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Spectrophotometric method for the determination of Pioglitazone in pharmaceutical dosage forms

P. G. Sunitha[a], N. Deattu, N. Umarani[b]

[a]College of Pharmacy, Madras Medical College, Chennai
[b]SRM College of Pharmacy, Department of Pharmaceutical Chemistry, SRM University, Kattankulathur

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Abstract

A simple and precise second derivative UV Spectrophotometric method was developed for the estimation of pioglitazone (PGZ) in pharmaceutical dosage form (tablets). The λ_{max} of PGZ in methanol was found to be 268nm. The second derivative spectrum shows well-resolved trough from excipients. Beer's law was obeyed in the concentration range of 10-60µg/ml. Results of analysis were validated statistically and by recovery studies. The proposed method is accurate, reproducible and can be successfully employed for the routine determination of PGZ in tablets.

Key words: Pioglitazone, second derivative spectrophotometry, tablets, validation.

INTRODUCTION

Pioglitazone is a thiazolidinedione oral anti diabetic similar to rosiglitazone [1]. Chemically it is 5-{p-[2-(5-Ethyl-2-pyridyl)ethoxy]benzyl}2,4-thiazolidinedione hydrochloride [2]. Literature review revealed very few analytical methods including HPLC [3] and MEKC [4] methods for the analysis of PGZ in pharmaceutical dosage forms.

The present work deals with the estimation of PGZ in tablets by a simple second derivative UV Spectrophotometric method. Spectrophotometric parameters are established for standardization of the method including statistical analysis of data.

RESULTS AND DISCUSSION

The optical and statistical parameters are furnished in Table –I. The results of sample analysis showed that the drug determined by the proposed method was in good agreement with the label claim proving the accuracy of the proposed method.

To study the accuracy and reproducibility of the proposed method, recovery experiments were carried out by adding a known amount of drug to preanalysed sample and the percentage recovery was calculated. The results are furnished in Table-II. The results indicate that there is no interference of other ingredients present in the formulation. Thus, the proposed method is simple, economical, accurate and reproducible and useful for the routine determination of PGZ in bulk and pharmaceutical dosage forms.

MATERIALS AND METHODS

Instrument: Shimadzu UV-VIS spectrophotometer -1650

Standard solution of PGZ: A 1mg/ml stock solution of PGZ was prepared by dissolving 100 mg of drug in 100 ml of methanol.

Sample preparation: Twenty tablets were weighed and powdered. A quantity equivalent to 50 mg of PGZ was weighed accurately, transferred to a beaker, dissolved in methanol, filtered through whatmann filter paper No.1 into 50 ml volumetric flask and made up to volume with methanol to get a concentration of 1 mg/ml.

Assay

The standard solution of PGZ was diluted suitably with methanol to get six different concentrations ranging from 10-60µg/ml. The above solutions were scanned over the range of 255 nm to 290 nm and the resulting spectra were derivatised to get second order derivative spectra. The amplitudes of the corresponding troughs were measured in mm and plotted against the concentration.

Table I Optical and statistical parameters

Parameter	Second derivative spectrophotometric method
Wavelength range (nm)	255-290
Beer's law limits (µg/ml)	10-60
Regression equation* (y)	y=0.016 + 0.0189c
Slope (b)	0.0189
Intercept (a)	0.016
Correlation coefficient(r)	0.9922
% RSD	0.0033
Standard error	0.0204

y=a+bc where c is the concentration of PGZ in µg/ml.

Sample analysis: Pharmaceutical formulation of PGZ was successfully analysed by the proposed method. Appropriate aliquots were subjected to the above method and the amount of PGZ was determined from the calibration curve. The results of sample analysis are furnished in Table-II.

Table II- Assay and recovery of PGZ in dosage forms

Drug	Labelled amount (mg)	Amount of standard drug added(mg)	Amount obtained* (mg)	Percentage recovery**
PGZ	15	3	15.03	99.33

*Average of six determinations.; **Average of three determinations.

CONCLUSION

The second derivative spectrophotometric method provides enhanced resolution and bandwidth discrimination and permits the selective determination of absorbing substances in samples in which non-specific interference may prohibit the application of simple spectrophotometric methods. The proposed method is accurate, reproducible and useful for the routine determination of pioglitazone in tablets.

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