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Three different spectrophotometric methods manipulating ratio spectra for determination of binary mixture of Amlodipine and Atorvastatin

Hany W. Darwish*, Said A. Hassan, Maissa Y. Salem, Badr A. El-Zeiny

Cairo University, Faculty of Pharmacy, Department of Analytical Chemistry, Kasr El-Aini Street, ET 11562, Cairo, Egypt

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ABSTRACT

Three simple, specific, accurate and precise spectrophotometric methods manipulating ratio spectra are developed for the simultaneous determination of Amlodipine besylate (AM) and Atorvastatin calcium (AT) in tablet dosage forms. The first method is first derivative of the ratio spectra (^{1}DD), the second is ratio subtraction and the third is the method of mean centering of ratio spectra. The calibration curve is linear over the concentration range of 3–40 and 8–32 μg/ml for AM and AT, respectively. These methods are tested by analyzing synthetic mixtures of the above drugs and they are applied to commercial pharmaceutical preparation of the subjected drugs. Standard deviation is <1.5 in the assay of raw materials and tablets. Methods are validated as per ICH guidelines and accuracy, precision, repeatability and robustness are found to be within the acceptable limit.

1. Introduction

Amlodipine (AM), 2[(2-aminoethoxy) methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridine carboxylic acid,3-ethyl,5-methylester (Fig. 1) [1] is a dihydropyridine derivative with calcium antagonist activity. It is used in the management of hypertension, chronic stable angina pectoris and prinzmetal's variant angina [2]. AM inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle [3–5].

Atorvastatin (AT) is chemically described as [R-(R*,R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid, calcium salt (2:1) trihydrate (Fig. 2) [1]. AT is a selective, competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl-coenzyme A to mevalonate, a precursor of the sterols, including cholesterol. It is used to reduce LDL-cholesterol, apolipoprotein B, and triglycerides and to increase ATL-cholesterol in the treatment of hyperlipidaemias [2–4].

Caduet® is the first commercial product that has been launched by Pfizer Ltd. for the simultaneous treatment of hypertension and dyslipidaemia [6]. Caduet® contains both AM besylate for the treatment of high blood pressure and AT calcium for the treatment of hypercholesterolaemia. Caduet® tablets are intended for oral administration and are available in several different strength combinations including 5(AM)/10(AT) mg, 10(AM)/10(AT) mg.

Literature survey revealed that Amlodipine besylate is official in British Pharmacopoeia [7]. There are many reported methods for the determination of either AM [8–10] or AT [11–13] alone, or in combination with other drugs in pharmaceutical dosage forms [14–20] or individually in biological fluids [21–24]. Different LC methods [25–30], spectrophotometric methods [31–33], chemometric methods [34], capillary electrophoresis [35], HPTLC [36], have been reported for the estimation of AM and AT in their mixture.

In this paper, three different methods manipulating ratio spectra for the simultaneous determination of Amlodipine besylate and Atorvastatin calcium in tablets are described. These methods show very simple and accurate way for the analysis of this binary mixture without the need of sophisticated instruments, expensive solvents or large number of samples. The mathematical explanation of the procedures is illustrated.

2. Experiment

2.1. Apparatus

Spectrophotometer: SHIMADZU dual beam UV–visible spectrophotometer (Kyoto/Japan), model UV-1650 PC connected to IBM compatible and a HP1020 laserjet printer. The bundled software, UV-Probe personal spectroscopy software version 2.21 (SHIMADZU) is used. The spectral band is 2 nm and scanning speed is 2800 nm/min with 0.1 nm interval.

* Corresponding author. Tel.: +20 113332163.
E-mail address: hdarwish75@yahoo.com (H.W. Darwish).

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