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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 area under curve 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 Area under Curve [AUC] in absorption spectra were measured between the wavelength range 237 to 247nm which 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 0.9998 and it has showed good linearity, precision during this concentration range. The % recovery was found to be 98.94-101.25. The LOD and LOQ were found to be 0.037 and 0.114µg/ml. The % relative standard deviation was found to be less than 2. According to ICH guidelines the method has been validated for linearity, precision, accuracy, robustness, ruggedness, LOD and LOQ. The developed and validated method can be successfully applied for routine quantitation of Rosuvastatin calciumin bulk and pharmaceutical dosage form.

KEYWORDS

Rosuvastatin calcium, Area under curve spectroscopy, Validation and Pharmaceutical formulations.

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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 production 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].

Literature survey revealed that there were few analytical methods have been reported for the determination of Rosuvastatin calciumin pure drugand 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 Area under curve Spectrophotometric method for estimation of Rosuvastatin calciumin bulk and tablet dosage form.

MATERIAL AND METHODS

Instrument

Ultraviolent-Visible double beam spectrophotometer, SHIMADZU (model UV-1800) with UV probe software. All weights were taken on weighing balance.

Chemicals

Rosuvastatin calciumpure 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.Area under Curve [AUC] in absorption spectra were measured between the wavelength range 237 to 247nmas the wavelength for detection (Figure No.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/mland pipette 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 were 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 ICH guidelines.

RESULTS AND DISCUSSION

Method

Area under curve spectroscopy.

Linearity

The linearity of an analytical method is its dimensions 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 and Area under Curve [AUC] in absorption spectra were measured between the wavelength of 237 to 247nm as absorbance values are shown in Table No.1 (Figure No.3). The calibration curve was prepared by plotting graph against the concentration and absorbance and therefore the graph shown in (Figure No.4). Statistical variables like slope, intercept, regression equation, correlation coefficient and Sandell's sensitivity were determined. (Table No.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 determined by intra-day and inter-day study. 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 No.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 kept constant and varied pure drug concentration. (Table No.4).

Ruggedness: The ruggedness is defined as the reproducibility of results when the method is performed under the variation in conditions. This includes different analyst, laboratories, instruments, temperature etc. Ruggedness was determined between different analyst; the value of %RSD was found to be less than 2. (Table No.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 individual analytical procedure is the smallest amount of analyte in a sample which can be quantitatively determined. LOD and LOQ were calculated by utilizing fallowing formula.

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

LOD and LOQ value of were found Rosuvastatin calcium be 0.037 and 0.114µg/ml.

Table No.1: Results of calibration curve at 237-247nm by Area under curve method

S.No	Concentration in µg/ml	Absorbance ± Standard deviation*
1	0	0
2	3	0.165±0.000943
3	6	0.314±0.001106
4	9	0.467±0.001572
5	12	0.614±0.002
6	15	0.780±0.003727
7	18	0.930± 0.002494

*Average of six determinations.

Table No.2: Regression parameter for Rosuvastatin calcium at 237-247nm by Area under curve method

S.No	Regression parameter	Results
1	Range (µg/ml)	3-18
2	Detection Wavelengths (nm)	237/247
3	Regression Equation	Y= 0.0514x+0.0043
4	Slope (b)	0.0514
5	Intercept (a)	0.0043
6	Correlation Coefficient (r^2)	0.9998
7	Sandell's equation	0.019
8	Limit of detection (µg/ml)	0.037
9	Limit of quantitation (µg/ml)	0.114

Table No.3: Determination of precision results for Rosuvastatin calcium at 237-247nm by Area under curve method

S.No	Concentration (µg/ml)	Intra-day Absorbance ±Standard deviation*	%RSD**	Inter-day Absorbance ±Standard deviation*	%RSD**
1	3	0.165±0.00037	0.226	0.166±0.001067	0.642
2	6	0.314±0.0015	0.47	0.314±0.000471	0.15
3	9	0.468±0.00057	0.123	0.466±0.001213	0.260
4	12	0.614±0.001213	0.197	0.616±0.001886	0.306
5	15	0.780±0.001374	0.176	0.782±0.001599	0.204
6	18	0.932± 0.000471	0.050	0.932± 0.000816	0.087

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

Table No.4: Determination of Accuracy results for Rosuvastatin calcium at 237-247nm by Area under curve method

S.No	Spiked Levels	Amount of Sample (µg/ml)	Amount of Standard (µg/ml)	Amount Recovered	% Recovery ±Standard deviation*	%RSD**
1	50	9	4.5	13.67	101.25 ±0.251	0.247
2	100	9	9	17.81	98.94 ±0.17	0.171
3	150	9	13.5	22.29	99.07 ±0.163	0.164

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

Table No.5: Determination of Ruggedness results for Rosuvastatin calcium at 237-247nm by Area under curve method

S.No	Analysts	Analyst 1	Analyst 2
1	Mean absorbance	0.468	0.469
2	±Standard deviation*	0.000764	0.001155
3	%RSD	0.163	0.246

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

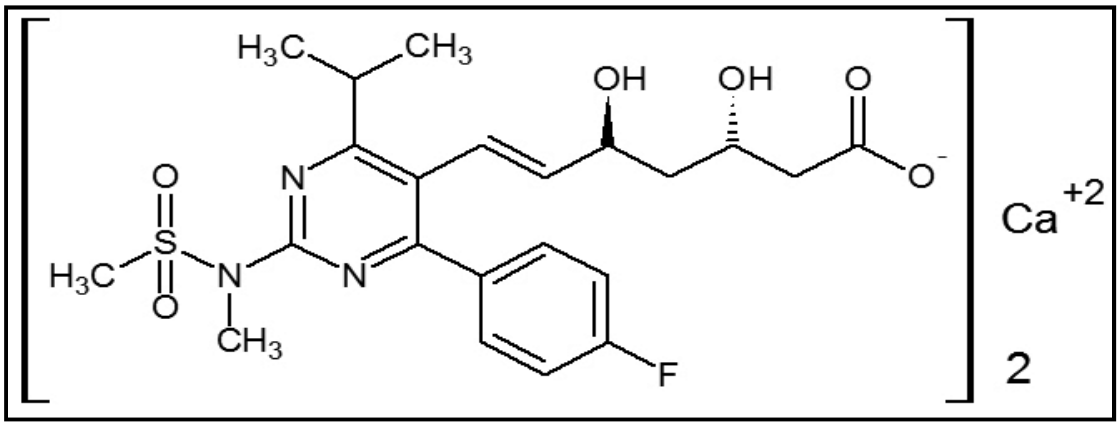

Figure No.1: Chemical structure of Rosuvastatin calcium

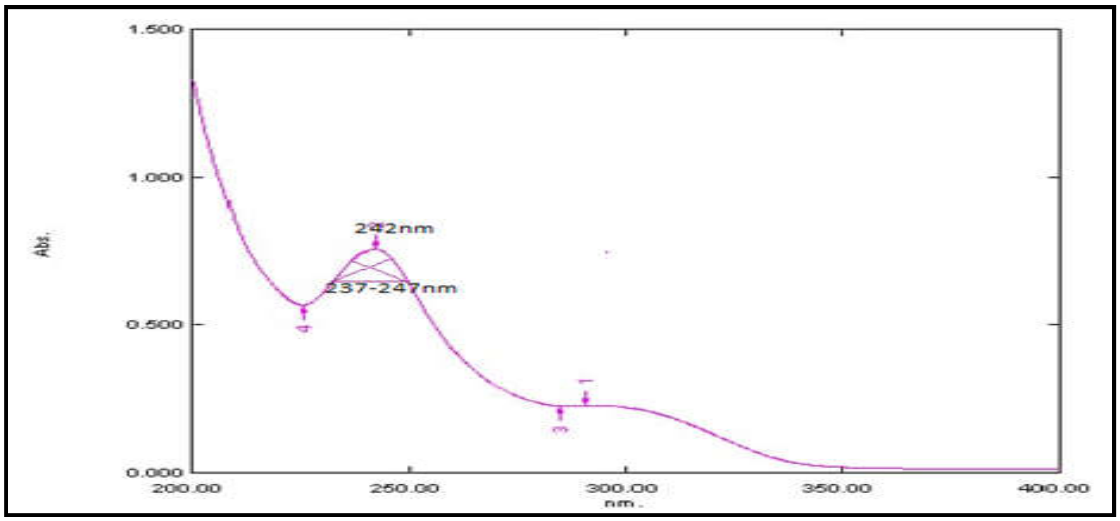

Figure No.2: Area under curve spectrum of Rosuvastatin calcium at 237-247nm

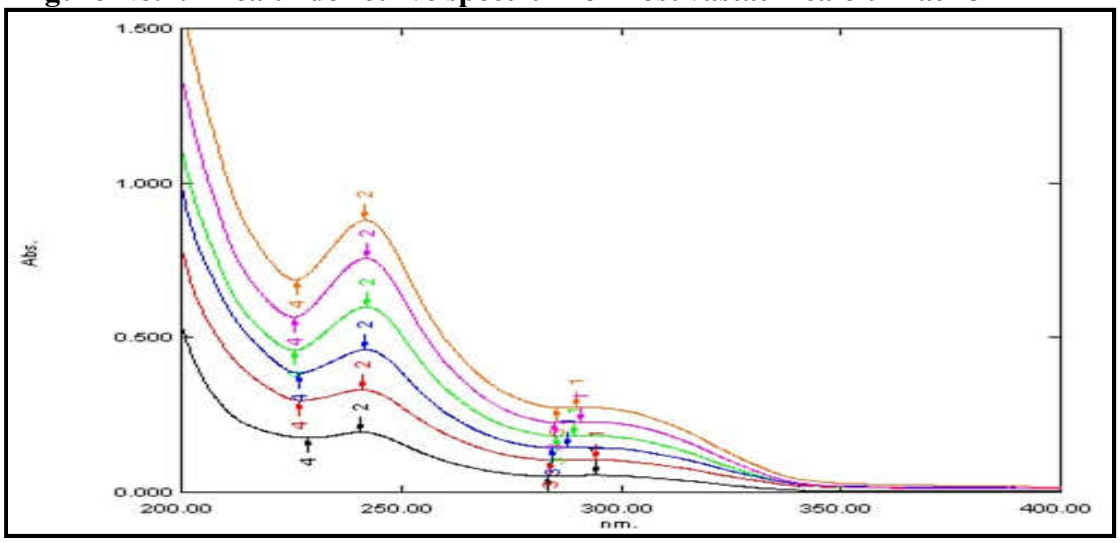

Figure No.3: Area under curve overlain spectra of Rosuvastatin calcium showing absorbance at237-247nm

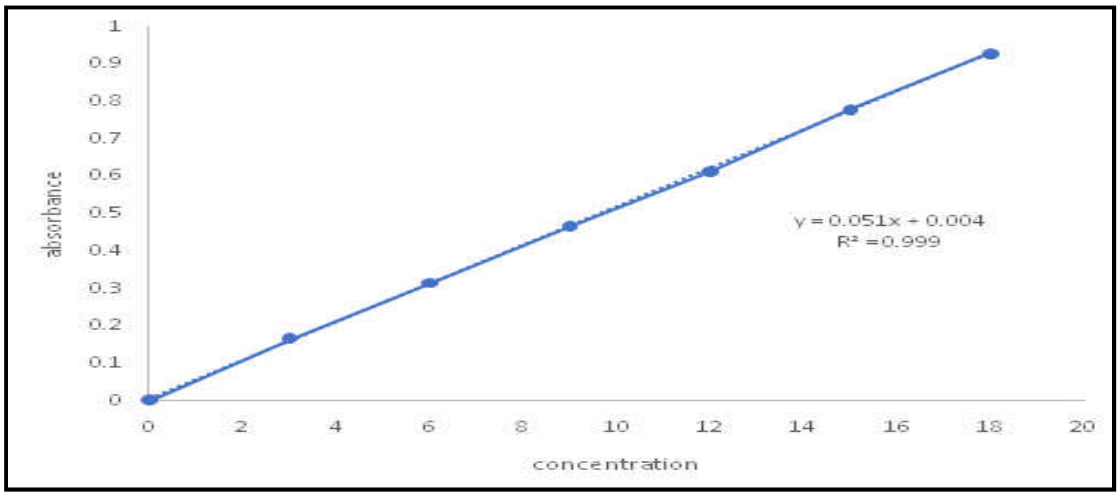

Figure No.4: Calibration curve of Rosuvastatin calcium at 237-247nm by Area under curve

CONCLUSION

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

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

BIBLIOGRAPHY

1. https://www.drugbank.ca /drug/DB00300.
2. Prajapati P B, Bodiwala K B, Marolia B P, Rathod I S, Shah S A. Development and validation of extractive spectrophotometric method for determination of rosuvastatin calcium in pharmaceutical dosage forms, *J Pharm Res,* 3(8), 2010, 2036-2038.
3. Gupta A, Mishra P, Shah K. Simple UV spectrophotometric determination of rosuvastatin calcium in pure form and in pharmaceutical formulations, *E-J Chem,* 6(1), 2009, 89-92.
4. Lahare R Y, Phuge A N, Gite A L, Jadhav A K. A review on ultraviolet spectrophotometric determination of rosuvastatin calcium in marketed formulation, *Int J Pure App Bio Sci,* 2(6), 2014, 169-174.
5. Rekha Rajeevkumar, Anbazhagan S, Rajeevkumar P. Analytical method development and validation of rosavastatin calcium in pure form and pharmaceutical formulations by UV spectroscopy, *Int J Pharm Tech Res,* 4(4), 2012, 1601-05.
6. Singh A, Baghel U S, Sinha M, Ashawat M S. Quantitative analysis of rosuvastatin calcium in bulk and solid pharmaceutical dosage forms using green and rapid fourier-transform infrared spectroscopic method, *Ind J of Pharma Sci,* 82(4), 2020, 632-639.
7. Patel B, Jadav A, Solanki H, Parmar S, Parmar V, Captain A. Development and validation of derivative spectroscopic method for the simultaneous estimation of rosuvastatin calcium and fenofibrate in tablet, *Int J Pharm Res and Rev,* 2(7), 2013, 1-6.
8. Sailaja B, Kumari K S. Analytical method development and validation for the estimation of rosuvastatin calcium in raw material and tablet formulation by UV spectrometric method, *Saudi J Med Pharm Sci,* 2(1), 2016, 7-11.
9. Shinde N G, Aloorkar N H. Development and validation of UV spectrophotometric method for simultaneous estimation of propranolol hydrochloride and rosuvastatin calcium in bulk drug and pharmaceutical dosage form, *Int J of App Pharm,* 4(5), 2015, 55-59.
10. Vishal V. Rajkondwar, Pramila Maini, Monika Vishwakarma. Characterization and method development for estimation and validation of rosuvastatin Calcium by UV–visible spectrophotometry, *Int J Theoret Appl Sci,* 1(1), 2009, 48-53.
11. Turabi Z M, Khatatbeh O A. Stability-indicating RP-HPLC method development and validation for the determination of rosuvastatin calcium in pharmaceutical dosage form, *Int J Pharm Sci Drug Res,* 6(2), 2014, 154-159.
12. Hazra K, Chowdary A, Devgan M, Shukla R, Sarkar B, Suryawanshi A. Development and validation of rp-hplc method for estimation of rosuvastatin calcium solid dispersions tablets, *Asian J Pharm Res,* 4(3), 2014, 122-125.
13. Rao A L, Suneetha D. Development and Validation of RP-HPLC method for the Estimation of Rosuvastatin in bulk and pharmaceutical dosage form, *Int J Chem Sci,* 8(2), 2010, 1308-1314.
14. Ramu K, Aleti P, Venisetty R K. Analytical method development and validation of simultaneous estimation of ezetimibe and Rosuvastatin in tablet dosage form by RP-HPLC, *Int J Pha Bi Sci,* 3(4), 2013, 343-353.

15. Kumar P, Ankalgi A D, Kaushal P, Ashawat M S. Method development and validation for multicomponent analysis of rosuvastatin calcium and losartan potassium in bulk drug by RP-HPLC, *J Drug Del and Thera,* 10(5), 2020, 76-84.
16. Gajjar A K, Shah V D. Development and validation of a stability-indicating reversed-phase HPLC method for simultaneous estimation of rosuvastatin and ezetimibe from their combination dosage forms, *Eura J Anal Chem,* 5(3), 2010, 265-283.
17. Khile A S, Devi N G, Rao M S, Ramachandran D. Development and validation of RP-LC method for simultaneous estimation of rosuvastatin and ezetimibe in bulk and its pharmaceutical formulations, *Am J Pharm Tech Res,* 7(2), 2017, 268-278.
18. Celina N, Anushka B. Development and Validation of a Novel Cleaning Validation and Assay Method for Simultaneous Estimation of Rosuvastatin and Fenofibrate by RP-HPLC, *W J of Pharma Res,* 7(3), 2018, 1454-65.
19. Purkar A J, Balap A R, Sathiyanarayanan L, Mahadik K R. Development and validation of HPTLC method for simultaneous determination of Rosuvastatin calcium and aspirin in its pure and pharmaceutical dosage form, *Int J Pharm Sci,* 6(5), 2014, 704-706.
20. Dhamdhere R, Kulkarni A, Kshirsagar S S. Development and validation of HPTLC method for Niacin and Rosuvastatin calcium in synthetic mixture, *J Seybold Rep,* 15(9), 2020, 194-208.
21. Kalyankar G G, Ghariya V V, Bodiwala K B, Lodha S R, Joshi S V. Development and validation of HPTLC method for simultaneous estimation of fenofibrate and Rosuvastatin in tablet dosage form, *J Pharm and App Sci,* 3(1), 2016, 1-7.
22. Tank P H, Vadalia K R, Dedania Z R. Development and validation of HPTLC method for simultaneous estimation of rosuvastatin calcium and aspirin in capsule dosage form, *Int J Pharm Sci and Res,* 3(10), 2012, 3867-3870.

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