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Spectrophotometric Method for Simultaneous Estimation of Atorvastatin and Amlodipine in Tablet Dosage Form

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ABSTRACT

Atorvastatin is an antihyperlipoproteinemic drug and amlodipine is an antihypertensive drug. A simple, precise, rapid and selective spectrophotometric method has been developed for the simultaneous determination of atorvastatin and amlodipine in tablet dosage forms. The method involves solving of simultaneous equations based on measurement of absorptivity at two wavelengths 242nm and 364nm. Linearity range for atorvastatin and amlodipine were 1-20µg/ml and 1-50µg/ml respectively.
Keywords: Atorvastatin, Amlodipine, Estimation, Recovery.

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INTRODUCTION

Atorvastatin calcium [1], chemically, 1*H*-pyrrole-1-heptanoicacid,[R-(R*,R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-calciumsalt (2:1), is an antihyperlipoproteinemic drug [2], used for treatment of hypercholesterolemia. Atorvastatin is an HMG-CoA reductase inhibitor that appears to lower LDL and triglycerides more than other drugs in its class at recommended doses [3]. Amlodipine [4], chemically, 2-[(2-Aminoethoxy)-methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridine dicarboxylic acid, 3-ethyl-5-methyl ester. Literature survey reveals that various spectrophotometric [5,6] and HPLC [7,8] methods are available for the determination of atorvastatin and amlodipine in pharmaceutical dosage forms. In this communication we propose a fast, very simple and accurate spectrophotometric method for simultaneous estimation of atorvastatin and amlodipine in tablet dosage forms.

EXPERIMENTAL

A Double beam UV-VIS Spectrophotometer-ELICO-SL 164 with 1cm matched quartz cells was used. Pure atorvastatin calcium was obtained as a gift sample from M/s. Micro Labs Ltd., Bangalore. Pure amlodipine besilate was obtained as a gift sample from M/s. Dr.Reddy's Laboratories Ltd., Hyderabad. The solvents used for the experiment were methanol (HPLC grade) and distilled water. A standard stock solution of 1mg/ml of atorvastatin and 1mg/ml of amlodipine is prepared in methanol and used for estimation. For construction of calibration graph stock solutions were further diluted with distilled water. UV absorption spectra of amlodipine show significant absorption in between 200 and 400nm with λmax at 238nm and 364nm. Atorvastatin shows its maximum absorption at 242nm. It does not have any absorption at 364nm. However both the drugs have strong overlapping absorption at about 238nm. The Beer's law limits for atorvastatin is 1-20µg/ml at 242nm and for amlodipine 1-50µg/ml at 364nm and 238nm. Absorbances of both the drugs are practically additive at 238nm. The estimation of amlodipine has been done at 364nm using its absorptivity value, free of interference from atorvastatin. An accurate estimation of atorvastatin at 242nm has been achieved after correction for absorption by amlodipine.

Atorvastatin and amlodipine solutions of known concentrations were scanned on spectrophotometer and E1% values calculated at 242nm and 364nm are as follows-

Drug	242nm	364nm
Atorvastatin calcium	460	0
Amlodipine besilate	230	450

Quantitative estimation of atorvastatin calcium and amlodipine besilate was carried out by solving following simultaneous equations or by absorbance correction method.

$A_1 = 460C_1 + 0C_2$
$A_2 = 230C_1 + 450C_2$
Where A_1 and A_2 =Absorbance of sample at 242nm and 364nm respectively.
C_1 = Concentration (g%w/v) of atorvastatin calcium in sample
C_2 = Concentration (g%w/v) of amlodipine besilate in sample

For analysis of tablet formulation an accurately weighed powder equivalent to 10mg of atorvastatin and 5mg of amlodipine was taken in a 25ml volumetric flask. The powder was dissolved in 15ml methanol, shaken thoroughly and made upto 25ml with methanol. Then the solution was filtered through whatman filter paper and further diluted with distilled water to get the concentrations of 8µg/ml and 4µg/ml of atorvastatin and amlodipine respectively. Absorbances of sample solution were recorded at 242nm and 364nm. The results obtained are shown in Table-1.

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RESULTS AND DISCUSSION

To study accuracy, reproducibility, reliability and the interference from excipients used in the formulation, recovery studies were carried out by standard addition method. The recovery of added standard was found at different levels for each drug. From the total amount of drug found, the percentage recovery was calculated (Table-2). The regression equation is Y=0.002713X+0.0436 and the correlation coefficient were found to be 0.9999 for atorvastatin calcium. The regression equation is Y=-0.0019+0.0198X and the correlation coefficient were found to be 0.9998 for amlodipine besilate. These values suggest the level of precision of the method. The mean recoveries of atorvastatin calcium and amlodipine besilate were 99% and 98.6% respectively.

Table-1: Results of assay

Formulation	Drug	Label claim (mg)	Amount found*		C.V.(%)
			(mg)	%	
Tab-1	Atorvastatin	10.0	9.97±0.027	99.61	0.546
	Amlodipine	5.0	4.99±0.05	99.98	0.234
Tab-2	Atorvastatin	10.0	9.824±0.156	98.78	0.943
	Amlodipine	5.0	5.05±0.040	100.46	0.819

Table-2: Recovery studies

S.No.	Drug Name	Amount of standard added to pre-analysed drug solution	Amount found* (µg/ml)	% Recovery
1	Atorvastatin (40µg)	10µg	4.95	99.0
	Amlodipine (20µg)	10µg	2.91	98.3
2	Atorvastatin (40µg)	10µg	4.98	99.5
	Amlodipine (20(µg)	10µg	2.96	98.6

* Mean of five determinations.

CONCLUSION

Thus the proposed method for simultaneous estimation of atorvastatin calcium and amlodipine besilate in tablet dosage forms was found to be rapid, sensitive, simple, accurate and economical. High percentage of recovery shows that the method is free from the interference of excipient(s) used in formulation. Therefore the method can be useful in routine quality control of these drugs.

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REFERENCES

[1] O' Neil MJ. The Merck Index, 13th Edition. Merck & Co., In., Whitehouse Station, NJ, 2001, pp. 865.

[2] Reynolds JEF. Martin Dale- The Extra Pharmacopoeia, 31st Edition. The Royal Pharmaceutical Society, London, 1996, pp.1302.

[3] Lippincott W. Remington- The Science and Practice of Pharmacy, 21st Edition,Vol-II. Wolters Kluwer Health (India) Pvt. Ltd., New Delhi, 2007, pp.1368.

[4] O' Neil MJ. The Merck Index, 13th Edition. Merck & Co., In., Whitehouse Station, NJ, 2001, pp. 488.

[5] Juyal V, Chaudhary M, Kumar P, Gnanarajan G, Yadav PK. J Pharm Res 2008; 1: 182-187.

[6] Sahu R, Vandana Patel B. Indian J Pharm Sci 2007; 69: 110-111.

[7] Mohammadi A, Rezanour N, Dogaheh MA, Bidkorbeh FG, Hashem M, Walker RB. J Chromatogr B 2007; 846: 215-221.

[8] Chaudhari BG, Patel NM, Shah PB. Chem Pharm Bull 2007; 55: 241-246.