Available online on www.ijddt.com
International Journal of Drug Delivery Technology 2018; 8(3); 121-126
doi: 10.25258/ijddt.8.3.2

ISSN: 0975 4415

Research Article

Novel First Order Derivative UV Spectrophotometric Method for the Determination of Glimepiride in Solid Dosage Forms

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Received: 2nd Jan, 18; Revised: 21st Jul, 18, Accepted: 31st Jul, 18; Available Online: 25th Sep, 2018

ABSTRACT

Objective: An easy, perfect, specific and exact process has been studied for the simultaneous estimation of Glimepiride pure drug form as well as tablet dosage forms. Methods: A UV method for quantitative evaluation of Glimepiride by first order derivative peak detect method for determination in bulk as well as tablet dosage form is reported as there was a need to expand novel methods to analyze the drug. Results: Glimepiride has absorbance first derivative maxima at 225 nm in Methanol. Glimepiride follows Beer's law in concentration range of 5-25µg/ml. The outcomes of the study were validated statistically and recovery studies were performed as per ICH guide lines. Conclusion: Thus the projected method can be applied competently for the estimation of Glimepiride in regular analysis in its dosage forms.

Keywords: Glimepiride, first order derivative method, UV Spectrophotometric peak determination.

INTRODUCTION

Glimepiride is 1-[[p-[2-[3-ethyl-4-methyl-2-oxo-3-pyrrolinepyrroline-1-carboxamido] ethyl]-phenyl]-sulfonyl]-3-[trans-4-methylcyclohexyl] urea[1].

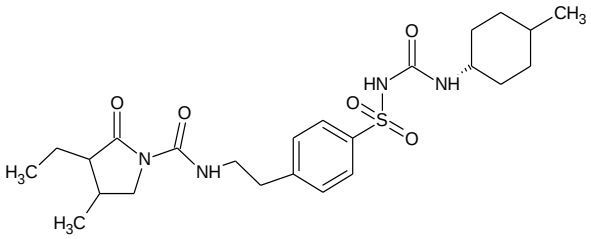
Glimepiride is used with a proper diet exercise program to control high blood sugar in people with type 2 diabetes . It may also be used with other diabetes medications. Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, loss of limbs, and sexual function problems. Proper control of diabetes may also lessen your risk of a heart attack or stroke. Glimepiride belongs to the class of drugs known as sulfonylureas. It lowers blood sugar by causing the release of the body's natural insulin[2].

Review literature revels that lot of work has been carried out for routine analysis of drugs in exiting formulation and bulk drug. A number of references are available for the present study to develop analytical method. On literature survey, it was found that different methods for determination of Glimepiride have been reported. Validated RP-HPLC for determination of Glimepiride [3-6], Analysis of Glimepiride by HPLC[7] and Estimation by UV spectrophotometric method[8]. However, there is no first order derivative UV spectrohotometric peak detect method found for estimation of Glimepiride. So there is need for development of new method.

MATERIALS AND METHODS

Materials

Shimadzu 1800 spectronic UV Spectrophotometer with 1cm matched quartz cells was used for data collection and analysis. Methanol was used as a solvent for drug substance.



Methodology

Preparation of standard stock solution

The standard stock solution was arranged by transferring 50 mg Glimepiride in to a 100 ml volumetric flask. 50 ml Methanol was transfered in to this volumetric flask and then shaked well and dissolved. Then the quantity was prepared up to the mark with Methanol to give a solution containing 1000 µg/ml Glimepiride. From this solution 5 ml was transfer to 50 ml volumetric flask besides the volume was attuned in the direction of the mark using the Methanol to give a solution containing 100 µg/ml of Glimepiride.

Determination of λ max

Accurate volume 2.5 ml of standard stock solution of Glimepiride was transfered to 50 ml volumetric flask & the volume were adjusted to the mark with methanol as solvent to get the solution of concentration 5 µg/ml. After that the prepared solution was scanned in the UV range 221-250 nm. The λ max was found to be 225 nm. The spectrum of Glimepiride was recorded. (Figure 1)

Stability of Drug in Selected Solvent

The stability of the drugs in the selected solvent was found by evaluate the absorbance of the drug solutions (10µg/ml) at different time interval. After the every 15 mins the

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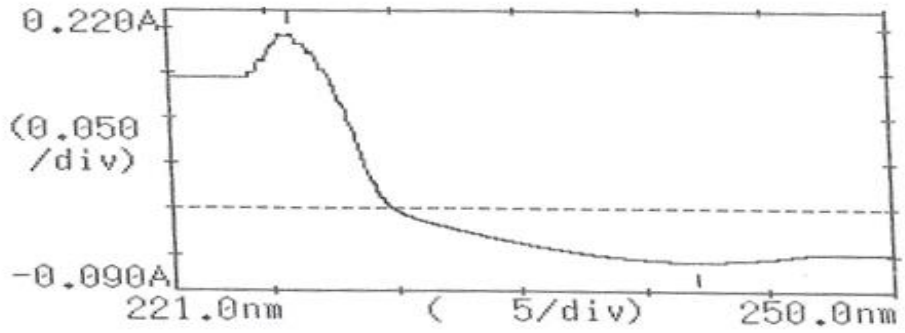

Figure 1: First derivative Spectrum of Glimepiride

Table 1: Stability Data for Glimepiride.

Sr. No.	Time (min)	Absorbance
1	0	0.051
2	15	0.055
3	30	0.050
4	45	0.053

Table 2: Standard Calibration Table for glimepiride 225 nm.

Sr. No.	Concentration of Glimepiride (µg/ml)	Absorbance at 225 nm
1	5	0.028
2	10	0.051
3	15	0.085
4	20	0.114
5	25	0.141

Table 3: Assay of Glimepiride in Tablet Form.

Amount Taken (mg/tablet)	Amount found (mg/tablet)	Amount found (%)
1	0.99	95.34
1	1.04	100.65
1	1.03	100.55
1	0.95	99.28
1	1.04	100.65
	Mean	99.294
	SD	2.2852
	CV	0.0230

absorbance was calculated. For Glimepiride the stability data is given in table 1 below:

Selection of Analytical Wavelength Range

By the use of Shimadzu 1800 spectronic UV-Visible Spectrophotometer the derivative spectra of Glimepiride were taken at N=2 & the standard solutions of Glimepiride in Methanol (5µg/ml each) subjected to a scan 221nm to 250 nm. The λ max was found to be at 225 nm. The first order derivative of the spectra's with N=2 were proposed to proceed for selection of analytical wavelength.

Linearity

From the standard stock solution of Glimepirde, appropriate aliquots were pipette out into 50 ml of volumetric flask and dilutions were made with methanol for working standard solution of Glimepirde 5, 10, 15, 20, 25 µg/ml. The difference in amplitude of Glimepirde were measured in the first derivative mode with N=2 of instrument at 225 nm. The calibration curve of the drug Glimepirde was plotted. (Figure 2) The concentration range over which the drug followed linearity was chosen as an analytical concentration range i.e. 5-25 µg/ml for Glimepirde.

(Table 2, Figure 3 to 7)

Validation of the proposed method:

Estimation of Drug (Glimepiride) from Dosage Form: (Tablet Assay Study)

Brand name: GLIMESTAR ® - 1

Standard

From the standard stock solution of Glimepiride, appropriate aliquots were pipette out into 50 ml of volumetric flask and methanol is used for dilutions to obtain standard solution of Glimepiride 10µg/ml. This concentration was scanned at wavelength of 225nm in derivative mode with N=2.

Sample

For analysis of marketable tablet formulation; brought the marketed brands tablet strips of Glimepiride. Total weight of the all tablet was recorded. Afterward separately take 10 tablet weights. Crush the tablet by using mortar. Then calculated weight to be taking followed by prepare the 100 µg/ml stock solution. Prepare the 10 µg/ml solution and take the absorbance at 225 nm. These concentrations were scanned at wavelength of 225 nm in derivative mode with N=2. Results are shown in following table: (Table 3)

Accuracy (Recovery Study)

Accuracy of method was studied by using recovery experiments. The recovery study was carried out by adding known amount of powder sample from capsule. Recovery was performed at 3 levels, 80, 100 and 120% of Glimepiride standard concentration. The recovery samples were prepared in before mentioned procedure. 3 samples were prepared for each recovery level. The solutions were analyzed. % recoveries were calculated by using following formula:

$$\% \text{ Recovery} = \frac{\text{Observed amount of compound in sample}}{\text{Amount of all compound present in sample}} \times 100$$

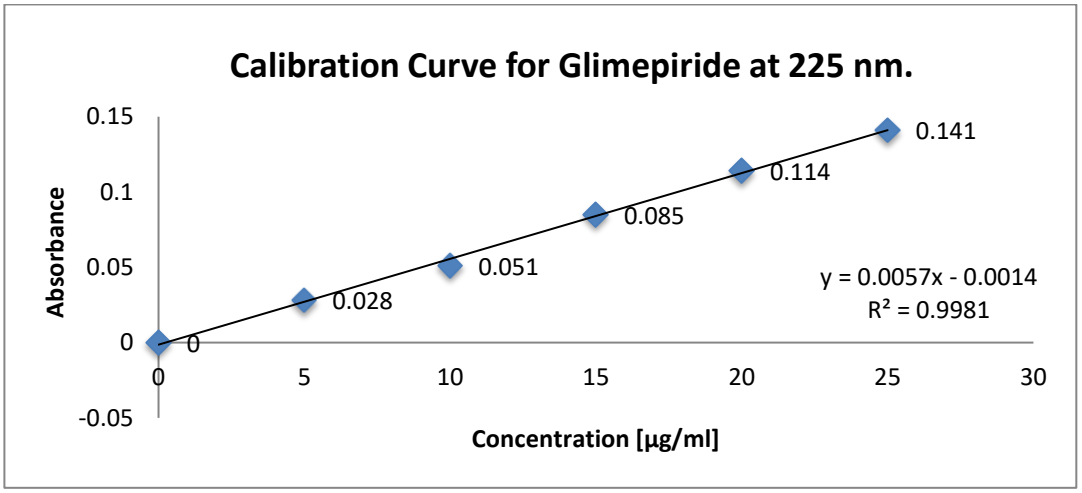

Figure 2: Standard Calibration Curve for Glimepiride at 225 nm.

The following Figures represent the linearity of Glimepiride at 225 nm.

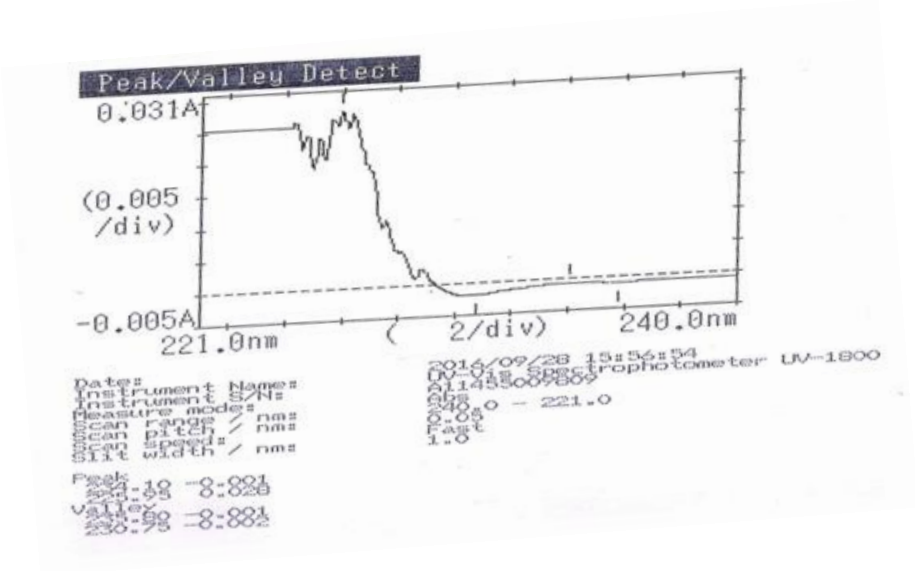

Figure 3: First derivative spectrum of Glimepiride concentration 5µg/ml.

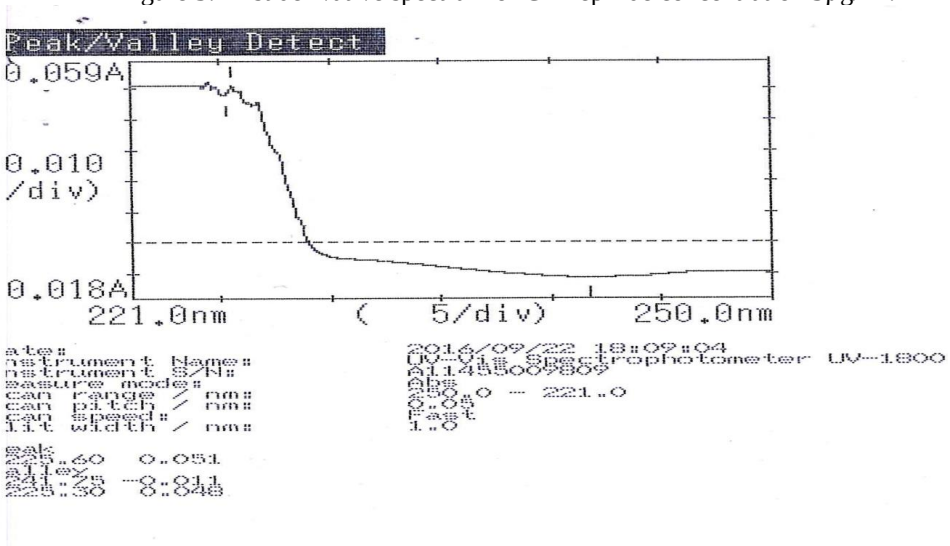

Figure 4: First derivative spectrum of Glimepiride concentration 10 µg/ml.

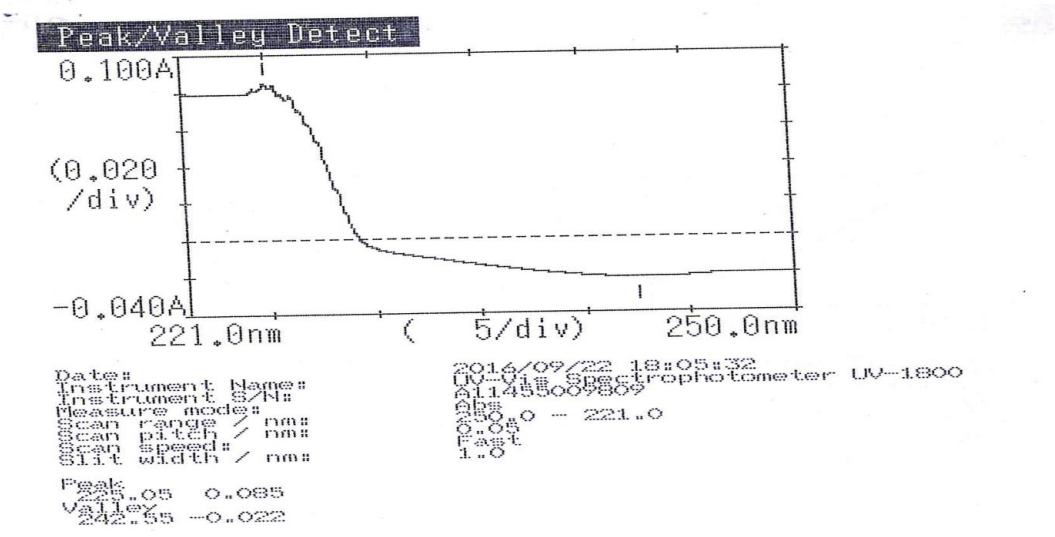

Figure 5: First derivative spectrum of Glimepiride concentration 15 µg/ml.

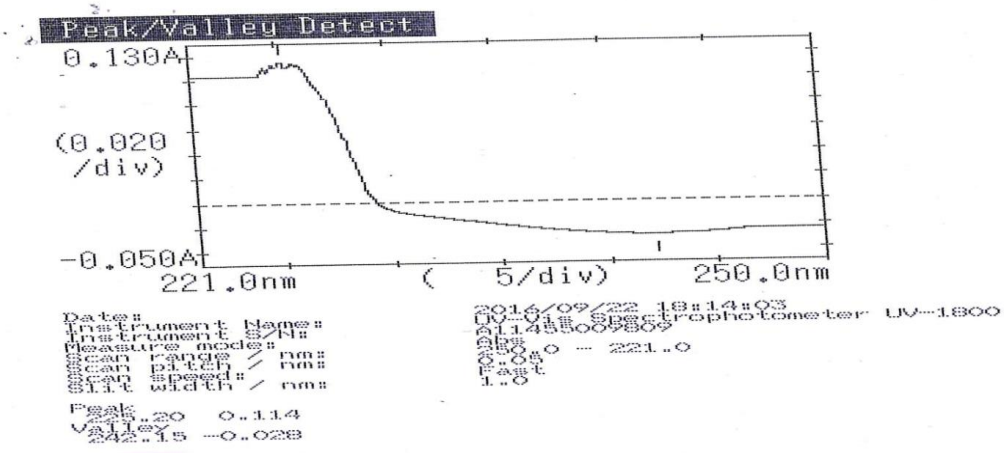

Figure 6: First derivative spectrum of Glimepiride concentration 20 µg/ml.

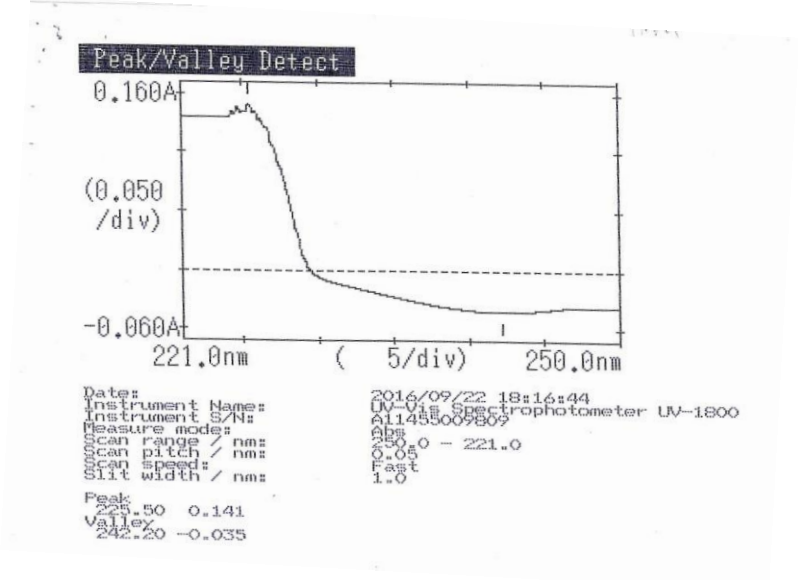

Figure 7: First derivative spectrum of Glimepiride concentration 25 µg/ml.

The recovery values are summarized in following table:

Precision

The precision (inter–day) was evaluated by using four independent sample of Glimepiride. Intermediate precision (inter-day precision) of the process was also

Table 4: Accuracy parameters.

Level of % Recovery	Amount present (mg)	Amount of standard added (mg)	Total amount recovered (mg)	% Recovery	% mean Recovery	SD	CV
80	1	80	79.38	99.225			
80	1	80	80.12	100.15	99.71	0.4643	0.0046
80	1	80	79.81	99.76			
100	1	100	99.96	99.96			
100	1	100	99.89	99.89	100.04	0.2079	0.0020
100	1	100	100.28	100.28			
120	1	120	120.03	100.02			
120	1	120	119.98	99.98	99.74	0.4507	0.0045
120	1	120	119.07	99.22			

Table 5: Determination of Precision.

Sample Number	Assay of Glimepiride as % of labeled amount			
	Analyst- 1	Analyst-2	Analyst-3	Analyst-4
1	99.80	100.37	99.60	100.23
2	99.45	99.25	100.70	100.12
3	100.12	99.40	99.28	99.50
4	99.10	99.71	99.82	99.02
5	99.38	100.10	99.68	99.05
Mean	99.57	99.766	99.816	99.584
S.D.	0.395854	0.468967	0.532428	0.57335
CV	0.003975	0.004700	0.005334	0.005757

performed by using four different analysts in the same laboratory. The values obtained by four analysts were summarized in table:

RESULTS

The standard solutions of Glimepiride in Methanol subjected to a scan at the series of wavelengths of 221 nm to 250 nm at First order and the derivative spectra were taken at N=2 using Shimadzu 1800 spectronic UV-Visible spectrophotometer and λ max found to be 225 nm (Figure 1). The calibration curve of Glimepiride was found to be linear at conc. Range 5 to 25 µg/ml at 252 nm Figure 2 to 7. There for, it was clear that Glimepiride can be determined in presence of methanol with no intervention of any irrelevant substance in pharmaceutical products. With the intention of determining the practicability of the developed technique for the assessment of commercially available brand (GLIMESTAR ® - 1) of medicinal formulations, the technique was initially attempted on bulk drugs in their synthetic mixture sample as well as concentrations were estimated. Then the technique was subjected to the assay of in marketed dosage forms and satisfactory results were attained within the appropriate limits as per the content of the label claim for Glimepiride.

DISCUSSION

The newly developed method was validated as per the international guidelines and parameters. The novel method for the quantitative investigation of Glimepiride was subjected to different validation parameters like specificity and selectivity in presence of formulation additives and excepients, studied for Linearity and range at different levels of concentrations and calibration standards where the determination range was optimized, accuracy was proved by recovery studies at different concentration levels, precision was established through inter day precision studies, where the samples were subjected to changed conditions other than optimized parameters.

CONCLUSION

From the above experimental studies it is concluded that First Order Derivative peak detect method developed for estimation of Glimepiride was suitable for the routine determination of Glimepiride. The proposed method for the selected drug Glimepiride was found to be precise and accurate. The most important striking features of Spectrophotometric methods are their rapidity and simplicity. The newly developed method is alternative to HPLC methods and better than zero order UV Spectrophotometric methods. Results of validation parameters demonstrate that these performed analytical procedures are suitable for its intended purpose and meet the criteria defined in ICHQ2A/B guidelines.

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