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## Assay of rosiglitazone by extractive spectrophotometry

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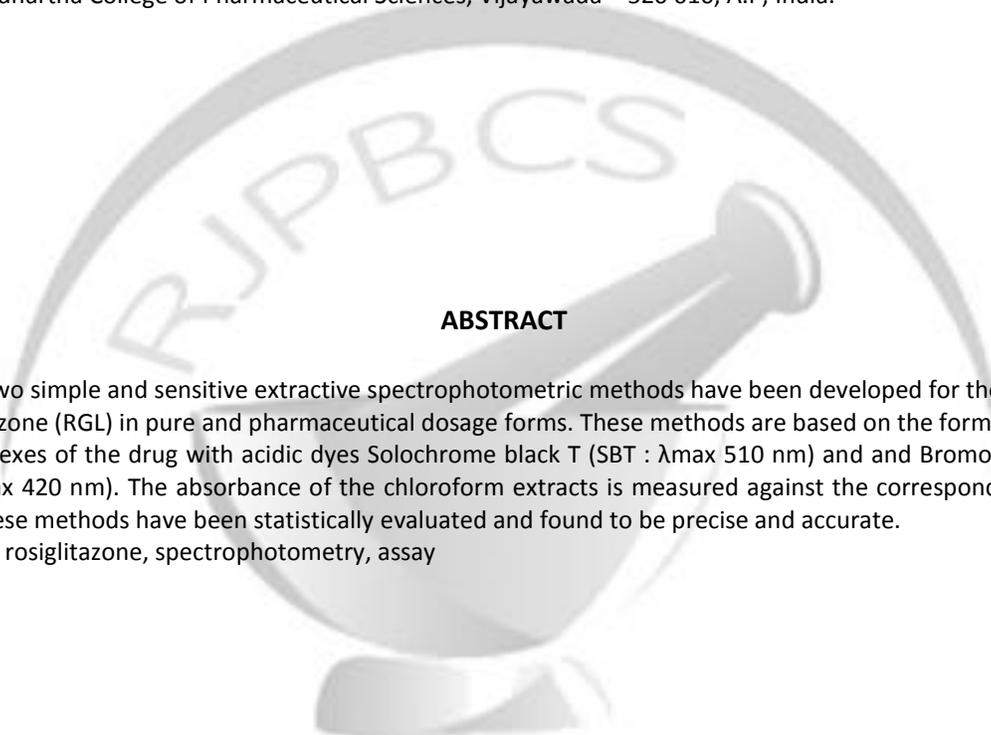
**ABSTRACT**

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 acidic dyes Solochrome black T (SBT : λmax 510 nm) and and Bromothymol Blue (BTB : λmax 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:** rosiglitazone, spectrophotometry, assay

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## 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 SBT and BTB.. Extractable complexes showed absorption maximum at 510 and 420 nm respectively. Beers law is obeyed in the concentration ranges of 5-25µg/ml and 2-6 µg/ml respectively. The results of analysis for the two methods have been validated statistically and by recovery studies.

## EXPERIMENTAL

### Preparation of reagents

1. Solochrome Black T Solution: 0.5 g of SBT dye was dissolved in 100 ml of distilled water.

2. Bromothymol Blue Solution: 0.1 g of BTB dye was dissolved in 100 ml of distilled water.

3. Acid phthalate buffer pH 2.2 [I.P]

4. 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 into a series of 125 ml separating funnels. To these 1 ml of buffer solution (pH 2.2) and 1 ml of SBT dye were 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 Pink colored chromogen was measured at 510 nm against reagent blank and the amount of RGL present in the sample solution was computed from its calibration curve.

**Method B:** 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 BTB 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 RGL 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 [1-9].

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

| Parameters | Method A | Method B |
|---|---|---|
| $\lambda_{max}$ (nm) | 510 | 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$^{-1}$) | $5.53 \times 10^3$ | $1.988 \times 10^4$ |
| Regression equation(Y*) | | |
| Slope(b) | 0.0231 | 0.1155 |
| Intercept(a) | 0.073 | 0.0286 |
| Correlation coefficient(r) | 0.9993 | 0.9995 |
| %Relative standard deviation** | 1.062 | 1.19 |
| %Range of error | | |
| 0.05 significance level | 0.892 | 0.984 |
| 0.01 significance level | 1.301 | 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 | 4.83 | 4.85 | 99.15 | 99.35 |
| Tablet 2 | 5 | 4.85 | 4.96 | 99.26 | 99.46 |
| Tablet 3 | 10 | 9.76 | 9.85 | 98.85 | 99.35 |
| Tablet 4 | 10 | 9.85 | 9.95 | 99.16 | 99.46 |

**\*** 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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