Research Article

Determination of Rosuvastatin Calcium in bulk and Pharmaceutical dosage forms by using UV-Spectrophotometric method

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Abstract

Objective: The aim of the present work was to develop a simple and sensitive UV spectrophotometric method for the estimation of rosuvastatin calcium in bulk and in pharmaceutical dosage form. **Material and methods:** Rosuvastatin calcium exhibits maximum absorbance at 244 nm with apparent molar absorptivity of 7.1862×10^4 L/mol.cm in methanol as solvent. Beer's law was found to be obeyed in the concentration range 2-18 µg /ml for rosuvastatin calcium. **Result and discussion:** The results of the study demonstrated that the developed procedure was accurate, precise and economical. This method is further extended to pharmaceutical dosage form. **Conclusion:** In this method, no interference from any pharmaceutical additives and diluents were found. The validation of the analysis was done by statistically and recovery studies.

***Key words*:** Rosuvastatin calcium, UV spectrophotometric method, Validation

Introduction

Rosuvastatin Calcium is one of the most potent statins, and is approved for reducing circulating low-density lipoprotein cholesterol (LDL-C) levels. It occurs as a white crystalline powder and chemically known as E,3R,5S)-7-[4-(4-fluorophenyl)-2- [methyl(methyl sulfonyl)amino]-6-propan-2-ylpyrimidin-5-yl]-3,5-dihydroxyhept-6-enoate with molecular weight of 1001.14 g/mol (Luvai et al., 2012). It is a lipid lowering drug used in the treatment of hypercholesterolemia to prevent cardiovascular disease (Sweetman and Martindale, 2005). Rosuvastatin is a fully synthetic competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to mevalonate, a precursor of cholesterol. Common dosage forms are tablets and capsule (Ahmad et al., 2012). As per literature survey it reveals that, only few analytical techniques have been developed for the estimation of rosuvastatin calcium in bulk and pharmaceuticals such as High performance thin layer chromatography (HPTLC) method (Uma Devi et al., 2011), one Reverse phase high performance liquid chromatographic (RP-HPLC) method (Pandya et al., 2010) and few LC-MS methods (Singh et al., 2005). In this study an attempt was made to develop a simple spectrophotometric method for the estimation of the present drug in dosage form. A similar method was reported by many authors (Gupta et al., 2009; Sevda et al., 2011; Patel et al., 2012; Gajjar et al., 2010; Prajapati et al., 2010; Shinde et al., 2015) for the estimation of rosuvastatin calcium by UV spectrophotometric method.

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Material and methods

Apparatus

A UV-Visible spectrophotometer (UV- 1700, Pharmaspec, Shimadzu, Kyoto, Japan) with one cm matched quartz cells was used for all absorbance measurements and Digital electronic balance (Sansui, Tokyo, Japan) was used for weighing of all samples.

Chemicals

Pure rosuvastatin calcium was obtained from M/s Sun pharmaceuticals Industry Ltd., Gurgaon, Haryana, India with purity of 99.9 % respectively. Methanol AR was purchased from Sd fine chemicals, Mumbai, India. Tablet formulation 10 mg of rosuvastatin calcium was procured from the local pharmacy.

Determination of wavelength maxima (λmax)

Rosuvastatin calcium was scanned in methanol. Accurately weighed 100 mg of drug was dissolved in 100 mL of respective media (1000 µg/mL). From this solution 10 mL solution was pipette out in 100 mL of volumetric flask and volume was made (100 µg/mL) and marked as stock solution. From the above stock solution 2 mL was transferred in 100 mL of volumetric flask and volume was made (2µg/mL). This solution was than scanned over the range of 200 to 400 nm against a blank using Shimadzu, UV-visible spectrophotometer. The wavelength at which maximum absorbance was achieved was considered as the wavelength maxima (λmax) for the pure drug (Prajapati et al., 2010).

Preparation of calibration curve

Calibration curve of drug Rosuvastatin calcium was prepared in methanol. Accurately weighed 100 mg of drug was dissolved in 100 mL of respective media (1000 µg/mL). From this solution 10 mL solution was pipetted out in 100 mL of volumetric flask and volume was made (100µg/mL). From the above stock solution aliquots of 2, 4, 6, 8, 10, 12, 14, 16, 18 mL were transferred to series of 100 mL of volumetric flask and volume was made with different media to get serial dilutions containing 2-18 µg/mL of drug substance. The absorbance values corresponding to each concentration in different media was recorded using Shimadzu, UV-visible spectrophotometer (Sevda et al., 2011; Shinde et al., 2015).

Procedure for tablets

To estimate the drug in pharmaceutical dosage forms two commercial formulations Rozavel (M/s Sun Pharmaceuticals) and Crestor (M/s AstraZeneca) were purchased from local pharmacy. The average weight of each tablet with and without coating was calculated by weighing 20 tablets. Ten tablets were powdered finely in a mortar pestle. Powder equivalent to 50 mg of drug was successively extracted with methanol (4 × 20 mL) and the extracts transferred quantitatively into 100 mL volumetric flask after through 0.22 µm membrane filter. Then make up the volume with methanol (500µg/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. Absorbance was read and concentrations of rosuvastatin 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 (Gupta et al., 2009).

Statistical analysis

All the experiments were performed in triplicate and all data are reported as mean ± standard deviation (SD).

Results and discussion

The solution of pure drug was scanned in methanol using Shimadzu, UV-visible spectrophotometer as shown in figure 1. The Absorbance maximum was found to be 244nm. The molar absorptivity of rosuvastatin calcium was found to be 7.1862×10^4 L/mol.cm in methanol as solvent. The calibration curve of Rosuvastatin calcium was prepared in methanol as shown in table 1 and figure 2. Calibration curve was plotted between absorbance and concentration. The value of regression coefficient (R^2) was determined to be 0.9969 which was found to be near 1 and the linear regression of absorbance on concentration gave the equation y = 0.047x+0.0967 as shown in table 2. The curve was found to be linear in the concentration range of 2-18 µg/mL and was in accordance with Beers-Lambert law. The statistical analysis of dosage forms has been shown in table 3.

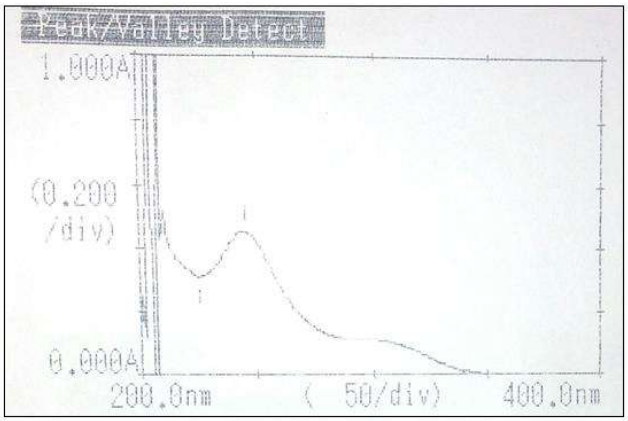

Figure 1. UV-Visible spectrum of drug in methanol

Table 1. Calibration curve of rosuvastatin calcium in methanol (mean ± S.D., n =3)

S. No.	Concentration (µg /ml)	Absorbance* ± S.D	±C.V.
1	2	0.09± 0.004	0.532
2	4	0.178± 0.006	0.345
3	6	0.288± 0.002	0.642
4	8	0.378± 0.002	0.984
5	10	0.486± 0.003	0.256
6	12	0.578± 0.002	0.509
7	14	0.67± 0.003	0.945
8	16	0.744± 0.002	0.676
9	18	0.851± 0.003	0.845

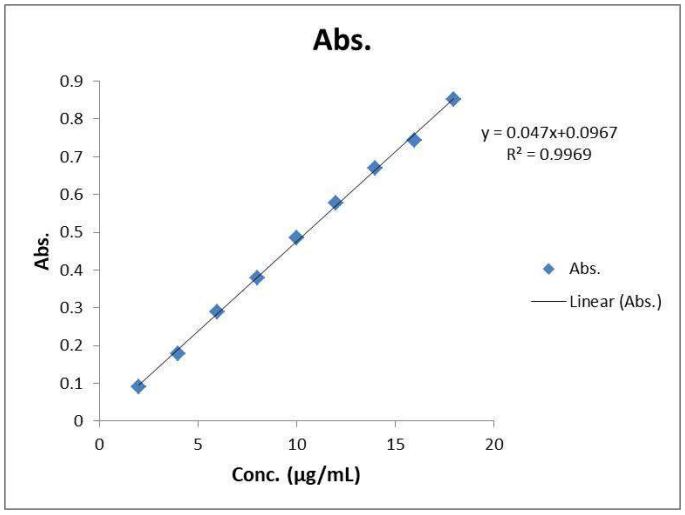

Figure 2. Calibration curve of rosuvastatin calcium in Methanol

Table 2. Optical characteristics of the calibration curve of rosuvastatin calcium

Parameters	Values
λ max (nm)	244
Beer's Law Limit, µg /ml	2-18
Slope (b)	0.047
Intercept (a)	0.0967
Regression equation (y= a+ bx)	0.047+0.0967
Regression coefficient (r^2)	0.9969
Molar absorptivity, L/mol.cm	7.1862×10^4
Sandell's sensitivity (µg /cm^2 × 0.001 absorbance unit)	0.0142

Table 3. Statistical analysis of rosuvastatin tablets

S. No.	Brand	Label claim mg/tab	Amount found mg/tab*	% Label claim ±SD	SE*
1.	Rozavel (10mg)	10	9.9804	9.98±0.0124	0.0049
2.	Crestor (10mg)	10	9.9905	9.99±0.0112	0.0054

*Average of six determinations

For the evaluation of validity and reproducibility of the method, a known amount of drug was added to the analyzed sample of the tablet powder and the mixture was analyzed for drug content. The percent recovery was found to be within range as shown in table 4. The drug showed the absorption maxima at 244 nm and obeyed the Beer's Law in the concentration range 2-18µg/mL. The interference from the pharmaceutical additives and excipients are absence shown by recovery experiments.

Table 4. Recovery studies of rosuvastatin tablets

S. No.	Brand	Amount added (mg)	Amount found, (mg*)	% Recovery ±SD*
1.	Rozavel (10mg)	10	58.8872	99.85±0.0624
2.	Crestor (10mg)	10	59.8568	99.94±0.0598

*Average of six determinations

Conclusion

So as per the study it can be said that the proposed method is simple, precise, accurate and economical which can be very well applied to the marketed samples.

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Conflict of interest

All authors have none to declare.

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