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NOTE

Spectrophotometric Determination of Pravastatin Sodium in Pharmaceutical Oral Solid Dosage Forms

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Two simple, sensitive and reproducible spectrophotometric methods (methods **A** and **B**) were developed for estimation of pravastatin sodium in pure as well as in pharmaceutical formulations. Method **A** is based on the reduction of ferric to ferrous ions followed by complexation with 2,2'-bipyridyl to produce an orange red chromogen at λ_{max} of 522 nm and method **B** is based on the reduction of ferric to ferrous ions followed by complexation with 1,10-phenanthroline to produce an orange red chromogen at λ_{max} of 510 nm and both obeyed Beer's linearity in the concentration range of 50-250 µg/mL for method **A** and 20-100 µg/mL for method **B**. These methods were extended to pharmaceutical formulations.

Key Words: Spectrophotometric determination, Pravastatin sodium.

Pravastatin sodium is an antihyperlipoproteinemic agent and is chemically (βR, δR,1S,2S,6S,8S,8Ar)-1,2,6,7,8,8a-hexahydro-β,δ,6-trihydroxy-2-methyl 8-[(2s)-2-methyl-1-oxobutoxy]-1-naphthalene hepatonic acid monosodium. Literature survey reveals that few methods have been reported for the determination of pravastatin sodium which includes LC/MS/MS, HPLC[1-4] in serum and plasma.

The present methods describe the reaction of pravastatin sodium with ferric chloride and 2,2'-bipyridyl to develop an orange coloured chromogen which exhibits absorption maximum at 522 nm (method **A**), ferric chloride and 1,10-phenanthroline to develop an orange coloured chromogen which exhibits absorption maximum at 510 nm (method **B**).

All the measurements were made using Shimadzu UV-visible spectrophotometer with 1 mm matched quartz cells. All the chemicals used were of analytical grade. Ferric chloride (270 mg in 100 mL water), aqueous solution of 2,2'-bipyridyl 0.01 M (156 mg in 100 mL water) for method **A**. Aqueous solution of 1,10-phenanthroline 0.01 M (198 mg in 100 mL water), ferric chloride (270 mg in 100 mL water) for method B.

Preparation of standard solutions: Accurately weighed 100 mg of pravastatin sodium was dissolved in 100 mL distilled water to obtain 1 mg/mL stock solution and the stock solution was further diluted with distilled water to obtain a working standard solution.

Preparation of sample solution: An accurately weighed amount of tablet powder (pravastatin sodium) equivalent to 25 mg was dissolved in 25 mL of distilled water and filtered. The first few mL of the filtrate was discarded and the remaining solution was used for analysis of formulation of pravastatin sodium.

Assay procedure

Method A: Aliquots of standard drug solution ranging from 0.5-2.5 mL were transferred to a series of 25 mL volumetric flask. To each flask, 3 mL of 2,2′-bipyridyl and 1 mL of ferric chloride were added and heated to 100 ºC for 15 min and cooled. The solutions were made up to volume with water. The absorbance of orange coloured chromogen was measured at 522 nm against a reagent blank. The coloured species were stable for more than 1 h. The amount of the drug in the sample was computed from the calibration curve.

Method B: Aliquots of standard drug solution ranging from 0.5-2.0 mL were transferred to a series of 25 mL volumetric flask. To each flask, 3 mL of 1,10-phenanthroline and 2 mL of ferric chloride were added and heated to 100 ºC for 15 min and cooled. The solutions were made up to volume with water. The absorbance of orange coloured chromogen was measured at 510 nm against a reagent blank. The coloured species were stable for more than 1 h. The amount of the drug in the sample was computed from the calibration curve.

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar extinction coefficient, per cent relative standard devaition were calculated and the results are summarized in Table-1. Regression characteristics like slope, intercept, correlation coefficients and % range of error (95 % confidence interval) were calculated are shown in Table-1

TABLE-1
OPTICAL CHARACTERISTICS FOR PRAVASTATIN SODIUM

Parameters	Pravastatin sodium	
	2,2'-Bipyridyl and $FeCl_3$	1,10-Phenanthroline and $FeCl_3$
λ_{max} (nm)	522	510
Beer's law limit (μg mL^{-1})	50-100	20-100
Molar absorptivity (L mol^{-1} cm^{-1})	1.3647×10^3	2.9404×10^3
Sandell's sensitivity (μg cm^{-2} / 0.001 abs. unit)	0.3274	0.1522
Slope (m)	342.5624	163.7942
Intercept (c)	-5.86591	-3.32284
Regression equation (Y = mx + c)	0.005096	0.072850
Correlation coefficient	0.998770	0.998753
Relative standard deviation (%)*	0.474900	0.132480
% Range of error (95 % confidence interval)	0.093090	0.029940

*Each average of three determinations.

Commercial formulations of pravastatin sodium were successfully analyzed by the proposed methods. The values obtained by the proposed methods are presented

in Table-2. As an additional demonstration of accuracy, a fixed amount of drug was added to the pre-analyzed formulations and recovery experiments were performed. These results are summarized in Table-2. There is no interfernece in the proposed analytical methods.

TABLE-2
ASSAY AND RECOVERY OF PRAVASTATIN SODIUM IN FORMULATIONS

Tablet	Label claim (mg)	Amount found by the proposed method* (mg)		% Recovery by the proposed method*	
		2,2'-Bipyridyl and $FeCl_3$	1,10-Phenanthroline and $FeCl_3$	2,2'-Bipyridyl and $FeCl_3$	1,10-Phenanthroline and $FeCl_3$
Pravastatin sodium	20	20.096	19.98	100.25	100.50
		20.042	19.99	99.50	100.50
		19.873	19.94	99.25	99.25

*Each average of three determinations.

In conclusion the proposed spectrophotometric methods for the estimation of pravastatin sodium are simple sensitive, accurate and can be used for routine quality control of these drugs in bulk as well as in pharmaceutical formulations.

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