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GAVIN PUBLISHERS

Archives of Analytical and Bioanalytical Separation Techniques

El-Abasawi NM et al. Arch Anal Bioanal Sep Tech: AABST-107.

Research Article

DOI: 10.29011/AABST-107. 100007

Determination of Pravastatin Sodium Using Atomic Absorption Spectrometry Based on its Sodium Content

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Citation: El-Abasawi NM, Attia KAM, Abo-Serie AAM, Morshedy S, Abdel-Fattah A (2018) Determination of Pravastatin Sodium Using Atomic Absorption Spectrometry Based on its Sodium Content. Arch Anal Bioanal Sep Tech: AABST-107. DOI: 10.29011/AABST-107. 100007

Received Date: 30 June, 2018; **Accepted Date:** 03 August, 2018; **Published Date:** 10 August, 2018

Abstract

Atomic spectroscopy is one of the most widely used methods for quantitative elemental analysis. An atomic absorption spectrometric method was developed and validated as a direct, simple and sensitive method for determination of pravastatin sodium which, based on its sodium content at 589 nm without tedious or complex procedures. The developed method is very sensitive regarding LOD (0.026 ppm of sodium equivalent to 0.479 µg/ml), LOQ (0.079 ppm of sodium equivalent to 1.454 µg/mL) with a linear range of (0.2 - 1.0 ppm equivalent to 3.37 - 16.84 µg/ml). The proposed method was validated according to International Conference on Harmonization (ICH) guidelines and successfully applied for the determination of pravastatin sodium in its dosage form.

Keywords: Pravastatin Sodium; Absorption Spectrometry; Elemental Analysis; Selective Determination

Introduction

Pravastatin sodium is sodium (3R,5R)-7-{(1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-6-hydroxy-2-methyl-8-[(S)-2-methylbutyryloxy]-1-naphthyl}-3,5-dihydroxyheptanoate [1-2]. It is a selective and competitive inhibitor of 3-hydroxy-3-methylglutaryl -coenzyme A (HMG-CoA) reductase. Atomic Absorption Spectroscopy (AAS) is a spectroanalytical procedure for the quantitative determination of chemical elements using the absorption of optical radiation (light) by the free atoms in the gaseous state. It is generally acknowledged that if sufficient analyte is present in the sample, then it should be determined using a flame technique because this has added advantages of being rapid (assuming only a few elements need be determined) and, in comparison with alternative techniques, very simple to use. AAS can be used to determine over 70 different elements in solution, or directly in solid samples via electrothermal vaporization. Reviewing the literature on the determination of pravastatin in pharmaceutical dosage forms and/or biological fluids, including HPLC methods for the determination of pravastatin are reported [3-6], LC [7-9], Spectrophotometric methods [10-15], electrochemical methods [16], electrophoresis [17]. The main goals of analytical atomic spectrometry are to attain the lowest limits of detection (down to single atoms), use the broadest dynamic range, suppress the matrix effect, eliminate spectral interferences, minimize the time and cost required for sample preparation [18]. Reviewing the literature on the pravastatin sodium in its commercial dosage form, reveals that there is no atomic spectrometric method was applied for determination of pravastatin sodium. The main aim of this work is to develop a simple, sensitive and inexpensive atomic absorption spectrometry method for the determination of pravastatin-sodium in its pure and dosage forms through estimation of its sodium content.

Experimental

Materials

Pure Samples: Pure pravastatin (99.52%) was kindly supplied by kindly supplied by National Organization for Drug Control and Research, Giza, Egypt.

Pharmaceutical preparation: Lipostat® tablets labeled to contain 40 mg of pravastatin per tablet (B.No. N109338), manufactured by SmithKline Beecham, Egypt Cholestate® tablets labeled to contain 10 mg of pravastatin per tablet (B.No. HP0013), manufactured by Hi-Pharm, Egypt.

Chemicals and Reagents: Water used throughout the procedure was freshly double distilled.

Apparatus: A thermo elemental atomic absorption flame spectrophotometer, (Cambridge - UK) serial no. JE710572 computed with solar data station software version 9.03. Sodium was measured at wavelength 589 nm, band pass 0.5 nm, relative noise 1.0 nm, lamp current 10 mA, integration time 5 second.

Standard Solutions

A stock solution of the pravastatin (0.1mg/ml) was prepared by dissolving 10 mg of pravastatin-sodium in 50 ml double distilled water and the volume was completed to 100 ml with the same solvent.

Procedures

General Procedure

Aliquots of the standard pravastatin-sodium solution (0.1mg/ml) containing (36.8-184.2µg) m of the drug equivalent to (2-10 ppm Na) were transferred into a series of 10-ml volumetric flasks, completed to the mark with double distilled water. The drug was determined through its sodium content at 589 nm.

Procedure for Pharmaceutical Preparation

Ten tablets of **Lipostat®** and **Cholestate®** tablets labelled to contain 40 mg and 10 mg of pravastatin-sodium per tablet respectively were weighed, finely powdered and mixed carefully. An accurately weighed quantity of the powder equivalent to 10 mg of pravastatin sodium was introduced into a 100-mL volumetric flask, extracted with 50 ml double distilled water by shaking for 5 minutes. The volume was completed to the mark with the same solvent and then filtered to obtain a solution labeled to contain (0.1 mg/ml) to be analyzed by the proposed method. The drug concentrations were calculated from the corresponding regression equation.

Reported Method [19]

Pravastatin and pioglitazone were determined simultaneously using the first derivative method at 249.7 and 277 nm for pravastatin and pioglitazone, respectively. This method was applied on Pravazon® capsules which contain 10 mg of each drug per capsule.

Results and Discussions

In the Present Study: A simple and sensitive Atomic Absorption Spectrometry (AAS) procedure was suggested for quantitative determination of pravastatin-sodium through its sodium content at λs_{589} nm.

Method Validation [20-21]

Linearity and Range

Under the described experimental conditions, the calibration graph for the method was constructed by plotting the absorbance values versus drug concentrations in µg/ml. The regression plot was found to be linear over the range of (36.8-184.2 µg/ml) of pravastatin-sodium equivalent to (0.2-1 ppm) of sodium; as shown in figure 1. Linearity range, regression equation, intercept, slope and the determination coefficient for the calibration data were presented in Table 1.

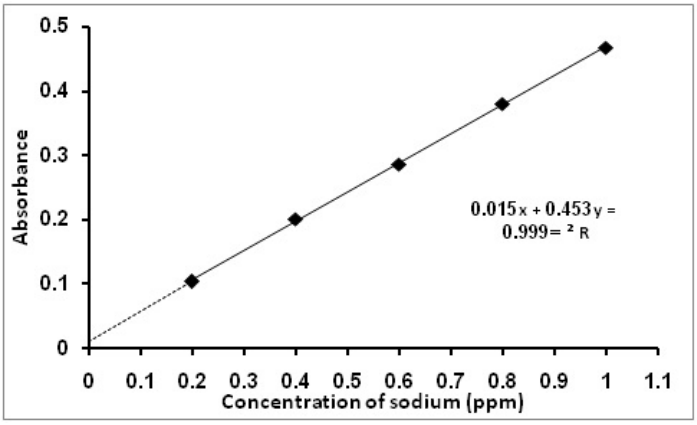

Figure 1: Calibration graph of pravastatin sodium by the proposed atomic absorption spectrometry method.

- **Limits of Detection and Quantitation**

LOD and LOQ values were calculated according to ICH guidelines [20] from the following equations:

LOD = 3.3 σ / S

LOQ = 10 σ/ S

Where σ is the residual standard deviation of regression lines and S is the slope of the calibration curve.

LOD and **LOQ** values were calculated for the proposed procedures and the obtained results indicated the sensitivity of the proposed method as shown in Table 1.

- **Accuracy and Precision**

The values of **% Recovery** confirm excellent accuracy. Moreover, the small values of **%RSD** indicate the high precision of the method, as shown in Table 1.

- **Specificity**

The standard addition technique was applied to check the

specificity of the described method by adding aliquots of the studied drug in its pure form (equal to 0.2, 0.4 and 0.6 ppm of sodium) to already analyzed pharmaceutical preparation (aliquots equivalent to 0.2, 0.4 and 0.6 ppm of sodium) and the percent recovery of the pure added was calculated. The data listed in Table 2 indicate no matrix interference.

Pharmaceutical Applications

The proposed method was applied for the selective determination of pravastatin-sodium in **Lipostat®** tablet. Satisfactory results were obtained in good agreement with the label claim. The obtained results were statistically compared to those obtained by the reported method [19]. No significant differences were found by applying t-test and F-test at 95% confidence level [22] indicating good accuracy and precision of the proposed method for the analysis of the studied drug in its pharmaceutical dosage form, as shown in Table 3.

Conclusion

Atomic absorption spectroscopy method was successfully applied for determination of pravastatin sodium. This method has the advantages of being sensitive and selective without any interference as it selectively determines the metal (sodium) content in the samples to be analyzed. The application of the proposed method on the different brands was done was recovery 0f 101.25 and 101.45 for pravastatin in Lipostat® and Cholestate®, respectively.

Parameters		Atomic absorption spectrometry
Wavelength (nm)		589
Linearity range	ppm	0.2 - 1.0
	(µg/mL)	3.37-16.84
- Regression Equation		**Y^{*}= bx^{**}+ a**
- Slope (b) - Intercept (a)		0.4537 0.0153
Determination coefficient (r^2)		0.9996
Accuracy (%Recovery)		101.52
Precision (%RSD)***	Repeatability	1.371
	Intermediate precision	1.541
LOD	ppm	0.026
	(µg/ml)	0.479
LOQ	ppm	0.079
	(µg/ml)	1.454
Y^{*} Absorbance of sodium at 589 nm. x^{**}Pravastatinconcentration in (ppm). ***Values for 3 determinations of 3 different concentrations.		

Table 1: Regression and validation data for determination of pravastatin-sodium by the proposed atomic absorption spectrometry method.

Pharmaceutical (ppm)		Pure (ppm)		%Recovery
Lipostat®				
Taken	Found*	Added	Found	
0.2	0.2025 *	0.2	0.2021	101.05
		0.4	0.4028	100.7
		0.6	0.6029	100.48
Mean±%RSD				100.74±0.284
Cholestate®				

0.2	0.2029*	0.2	0.2023	101.15
		0.4	0.4037	100.93
		0.6	0.6021	100.35
				100.81 ±0.409
* Average of five determinations.				

Table 2: Recovery study of pravastatin-sodium by adopting the standard addition technique via the proposed Atomic absorption spectrometry method.

Parameters	Atomic absorption spectrometry	Reported method [6]
n*	5	5
Average (% Recovery)	101.25	100.07
%RSD	1.307	0.564
Student's t-test (2.306)**	0.584	——
F value (6.388)**	1.758	——

*** Number of measurements**

**** The values in parenthesis are tabulated values of "t" and "F" at (P = 0.05).**

Table 3: Determination of pravastatin-sodium in Lipostat® tablet by the proposed atomic absorption spectrometry and reported methods.

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