4: Validation parameters for standard Gliclazide

Parameter	Value
λmax (nm)	232
Beer's range (µg/ml)	2-20
Molar absorptivity (l/mol/cm)	1.4962×104
Correlation coefficient (r2)	0.9970
Regression equation	y = 0.047x-0.043
Sandell's sensitivity (µg/cm2 /0.001AU)	0.021616
Intercept (a)	-0.2104
Slope (b)	0.0463
Limit of detection (LOD µg/ml)	0.31
Limit of quantification (LOQ µg/ml)	0.92
Precision (% RSD)*	0.56

* Indicates mean of six determinations (n=6)

CONCLUSION:

An approved UV Spectrophotometric technique has been produced for the assessment of Gliclazide in mass as well as drug measurement's structure. The created technique was viewed as simple, exact, precised, specific and reproducible and straight over the fixation range examined. The proposed technique can be utilized for routine examination of Gliclazide in mass as well as drug details.

Conflict of Interest

The authors affirm that they have no known financial or interpersonal conflict that might have looked to have an impact on the research performed in this paper.

Acknowledgement

Authors are thankful to JB Chemicals thane for providing gift sample of drug. The required resources to perform work provided by Valmik Naik College of Pharmacy, Telwadi Kannad, for which the authors are grateful.

REFERENCES:

1) Tripathi KD. Essentials of Medical Pharmacology; Jaypee Bros. Medical Publishers, New Delhi, 2008, Ed. 7, 266. https://doi.org/10.5005/jp/books/10282

2) Samina AJ, Snehal PM, Poonam SK, Yogesh VP, Kishor BB. Development and validation of UV spectrophotometric method for the determination of gliclazide in tablet dosage form. Der Pharma Chemica. 2011; 3 (4):338-343.

3) Brunton LL, Lazo JS, Parker KL. Goodman and Gillman's The Pharmacological basis of therapeutics. 11thed. Mcgraw-Hill medical publishing division, New York. 2006.

4) Aburuz S, Millership J, McElnay J. The development and validation of liquid chromatography method for simultaneous determination of glipizide, gliclazide, glibenclamide in plasma. J Chromatogr B.2005;(817): 277-282. https://doi.org/10.1016/j.jchromb.2004.12.018 PMid:15686996

5) Revathi R, Saravanan VS, Mohan RP, Ethiraj T, Ganesan V. Spectrophotometric estimation of gliclazide in bulk and pharmaceutical dosage forms. International Research Journal of Pharmacy.1 (1); 2010: 277-281.

6) Amit A, Hemant KJ. Development and validation of RP-HPLC method for estimation of gliclazide in bulk and tablet dosage form. American Journal of PharmTech Research. 2015; 5(3): 658-667.

7. Amruta BL, Minal RG, Sawant SD. Simultaneous UV spectrophotometric method for estimation of gliclazide and metformine hydrochloride in tablet dosage form. Der Pharma Chemica. 2012; 4 (3): 854-859.

8. Jugasmita K, Prakash KV, Manasa G, Praveena R. Method development and validation of gliclazide in API and its pharmaceutical dosage form by UV-visible spectrophotometry. Research and reviews: Journal of Pharmacy and Pharmaceutical Sciences. 2014; 3(3): 33-36.

9. Lopamudra A, Ghatak S, Mishra US, Murth PN. Zero order and first order derivative method development and validation of gliclazide in its bulk and pharmaceutical dosage form. Der Pharmacia Sinica. 2011; 2 (4): 295-300.

10. Rajeswari R, Jeyaprakash K, Bioactive potential analysis of brown seaweed Sargassum wightii using UV-VIS and FT-IRM Journal of Drug Delivery and Therapeutics. 2019;9(1):150-153 https://doi.org/10.22270/jddt.v9i1.2199

11. Ramu B, Chandrul KK, Pandiyan PS, Bio-Analytical Method Development of Repaglinide Drug Delivery Systems, Journal of Drug Delivery and Therapeutics. 2019;9(6):140-142 https://doi.org/10.22270/jddt.v9i6.3718