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PharmTech

International Journal of PharmTech Research
CODEN (USA): IJPRIF ISSN : 0974-4304
Vol.1, No.4, pp 1017-1019, Oct-Dec 2009

DEVELOPMENT OF SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF PRAVASTATIN SODIUM IN BULK AND TABLET FORMULATIONS

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ABSTRACT:A novel, simple and rapid UV spectrophotometric determination method for pravastatin sodium (PRA) was successfully developed and validated for the assay of in tablets. The proposed method shows the maximum absorbance at 240 nm .beer's law was obeyed in the concentration range of 2-18µg/ml. The method was validated in terms of linearity, precision (relative standard deviation 1.36%), accuracy and specificity. The proposed method is the only method available for spectrophotometric determination of the drug. It is simple, precise, accurate, sensitive and reproducible and can be used for the routine quality control testing of the marketed formulations.
Keywords: pravastatin sodium (PRA)**,** Ultraviolet spectrophotometer.

INTRODUCTION

Pravastatin sodium (PRA), a mono-sodium salt of Pravastatin (PVS, Fig. 1), hexahydro-6-hydroxy-2-methyl-8-(2-methylbutyryloxy)-1-naphthyl-3,5-dihydroxyheptanoate is an anti-hypercholesterolemic agent having an inhibitory activity against 3-hydroxy-3-methylglutaryl coenzyme A (HMG CoA) reductase, the rate-determining enzyme in the cholesterol synthesis .the drug is available in the tablet dosage form and if official in B.P[1]. As to our best knowledge, no UV spectrophotometric method has been described for the determination of this drug. So far only HPLC[2-4], HPTLC[5], Mass[6], SLC[7-8], Volta metric[9] methods have been reported for estimation of pravastatin sodium in formulations as well as in human plasma. But all these methods are more time consuming and expensive than simple spectophotometric method. Hence, the aim of the present investigations is to develop a simpler, rapid and cost –effective analytical method for determination of pravastatin sodium in bulk and drug in tablet dosage form suitable for routine quality control analysis and stability tests.

MATERIALS AND METHOD

A single beam Systronics117 UV Visible Spectrophotometer having two matched quartz cells, with 1 cm light path, was employed for spectral measurement. Pravastatin sodium (PRA) working standard was procured as a gift sample from Dr.Reddy's Pharmaceuticals Ltd., Hyderabad, and its tablets (10 mg per tablet) were from Bristol-Myers Squibb Co. Distilled water was used throughout the investigation.A solution of pravastatin of concentration 1000 µg/mL was prepared by dissolving 50mg of the pure drug in 50 mL of distilled water. Standard stock solution was suitably diluted with distilled water to give a concentration range of 2-18µg/mL .The solutions were scanned in the UV range200-300 Fig: 1, the absorbance was measured at 240 nm against blank. The above method was used to determine pravastatin sodium in tablets .Twenty tablets were weighed and powdered. The powered drug equivalent to 50 mg of pravastatin was weighed accurately and transferred into a suitable flask. The tablet powder was dissolved in distilled water and filtered through a whatman filter no: 41.this filtrate was diluted to 50mL with distilled water. Further dilution was done to get concentration of 10, 15, 20 µg/mL of pravastatin sodium solution in water. The absorbances of these solutions were measures at 240 nm .The drug content of the preparation was calculated using the standard curve (fig: 2). The results were reported in table: 1 .The recovery studies were conducted by the addition of different amounts of pure drug to a known concentration

of pre analyzed tablet solution .To reveal that (99.5±0.79) percentage recovery was calculated by using formula given below

$$\% \text{ Recovery} = \frac{N \sum x y - \sum y \sum x}{N (\sum x^2) - (\sum x)^2}$$

x- Amount of standard drug added
y- Amount of drug found by proposed method
N- Number of observations

RESULTS AND DISCUSSION

The proposed method shows absorption maxima at 240 nm and obeyed Beer's law in concentration range of 2-18µg/ml. The percentage recovery value (97.6)indicate that there no interference of the excipients in the formulation the low value of slandered deviation and co-efficient of variation indicate that the proposed method is precise table .all statistical data prove validity of proposed method, which can be applied in industries for routine analysis of this drug from tablet.

ACKNOWLEDGEMENT

Dr. Reddy's Laboratory Hyderabad Ltd. For providing Pravastatin sodium as a gift sample for this work. Prof., Ch. Babu Rao, principal, Hindu College of Pharmacy for providing the required facilities for research work.

Table 1: Analysis of marketed formulations of pravastatin sodium

Formulations	Label Claim (mg)	Estimated amount		Percentage recovery
		mg	Percentage	
Tablet 1	10	10.01	100.1	98.89
Tablet 2	10	9.87	98.7	97.6
Tablet 3	10	9.77	97.7	99.27
Tablet 4	10	10.26	102.6	100.1

Note: each reading was average of five readings

Table 2: Optical characterization and statistical data of the pravastatin sodium

S.No.	Parameter	Values
1	Maximum wavelength	240 nm
2	Beer's law limit (µg/ml)	2-18
3	Molar extinction coefficient (moles/lit)	5.4×10^{-5}
4	%Recovery	97.6-100.1
5	Correlation coefficient	0.9999
6	Regression equation Slope Intercept	 0.0549 0.0025
7	Relative standard deviation	1.36%

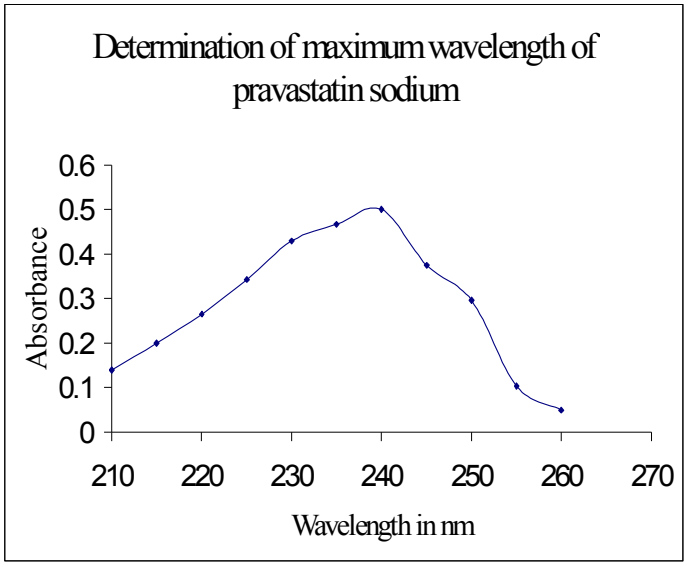

Fig: 1 Determination of maximum wavelength of pravastatin sodium

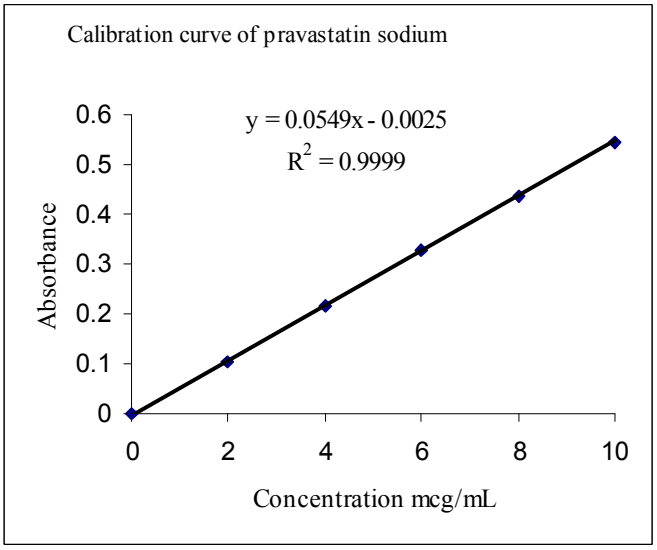

Fig: 2 Calibration curve of pravastatin sodium

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