Simple UV Spectrophotometric Determination of Rosuvastatin Calcium in Pure Form and in Pharmaceutical Formulations

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Abstract: A new, simple and sensitive spectrophotometric method in ultraviolet region has been developed for the determination of rosuvastatin calcium in bulk and in pharmaceutical formulations. Rosuvastatin exhibits absorption maxima at 244 nm with apparent molar absorptivity of 7.2345×10^4 L/mol.cm in methanol. Beer's law was found to be obeyed in the concentration range of 2-18 µg/mL. The method is accurate, precise and economical. This method is extended to pharmaceutical preparations. In this method, there is no interference from any common pharmaceutical additives and diluents. Results of the analysis were validated statistically and by recovery studies.

Keywords: Spectrophotometric determination, Rosuvastatin calcium, Validated

Introduction

Rosuvastatin calcium (ROSU) is chemically *bis* [(E)-7 [4-(4-fluorophenyl)-6 isopropyl- 2-[methyl (methyl-sulphonyl) amino] pyrimidin-5-yl] (3R, 5S) -3,5-dihydroxyhept-6-enoic acid] Calcium salt. It is a lipid-lowering drug¹⁻². It inhibits the enzyme 3-hydroxy-3-methyl glutaryl coenzyme A (HMG-CoA) reductase, the rate limiting enzyme that converts HMG-CoA to mevalonate a precursor of cholesterol and thereby checks the synthesis of cholesterol. It is used in the treatment of hyper-cholesterolemia and dyslipidemia³⁻⁴. A survey of literature^{5,6} showed few solid phase extraction using tandem MS, few LC-MS methods⁷⁻⁹ and one HPTLC method¹⁰ for the estimation of ROSU in pharmaceutical preparations and in biological fluids.

To the best of our knowledge, there is no report of UV-Visible spectrophotometric method for its estimation. Therefore, an attempt was made to develop a simple spectrophotometric method for the estimation of the present drug in formulations *i.e.* tablets.

Experimental

Apparatus

A GBC Cintra-10 double beam UV-Visible spectrophotometer (Australia) equipped with 10 mm matched quartz cells was used in the present investigation. A sartorius analytical balance was used.

Chemicals and reagents

Methanol (AR) (Qualigens) was used in the present study. Pure rosuvastatin obtained from M/s Torrent Pharmaceuticals Ltd., Ahmedabad, was used as such without further purification.

Recommended procedure and calibration curve

ROSU (100 mg) was accurately weighed and dissolved in 100 mL methanol to form a stock solution (1000 $\mu\text{g/mL}$). The stock solution was further diluted suitably with methanol to get a working standard solution of concentration 100 $\mu\text{g/mL}$. This working standard solution was suitably diluted to give a concentration of 14 $\mu\text{g/mL}$ and this was then scanned in UV range. This showed an absorption maximum at 244 nm (Figure 1). Aliquots (0.2, 0.4, ..., 1.8) mL of working standard solution corresponding to 2-18 μg were taken in a series of 10 mL volumetric flask and volume made up with methanol. The absorbance measurements of these solutions were carried out against methanol as blank at 244 nm. A calibration curve of ROSU was plotted. The concentration of the unknown was read from the calibration graph or computed from the regression equation.

Figure 1. Rosuvastatin scanned in UV range (in Methanol).

Procedure for tablets

Two commercial formulation, fortius (M/s Nicholas Piramal) and rosuvas (M/s Ranbaxy Ltd.) were purchased from local market. The average weight of each tablet (before and after removing coating) was calculated by weighing 20 tablets. Ten tablets were powdered finely in a glass mortar. Powder equivalent to 50 mg of rosuvastatin was successively extracted with methanol (4 x 20 mL) and the extracts transferred quantitatively into 100 mL volumetric flask after filtering through Whatman No. 1 filter paper. The volume was then made up with methanol (500 µg/mL). Then this solution was further diluted with methanol to get working standard solution of 50 µg/mL. Suitable volume of this solution was taken in 10 mL volumetric flask and volume was made up with methanol. Absorbances were read and concentrations of ROSU determined using the calibration curve. Calculations were then made with the dilution factor to find out the concentration of the drug in tablets. The experiments were repeated six times to check its reproducibility.

Results and Discussion

The proposed method for determination of ROSU showed molar absorptivity of 7.2345×10^4 L/mol.cm. Linear regression of absorbance on concentration gave the equation $y = 0.0726x + 0.001$ with a correlation coefficient (r) of 0.9978 (Table 1). Statistical analysis of commercial formulations has been shown in Table 2.

Table 1. Optical characteristics of ROSU.

Parameters	Values
$\lambda_{\max}$, nm	244
Beer's Law Limit, µg/mL	2-18
Molar absorptivity, L/mol.cm	7.2646×10^4
Sandell's sensitivity (µg/cm ² x 0.001 absorbance unit)	0.0137
Regression equation	$y = ax + b$
Slope (a)	0.0726
Intercept (b)	0.001
Correlation coefficient (r)	0.9978

Table 2. Statistical analysis of ROSU tablets.

S.No	Brand	Label claim mg/tab	Amount found mg/tab*	%Label claim±SD*	SE*
1.	ROSUVAS (10 mg)	10	9.9904	9.99±0.0140	0.0057
2.	FORTIUS (10 mg)	10	9.9892	9.98±0.0108	0.0044

*Average of six determinations

To evaluate the validity and reproducibility of the method, known amount of pure drug was added to the analyzed sample of tablet powder and the mixture was analyzed for the drug content using the proposed method. The percentage recovery was found to be within range (Table 3). Rosuvastatin exhibited maximum absorption at 244 nm and obeyed Beer's Law in the concentration range of 2-18 µg/mL. The recovery experiments indicated the absence of interference from the commonly encountered pharmaceutical additives and excipients.

Table 3. Recovery studies of ROSU tablets.

S.No.	Brand	Amount added, mg	Amount found, mg*	%Recovery $\pm$ S.D.*
1.	ROSUVAS (10 mg)	10	59.9976	99.99 $\pm$ 0.0766
2.	FORTIUS (10 mg)	10	59.9563	99.92 $\pm$ 0.0658

*Average of six determinations.

Thus it can be said that the proposed method is precise, accurate and economical which can be very well applied to the marketed samples.

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