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SIMULTANEOUS SPECTROPHOTOMETRIC ESTIMATION OF TELMISARTAN AND ATORVASTATIN CALCIUM IN TABLET DOSAGE FORM

D. SARASWATHI, V. NIRAIMATHI, J. PRIYADHARISINI and A. JERAD SURESH*

Department of Pharmaceutical Chemistry, Madras Medical College, CHENNAI – 600003 (T.N.) INDIA

ABSTRACT

Three new simple, accurate and precise spectrophotometric methods have been developed for simultaneous determination of telmisartan and atorvastatin calcium in pharmaceutical dosage form. Method A and Method B involve the first and second order derivative method for simultaneous estimation of these two drugs. Method C involves the area under curve for first order derivative spectrum. Both the drugs obey the Beer's law in the range 5-30 µg for atorvastatin calcium and 5-40 µg for telmisartan. The results of analysis have been validated statistically and by recovery studies.

Key words: Telmisartan (TEL), Atorvastatin calcium (ATV), Derivative spectrophotometry, Area under curve (AUC).

INTRODUCTION

Telmisartan is 4-[1,4–dimethyl-2-propyl-(2,6-bi-1H-benzimidazole]-1-yl)methyl] [1,1-biphenyl]-2-carboxylic acid. Telmisartan is a new angiotensin II receptor antagonist for the treatment of essential hypertension usually given in combination with atorvastatin. Atorvastatin calcium is (βR,dR)-2(4-fluorophenyl)-β,d-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid, calcium salt, is a synthetic cholesterol lowering agent. Literature survey of these two drugs revealed that some spectrophotometric, RP-HPLC, HPTLC methods have been developed for individual drugs and in combination with other drugs[1-12]. No method has been developed for the simultaneous estimation of telmisartan and atorvastatin calcium in formulations.

*Author for correspondence; E-mail: ajsuresh2001@yahoo.co.uk

EXPERIMENTAL

Instrumentation

All spectral measurements were made on Shimadzu UV-VIS spectrophotometer – 1650 with 1 mm matched quartz cells.

Preparation of standard stock solution

An accurately weighed quantity of 25 mg of TEL and ATV were separately taken in a 50 mL volumetric flask, dissolved in methanol and made up to volume using methanol to get 500 μg/mL, respectively.

Preparation of sample solution

The average weight of 20 tablets was determined and finely powdered. The powder equivalent to 40 mg of TEL was taken in 50 mL volumetric flask and dissolved in 25 mL of methanol and then made up to volume with methanol. The solution was then filtered through Whatman filter paper No. 41, the first few mL of the filtrate was discarded and remaining solution was used for further analysis.

Assay procedure

Method A: First derivative spectrophotometry

Mixed standards were prepared in the ratio 1 : 4 of ATV and TEL ranging from concentration 1-6 μg/mL and 4-24 μg/mL of ATV and TEL, respectively and scanned in the range of 200-400 nm using distilled water as blank. Similarly, the sample solutions were also scanned. The normal spectra obtained were derivatised for the first order[14]. The overlain spectra of mixed standards of TEL and ATV are shown in Fig. 1. The amplitudes were measured from 225-242 nm for ATV and from 283.2-312.2 nm for TEL. The amount of ATV and TEL in marketed sample was computed from the calibration curve obtained by plotting the amplitude versus concentration for ATV and TEL individually. The results of analysis of tablet formulation are reported in Table 2.

Method B: Second derivative spectrophotometry

The mixed standard solutions of ATV and TEL were scanned between 200-400 nm using distilled water as a blank. The primary spectra so obtained were derivatised for the second order[14]. The overlain spectra of mixed standards of TEL and ATV are shown in Fig. 2. The amplitudes were measured at 241 nm for ATV and 296 nm for TEL. The amount of ATV and TEL in marketed sample was computed from the calibration curve obtained by

plotting the amplitude versus concentration for ATV and TEL individually. The results of analysis of tablet formulation are reported in Table 2.

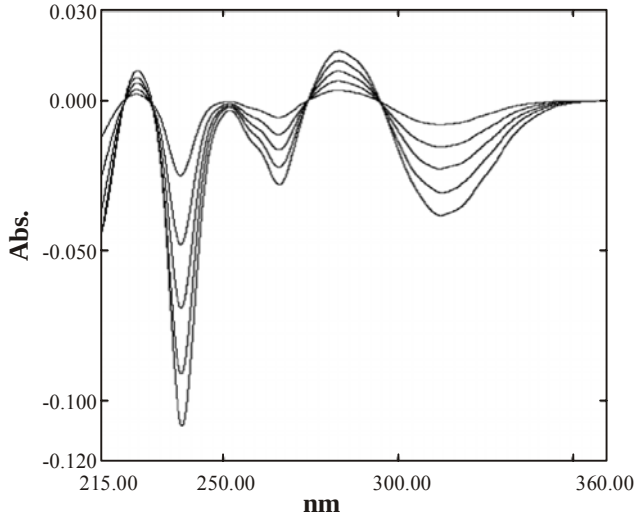

Fig. 1: Overlain spectra of first derivative of mixed standards of ATV and TEL

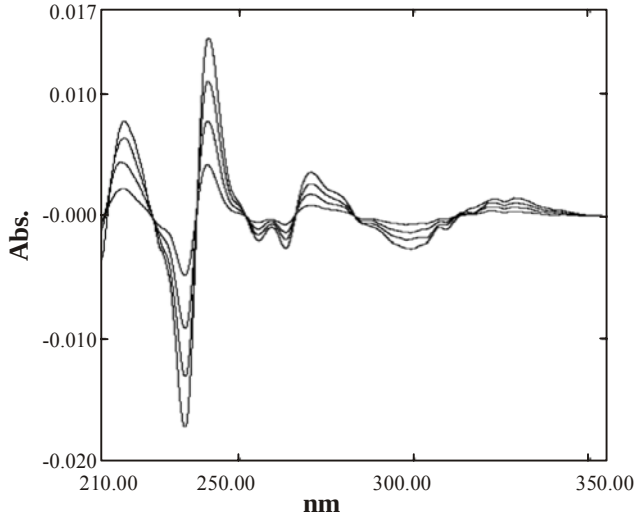

Fig. 2: Overlain spectra of second derivative of mixed standards of ATV and TEL

Method C: AUC for first derivative spectrophotometry

The mixed standard solutions of ATV and TEL were scanned between 200-400 nm using distilled water as a blank. The primary spectra so obtained were derivatised for the

first order. The area under curve[13] in the first order spectrum between 224.6-251.2 nm for ATV and 283-342.2 nm for TEL (Fig. 3) were measured by using the inbuilt software. The amount of ATV and TEL in marketed sample was computed from the calibration curve obtained by plotting the area versus concentration for ATV and TEL individually. The results of analysis of tablet formulation are reported in Table 2.

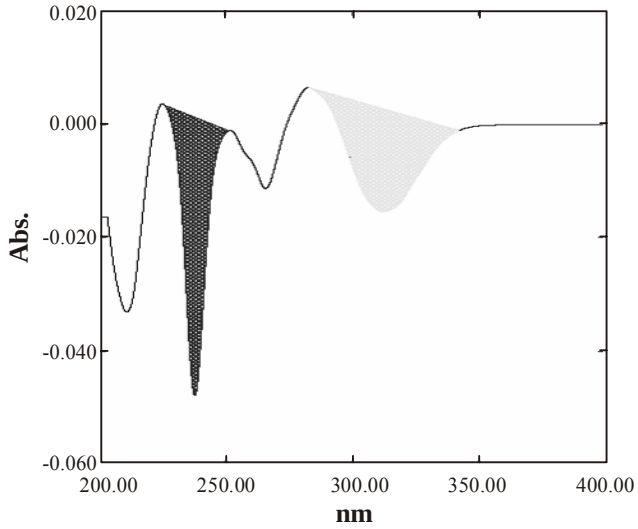

Fig. 3: AUC of first derivative spectrum of mixed standards of ATV and TEL

Recovery studies

To ensure the accuracy and reproducibility of the results obtained, recovery experiments were performed by adding known amounts of pure drug to the previously analyzed formulation samples and these samples were reanalyzed by the proposed methods. The percentage recoveries thus obtained are given in the Table 2.

RESULTS AND DISCUSSION

The optical characteristics such as RSD, regression equation, correlation coefficient, slope and intercept for the three methods were calculated and the results are summarized in Table 1. The amount and % of amount obtained by the proposed methods are presented in Table 2. Interference studies revealed that the excipients and additives did not interfere. Hence, these methods are most economic, simple, sensitive and accurate and can be used for the simultaneous determination of ATV and TEL in pharmaceutical preparations.

Table1: Optical characteristics and validation of the proposed methods

Parameters	Method A		Method B		Method C	
	ATV	TEL	ATV	TEL	ATV	TEL
λ_{max}/Wave length range	225- 242	283.2-312.2	241	296	224.6-251.2	283-342.2
Beer's law limit (µg/mL)	5-30	5-40	5-30	5-40	5-30	5-40
Linearity range (µg/mL)	1-6	4-24	1-6	4-24	1-6	4-24
Slope	28.7714	4.5357	17.6286	2.4643	0.2357	0.0646
Intercept	1.5714	-0.1427	0.7619	-0.1526	0.0036	0.0119
Regression equation (y = mx + c)	28.7714x + 1.5714	4.5357x-0.1427	17.6286x +0.7619	2.4643x-0.1526	0.2357x+ 0.0036	0.0646x+ 0.0119
Corelation coefficient	0.9994	0.9997	0.9992	0.9994	0.9996	0.9998
% RSD	0.2261	0.4812	0.1951	0.8600	0.5021	0.9321
LOD	0.0360	-0.2252	0.3137	-0.4145	0.1150	1.3271
LOQ	0.1092	-0.6824	0.9508	-1.2560	0.3487	4.0217

Table 2: Results of tablet formulation and recovery studies

Method	Drug	Label claim (mg/tablet)	Amount obtained (mg)*	% Amount found	**% Recovery by the proposed methods*
Method A	ATV	10	9.92	99.2	100.5
	TEL	40	40.43	101.08	101.04
Method B	ATV	10	9.94	99.4	100.8
	TEL	40	40.28	100.71	100.2

Cont…

Method	Drug	Label claim (mg/tablet)	Amount obtained (mg)*	% Amount found	**% Recovery by the proposed methods*
Method C	ATV	10	9.86	98.6	101.2
	TEL	40	39.76	99.41	100.4

*Average of three determinations, ATV-Atorvastatin, TEL-Telmisartan.
** After spiking the sample

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