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Spectrofluorimetric estimation of Rosiglitazone in tablet dosage form

CHUNGATH THOMAS TELNY[1*], J. BAGYALAKSHMI[2] and T.K. RAVI[2]

[1*]Department of Pharmaceutical Analysis, St James College of Pharmaceutical Sciences, River Bank,Chalakuddy-680 307(India)
[2]Department of Pharmaceutical Analysis, Sri Ramakrishna Institute of Paramedical Science, Coimbatore- 641044 (India)

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ABSTRACT

A simple and highly sensitive spectrofluorimetric method was developed for the estimation of Rosiglitazone in tablet dosage form. The native fluorescence of the drug in methanol was measured at an excitation wavelength of 297nm and emission wavelength of 311nm. Rosiglitazone was estimated in nanograms and its linearity was found to be 1-5ng/ml. The method was found to be rapid, precise and accurate which can be applied for the routine estimation of rosiglitazone in tablet dosage forms.

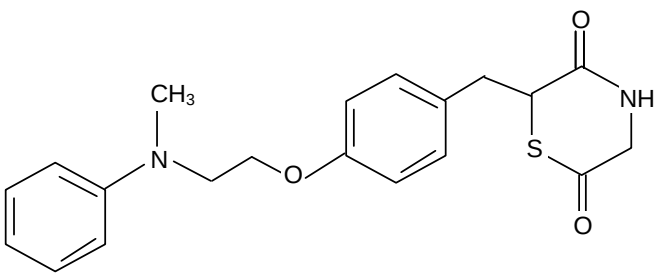
Key words: Fluorescence, rosiglitazone, oral antidiabetic agent and tablets.

INTRODUCTION

Rosiglitazone is a thiazolidinedione antihyperglycemic drug used in the treatment of type 2 diabetes mellitus and chemically, it is (±)-5-{p-[2- (methyl-2-pyridylamino)ethoxy]benzyl}-2,4-thiazolidinedione maleate.[1] Like all other thiazolidinediones, the mechanism of action of rosiglitazone is by activation of the intracellular receptor class of the peroxisome proliferator-activated receptors (PPARs), specifically PPARγ. Rosiglitazone is a selective ligand of PPARγ, and has no PPARα-binding action. Apart from its effect on insulin resistance, it appears to have an anti-inflammatory effect: nuclear factor kappa-B (NFκB) levels fall and inhibitor (IκB) levels increase in patients on rosiglitazone[2].

The literature survey reveals that HPLC, [3]first derivative spectrophotometry[4]and LCMS[5] have been employed to estimate rosiglitazone in tablet dosage forms.

In this paper, a study about the native fluorescence of rosiglitazone was estimated. This method was found to be highly sensitive, precise and stable method for the estimation of rosiglitazone in tablet dosage form. Pure authentic sample of rosiglitazone was procured from (Microlabs, Bangalore).



EXPERIMENTAL

Instrumentation

The spectra and intensity of fluorescence were measured with JASCO FP- 750 Spectrofluorimeter (JASCO, Japan).

Chemicals and Reagents

All chemicals used were of analytical grade. All stock solutions were freshly prepared using methanol.

Preparation of standard stock solution

A stock solution of rosiglitazone (100µg/ml) was prepared by dissolving rosiglitazone in methanol, and this solution was further diluted with methanol so as to get a final concentration of 10ng/ml which was considered as the working standard solution.

From the working standard solution 10ng/ml,1-5ml of rosiglitazone was pipetted out and made up with methanol to obtain a concentration of 1-5 ng/ml. The excitation and emission wavelength was measured by keeping the excitation and emission bandwidth at 10nm respectively.

Development of experimental fluorescence

Excitation wavelength was fixed at one of the known absorption maximal wavelength of rosiglitazone in methanol (297nm) and emission wavelength was varied to determine with optimum wavelength. Optimum emission wavelength found above was fixed and the excitation wavelength was varied to determine the effect of latter on fluorescent intensity and optimum excitation wavelength corresponding to maximum fluorescence was determined. And therefore the fluorescence intensities of rosiglitazone was measured at $\lambda_{ex}/\lambda_{em}$ = 297nm/311nm in a 1cm quartz cell with a bandwidth of 10.0nm for the excitation and emission spectra's.

Calibration curve

In a series of 10ml standard flasks, aliquots of samples ranging a concentration of 1-5ng/ml of standard rosiglitazone solutions were prepared and a calibration graph was plotted. The fluorescence of these solutions was measured against blank methanol with 297nm and 311nm as excitation and emission wavelength respectively.

Estimation of tablets

For the analysis of tablets, 20 tablets were weighed and crushed in to a fine powder. An accurately weighed powder sample equivalent to 10mg of rosiglitazone was transferred to a 100ml standard flask and dissolved and the volume was made up with methanol. The solution was filtered through whatman filter paper no.41. The solution was then further diluted with methanol to get a final concentration of 1-5ng/ml and was analyzed as described in calibration curve.

RESULTS AND DISCUSSION

In this work, it is found that rosiglitazone gave native fluorescence in methanol, which is due to the presence of N-CH_3 group, when measured at an excitation and emission wavelength of 297nm and 311nm respectively. Fluorescence intensity is linearly correlated with the concentration of rosiglitazone (1-5ng/ml). The proposed method was done for various tablet dosage forms of rosiglitazone and the results are given in Table 1. The validated parameters are shown in Table 2.

Table 1: Analysis of samples of rosiglitazone maleate

Sample	Percentage recovery
Tablet 1	100.44
Tablet 2	99.76
Tablet 3	99.01

Table 2: Validation parameters

Parameters	Proposed method
Linearity range(ng/ml)	1-5
Correlation coefficient(r^2)	0.9996
Accuracy (%)	99.56
Stability studies	3hrs

CONCLUSION

The proposed method is a simple, accurate and economical method, which can be used for the routine analysis of rosiglitazone in tablet dosage forms.

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