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[Research article]

SPECTROPHOTOMETRIC ESTIMATION OF ROSUVASTATIN CALCIUM IN BULK & PHARMACEUTICAL FORMULATIONS

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ABSTRACT

Rosuvastatin calcium of the class statins is used for primary hyperlipidemias. It is a selective and competitive inhibitor of HMG-CoA reductase. In the present work, simple, sensitive and economic spectrophotometric method has been developed for quantitative determination of Rosuvastatin calcium. In the present spectrophotometric method Rosuvastatin calcium was dissolved in double distilled water. It exhibited an absorption maximum at 241 nm and obeyed Beer's law in the concentration range of 5-25µg/ml. The results of analysis have been validated and found to be sensitive, precise and accurate for quantitative determination of Rosuvastatin calcium in bulk drug and pharmaceutical formulations.

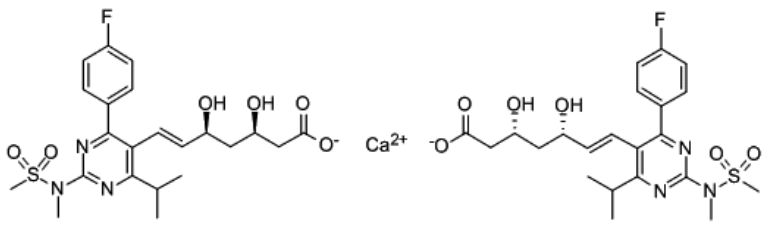
Key words: Rosuvastatin calcium, Water, UV spectrophotometer.

INTRODUCTION

Rosuvastatin calcium, a member of drug class statins is a selective and competitive inbitor of HMG-CoA reductase for primary hyperlipidemias [1]. Literature survey reveals that few analytical methods were reported for the estimation of Rosuvastatin. They include High performance liquid chromatography (HPLC) [2, 3] Liquid chromatography (LC) [4] detection for the estimation in human plasma and serum samples, High performance thin layer chromatography (HPTLC) [5] etc. A few spectrophotometric methods [6-10] for the determination of Rosuvastatin were also reported. However there is a need to develop a simple economic method that could be extended for estimation of Rosuvastatin calcium in Pharmaceutical educational institutions, industries, labs, health care units, etc.

Structure

Molecular structure of Rosuvastatin calcium [11]



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MATERIALS & METHODS

Material

Bulk drug of Rosuvastatin calcium was obtained as a gift sample from Micro Labs, Bengaluru. Formulation of the Rosuvastatin that was used for the study is Rosufine of Morpen Laboratories containing 10 mg and were procured from local market.

Equipment

Shimadzu 1800 UV Spectrophotometer with 1 cm matched quartz cell were used

Solvent

Double distilled water

Standard Drug Solution

Accurately weighed 100mg of Rosuvastatin calcium (Bulk Drug) was dissolved in 100ml of double distilled water to obtain a concentration of 1000µg/ml (Stock Solution).

From the above stock solution A, 10ml was pipetted out into 100ml calibrated volumetric flask and volume was made up to the mark with double distilled water to obtain a final concentration 100µg/ml (Working standard solution).

Preparation of Calibration Curve

Fresh aliquots from working standard solution (100µg.ml) ranging from 0.5 to 2.5ml (1ml = 100µg) were transferred into a series of 10ml calibrated volumetric flask and volume was made up to the mark by double distilled water to provide final concentration of 5 to 25 µg/ml. The absorbance of the solutions was measured at 241nm against water as blank. Calibration curve was prepared by plotting absorbance versus concentration of drug.

Assay procedure for pharmaceutical tablets

For the analysis of Rosuvastatin calcium a brand of commercially available tablets were purchased. The sample of tablet claimed to contain 10mg of active drug. 10 tablets were weighed and grounded into fine powder. An accurately weighed portion of the powder equivalent to 100mg of Rosuvastatin was transferred into a 100ml volumetric flask containing small quantity of double distilled water and the solution was shaken thoroughly for about 10-15min. The final volume (100ml) was made with double distilled water to obtain a solution of 1000µg/ml (Stock Solution).From the above stock solution, 10ml of the solution was pipetted out into a 100ml calibrated volumetric flask and volume was made up to mark with double distilled water to obtain final concentration of 100µg/ml (Working standard solution).

Subsequent dilutions of this solution were made with double distilled water to get aliquots of concentration range 5-25µg/ml and were analysed at the selective analytical wavelength of 241nm.

The amount of Rosuvastatinin the sample & its % purity were computed from:

Amount of drug (mg) = A_T / A_S * Conc. of standard * dilution factor *Average weight

% Purity = Amount of drug (mg) * 100 / Label Claim

RESULTS

Fig: 1. Absorption spectrum of ROSUVASTATIN CALCIUM with water (λ_{max} 241nm)

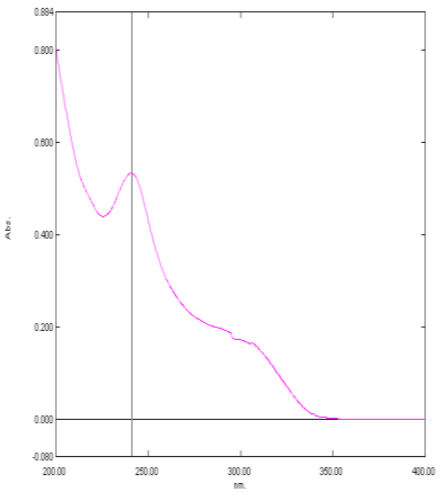

Fig: 2-Calibration curve of ROSUVASTATIN CALCIUM with water

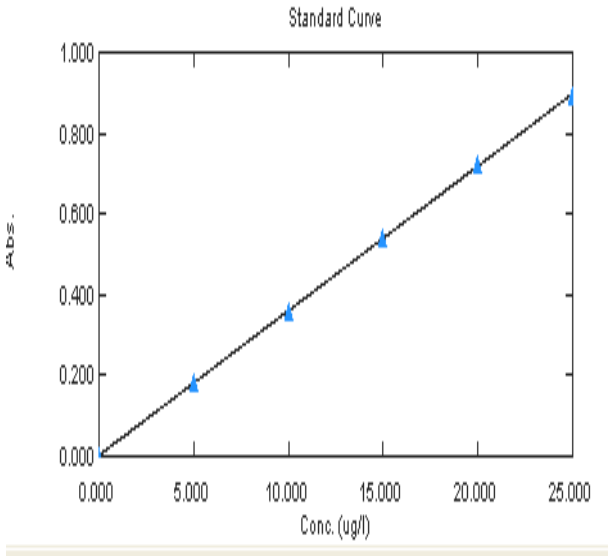

Table-1: Calibration Curve of Rosuvastatin calcium by UV spectroscopy

Concentration µg/ml	**Absorbance***
0	0.000
5	0.185
10	0.356
15	0.543
20	0.725
25	0.892

*Average of three readings

Table-2: Optical characteristic and precision

Parameters	**UV Method**
λ_{max} (nm)	241
Beer's law limits (µg/ml)	5-25
Molar absorptivity (lit. mol^{-1} cm^{-1})	5.35×10^{-7}
Limit of Detection (LOD/ $mcgml^{-1}$)	2.2558
Limit of Quantification (LOQ/ $mcgml^{-1}$)	6.8360
Regression equation (Y*)	
Slope (b)	4.36×10^{-4}
Intercept (a)	$- 1.11 \times 10^{-3}$
Correlation coefficient (r)	0.99952
% RSD**	1.3724

*Y=bC+a, where C is the concentration of ROSUVASTATIN calcium in µg/ml and Y is the absorbance, **Average of eight determinations.

Table-3: Evaluation of ROSUVASTATIN CALCIUM in pharmaceutical dosage form (tablets) by UV Spectroscopic method

Sample	Labelled amount (mg)	Amount of drug found by the proposed method* (mg)	% Recovery of the proposed method
T_1	10	9.9	99

T_1 are tablets from manufacturer Morpen Laboratories.

Table-4: Recovery studies of ROSUVASTATIN CALCIUM by UV method

Amount of Drug in formulation (ml)	Amount of drug added (ml)	Amount of drug recovered (mg)	% Recovery	Mean Recovery
1	0.5	4.99	96.54	100.05
1	1.0	13.10	99.71	
1	1.5	25.40	103.9	

DISCUSSION

The absorbtion maxima detrermined through this method was 241nm (fig.1). The optical characteristics are summarized in Table2.The results showed that the method has reasonable precision with low %R.S.D. Assay showed 99% purity of the pharmaceutical dosage form (table 3).The linearity of the method was established from the regression line equation given in table 1. The results showed a linear relationship between concentration and absorbance for the range of 5-25μg/ml (UV method). The result of the recovery study (table 4) establishes the accuracy of the method.

CONCLUSION

The proposed method was found to be economic, accurate, precise, linear, selective, less time consuming with sensitivity. Thus it can be extended for routine analysis of Rosuvastatin calcium in pharmaceutical industries, hospitals and research laboratories.

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