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## Development and Validation of UV Spectrophotometric Method for Saroglitazar Tablets

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### ABSTRACT:

A new, simple, precise, accurate, reproducible and economical and sensitive UV - Spectrophotometric method has been developed for the estimation of Saroglitazar in bulk and pharmaceutical dosage form. The determination was made at 294 nm for Saroglitazar over the concentration range of 8-24 µg/ml with mean recovery of 99.91%. The LOD and LOQ were found to be 0.50 µg/ml and 1.52 µg/ml respectively. Methanol was used as solvent. The validation of method was carried out as per ICH Guidelines.

**KEY WORDS:** Saroglitazar, UV Spectrophotometric method, Validation, LIPAGLYN Marketed formulation

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### INTRODUCTION:

Analysis of pharmaceutical product is very important as it concerned with quality of life. Saroglitazar belongs to the class of 'glitazars', dual Peroxisome Proliferator Activated Receptor (PPAR) agonists with affinity towards both PPAR $\alpha$  and PPAR $\gamma$ . Saroglitazar has a predominant affinity for the PPAR $\alpha$  isoform, and a moderate affinity for PPAR $\gamma$ , and has shown beneficial effects on lipids and glycemic controls without side effects. It reduces triglycerides and LDL cholesterol, it increases HDL cholesterol, and also shows a reduction in Fasting Plasma Glucose and glycosylated haemoglobin. Till date no analytical method was reported for quantitative estimation of Saroglitazar. Saroglitazar is a novel antidiabetic drug launched in India by Cadila Pharmaceuticals Ltd. Literature survey reveals that there is no any analytical method has been developed and validated for Saroglitazar. The present manuscript describes simple, accurate, precise, reproducible, and economical UV Spectrophotometric method for the estimation of Saroglitazar in bulk and pharmaceutical dosage form.<sup>(1-10)</sup>

### MATERIAL AND METHODS

#### Instruments

Spectrophotometric measurements were performed on Shimadzu UV –visible double beam spectrophotometer (Model- 1800). All weighing were done on electronic analytical balance (Wensar Dab220).

#### Chemicals and Reagents

Saroglitazar bulk powder was obtained from India. The formulation Lipaglyn™ was

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procured from the local market. All other chemicals used were of analytical grade. Calibrated glass wares were employed throughout the work.

### Selection of a Solvent

Methanol was selected as a solvent for Saroglitazar.

### Preparation of Standard Stock Solution

Standard stock solution A:-100mg of Saroglitazar drug sample was weighed accurately and transferred to 100ml volumetric flask and diluted upto the mark with methanol (1000µg/ml).

Standard working solution:-From stock A 10 ml was pipetted out and was diluted upto 100ml with methanol in 100ml volumetric flask (100µg/ml).

### Preparation of Working Solutions

This series consisted of different concentrations of standard Saroglitazar solution ranging from 8-24µg/ml. The solutions were prepared by pipetting out 0.8, 1.2, 1.6, 2.0, and 2.4 of the working stock solution of Saroglitazar (100µg/ml) into series of 10 ml volumetric flasks and the volume was adjusted to mark with methanol to make 8, 12, 16, 20, and 24µg/ml solution of Saroglitazar.

### Selection of Analytical Wavelength

By appropriate dilution of standard drug working solution with methanol, solution containing 16 µg/ml of Saroglitazar was scanned in the range of 200-800 nm. Overlain spectra show 294 nm as the  $\lambda_{max}$  of Saroglitazar.

### Assay of Pharmaceutical dosage form

Twenty tablets were weighed accurately. Powder equivalent to 10 mg of Saroglitazar was weighed and transferred in a 100 ml volumetric flask and methanol was added. This solution was sonicated for 15 minutes and final volume was made to the mark with methanol. The solution (1.5ml) was transferred in a 10 ml volumetric flask and diluted to the mark with methanol to obtain sample solution. The sample solution was assayed as per proposed method.

### Method Validation

Method validation was performed following ICH guidelines. The proposed method has been extensively validated in terms of linearity, accuracy and precision, limit of detection and limit of quantification.

### Linearity (Calibration curve)

Calibration curve was plotted over a wide concentration range and the linear response was observed over a concentration range of 8-24 µg/ml for Saroglitazar. Accurately measured standard working solutions of Saroglitazar (0.8, 1.2, 1.6, 2.0, and 2.4ml) were transferred to a series of 10 ml of volumetric flasks and diluted to the mark with Methanol, and the absorbance was measured (n=3) at 294 nm. The calibration curve was constructed by plotting absorbance v/s. concentrations. The linear regression equation was  $y = 0.032x + 0.021$  ( $R^2 = 0.998$ )

### Accuracy

Accuracy was assessed by determination of the recovery of the method by addition of standard drug to the prequantified sample preparation at three different concentration levels 80 %, 100 % and 120 %, taking in to consideration percentage purity of added drug sample. The amount of Saroglitazar was estimated by applying obtained values to the respective regression line equations. Each concentration was analysed 3 times and average recovery was measured.

### Precision

The precision of an analytical procedure expresses the closeness of agreement between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions. The precision of the method was verified as repeatability, intra-day, inter-day and reproducibility.

Repeatability (intra assay) was determined by analyzing 8 µg/ml, 12 µg/ml, 16 µg/ml, 20 µg/ml and 24 µg/ml solutions three times. From the working standard solution of Saroglitazar (100 µg/ml) appropriate volumes 0.8 ml, 1.2 ml, 1.6 ml, 2.0 ml and 2.5 ml were taken in 10 ml volumetric flask and diluted up to mark with methanol to get 8 µg/ml, 12 µg/ml, 16 µg/ml, 20 µg/ml and 24 µg/ml. Each of the concentration was prepared in triplicate.

The absorbances of the solutions were measured and % C.V was calculated.

### Limit of Detection and Limit of Quantification

ICH guideline describes several approaches to determine the detection and quantification limits. These include visual evaluation, signal-to-noise ratio and the use of standard deviation of the response and the slope of the calibration curve. In the present study, the LOD and LOQ were based on

the third approach and were calculated according to the  $3.3 \times (SD/Slope)$  and  $10 \times (SD/Slope)$  criteria, respectively; where SD is the standard deviation of y-intercept of regression line and S is the slope of the calibration curve.

## RESULT AND DISCUSSION

A reliable method was developed for the estimation of the Saroglitazar in bulk and pharmaceutical dosage form by UV Spectrophotometry. Beers law was obeyed in concentration range of 8-24 $\mu\text{g/ml}$  for Saroglitazar at 294 nm. The correlation coefficient was found to be  $R^2 = 0.998$ . The mean % recoveries were found to be in the range of 98.19-100.48%. Precision (% RSD) of Saroglitazar was found to be 0.51-1.30 %. The LOD and LOQ were 0.50 $\mu\text{g/ml}$  and 1.51 $\mu\text{g/ml}$  of Saroglitazar respectively. The proposed method was precise, accurate and reproducible and acceptable recovery of the analytes, which can be applied for the analysis of Saroglitazar in marketed formulation.

## CONCLUSION

The results of our study indicate that the proposed UV spectroscopic method is simple, rapid, precise and accurate. The developed UV spectroscopic method was found suitable for determination of Saroglitazar in pharmaceutical dosage form without any interference from the excipients. This method is repeatable and selective for the analysis of Saroglitazar. It can therefore be concluded that use of the method can save time and money and it can be used in small laboratories with accurate and wide linear range.

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## TABLES AND FIGURES

**Table 1: Regression analysis data and summary of validation parameters for the proposed method**

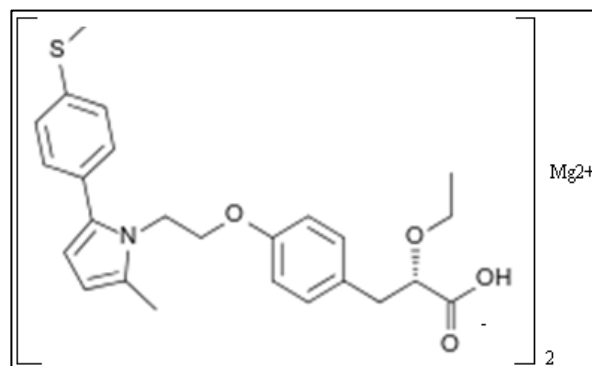
SR.NO	PARAMETERS	RESULTS
1	Linearity and Range( $\mu\text{g/ml}$ )	8-24
2	Correlation coefficient	0.998
3	Precision (%RSD)	
	1.Repeatability	0.51-1.30
	2.Intraday	0.19-0.40
	3.Interday	0.56-1.15
4	Accuracy (%Recovery)	98.19-101.06
5	LOD( $\mu\text{g/ml}$ )	0.50
6	LOQ ( $\mu\text{g/ml}$ )	1.52
7	Assay	101.92

**Table 2: Recovery data of proposed method**

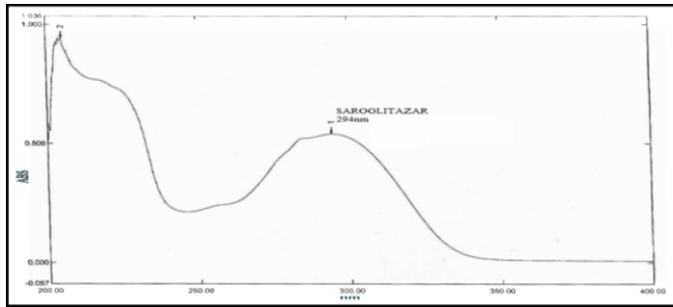
Level spiked	Sample amt. ( $\mu\text{g/ml}$ )	Std. amt. added	Total amt.	Amt. of Std. recovered ( $\mu\text{g/ml}$ )	Avg. % Recovery $\pm$ SD	% RSD
80	10	8	18	8.04	100.48 $\pm$ 1.1238	1.11
100	10	10	20	10.11	101.06 $\pm$ 0.9504	0.94
120	10	12	22	11.78	98.19 $\pm$ 0.2066	0.21

**Table 3: Analysis of Saroglitazar by proposed method**

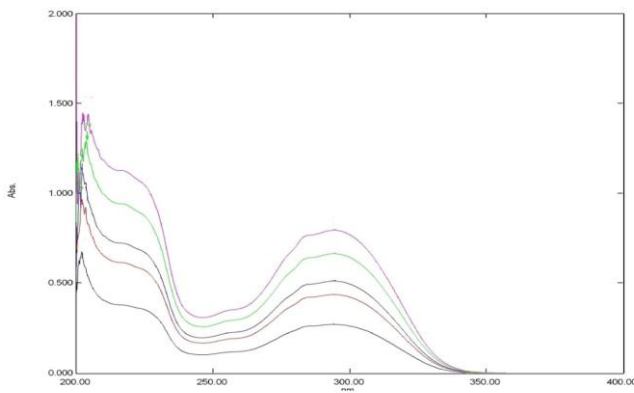
Brand name	Amt taken ( $\mu\text{g/ml}$ )	Amt found ( $\mu\text{g/ml}$ )	% Amt found (n=3)	Mean $\pm$ SD	%RSD
Lipaglyn	15	15.28	101.86	101.92 $\pm$ 0.3055	0.29
		15.34	102.26		
		15.25	101.66		



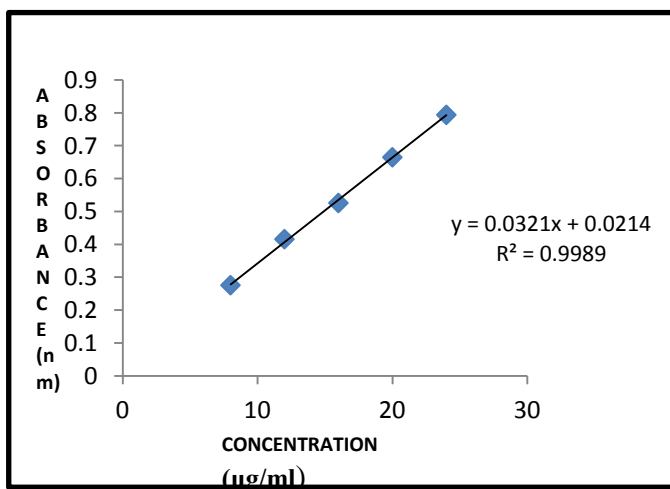
**Figure 1: Structure of Saroglitazar**



**Figure 2:** UV Spectrum for Saroglitazar (16 µg/ml) at 294 nm



**Figure 3:** Overlain spectrum of Saroglitazar (8-28µg/ml) in 0.1 N Methanol.



**Figure 4:** Calibration curve of Saroglitazar at 294 nm in Methanol.

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