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ASSAY OF ROSIGLITAZONE BY VISIBLE SPECTROPHOTOMETRY

V.Jagathi*, G.Devala Rao, P.Sai praveen and CH.Manohar Babu
K.V.S.R.Siddhartha college of pharmaceutical sciences, Vijayawada–520 010, A.P, India.
Email: vallurijagathi@gmail.com

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ABSTRACT:

Two simple and sensitive extractive spectrophotometric methods have been developed for the estimation of rosiglitazone (RGL) in pure and pharmaceutical dosage forms. These methods are based on the formation of ion-pair complexes of the drug with basic dyes 3-Methyl-2-benzothiazolinone hydrazone (MBTH λ_{max} 630 nm) and Bromocresol green (BCG : λ_{max} 420 nm). The absorbance of the chloroform extracts is measured against the corresponding reagent blanks. These methods have been statistically evaluated and found to be precise and accurate.

Keywords: Spectrophotometric method, RGL, MBTH, Bromocresol green.

INTRODUCTION:

Rosiglitazone (RGL) is chemically called 5-[[4-[2-(methyl-pyridin-2-ylamino) ethoxy] phenyl] methyl]-1, 3-thiazolidine-2, 4-dione is official in Indian Pharmacopoeia. Literature survey reveals that visible spectrophotometric methods have not been reported for its quantitative determination in its pure form and pharmaceutical formulations. In the present investigation two simple and sensitive extractive spectrophotometric methods have been developed for the determination of RGL. The developed methods involve the formation of colored chloroform extractable complexes with MBTH and BCG. Extractable complexes showed absorption maximum at 630 and 420nm respectively. Beers law is obeyed in the

concentration ranges of 10-30 µg/ml and 5-25µg/ml respectively. The results of analysis for the two methods have been validated statistically and by recovery studies.

EXPERIMENTAL:

Preparation of reagents:

1. 3-Methyl-2-benzothiazolinone hydrazine : 0.2% of MBTH in 100 ml of water

2. $FeCl_3$: 0.75 mg in 25 ml of water

3. HCl (0.5N) : 2.125 ml in 50 ml

4. Bromocresol Green Solution: 0.5 g of BCG dye was dissolved in 100 ml of distilled water

5. Standard drug solution: About 100mg of Rosiglitazone was accurately weighed and dissolved in 100 ml of water to obtain a stock solution of 1 mg/ml. This solution was further diluted with distilled water to get working standard solution of 100 µg/ml.

ASSAY PROCEDURES:

Method A: Aliquots of working standard solution of RGL ranging from 0.5-2.5 ml were transferred in to a series of 10ml volumetric flasks. To these 2ml of MBTH and shaken for 2 min. Then 2 ml of $FeCl_3$ and 1ml Hcl is added & Finally made upto 10ml with water. The absorbance of the red colored chromogen was measured at 630 nm against reagent blank and the amount of Rosiglitazone present in the sample was computed from its calibration curve.

MethodB: Aliquots of working standard solution of RGL ranging from 0.2-0.6 ml were transferred into a series of 125 ml separating funnels. To these 2 ml of BCG dye was added. The total volume of aqueous phase was adjusted to 10 ml with distilled water and 10 ml of chloroform was added. The contents were shaken for 2 minutes. The two phases were allowed to separate and the absorbance of the Yellow colored chromogen was measured at 420 nm against reagent blank and the amount of Rosiglitazone present in the sample solution was computed from its calibration curve.

RESULTS AND DISCUSSION: The optical characteristics such as beers law limits, Sandell's sensitivity, molar extinction coefficient, percent relative standard deviation, percent range of error(0.05 and 0.01 confidence limits) were calculated for both the methods and results are summarized in Table 1. The values obtained for the determination of RGL in Pharmaceutical formulations (Tablets) by the proposed methods are presented in Table 2. Studies reveal that the common excipients and other additives usually present in the Tablets did not interference in the proposed methods.

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

Parameters	Method A	Method B
λ_{max} (nm)	630	420
Beer's law limit(µg/mL)	5-25	2- 6
Sandell's sensitivity(µg/cm^2/0.001 abs. unit	0.0331	0.0099
Molar absorptivity(litre.mole^{-1}.cm^{-1})	5.53×10^3	1.988×10^4
Regression equation(Y*)		
Slope(b)	0.0231	0.1155
Intercept(a)	0.073	0.0286
Correlation coefficient(r)	0.9990	0.9994
%Relative standard deviation**	1.15	1.19
%Range of error		
0.05 significance level	0.846	0.984
0.01 significance level	0.921	1.042

*Y = a + bx, where 'Y' is the absorbance and x is the concentration of rosiglitazone in µg/mL

**For six replicates

Table-2: Estimation of Rosiglitazone in Pharmaceutical Formulations.

Formulations (Tablets)	Labelled amount(mg)	Amount found* by proposed method		% recovery** by proposed method	
		Method A	Method B	Method A	Method B
Tablet 1	5	4.92	4.88	99.15	99.34
Tablet 2	5	4.76	4.90	99.28	99.45
Tablet 3	10	9.89	9.85	98.85	99.36
Tablet 4	10	9.85	9.92	99.12	99.48

***** Average of six determinations

******Recovery of amount added to the pharmaceutical formulation

(Average of three determinations)

CONCLUSION: The proposed methods are applicable for the assay of drug RGL and have an advantage of wider range under Beers law limits. The proposed methods are simple, selective and reproducible and can be used in the routine determination of RGL in pure form and formulations with reasonable precision and accuracy.

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Corresponding author*

V.Jagathi*,
K.V.S.R.Siddhartha college of pharmaceutical sciences,
Vijayawada–520 010, A.P, India.
Email: vallurijagathi@gmail.com