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Spectrophotometric methods for the determination of Rosuvastatin

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ABSTRACT

Three simple and sensitive spectrophotometric methods have been developed for the estimation of Rosuvastatin in bulk and pharmaceutical dosage forms. Method A is based on oxidation followed by complex formation of the drug with 2, 5 dihydroxy 3, 6 dichloro 1, 4 benzoquinone (chloralinic acid λ_{max} 530 nm). The absorbance of the colored species is measured against the corresponding reagent blank at 530nm. Method B is based on salt formation of the drug with picric acid (λ_{max} 440nm). Method C is based on oxidation followed by complex formation of the drug with potassium permanganate ($KMnO_4$ λ_{max} 410nm). These methods have been statistically evaluated and found to be precise and accurate.

Key words: Spectrophotometric, Rosuvastatin.

INTRODUCTION

Rosuvastatin which is chemically Bis (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl (methyl sulfonyl) amino] pyrimidin-5-yl] (3R, 5S)-3, 5-dihydroxyhept 6-enoic acid] calcium salt is an anti hyperlipidemic agent. A number of methods such as HPTLC, LC-MS were reported for the estimation of Rosuvastatin. Literature survey reveals that visible spectrophotometric methods have not been reported for its quantitative determination in its bulk drug and pharmaceutical formulations. In the present investigation three simple and sensitive spectrophotometric methods have been developed for the determination of Rosuvastatin. The developed methods involve the formation of colored complexes with chloranilic acid, picric acid and potassium permanganate reagents. The colored chromogens showed absorption maximum at 530nm, 440nm, and 410nm respectively. Beers law is obeyed in the concentration ranges of 1-3µg/ml, 0.25-1.25µg/ml and 0.25-1.25µg/ml respectively. The results of analysis for the three methods have been validated statistically and by recovery studies tabulated in table-2.

EXPERIMENTAL

Preparation of reagents

1. Chloralinic acid (0.014M in acetone): 73mg of Chloralinic acid in 25ml acetone was prepared.
2. Picric acid (0.4%w/v): 400mg in 100ml of chloroform.
3. Potassium permanganate (0.019M): 0.015g in 50ml distilled water, from this 1ml was diluted to 25ml with distilled water.
4. Standard drug solution for Method A: About 25mg of Rosuvastatin was accurately weighed and dissolved in 5ml of Dimethyl formamide, to this add 1drop of methyl red indicator titrate then with 0.1NHcl until yellow

color appears and make up the volume with acetone to get working standard solution of 1mg/ml

5. Standard drug solution for Method B & C: About 100mg of Rosuvastatin was accurately weighed and dissolved in 100 ml of Methanol to obtain a stock solution of 1 mg/ml. This solution was further diluted to get working standard solution of 100 µg/ml.

Assay procedures

Method A

Aliquots of working standard solution of Rosuvastatin ranging from 0.1-0.3 ml were transferred into a series of 10 ml volumetric flasks. To this 1 ml of chloranilic acid was added. The total volume was made up to 10ml with acetone. The absorbance of the pink colored chromogen was measured at 530 nm against reagent blank and the amount of Rosuvastatin present in the sample solution was computed from its calibration curve.

Method B

Aliquots of working standard solution of Rosuvastatin ranging from 0.25 -1.25 ml were transferred into a series of 10ml volumetric flasks. To this 1 ml of picric acid was added. The total volume was made up to 10ml with chloroform. The absorbance of the colored chromogen was measured at 440nm against reagent blank. The amount of drug present in the sample solution was computed from its calibration curve.

Method C

Aliquots of working standard solution of Rosuvastatin ranging from 0.25 -1.25 ml were transferred into a series of 10ml volumetric flasks. To this 1 ml of potassium permanganate was added and allowed to stands for 20minutes. The total volume was made up to 10ml with water. The absorbance of the cherry red colored chromogen was measured at 410nm against reagent blank. The amount of drug present in the sample solution was computed from its calibration curve.

RESULTS AND DISCUSSION

The optical characteristics such as beers law limits, Sandell's sensitivity, molar extinction coefficient, percent relative standard deviation, percent range of error(0.05 and 0.01 confidence limits) were calculated for all the methods and results are summarized in Table 1. The values obtained for the determination of Rosuvastatin in Pharmaceutical formulations (Tablets) by the proposed methods are presented in Table 2. Studies reveal that the common excipients and other additives usually present in the Tablets did not interfere in the proposed methods.

Table 1: Optical characteristics, precision and accuracy of the proposed method

Parameters	Method A	Method B	Method C
λ_{max} (nm)	530	440	410
Beer's law limit(µg/mL)	1-3	0.25-1.25	0.25-1.25
Sandell'sensitivity(µg/cm^2/0.001abs.unit)	0.5291	0.023	0.019
Molar absorptivity(litre.mole^{-1}.cm^{-1})	0.8345×10^4	1.91×10^5	2.3×10^5
Regression equation(Y*)			
Slope(b)	0.194	0.396	0.401
Intercept(a)	0.0228	0.0331	0.092
Correlation coefficient(r)	0.9993	0.9995	0.9998
%Relative standard deviation**	1.536	0.756	1.084
%Range of error			
0.05 significance level	0.128	0.632	0.906
0.01 significance level	0.190	0.935	1.341

*Y = a + bx, where 'Y' is the absorbance and x is the concentration of Rosuvastatin µg/mL

**For six replicates

Table 2: Estimation of rosuvastatin in pharmaceutical formulations

Formulations (Tablets)	Labelled amount (mg)	Amount found* by proposed method			% recovery** by proposed method		
		Method A	Method B	Method C	Method A	Method B	Method C
Tablet 1	10	9.6	9.4	9.5	99.57	99.64	99.78
Tablet 2	10	9.5	9.7	9.4	99.78	99.86	99.64
Tablet 3	40	39.49	39.37	39.78	98.89	99.35	99.21
Tablet 4	40	39.78	39.92	39.49	99.21	99.39	99.89

* Average of six determinations

**Recovery of amount added to the pharmaceutical formulation (Average of three determinations)

CONCLUSION

The proposed methods are simple, selective and reproducible and can be used in the routine analysis of Rosuvastatin in bulk and pharmaceutical formulations with reasonable accuracy and precision.

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