Asian Journal of Chemistry Vol. 18, No. 4 (2006), 3227–3229

NOTE

Simultaneous Estimation of Atorvastatin and Amlodipine by Reverse Phase High Performance Liquid Chromatography

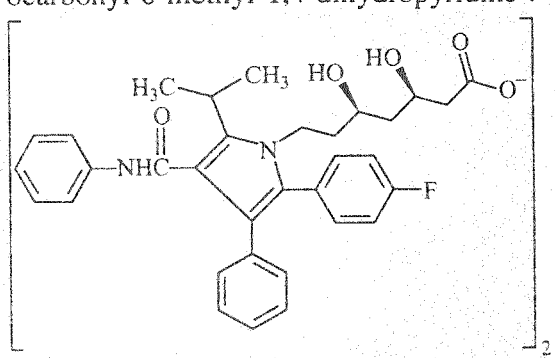
V.V. RAJKONDAWAR
Department of Chemistry
Motilal Vigyan Mahavidyalaya College, Bhopal-462 002, India

A simple, accurate, rapid, reproducible HPLC method has been developed for simultaneous estimation of atorvastatin and amlodipine using a mobile phase consisting 0.05 M potassium dihydrogen phosphate and acetonitrile in the ratio of 50 : 50 at a flow rate 1.0 mL/min. A Zorbax XDB 250 × 4.6 mm, C_{18} column was used as a stationary phase. Quantification was performed using UV detector at 235 nm. The method showed good resolution between two peaks. The result was validated by linearity and recovery studies.

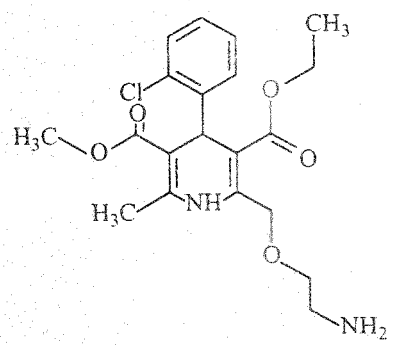
Key Words: Estimation, Atorvastatin, Amlodipine, HPLC.

Atorvastatin is a selective, competitive inhibitor of HMG-CoA reductase[1], the rate-limiting enzyme that converts 3-hydroxy-3-methyl-glutary coenzyme-A to mevalonate[2–4]. Chemically, it is designated as (βR, δR)-2-(-4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid.[5]

Amlodipine inhibits the movement of calcium ion (Ca^{2+}) across the cell membrane into a vascular smooth muscle and myocytes[1], action is greater in the arterial resistance vessels causing peripheral vasodilatation and reduction in after load[2–4]. Chemically, it is designated as 2-[(2-aminoethoxy)-methyl)]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3]-5-pyridine dicarboxylic acid 3-ethyl-5-methyl ester, (I)-2-[(2-aminoethoxy)]-4-(2-chlorophenyl)-3-ethoxycarbonyl-5 meth-oxocarbonyl-6-methyl-1,4-dihydropyridine[5].



Ca^{2+} $3H_2O$;



Atorvastatin calcium Amlodipine besylate

The composition of atorvastatin and amlodipine is used for treating angina pectoris, arteriosclerosis and combined hypertension and hyperlipidemia[6]. An attempt has been made in this work to devise a simple and accurate HPLC method for simultaneous estimation of atorvastatin and amlodipine.

The separation was carried out on Agilent 1100 series HPLC system equipped with quaternary gradient solvent delivering pump, an automated sample-injecting device, diode array detector, with a chemstation software. Sample of atorvastatin and amlodipine was received from Dr. Reddy's Lab, Hyderabad and Golchem Industries, Hyderabad, respectively and tablet purchased from the local market, HPLC grade acetonitrile and potassium dihydrogen orthophosphate AR Grade purchased from E. Merck and Spectrochem, respectively. HPLC grade water was prepared by using Milli-Q purification system (Millipore, USA).

Mobile phase: Filtered and degassed mixture of buffer and acetonitrile was prepared in the ratio 50 : 50, where the buffer was (0.05 M potassium dihydrogen orthophosphate) and pH = 4.5.

Chromatographic conditions: The liquid chromatograph was equipped with a 235 nm detector and 250 mm length and 4.6 mm id, octadecyl silane column that contains 5 micron packing chemically bonded to porous silica particles; the flow rate was 1.0 mL/min and at ambient column temperature.

Standard preparation: Accurately weighed quantities of atorvastatin and amlodipine were dissolved in mobile phase to obtain solutions having known concentration of about 0.2 mg/mL atorvastatin and 0.3 mg/mL amlodipine. The above solutions were diluted with mobile phase to obtain a solution having known concentration of about 20 and 10 mcg/mL of atorvastatin and amlodipine, respectively.

Assay preparation for commercial formulation: Transferred 10 tablets into 500 mL volumetric flasks; about 300 mL mobile phase was added and sonicated until the tablets were dissolved. The flask was cooled and made up to volume with mobile phase; the solution was mixed and centrifuged to get clear solution, further diluted quantitatively and stepwise with mobile phase to obtain a solution having concentrations of 20 mcg/mL atorvastatin and 10 mcg/mL amlodipine, respectively.

Procedure: 20 μL of the standard preparation and the assay preparation were separately injected and the chromatographs were recorded (Fig. 1).

Linearity: Linearity was demonstrated by analyzing five different concentrations of active compound peak areas recorded for all the peaks and plotted peak area *vs.* concentration of atorvastatin and amlodipine were found to be linear. Coefficient of correlation for atorvastatin was 0.9990 and amlodipine was 0.9993.

Accuracy: Accuracy was done by recovery study using standard addition method, known amount of standard atorvastatin and amlodipine was added into the preanalyzed sample and subjected them to proposed HPLC method. Results of recovery studies are shown in Table-1.

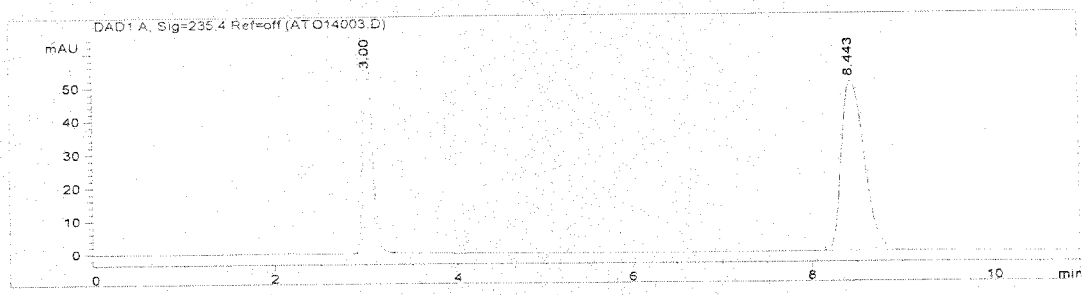


Fig. 1. HPLC chromatogram for simultaneous estimation of atorvastatin and amlodipine

TABLE-1
RECOVERY OF PURE ADDED TO FORMULATIONS

Drug's name	Amount of drugs added (mg)	Amount of drugs recovered (mg)	Recovery (%)	Mean recovery (%)
Atorvastatin	10.15	10.21	100.59	
	20.85	20.74	99.47	100.20
	29.95	30.12	100.56	
Amlodipine	15.12	15.20	100.52	
	30.45	30.35	99.67	100.13
	45.25	45.35	100.22	

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(*Received*: 9 November 2005; *Accepted*: 2 May 2006) AJC-4890