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VALIDATED SPECTROPHOTOMETRIC METHOD FOR THE QUANTITATION OF ROSUVASTATIN CALCIUM IN BULK AND TABLET DOSAGE FORM

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ABSTRACT

Simple, precise and accurate zero order derivative spectroscopic method has been developed and validated for the estimation of Rosuvastatin calcium in bulk and Pharmaceutical dosage form. The drug shows maximum absorption (λ max) at 242nm in Acetonitrile solution and obeys Beer's law in the concentration range of 3-18µg/ml. The linearity study was carried out and regression coefficient was found to be 0.9999=b and it has showed good linearity, precision during this concentration range. The % recovery was found to be 98.54-100.55. The LOD and LOQ were found to be 0.076 and 0.23µg/ml. The % relative standard deviation were found to be less than 2. According to ICH guidelines the technique has been validated for linearity, precision, accuracy, robustness, ruggedness, LOD and LOQ. The developed and validated method can be successfully applied for routine quantification of Rosuvastatin Calcium in bulk and pharmaceutical dosage form.

KEYWORDS: Rosuvastatin Calcium, Zero order derivative spectroscopy, validation, pharmaceutical formulations.

INTRODUCTION

Rosuvastatin is in a class of medications called HMG-COA reductase inhibitors (statins), an enzyme found in the liver that plays a role in producing cholesterol. Rosuvastatin works by slowing the producing of cholesterol in the body to decrease the amount of cholesterol that may build up on the walls of the arteries and block blood flow to the heart, brain, and further parts of the body. It is also used to prevent the Cardiovascular disease in those at high risk and treat abdominal lipids.[1]

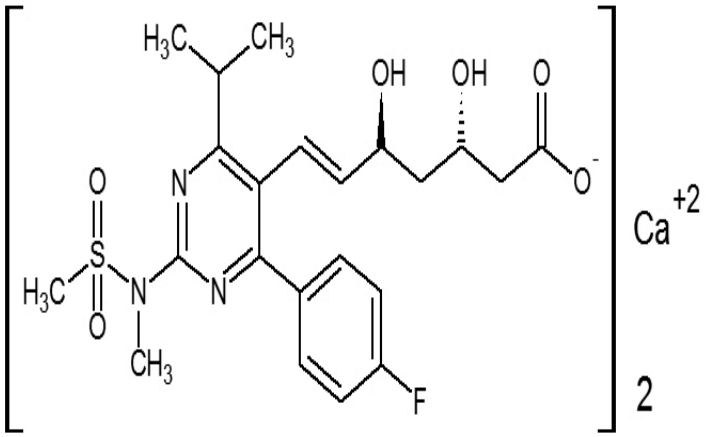

Fig. 1: Chemical structure of Rosuvastatin calcium

Literature survey revealed that there were few analytical methods have been reported for the determination of Rosuvastatin calcium in pure drug and pharmaceutical dosage forms by using UV spectrophotometric,[2-10] HPLC,[11-18] and HPTLC[19-22] so far.

The aim of present work is to develop and validate a novel, rapid, simple, precise and specific Zero order derivative UV Spectrophotometric method for estimation of Rosuvastatin calcium in bulk and tablet dosage form.

MATERIALS AND METHODS

Instrument: UV-Visible double beam spectrophotometer, SHIMADZU (model UV-1800) with UV probe software. All weights were taken in analytical balance.

Chemicals: Rosuvastatin calcium pure drug was obtained as a gift sample from Recipharma Ltd, Nelamangala, Bengaluru and its pharmaceutical dosage form Rosuvastatin calcium 20 tablet labelled claim 40mg from local pharmacy manufactured by Astra Zeneca Pharma India Ltd.

Solvent: Acetonitrile is used as a solvent.

Selection of analytical wavelength: Appropriate dilutions of Rosuvastatin calcium were prepared from standard stock solution and using spectrophotometer solution was scanned in the wavelength range 200-400nm. The absorption spectra obtained and show maximum absorbance at 242nm, as the wavelength for detection (Fig-2).

Preparation of standard stock solution: 100mg of Rosuvastatin calcium was weighed accurately and transferred in to 100ml volumetric flask and diluted in Acetonitrile up to mark. From this, the solution was further diluted into 100µg/ml and pipetted out 0.3, 0.6, 0.9, 1.2, 1.5, and 1.8ml into 10ml individual volumetric flask and diluted in Acetonitrile up to mark, this gives 3, 6, 9, 12, 15, and 18µg/ml concentration.

Preparation of sample solution: 20 tablets of Rosuvastatin calcium marketed formulations was weighed and powdered. A quantity of tablet powder equivalent to 100mg of Rosuvastatin calcium was transferred into a 100ml of volumetric flask then it was diluted with Acetonitrile and made up to the mark.

METHOD AND VALIDATION

The method was validated according to the ICH guidelines.

RESULTS AND DISCUSSION

Method: Zero order derivative spectroscopy

Linearity: The linearity of an analytical method is its dimension to show the test results that are directly proportional to the concentration of the analyte in the sample within the range. The linearity was established in the range of 3-18µg/ml was measured at 242nm and absorbance values are shown in table-1. The calibration curve was prepared by plotting graph against the concentration and absorbance and therefore the graph shown in Fig-3. Statistical variables like slope, intercept, regression equation, correlation coefficient and sandell's sensitivity were determined. (table-2).

Precision: The precision of an analytical method expresses the closeness of a series of individual analyte measurements obtained from multiple sampling of the equivalent sample. Precision was established by intra-day and inter-day studies. Intra-day precision was determined by analysing the same concentration for six times in a same day. Inter-day precision was determined by analysing the same concentration daily for six days. (table-3).

Accuracy: The accuracy of an analytical method says that closeness of test results obtained by that method to the true value. To assess the accuracy of the developed method, recovery studies were carried out at three different levels as 50%, 100% and 150%. In which the formulation concentration holds it constant and varied pure drug concentration. (table-4).

Ruggedness: The ruggedness is defined as the reliability of results when the method is performed under the variation in conditions. This includes distinct analyst, laboratories, instruments, temperature etc. Ruggedness was determined between distinct analyst, the value of %RSD was found to be less than 2. (table-5).

LOD and LOQ: The limit of detection is an individual analytical method is the smallest amount of analyte in a sample which can be reliably detected by the analytical method. The limit of quantitation is an discrete analytical procedure is the smallest amount of analyte in a sample which can be quantitatively determined. LOD and LOQ were calculated by using following formula.

LOD = 3.3(SD)/S and LOQ = 3(LOD)

LOD and LOQ value of were found Rosuvastatin calcium be 0.076 and 0.23µg/ml.

Table 1: Results of calibration curve at 242nm by zero order spectroscopy.

S. NO.	Concentration in µg/ml	Absorbance ± Standard deviation*
1	0	0
2	3	0.162±0.0015
3	6	0.320±0.0038
4	9	0.470±0.00571
5	12	0.622±0.0033
6	15	0.785±0.0030
7	18	0.941± 0.00521

**Average of six determinations.*

Table 2: Regression parameter Rosuvastatin calcium for by zero order spectroscopy.

Regression parameter	Results
Range(µg/ml)	3-18
λ_{max}(nm)	242
Regression Equation	Y= 0.052x+0.0031
Slope(b)	0.052
Intercept(a)	0.0031
Correlation coefficient(r^2)	0.9999
Sandell's equation	0.019
Limit of detection(µg/ml)	0.076
Limit of quantitation(µg/ml)	0.23

Table 3: Determination of precision results for Rosuvastatin calcium at 242nm by zero order spectroscopy.

Concentration (µg/ml)	Intra-day Absorbance ±Standard deviation*	%RSD**	Inter-day Absorbance ±Standard deviation*	%RSD**
3	0.170±0.0015	0.88	0.171±0.00095	0.55
6	0.329±0.0012	0.364	0.328±0.0015	0.47
9	0.472±0.0022	0.46	0.474±0.0023	0.49
12	0.630±0.00134	0.212	0.636±0.0023	0.36
15	0.790±0.00125	0.158	0.794±0.00186	0.23
18	0.921± 0.00125	0.136	0.932± 0.00157	0.16

***Average of six determinations, **percentage relative standard deviation.*

Table 4: Determination of Accuracy results for Rosuvastatin calcium at 242nm by Zero order spectroscopy.

Spiked Levels	Amount of Sample (µg/ml)	Amount of Standard (µg/ml)	Amount Recovered	% Recovery ±Standard deviation*	%RSD**
50	9	4.5	13.58	100.55 ±0.374	0.371
100	9	9	17.74	98.54 ±0.238	0.241
150	9	13.5	22.45	99.77±0.220	0.220

***Average of six determinations, **percentage relative standard deviation.*

Table 5: Determination of Ruggedness results for Rosuvastatin calcium at 242nm by Zero order spectroscopy.

Analysts	Analyst 1	Analyst 2
Mean absorbance	0.464	0.463
±Standard deviation*	0.00124	0.00226
%RSD	0.267	0.475

***Average of six determinations, **percentage relative standard deviation.*

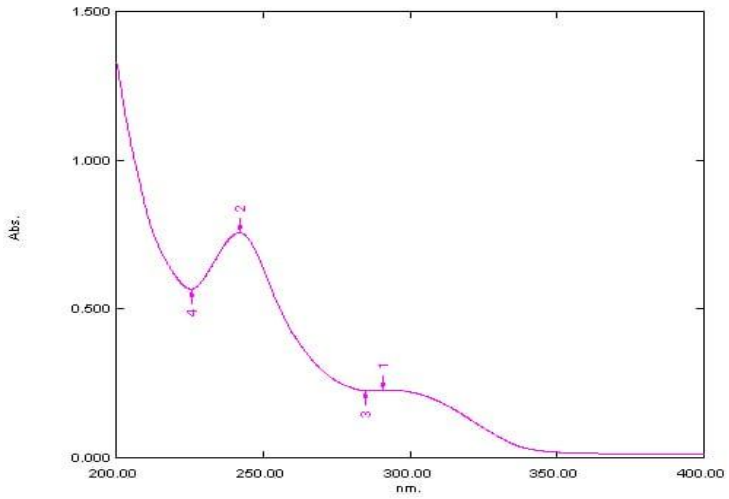

Fig. 2: Zero order spectrum of Rosuvastatin calcium at 242nm.

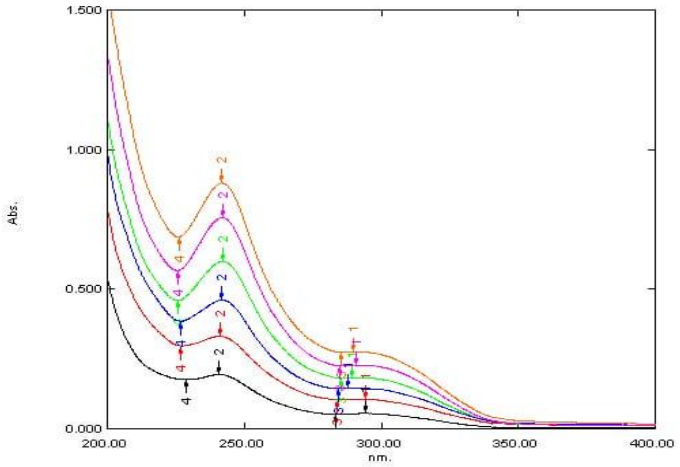

Fig. 3: Zero order overlain spectra of Rosuvastatin calcium showing absorbance at 242nm.

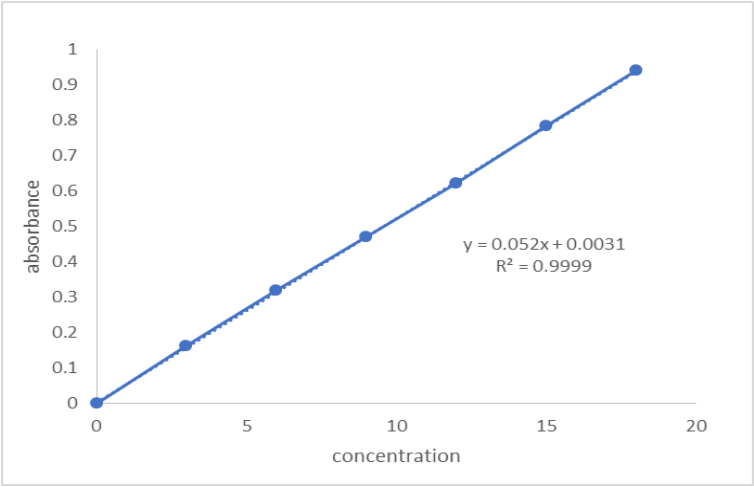

Fig. 4: Calibration curve of Rosuvastatin calcium by zero order spectroscopy.

CONCLUSION

As per ICH guidelines, the developed analytical method meets the acceptance criteria. It was concluded that the method is simple, specific, accurate, economical and sensitive and can be used for routine analysis of Rosuvastatin calcium in bulk drug and in pharmaceutical dosage forms.

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