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[Research article]

Estimation of Pioglitazone hydrochloride in Bulk and Pharmaceutical dosage form by UV- Spectroscopy

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ABSTRACT

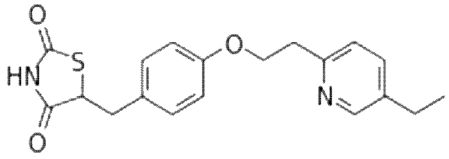
A simple, fast and reliable Spectrophotometric method was developed for determination of Pioglitazone hydrochloride in bulk and Pharmaceutical formulation. Spectrophotometrically, Pioglitazone hydrochloride was determined by measuring the maximum absorption at 270nm. Analytical Calibration curves were linear within a concentration range from 10 to 50µg/ml. The developed method was applied to directly and easily to the analysis of the pharmaceutical tablet preparations. % R.S.D was found to be 0.51 for piosis 30 mg Tablet. The %R.S.D values for all method validation parameters were found within 2% for the developed method. The method was completely validated. The results showed that this method can be used for rapid determination of Pioglitazone hydrochloride in bulk and Pharmaceutical tablet formulation with linearity, precision, accuracy specificity.

Key words: UV-Spectrophotometry, Pioglitazone hydrochloride, Pharmaceutical dosage form.

INTRODUCTION

Pioglitazone is a thiazolidinedione derivative Anti-Diabetic agent. Pioglitazone acts by binding to PPARγ, which activates insulin-responsive genes that regulate carbohydrate and lipid metabolism [(1)] it reduces the insulin resistance in liver and peripheral tissues and increases the expense of insulin dependent glucose. So the present work is aimed at development of UV-Spectroscopic method for the estimation of Pioglitazone hydrochloride in bulk & tablet dosage form .This present paper work comprises of Method development (To be done by UV) and Validation of the developed method to be done by using various validation parameters with specificity, accuracy, precision and economical using ICH guidelines for validation (ICH, 1995) [(2)].

Fig-1: structural formula of Pioglitazone hydrochloride [(3)]



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MATERIALS AND METHODS

Instrument

Absorption spectral measurements were carried out with a UV – Visible spectrophotometer (Analytical technologies model spectro 2060 plus version 5) was employed with spectral bandwidth of 5 nm and wavelength accuracy of 0.3nm (with automatic wavelength correction with a pair of 5 cm matched quartz cells).

Chemicals

Pioglitazone hydrochloride pure drug was supplied by Hetero Labs, India as gift sample and used as such. Spectroscopy graded Water and Analytical reagent grade Perchloric acid and Methyl acetate were used.

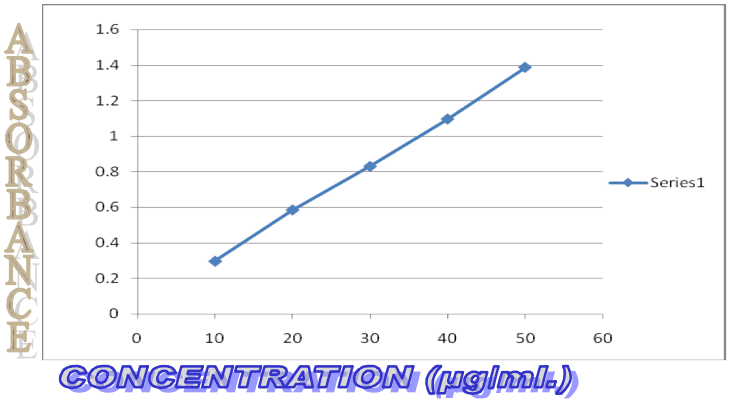
Preparation of standard stock solution

Standard solution of pioglitazone hydrochloride was prepared by dissolving 10mg of pioglitazone hydrochloride in 10ml of mobile phase (0.2M Perchloric acid in Methyl acetate) to get concentration 1000µg/ml. Different aliquots of above solution in the range 0.1 to 0.5 ml were transferred into series of 10ml volumetric flask and volume made up to the mark with water to obtain the concentrations 10 to 50µg/ml. scanning ranges was finalized for study and solutions were scanned on spectrophotometer in the UV range of 200-400nm.

Determination of λ max

From the stock solutions, a working standard was prepared. The absorption spectrum for pioglitazone hydrochloride, the absorption spectrum was recorded using 30µg/ml solution and the maximum absorption was found to be 270nm .The Calibration curves were prepared for pioglitazone in the concentration range of 10-50 µg/ml at selected wave lengths by diluting aliquot portions of stock solution of each drug. The plots of Beer's law limit are shown in Fig.2.

Fig.2 Calibration curve of Pioglitazone hydrochloride



Preparation of Sample solution

Sample label claim 30 mg. The average weight was determined with 20 tablets, which were grounded in a mortar until fine powder. Accurately weighed amount of powder equivalent to 10mg of pioglitazone hydrochloride was quantitatively transferred to a 10 ml calibrated volumetric flask with the mobile phase (0.2M Perchloric acid in Methyl acetate). The volume was made up to mark, shake for 15 min and filter the sample solution using Whatman filter paper No-1. From above solution 1ml was transferred to 10ml calibrated volumetric flask and made up to mark with the aid of (0.2M Perchloric acid in Methyl acetate) to obtain the concentration 100 µg /ml.From above solution 0.3ml was transferred to 10ml calibrated volumetric flask and made up to mark with the aid of (0.2M Perchloric acid in Methyl acetate) to obtain the concentration 30 µg/ml .Then the solution was scanned from 200-400nm.

The amount and % purity present in each Pioglitazone hydrochloride Tablet formulation was calculated & the results are shown in table 1.

Table 1: Analysis data of Tablet formulation

Drug	Label claim (mg/tab)	Assay (% of label claim) ± %RSD
Piosis	30	100.9±0.51

METHOD VALIDATION

The method was validated with reference to linearity, accuracy, precision, and specificity, ruggedness. [4, 5]

Linearity

Linearity was performed by taking aliquots of 0.1, 0.2, 0.3, 0.4 and 0.5 mL from stock solution (1mg/ml) in 10ml volumetric flasks and diluted up to the mark with the (0.2M Perchloric acid in Methyl acetate) such that the final concentration of pioglitazone in the range of 10 to50 µg/ml. Under the experimental conditions described the graphs obtained by plotting concentration (µg/ml) Vs absorbance .The observations and calibration curve is shown in Table 2 and Fig.2

Table 2: OPTICAL CHARACTERISTIC AND LINEARITY DATA

Parameters	Observations
λmax for pioglitazone hydrochloride	270 nm
Beer's law limits	10-50 µg/ ml
Correlation coefficient	0.9996
Regression equation (Y=mx+c)	Y= 0.0334+0.027x
Intercept(a)	0.0334
Slope(b)	0.02686
Molar absorptivity	10437.4L/Mole/Cm
Sandell sensitivity	0.0376 µg/ ml

Accuracy

The accuracy was assessed by determining the %RSD values at 100% level (n=10). The resulting solutions were then reanalyzed by proposed method.The results are shown in table 3.

Table 3: Accuracy studies

Level of accuracy	%RSD
100%	1.73

Precision

Precision of the methods was studied as intra-day, interday. Intra-day, study was performed by analyzing, the three different concentration of the drug (80%, 100%, 120%) in the same day. Inter-day precision was performed by analyzing three different concentration of the drug (80%, 100%, and 120%) for three days in a week. The results are shown in table 4&5.

Table 4: Results from interday precision

	INTERDAY PRECISION								
	DAY-1			**DAY-2**			**DAY-3**		
	24 µg/ml	30 µg/ml	36 µg/ml	24 µg/ml	30 µg/ml	36 µg/ml	24 µg/ml	30 µg/ml	36 µg/ml
%RSD	0.55	1.79	0.42	0.47	0.77	0.63	0.24	1.73	0.44

Table5: Results from Intraday Precision

INTRADAY PRECISION							**REPEATABILITY**		
	10.30AM			**3.30PM**			**12.30 PM**		
	concentration(µg/ml)			**concentration(µg/ml)**			**Concentration(µg/ml)**		
	24	30	36	24	30	36	24	30	36
% RSD	0.24	0.07	0.42	0.71	0.35	1.15	0.09	0.09	1.15

RUGGEDNESS OF TEST METHOD

Analyst to analyst: Analyst to Analyst variability study was conducted with different analysts under similar conditions at different concentration levels (24 µg/ml, 30µg/ml, 36 µg/ml). Triplicate samples were prepared and each was analyzed as per test method and the results are shown in table 6.

Table 6: results from ruggedness

	RUGGEDNESS					
	Analyst-1			**Analyst-2**		
	24 µg/ml	30 µg/ml	36 µg/ml	24 µg/ml	30µg/ml	36 µg/ml
%RSD	0.71	1.66	0.33	0.24	0.71	0.32

RESULT AND DISCUSSION

Pioglitazone hydrochloride is an oral anti diabetic agent used in the treatment of type 2 diabetes mellitus and also known as non-insulin dependent diabetes mellitus (NIDDM) or adult onset diabetes. A simple, an accurate and economic, precise and reproducible UV Spectroscopy method has been developed for the estimation of Pioglitazone hydrochloride in bulk and tablet dosage form and validated by ICH guidelines. The standard (30 µg/ml) was scanned between 200-400nm and maximum absorption was recorded at 270 nm. The linearity range of 10-50 µg/ml proved that it obeyed Beer's Law and the correlation coefficient (r2) was found to be 0.9996 at 270 nm with an intercept of 0.0334 and a slope of 0.02686 complied ICH. The drug sample was analyzed by UV spectroscopy and the average content of drug present in the formulation was found to be 100.9 %. All statistical data proves validity of the methods and can be used for routine analysis of pharmaceutical formulation.

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