

UV-SPECTROPHOTOMETRIC DETERMINATION OF PIOGLITAZONE IN PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

A simple UV-spectrophotometric method has been developed for the quantitative estimation of pioglitazone in bulk and pharmaceutical dosage forms. pioglitazone hydrochloride has absorption maxima at 224.4 nm in ethanol and obeyed Beer's law in the concentration range of 5-25 μ g/mL. The results of method has been validated statistically and by recovery studies.

Key words: Pioglitazone, UV spectrophtometry

INTRODUCTION

pioglitazone hydrochloride¹⁻³ is chemically (±)-5-{p-[2-(5-ethyl-2-pyridyl) ethoxy] benzyl}-2,4-thiazolidinedione hydrochloride and used as anti-diabetic. It is used in the management of type-II diabetes mellitus. It is not official in any pharmacopoeia. No analytical methods are found in literature for its quantitative determination except two^{4,5}. The present work deals with UV spectrophotometric estimation of the drug in bulk and its dosage forms where the drug exhibits absorption maxima at 224.4 nm in ethanol and obeyed Beer's law in the concentration range of 5-25 µg/mL.

EXPERIMENTAL

Reagents Anhydrous ethanol (Qualigens, Mumbai), pioglitazone hydrochloride (Strides Pharmaceuticals, Bangalore).

Working standard of drug solution

A standard solution containing 1 mg/mL of pioglitazone hydrochloride was prepared in

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anhydrous ethanol. From this, a working standard containing 100 μ g/mL was prepared by diluting with anhydrous ethanol.

Sample preparation

Three brands of commercial tablets were analyzed by the proposed method. In each case 10 tablets of formulation containing 30 mg of pioglitazone hydrochloride were accurately weighed and powdered. Weight of each tablet powder equivalent to 100 mg of drug was taken in 50 mL of anhydrous ethanol and shaken for 15 min, filtered into 100 mL volumetric flask through cotton wool and the remaining amount of anhydrous ethanol was added through tablet powder to make up to 100 mL. Final concentration was brought up to 100 μ g/mL with anhydrous ethanol.

Instrument

A Shimadzu UV/Vis double beam spectrophotometer (Model 1700) with 1 cm matched quartz cells was used for all absorbance measurements.

Assay procedure

Aliquots of pioglitazone hydrochloride ranging form 0.5-2.5mL (1 mL = 100 µg) were transferred into series of 10 mL volumetric flasks and the volumes were made up to 10 mL with anhydrous ethanol. The absorbance was measured at 224.4nm against solvent blank. The amount of pioglitazone hydrochloride in the sample was computed from calibration curve.

RESULTS AND DISCUSSION

The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and Sandell's sensitivity are presented in Table 1. The regression analysis using the method of least squares was made for the slope (b), intercept (a) and correlation (\mathbb{R}) obtained from different concentrations and results are summarized in Table 1.

Table 1. Optical characteristics, precision and accuracy of the proposed method

λ _{max}	224.4 nm
Beer' law limit (µg/mL) ©	5-25
Molar absorptivity (litre.mole ⁻¹ .cm ⁻¹)	1.4488×10^4
	Cont

Sandell's Sensitivity (µg/cm ² /0.001 abs. unit)	0.078
Regression equation (Y)*	
Slope (b)	0.03466
Intercept (a)	0.0283
Correlation coefficient (r)	0.99923
% RSD	0.1468
% Range of error**	
Confidence limit 0.05 level	0.008863
Confidence limit 0.01 level	0.001311

Y=a+b X where X is the concentration of pioglitazone hydrochloride in $\mu g/mL$ and Y is the absorbance at 224.4 nm.

** for eight measurements.

The percent relative standard deviation and percent range error (0.05 and 0.01 level of confidence limits) were calculated from the eight measurements. $\frac{3}{4}$ of the uppers Beer's law limits of pioglitazone are given in Table 1.

The results showed that the method has reasonable precision. The results obtained with proposed method for dosage forms (Table 2) confirm the stability of the method for pharmaceutical dosage forms (tablets).

Table 2. Assay and recovery	of pioglitazone hydrochloride in pharmaceutical
formulation	

Pharmaceutical formulation	Labeled amount (mg)	Amount found ^a (mg)	Percentage recovery ^b
Tablet A	30	30.1 ± 0.2	100.21
Tablet B	30	29.9 ± 0.19	99.82
Tablet C	30	30.1 ± 0.15	99.91

 $a = Average \pm S.D$ of eight determinations

b = Recovery of 30 mg added to pharmaceutical formulations (average of 5 determinations)

In order to justify the reliability and suitability of the proposed method known quantities

of pure pioglitazone hydrochloride was added to its pre-analyzed formulations and the mixtures were analyzed by the proposed method. The results of recovery studies are summarized in Table 2. The other active ingredients and excepients usually present in pharmaceutical dosage forms like starch, talc, magnesium stearate did not interfere at their regularly added levels.

The proposed UV spectrophotometric method is simple, sensitive, accurate, economical and precise and can be utilized for the routine determination of pioglitazone hydrochloride in bulk and pharmaceutical dosage forms (tablets).

ACKNOWLEDGEMENTS

The authors are thankful to M/s Stride Pharmaceuticals, Bangalore for providing drug sample for research and the Principal, H. K. E.'s College of Pharmacy, Gulbarga for providing the facilities to carry out the present work.

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Accepted : 05.07.2008