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Analytical Method Development and Validation for The Estimation of Pioglitazone Hydrochloride in Bulk and Formulation by UV-Spectrophotometry

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ABSTRACT

The present work deals with the development of reliable method for the estimation of pioglitazone hydrochloride by using UV spectroscopy. The pioglitazone hydrochloride showed absorption maxima at wavelength 268nm respectively. The linearity range for pioglitazone hydrochloride was in the range of 10-50µg/ml with correlation coefficient of 0.999. The precision was carried out for pioglitazone hydrochloride and value was found to be less than 2. The proposed method's results were found satisfactory and are suitable for determination of pioglitazone hydrochloride for routine quality control of drug in bulk and formulation. This method is validated according to ICH guidelines Q2R1.

Keywords: Pioglitazone hydrochloride, ICH guidelines, validation, method development.

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INTRODUCTION

Pioglitazone is an oral antidiabetic agent belonging to the class of thiazolidinedione 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 monohydrochloride belongs to a different chemical class and has a different pharmacological action than the Sulfonylureas, metformin, or α glucosidase inhibitors. The simplicity of the method allows for application in laboratories that lack sophisticated analytical instruments such as LC-MS/MS or GC-MS/MS that are complicated, costly and time consuming rather than a simple UV method. The present investigation by the author describes a simple, specific, rapid, accurate and precise UV method for the determination of Pioglitazone hydrochloride from bulk sample.[12]

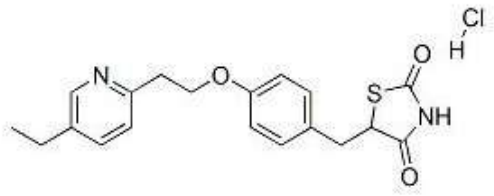

Figure 1: Structure of pioglitazone hydrochloride

MATERIALS AND METHOD

Instrumentation:

Analysis was performed using ELICO SL 210 Double beam UV VIS Spectrophotometer. The output signal was monitored and processed using Spectra treats software.

Chemicals:

Pioglitazone hydrochloride drug sample was procured from MSN Organics private limited, Hyderabad, methanol HPLC grade and double distilled water HPLC grade were procured from s d fine-chem. limited. Tablets were procured from local marketed formulation (pioglar 30mg – sun pharmaceutical India, Ltd).

Diluent: Methanol HPLC grade.

Preparation of stock and working standard solutions:

10mg of pioglitazone was accurately weighed and transferred into a 10ml volumetric flask containing methanol and made upto mark (1000µg/ml). From stock solution 1 ml was pipetted and transferred into another 10ml volumetric flask and upto mark the volume with methanol

(100µg/ml). From the working standard 1ml solution was pipetted into another 10ml volumetric flask and made upto mark (10µg/ml).[1]

Determination of absorption maxima and calibration curve:

The standard solution of pioglitazone (10µg/ml) was scanned against methanol as blank between 200-400nm. Spectrum was recorded and the suitable absorption maxima was selected as 268nm. Various aliquots of standard stock solution were made and diluted with methanol as diluent upto 10ml to give a final concentration of 10, 20, 30, 40 &50µg/ml. Then the absorbance of these solutions was measured at 268nm and the corresponding values were plotted as a calibration curve.[2]

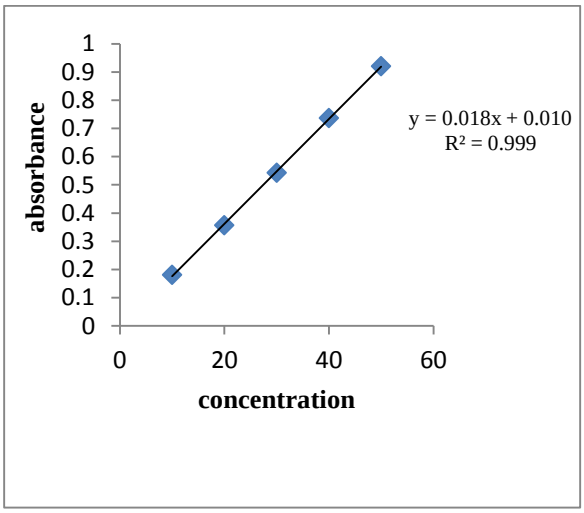

Figure 2: Calibration curve of pioglitazone hydrochloride in methanol.

Method parameters

Linearity: suitable aliquots of working standard solution of pioglitazone (1-5ml) were taken in 10ml volumetric flasks. The volume was made upto mark with HPLC grade methanol to prepare a series of standard solutions containing 10-50µg/ml concentrations. Absorbance was measured at 268nm against blank (methanol). A graph was plotted using concentration on x-axis and absorbance on y-axis. Correlation was found to be 0.999.[3]

Table 1: Linearity Results

Concentration (µg/ml)	Absorbance
10	0.1807
20	0.3569
30	0.5423
40	0.7361
50	0.9199

Precision:

Precision of an analytical method was determined by analysis of multiple sampling of same

homogenous sample.10µg/ml standard solution was scanned at 268nm for 6 times and its %RSD was calculated.[4]

Table 2: Precision results

Concentration (mg/ml)	Absorbance Interday precision	Absorbance Intraday precision
10	0.1807	0.1743
10	0.1807	0.1731
10	0.1803	0.1737
10	0.1812	0.1737
10	0.1804	0.1742
10	0.1802	0.1744
%RSD	**0.19%**	**0.23%**

Accuracy:

Accuracy of a method is expressed as the closeness of agreement between found value and reference value. Accuracy is done by spiking triplicate concentrations (80%,100% & 120%) of standard pioglitazone solution with known concentration of sample solution. Recovery and %RSD was calculated.[5]

Table 3: Accuracy results

Levels (%)	Standard+ Sample	Absorbance	% Recovery	% RSD
80	20+10	0.4542	98.78	0.08
	20+10	0.4543	98.88	
	20+10	0.4544	98.98	
100	30+10	0.6411	100.3	0.10
	30+10	0.6412	100.4	
	30+10	0.6413	100.5	
120	40+10	0.8338	99.18	0.09
	40+10	0.8339	99.28	
	40+10	0.8340	99.39	

Robustness:

Robustness of an analytical procedure is the measure of its capability to remain unaffected by small but deliberate variations in method parameters indicating its reliability.[6]

Table 4: Robustness results

Concentration (mg/ml)	Absorbance at 267nm	Absorbance at 269nm
10	0.1811	0.1727
10	0.1809	0.1733
10	0.1809	0.1725
10	0.1804	0.1725

10	0.1810	0.1723
10	0.1811	0.1723
%RSD	0.11	0.17

Ruggedness:

The degree of reproducibility of test results obtained by the analysis of samples under various test conditions such as laboratory variations.[7]

Table 5: Ruggedness results

Concentration (µg/ml)	**Absorbance**			
	Day 1 ELICO		**Day 2 SYSTRONICS**	
	Analyst 1	**Analyst 2**	**Analyst 1**	**Analyst 2**
10	0.1811	0.1809	0.176	0.1789
	0.1814	0.1811	0.176	0.1787
	0.1821	0.1810	0.181	0.1785
	0.1823	0.1809	0.176	0.1789
	0.1813	0.1811	0.180	0.1791
	0.1828	0.1804	0.176	0.1791
%RSD	0.33	0.11	0.18	0.56

LOD:

Limit of detection of an individual analytical procedure is the lowest amount of analyte in the sample which can be detected.[8]

LOQ:

Quantification limit of an individual analytical procedure is the lowest amount of analyte in sample which can be quantitatively determined with suitable precision and accuracy.[9]

RESULTS AND DISCUSSION

The pioglitazone hydrochloride was soluble methanol. The absorption maxima was found to be 0.999. Series of standard concentrations were scanned at 268nm and the results were found to be linear with correlation coefficient of 0.999. The method was validated in terms of accuracy, precision, LOD & LOQ. The results of all the parameters were within the limits indicating that proposed method is accurate for analysis of pioglitazone hydrochloride.[10]

Table 6: Results of validation parameters

Parameters	**Results**
Λmax	268nm
Slope	0.018
Intercept	0.010
Linearity range (µg/ml)	10-50

Precision (%RSD)	Interday-0.19
	Intraday-0.23
Accuracy (recovery)	80%-98.78
	100%-100.3
	120%-99.18
Robustness (%RSD)	At 267nm-0.11
	At 269nm-0.17
Ruggedness (%RSD)	Analyst 1-0.33
	Analyst 2-0.11
LOD	0.0001
LOQ	0.0009

CONCLUSION

The above developed method is simple, economical and precise for analytical validation of pioglitazone HCL. The results obtained are within the limits hence the developed method is useful for routine analysis.[11]

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