ESTIMATION OF PRAVASTATIN SODIUM BY SPECTROPHOTOMETRIC METHOD

Y. SRINIVASA RAO, G. HARITHA, P. NAYANA TARA, K. P. R. CHOWDARY and J. V. L. N. SESHAGIRI RAO*

Department of Pharmaceutical Sciences, Andhra University,
VISAKHAPATNAM-530 003 (A.P.) INDIA
E-mail: yarraguntla@rediffrnail.com

ABSTRACT

A simple and reproducible spectrophotometric method has been developed for the estimation of pravastatin sodium. This method is based on the reaction of the drug with ferric chloride and potassium ferricyanide, which forms a green chromogen exhibiting absorption maxima at 737 nm.

Key words : Pravastatin sodium, spectrophotometric

INTRODUCTION

Pravastatin Sodium (PVS) is the monosodium salt of 1,2,6,7,8,8a-hexahydro-β,δ,6-trihydroxy-2-methyl-8-(2-methyl-1 -oxobutoxy)-1 -naphthalene hepatanoic acid[1]. PVS is an antihyperlipidemia drug, which is used lo reduce cholesterol and LDL levels by acting on HMG-CoA reductase. A few analytical methods[2,3] based on HPLC were reported earlier for determining the drug in plasma. The authors now propose a simple and reproducible spectrophotometric method for estimation of pravastatin sodium in pure and formulation forms. The method was standardized by establishing the spectrophotometric parameters with statistical analysis of the data. This method could be successfully extended to the pharmaceutical formulations containing pravastatin sodium to determine the drug.

EXPERIMENTAL

Materials

All the chemicals used in this study were of analytical or pharmaceutical grade. Solutions of ferric chloride (0.1M) and potassium ferricyanide (0.1% w/v) were prepared using double distilled water. Borosil (Grade A) glassware was used in the experiments. Two commercial samples of tablets containing PVS were chosen as sample formulations for testing the suitability of the proposed method to determine the drug in tablets. Spectral and absorbance measurements were made on a Systronics UV/Vis spectrophotometer (model 117) with 10 mm-matched quartz cells.

Standard and sample solutions

About 100 mg of pure sample of pravastatin sodium was accurately weighed and dissolved in 100 mL of distilled water. This stock solution was further diluted with distilled water to get a working standard solution containing 100 μg/mL of the drug. Twenty tablets of the drug were weighed and finely powdered. The stock solution of the formulation sample was prepared by dissolving in distilled water a quantity of the finely ground tablet powder equivalent to 100 mg of the drug. This solution was suitably diluted during analysis.

Assay Procedure

To a series of 10-mL graduated test tubes, aliquots ranging from 0.2 to 0.8 mL of the working standard solution of pravastatin sodium were added. To each of the flasks 2.5 mL of ferric chloride and 3.0 mL of potassium ferricyanide solutions were added in that order and the tubes were kept aside at room temperature for 20 minutes. The formation of a green colored chromogen was observed in the tubes. Appropriate quantity of distilled water was added to the tubes to make up the volume. The absorption maxima of the green colored complex formed was found to be at 737 nm. Later, the absorbances of the solutions in all the tubes were measured at 737 nm against a reagent blank. Using these values, a calibration curve with different concentrations of the drug on x-axis and the corresponding absorbances on the y-axis was plotted. On similar lines, to the suitably diluted tablet sample solution the reagents were added and the color developed. Its absorbance was measured at 737 nm. Using the calibration curve drawn for the pure drug sample, the amount of drug concentration corresponding to the absorbance measured for the test solution was found out. From this value the amount of the drug present in the original formulation was computed.

RESULTS AND DISCUSSION

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar extinction coefficient, percent relative standard deviation and percent range of error was calculated for this method and the results are summarized in Table-1. The values obtained for the determination of pravastatin sodium in tablets by the proposed method are compared with a UV method developed earlier in our laboratory (Table-2). To evaluate the validity and reproducibility of the method, known amounts of the pure drug were added to the previously analyzed sample solutions and the percent recoveries of the drug with the proposed method were found out (Table-2). Interference studies revealed that the common excipients and other additives usually present in tablet dosage forms did not interfere in the proposed method.

Table 1. Optical characteristics and precision data

Parameters	
Beer's law limit (μg/mL)	5-25
Sandell's sensitivity (μg/cm^2/0.001 absorbance unit)	0.02994

Molar extinction coefficent (L mole^{-1}.cm^{-1})	2.9826 x 10^3
% Relative standard deviation	0.6754
% Range of error	
0.05 confidence limits	± 0.5648
0.01 confidence limits	± 0.8356
Correlation coefficient	0.999382
Regression equation (Y = b + aC)*	
Slope (a)	0.03289
Intercept (b)	0.0002

* C is concentration in μg/mL and Y is absorbance unit.

Table 2. Assay of pravastatin sodium in tablets

Sample	Labelled amount(mg)	Amount obtained (mg)		Percent recovery by the proposed method
		Reference method*	Proposed method	
1	10	9.96	9.98	99.98
2	10	9.99	10.03	100.30

*UV method developed by the authors

REFERENCES

1. S. Budavan, (Ed), The Merck Index, 12th Edn ., Merck and Co. Inc, Whitehouse Station, N. J., (1996), p. 8431.

2. G. L. Peterson, *Anal. Biochem.,* **100**, 201 (1979)

3. D. B. Whigan, E. Ivasehkiv, and A. I. Cohen, *J. Pharm. Biomed. Anal.,* **7**, 907 (1984)