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RESEARCH ARTICLE

AREA UNDER CURVE UV SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF PIOGLITAZONE IN TABLET FORMULATIONS

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ABSTRACT

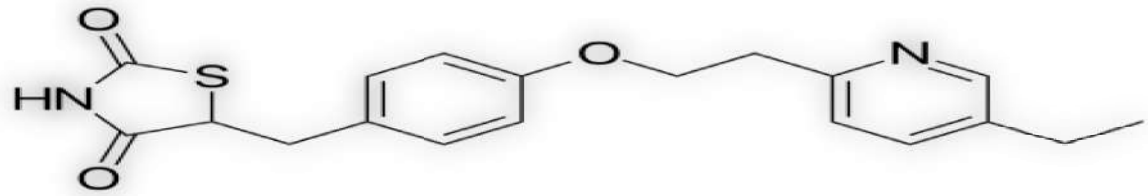
A simple, precise and economical procedure has been developed for the estimation of Pioglitazone in bulk drug and pharmaceutical dosage form using UV- spectrophotometer Shimadzu model UV 1800. Area under curve method was employed for estimation of Pioglitazone using analytical grade Methanol as solvent. Pioglitazone obeys Beer's law in concentration range 60-90µg/ml for the area between 249nm to 300nm.The recovery studies ascertained accuracy of purposed method and result validated according to ICH guideline. The result of analysis has been validated statistically by recovery studies. This method was successfully carried out for the estimation of Pioglitazone in tablet dosage form without the interference of common excipients.

INTRODUCTION

Pioglitazone is used with a diet and work out program as well as sometimes with other medications, to cure type 2 diabetes (situation in which the body does not use insulin generally and for that reason cannot manage the amount of sugar in the blood). It works by raising the body's sensitivity to insulin, a normal substance that helps manage blood sugar levels. Pioglitazone is not used to treat type 1 diabetes (circumstance in which the body does not generate insulin and, thus, cannot manage the quantity of sugar in the blood) or diabetic ketoacidosis (a severe state that may increase if high blood sugar is not treated). [1]

Pioglitazone is an oral antidiabetic agent belonging to the class of thiazolidinediones .[2]

Chemical structure: [3]



Pioglitazone [(±)-5-[[4-[2-(5-ethyl-2- pyridinyl) ethoxy] phenyl] methyl]-2, 4-] thiazolidinedione mono-hydrochloride belongs to a different chemical class and has a different pharmacological action than the sulfonylureas, metformin, or the a-glucosidase inhibitor. [4]

It is used in the management of type 2 diabetes mellitus. It improves sensitivity to insulin in muscle and adipose tissue and inhibits hepatic gluconeogenesis also improves glycemic control while reducing circulating insulin levels.

On literature survey, it was found that rapid RP-HPLC method for determination of Pioglitazone, analysis of Pioglitazone using RP-HPLC in tablet dosage form [5, 6], analysis of Pioglitazone by HPLC [7, 8], UV spectrophotometric method [9, 10, 11] have been reported for determination of Pioglitazone.

But there area under curve method not yet reported for the determination of Pioglitazone. Hence, investigation of new analytical methods is in need for the quantitative estimation of Pioglitazone.

MATERIALS AND METHODS

Materials

Shimadzu 1800 spectronic model UV Spectrophotometer with 1cm matched quartz cells was used as the instrument for data collection and analysis. Methanol was used as the solvent. Tablet brands were obtained from the local market for assay and recovery studies.

METHODS

Preparation of standard stock solution

Standard stock solution of Pioglitazone was prepared by dissolving accurately weighed quantity of Pioglitazone (25mg) in 100ml of methanol with sonication and transferred it to 100ml of volumetric flask. Volume was made up to the mark with methanol for obtaining standard stock solution of 100µg/ml concentration.

Determination of Area under curve

The standard solution of Pioglitazone (60µg/ml) was scanned in the wavelength range of 249nm to 300nm and the absorption maximum was found to be 268nm. Therefore, area between 265nm to 271nm was selected. (Figure 1)

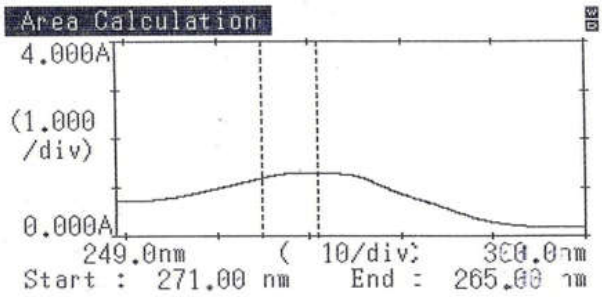


Figure 1 Area under curve of Pioglitazone

Stability of Drug in Selected Solvent

The stability of drug in selected solvent was determined by measuring the absorbance of the drug solution (60µg/ml) at different time intervals. After every 5min. of interval the abs. was measured the solution was found to be stable. (Table 1)

Table 1 Stability Data for Pioglitazone

Sr. No.	Time (min)	AUC
1	0	7.5642
2	05	7.5692
3	10	7.5799
4	15	7.5814

Linearity

From the standard stock solution of Pioglitazone, appropriate aliquots were pipette out into 25ml of volumetric flask and dilutions were made with acetone to produce working standard solution of Pioglitazone 60,65,70,75,80,85,90µg/ml. The difference in AUC of Pioglitazone was measured in the area from 271to 265nm.The calibration curve of the drug Pioglitazone was plotted. The concentration range over which the drug followed linearity was chosen as an analytical concentration range i.e. 60to 90µg/ml for Pioglitazone. (Table 2 and Figures 2 to 7)

Table 2 Calibration data Table for Pioglitazone

Sr. No.	Concentration	AUC
1	0	0
2	60	7.5642
3	65	8.2995
4	70	8.9494
5	75	9.4616
6	80	10.031
7	85	10.713
8	90	10.987

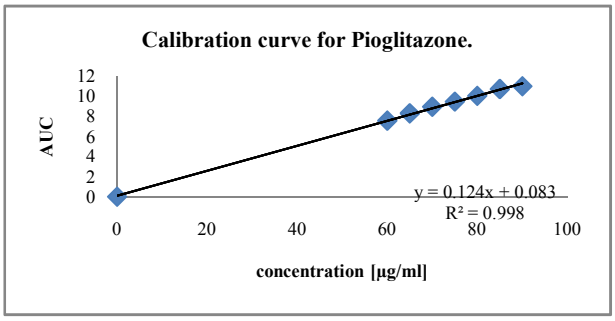


Figure 2 Calibration curve for Pioglitazone

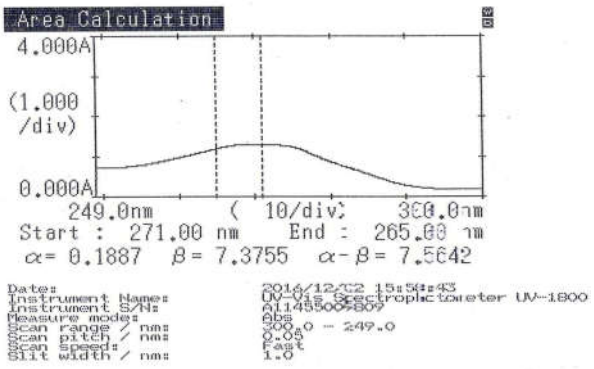


Figure 3 Area under curve of Pioglitazone 60µg/ml

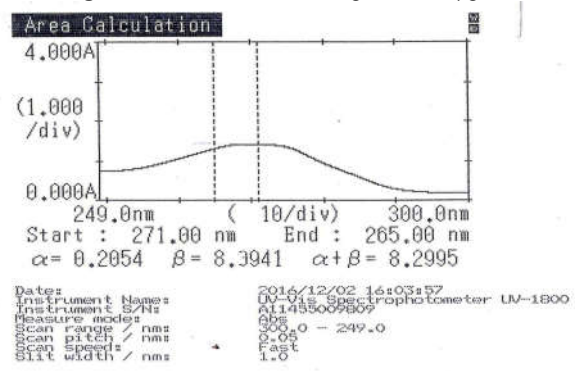


Figure 4 Area under curve of Pioglitazone 65µg/ml

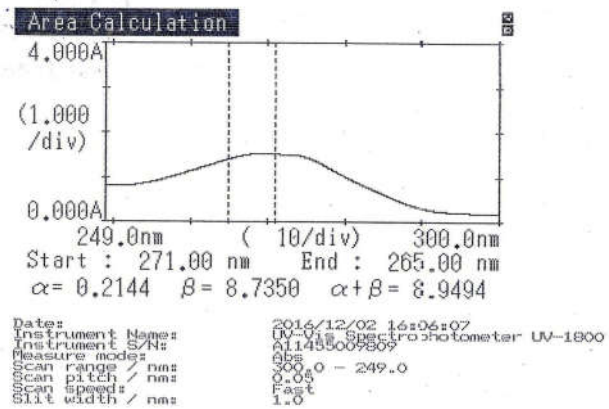


Figure 5 Area under curve of Pioglitazone 70µg/ml

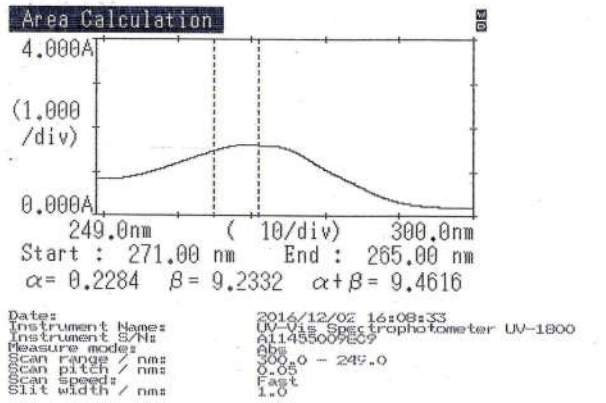


Figure 6 Area under curve of Pioglitazone 75µg/ml

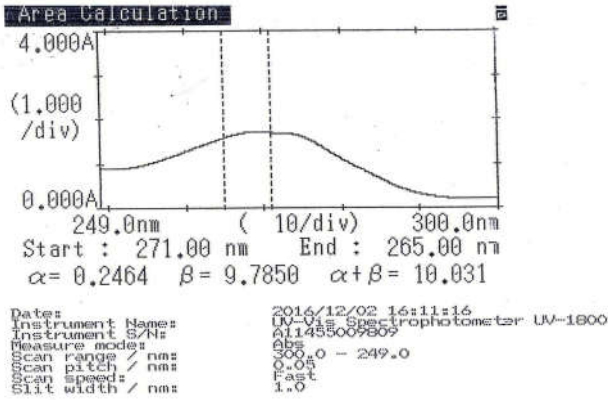


Figure 7 Area under curve of Pioglitazone 80µg/ml

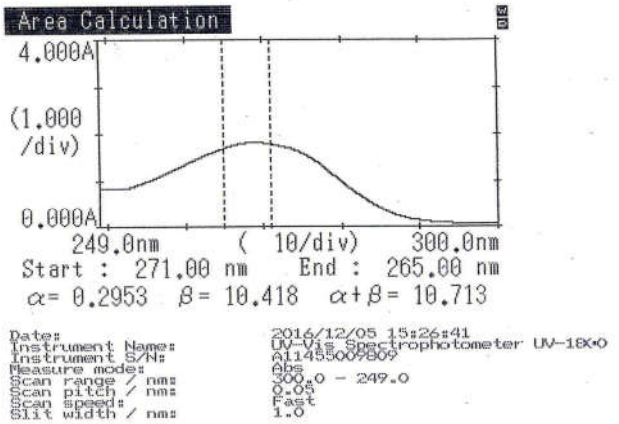


Figure 8 Area under curve of Pioglitazone 85µg/ml

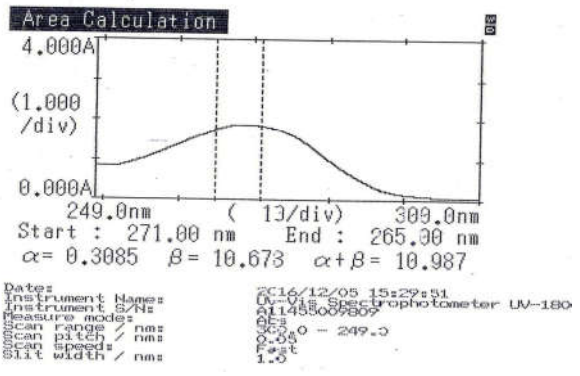


Figure 9 Area under curve of Pioglitazone 90µg/ml

Validation of proposed method

Estimation of Drug from Dosage Form: (Tablet Assay Study)
Brand name- ***PIOZ -7.5***

Standard

From the standard stock solution of Pioglitazone, appropriate aliquots were pipette out into 25ml volumetric flask and dilutions were made with methanol to obtain working standard solution of Pioglitazone 75µg/ml. This concentration was scanned at area of 271nm to 265nm.

Sample

Ten tablets of brand PIOZ -7.5 containing 7.5mg of Pioglitazone weighed, and finally powered with the help of mortar. Each uncoated tablet contains 7.5 mg of Pioglitazone. A quantity of powder sample of equivalent to 25 mg of Pioglitazone was taken into volumetric flask. And dilution was made to get concentration of 75µg/ml respectively. These concentrations were scanned at area between 271nm to 265nm. (Table 3)

Table 3 Assay for Pioglitazone in Tablet Form for Area under curve (AUC) method

Brand Name	Label Claim (mg/tablet)	Amount Found (mg/tablet)	% Of Label Claim	Mean	SD	CV
PIOZ -7.5	7.5	7.46	99.46	99.70	0.1729	0.0017
	7.5	7.48	99.73			
	7.5	7.49	99.86			
	7.5	7.47	99.6			
	7.5	7.49	99.86			

Accuracy (Recovery Study)

Recovery experiments are used for the study of accuracy method. This study was carried out by adding known amount bulk sample to the tablet and recovery was performed at three levels, 80, 100 and 120% of Pioglitazone standard concentration. Samples for recovery studies were prepared according to before mentioned procedure. 3 samples were prepared for each recovery level. The solutions of sample were analyzed and % recoveries were calculated by using fallowing formula.

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

The recovery values are summarized in following tables 4.

Precision

The precision (inter–day) was carried out by using four independent sample of Pioglitazone. The intermediate precision (inter-day precision) of the method was evaluated using four different analysts in the same laboratory. (Table 5)

RESULTS AND DISCUSSION

The standard solutions of Pioglitazone in Methanol subjected to scanning under area between 249nm to 300nm. For area under curve method using Shimadzu 1800 spectronic UV-Visible spectrophotometer. The calibration curve of Pioglitazone was found to be linear at conc. range 60 to 90µg/ml at area between 271nm to 265nm. Therefore, it was clear that Pioglitazone can be determined in the presence of methanol with no intervention of any irrelevant substance in pharmaceutical products.

Table 4 Result for accuracy parameters of Pioglitazone (Brand PIOZ - 7.5)

Label % recovery	Amount present (mg/tablet)	Amount Of Standard added (mg/tablet)	Amount Recovered (mg/tablet)	Total % recovery	%mean recovery	SD	CV
80	7.5	60	59.89	99.81			
80	7.5	60	60.01	100.01	99.95	0.1216	0.0012
80	7.5	60	60.02	100.03			
100	7.5	75	74.88	99.84			
100	7.5	75	75.02	100.02	99.95	0.1011	0.0010
100	7.5	75	75.01	100.01			
120	7.5	90	88.99	98.87			
120	7.5	90	89.94	99.93	99.57	0.6091	0.0061
120	7.5	90	89.93	99.92			

Table 5 Determination of Precision of Pioglitazone

Sample Number	Assay of Pioglitazone as % of Labelled amount (inter – day precision)			
	Analyst 1	Analyst 2	Analyst 3	Analyst 4
1	99.54	99.74	99.55	99.35
2	99.61	99.36	99.43	100.11
3	100.89	100.71	99.38	99.36
4	99.87	99.74	100.10	100.88
Mean	99.97	99.88	99.61	99.92
SD	0.6246	0.57685	0.3311	0.7294
CV	0.0062	0.0057	0.0033	0.0072

With the intention of determining the practicability of the developed technique for the assessment of commercially available brands (PIOZ – 7.5) 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 Pioglitazone. The newly developed method was validated as per the international guidelines and parameters. The novel method for the quantitative investigation of Pioglitazone was subjected to different validation parameters like specificity and selectivity in presence of formulation additives and excipients, 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 can be concluded that Area under curve method by UV spectrophotometry instrument developed for estimation of Pioglitazone. The proposed methods for the selected drugs were found to be precise and accurate. The most important features of spectrophotometric methods are their rapidity & simplicity. 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. The method is an excellent alternative to HPLC methods for routine analysis and accurate and better than the zero order UV spectrophotometric method.

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