



# Method development of Pioglitazone by UV Spectrophotometer

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## Abstract:

In the present research a simple, accurate, precise and cost effective UV-Vis spectrophotometric method for the estimation of Pioglitazone, in bulk and pharmaceutical dosage form was illustrated. The absorption maxima of the drug were found to be 234 nm in Methanol. A linear response was observed in the range of 02-12 µg/ml with a regression coefficient of 0.996. Validation parameters were carried out as per the guidelines of International Conference for Harmonization. This method can be used in the industries for determination of Pioglitazone to analyze the quality of formulation without interference of the excipients.

**Keywords:** Pioglitazone, Ultraviolet spectroscopy, Antidiabetic, Thiazolidinediones,  $\lambda_{max}$ .

## INTRODUCTION:

Pioglitazone is an oral antidiabetic agent belonging to the class of thiazolidinediones that acts primarily by decreasing insulin resistance. 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. 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  $\alpha$ -glucosidase inhibitors (1). Determination of pioglitazone by various analytical methods like spectrophotometric method (2) and HPLC and MECK method (3) in tablet dosage form, HPLC and solid phase extraction method in human serum (4) and in dog serum (5), HPLC and LC MS in human plasma (6-7) have been reported. Pioglitazone is not official in

any pharmacopoeia. There is a need for a simple, rapid, cost effective and reproducible method for assay of pioglitazone in its dosage forms. Therefore, it was thought of interest to develop simple, accurate, fast and cost effective method for the analysis of pioglitazone in its tablet formulation. This paper describes development and validation of simple, specific, sensitive, accurate and precise ultraviolet spectroscopic method for the estimation of Pioglitazone in bulk and its formulation.

## Material and methods:

### Zero order spectroscopic method:

Water used for dilution was distilled in the laboratory. A double beam UV spectrophotometer (Shimadzu UV-1800) was used with 1 cm matched quartz cell. Pioglitazone hydrochloride (antidiabetic) in bulk drug Formulation.

**Solvent Selection:**

Various solvents were selected for the solubility studies and it was found that Pioglitazon was soluble in the following solvents; dimethyl sulfoxide, dimethyl formamide, Methanol, 0.1 N HCl, chloroform, acetonitrile, etc. In the present investigation Methanol was selected as a solvent.

**Selection of analytical wavelength and absorption maxima:**

Appropriate dilutions were prepared for drug from the standard stock solution and the solutions were scanned in the wavelength range of 200-400 nm. The absorption spectra thus obtained was derivatized for zero order spectroscopy. This zero order spectrum was selected for the analysis of the drugs. The absorption maximum was found at 234 nm which can be further used for analysis. Values are recorded at Table No. 1 and represented graphically at Fig no. 1.

**Preparation of stock solutions:**

An accurately weighed 10.0 mg of pure drug Pioglitazone hydrochloride was taken in clean, dry 100 ml volumetric flask and dissolved in small volume of Methanol (10.0 – 20.0 ml). The solution was diluted to 100.0 ml with Methanol, resulting in 100.0 mcg/ml of drug concentration.

**Selection of analytical concentration range:**

Aliquots of 0.2 ml, 0.4 ml, 0.6 ml, 0.8 ml, 1.0 ml, 1.2 ml, & 1.4 ml of 100 µg/ml of Pioglitazone Hydrochloride were pipetted into six 10 ml volumetric flask The volume were made up to 10 ml with Methanol was measured at 234 nm against methanol as a blank. For standard solution analytical concentration range was found to be 02-12 µg/ml and overlain spectra was obtained.

**Calibration curve for the Pioglitazone:**

Aliquots of 0.2, 0.4, 0.6, 0.8, 1.0, 1.2ml of 100 µg/ml solution of Pioglitazone Hydrochloride was pipetted from stock solution into each of five 10

ml of volumetric flask. The volume was made up to 10.0 ml with Methanol. The absorbance of the solution was measured at 233.0 nm against Methanol as blank. The absorbance values are recorded in Table No. 3 and represented graphically in Fig No. 2.

**Table 1:** Determination of Absorption Maxima of Pioglitazone Hydrochloride in Methanol.

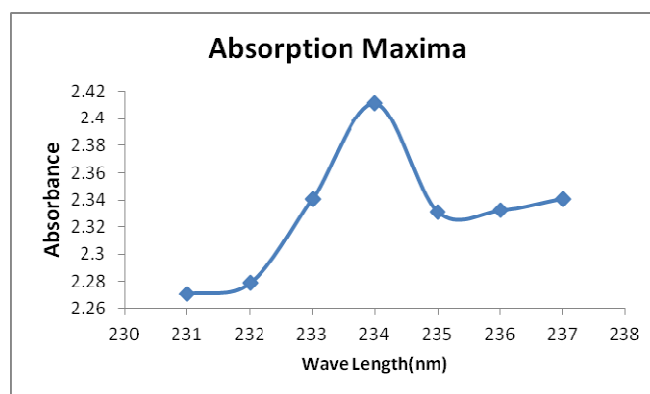
S. No.	Wave Length(nm)	Absorbance*
1.	231	2.271
2.	232	2.279
3.	233	2.341
5.	234	2.411
6.	235	2.331
7.	236	2.332
8.	237	2.341

**Result:** On scanning the absorption maxima of Pioglitazone hydrochloride 15 mcg/ml in Methanol was found out to be 234.0 nm.

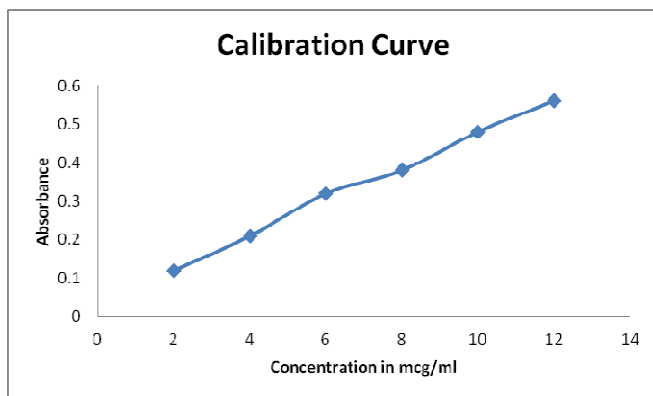
**Table 2:** Preparation of Standard Curve of Pioglitazone Hydrochloride in Methanol

S. No.	Standard Pioglitazone Hydrochloride Solution		Absorbance* at 234 nm.
	(ml)	(mcg/ml)	
1	0.2	2.0	0.12
2	0.4	4.0	0.21
3	0.6	6.0	0.32
4	0.8	8.0	0.38
5	1.0	10.0	0.48
6	1.2	12.0	0.56

\*Average of three readings.

**Fig. 1:** Determination of Absorption Maxima of Pioglitazone Hydrochloride in Methanol

**Fig 2:** Preparation of Standard Curve of Pioglitazone Hydrochloride in Methanol



**Result:** The calibration curve shows that Beer's law was obeyed in the concentration range 2.0 -12.0 mcg/ml of Pioglitazone hydrochloride in Methanol.

### Optical Characteristics:

The optical characteristics of the proposed method have been calculated. The values are given in Table No.4.

**Table No. 3:** Optical Characteristics

S. No.	Parameters	Results
1.	Absorption maxima (nm)	234.0
2.	Beer's law limits (mcg/ml)	2.0-12.0
3.	Molar extinction coefficient (mole <sup>-1</sup> cm <sup>-1</sup> )	5.13×10 <sup>-2</sup>
4.	Sandall's sensitivity (mcg/cm <sup>2</sup> /0.001)	4.385×10 <sup>-2</sup>
5.	Regression equation (y)	0.9962
	Slope (b)	0.04385
	Intercept (a)	0.038
6.	Coefficient of variance	62.257
7.	Standard deviation	0.164408
8.	Limit of detection (mcg/ml)	12.37
9.	Limit of quantitation (mcg/ml)	37.493

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