WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 7.523
Volume 7, Issue 2, 691-697. Research Article ISSN 2277– 7105

UV-SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF ROSIGLITAZONE MALEATE IN PHARMACEUTICAL DOSAGE FORMS

Snigdharani Behera*, Sujit Kumar Martha and Pratit Kanchan Sahu

Jeypore College of Pharmacy, Rondapalli, Jeypore, Koraput, Odisha – 764002.

Article Received on
01 Dec. 2017,
Revised on 21 Dec. 2017,
Accepted on 11 Jan. 2018
DOI: 10.20959/wjpr20182-10644

***Corresponding Author**
Snigdharani Behera
Jeypore College of Pharmacy, Rondapalli, Jeypore, Koraput, Odisha – 764002.

ABSTRACT

The objective of the proposed method is to develop simple & accurate method for the determination of Rosiglitazone maleate by UV spectrophotometric method in pharmaceutical dosage forms. Stock solution of Rosiglitazone was prepared & the calibration curve was drawn by suitable dilution of the standard solution. Commercially available Rosiglitazone tablet was taken & analysed. And the validation of the adopted method was ascertained by Precision & Accuracy. From the studies, it was found that, Rosiglitazone obeys linearity within the concentration range of 1-80µg/ml. From the results of precision study, it was found that the % R.S.D is less than 2%, which indicates that the method has good reproducibility. From the results of accuracy study, it was found that the % recovery values of pure drug from the pre-analysed solution of formulation were in between 97.5-98.12%, which indicates that the proposed method is accurate. The proposed method is specific while estimating the commercial formulations without interference of excipients and other additives.

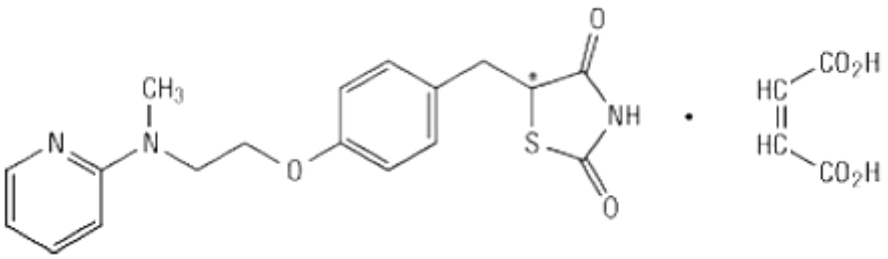
KEYWORDS: Rosiglitazone, Methanol, Precision, Accuracy, Validation.

INTRODUCTION

Rosiglitazone is a thiazolidinedione oral anti-diabetic that improves insulin sensitivity and is used for the treatment of type-II diabetes mellitus. Chemical name of Rosiglitazone maleate is 5-[[4-[2-(methyl-2-pyridinylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedione, (2Z)-2-butenedioate (1:1). Rosiglitazone maleate is a white crystalline powder, which is soluble in organic solvents such as ethanol, methanol, DMSO and dimethyl formamide (DMF). It is sparingly soluble in aqueous buffers.[1] Rosiglitazone is a prototypical Thiazolidinedione that

acts as a potent and selective peroxisome proliferator-activated receptor γ (PPARγ) ligand which binds vividly with PPARγ ligand binding domain and acts as an effective anti-diabetic agent in the treatment of type-II diabetes in humans.[2]

Structure of Rosiglitazone Maleate[3]



The UV-visible spectrophotometric methods which fall in the wavelength region 200-800nm are very simple, cheap & easy to carry out for the estimation of drugs in bulk form & their formulations.

OBJECTIVE

The objective of the proposed method is to develop simple & accurate method for the determination of Rosiglitazone maleate by UV spectrophotometric method in pharmaceutical dosage forms.

MATERIALS AND METHODS

Instrument

ARAMED electronic balance was used for weighing the samples. Shimadzu 1800 Double beam UV-Visible Spectrophotometer 1cm matched quartz cells was used for all spectral measurements.

Chemicals

All the chemicals used were of Analytical Reagent grade and procured from SD Fine Chemicals (SDFC), Mumbai, India.

Experimental Method

Spectral and absorbance measurements were made on SHIMADZU 1800 Double Beam UV-Visible Spectrophotometer by using 1cm quartz cells. In order to ascertain the maximum wavelengths of maximum absorption of the drug, different concentrations of the drug in methanol were scanned using UV-Visible Spectrophotometer within the wavelength region of

200-400nm against methanol as blank. The resulting spectrum is presented in figure-1 and the absorption curve showed characteristic absorption maximum at 248nm and 313nm for Rosiglitazone. To avoid any ambiguity in selecting any particular absorption maximum, a specific range of 290-340nm is selected for AUC method.[4,5]

Standard stock solutions of Rosiglitazone was prepared by dissolving 25 mg of Rosiglitazone in Methanol in a 25ml volumetric flask and volume was made up to the mark to get a solution of concentration 1mg/ml. The prepared stock solution was further diluted with methanol to get working standard solutions of Rosiglitazone. To construct Beer's Law plot for Rosiglitazone different aliquots of Rosiglitazone were taken and diluted to 10ml with methanol to get the working standard solutions as shown in table-1. Each solution were measured at λ_{max} range 290-340nm against methanol as blank the results are shown in table-1. The calibration curve for Rosiglitazone was plotted for taking concentration of drug on X-axis & area under curve on Y-axis and is shown in figure-2. The drug has obeyed Beer's Law in the concentration range of 1-80µg/ml. The optical characteristics for Rosiglitazone is shown in table-2.

For analysis of commercial formulations 20 tablets containing Rosiglitazone were taken and powdered. The powder equivalent to 10mg of Rosiglitazone was taken in a 100ml volumetric flask, containing 70ml of methanol & sonicated for 30 minutes. The volume was made upto 100ml with methanol and filtered. This was further diluted with methanol to get a concentration within the linearity range and the area under curve was measured against the blank at the range of 290-340nm and the results are shown in table-3.

The validation of the adopted method was ascertained by Precision & Accuracy. The precision of the proposed method was ascertained by actual determination of 8 replicates of fixed concentration of the drug within the Beer's range and finding out the absorbance by the proposed method.[6] From this absorbance, Mean, Standard Deviation and % of R.S.D was calculated and the readings are shown in table-4. To determine the Accuracy of the proposed method, recovery studies were carried out by taking different amounts (80%, 100%, 120%) of bulk samples of Rosiglitazone within the linearity range and adding to the pre-analysed formulation concentration. From that % recovery values were calculated. The results are shown in table-5.

RESULTS AND DISCUSSION

From the optical characteristics of the proposed method, it was found that, Rosiglitazone obeys linearity within the concentration range of 1-80µg/ml. From the results shown in precision table-4, it was found that the % R.S.D is less than 2%, which indicates that the method has good reproducibility. From the results shown in accuracy table-5, it was found that the % recovery values of pure drug from the pre-analyzed solution of formulation were in between 97.5-98.12%, which indicates that the proposed method is accurate and also reveals that the commonly used excipients and additives in the pharmaceutical formulations were not interfering in the proposed method.

Sample: Rosiglitazone (10 µg/ ml) **Analyst: Snigdharani Behera**

Reference: Methanol **Organization: SPER**

Instrument: SHIMADZU 1800 Double beam UV Visible Spectrophotometer

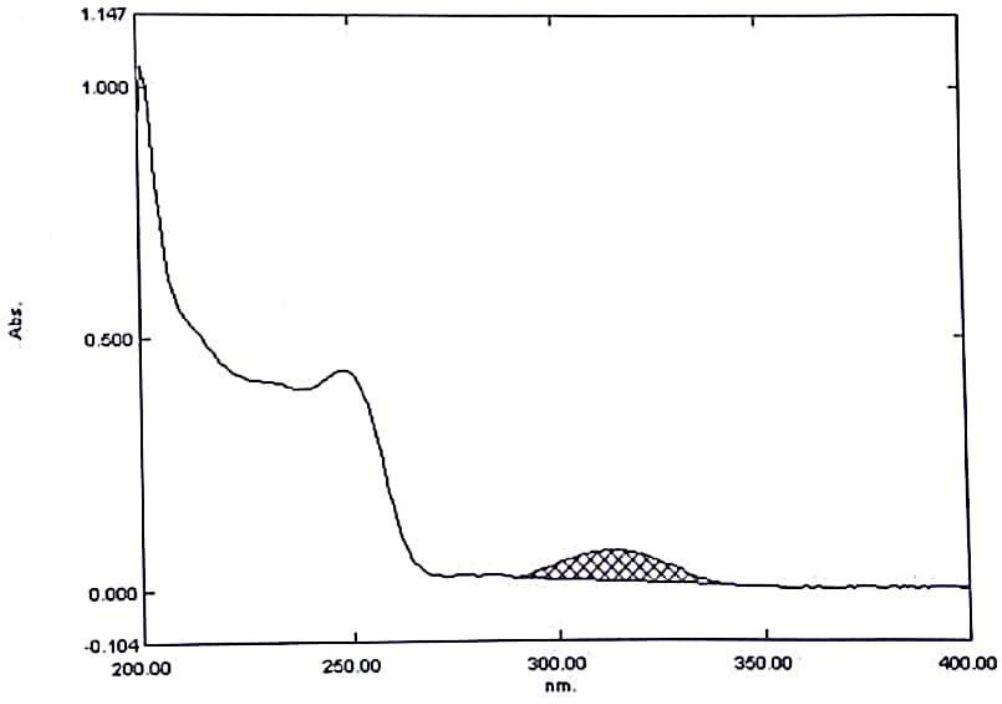


Figure – 1: UV Absorption Spectrum of Rosiglitazone maleate in Methanol

Table 1: Linearity Table for Rosiglitazone by UV Spectrophotometric method.

Concentration (µg/ml)	Area Under Curve
0	0
1	0.167
2	0.401
5	0.812
10	1.601
20	3.287
30	4.784
40	6.635
80	13.02

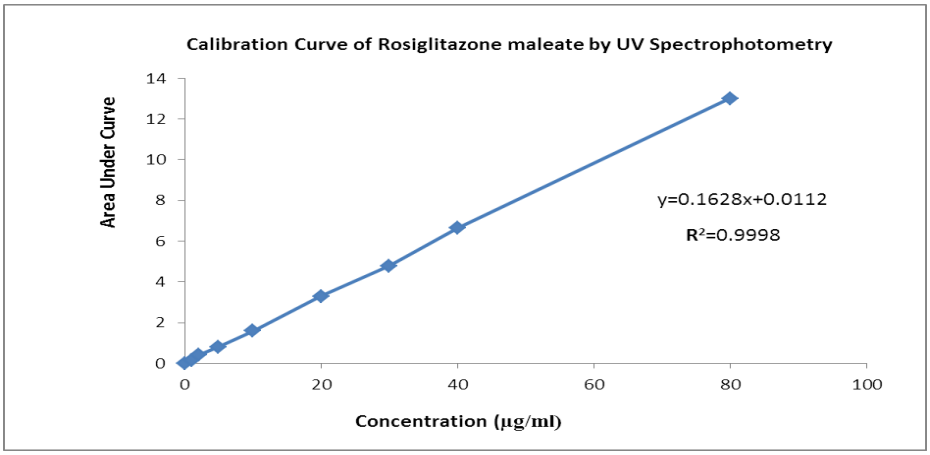


Figure-2: Calibration Curve of Rosiglitazone by UV-Spectrophotometric method in Methanol.

Table 2: Optical Characteristics for Rosiglitazone.

Parameters	Obtained Values
λ_{max} (Wave length range)	290-340
Beer's Law Limit (µg/ml)	1-80
Sandell's Sensitivity (µg/cm^2/0.001 AU)	0.0210
Molar Extinction Coefficient (L.mole^{-1}.cm^{-1})	2.254 x 10^4
% RSD	0.2407
Regression Equation	0.1628x + 0.0112
% Range of Error 0.05 confidence limits 0.01 confidence limits	 ±0.0026 ±0.0035
Correlation co-efficient	0.9998

Table 3: Analysis of commercial formulations.

Formulation	Labelled Amount (mg)	Observed Amount*(mg) ± S.D.	% Recovery by proposed method	% R.S.D.
ROGLIN Tablet (Aristo)	4	3.906±0.0011	97.65	0.0281

*** Each value is average of three determinations.**

Table 4: Precision.

Sl. No.	Concentration (µg/ml)	Area Under Curve	Statistical Analysis
1	10	1.603	Mean = 1.597 S.D. = ±0.003845 %R.S.D. = 0.2407
2	10	1.595	
3	10	1.595	
4	10	1.595	
5	10	1.595	
6	10	1.603	
7	10	1.601	
8	10	1.595	

Table 5: Accuracy.

Sample ID	Concentration (µg/ml)		% Recovery of Pure Drug	Statistical Analysis
	Pure Drug	Formulation		
S_1: 80%	8	10	97.5	Mean = 97.91 S.D. = 0.3587 %R.S.D. = 0.3654
S_2: 80%	8	10	98.12	
S_3: 80%	8	10	98.12	
S_4: 100%	10	10	97.7	Mean = 97.73 S.D. = 0.0577 %R.S.D. = 0.0590
S_5: 100%	10	10	97.8	
S_6: 100%	10	10	97.7	
S_7: 120%	12	10	97.91	Mean = 97.97 S.D. = 0.0520 %R.S.D. = 0.0530
S_8: 120%	12	10	98.0	
S_9: 120%	12	10	98.0	

CONCLUSION

The proposed method was simple, sensitive and reliable with good precision and accuracy. The proposed method is specific while estimating the commercial formulations without interference of excipients and other additives. Hence, this method can be used for the routine determination of Rosiglitazone maleate in pharmaceutical formulations.

BIBLIOGRAPHY

1. Wolff, M.E., ed. "Burger's Medicinal Chemistry", 5th Edn., Wiley Interscience, New York, 1981; 5: P-J9.
2. Goodman Gilman's, A., Rall, T.W., Nies, A.S. and Taylor, P., "Goodman and Gilman's The Pharmacological Basis of Therapeutics", 12th Edn, Mc Graw Hill book Company, New York, 1990; 142.
3. Sweetman S.C.; Martindale-The complete drug reference; 36th Edn, Monograph No.458.1, Pharmaceutical Press, London, UK, 2009; 458.
4. Sharma B.K.; Instrumental Methods of Chemical Analysis; 24th Edn, Goal Publishing House, Meerut, 2005; S-67.

5. Braun, R.D.; "Introduction to Instrumental Analysis"; 1st Edn, Mc Graw Hill book Company, New York, 1987; 112.
6. Onal A; Spectrophotometric & HPLC determinations of antidiabetic drugs rosiglitazone maleate and metformin hydrochloride in pure form and in pharmaceutical preparations; European Journal of Medicinal Chemistry, 2009; 44(12): 4998-5005.