Asian Journal of Chemistry Vol. 21, No. 5 (2009), 4118-4120

NOTE

Simultaneous Estimation of Amlodipine Besylate and Benazepril Hydrochloride Using Derivative Spectroscopy

CHETAN SAHAYA SAXENA* and S.C. CHTURVEDI
School of Pharmacy, Devi Ahilya Viswavidyalaya, Indore-452 001, India
E-mail: chetan_saxena1@yahoo.co.in

An accurate, sensitive and economical procedure for simultaneous estimation of amlodipine besylate and benazepril hydrochloride in tablet form has been developed. The method employed derivative spectroscopy, used first derivative spectra for the simultaneous estimation of amlodipine besylate and benazepril hydrochloride. The method is based on the measurement of the amplitude of the zero and first derivative spectra at 361 and 237 nm, respectively. Both drugs obey Beer's law in the concentration ranges employed for the analysis. The results of analysis have been validated statistically and by recovery studies.

Key Words: Estimation, Amlodipine besylate, Benazepril hydrochloride, UV-Visible spectrophotometer.

Amlodipine besylate (AB), 3-ethyl-5-methyl(4R-S)-2-[(2-aminoethoxy)-methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3-5-dicarboxylate-benzenesulphonate is used as calcium antagonist. Several spectrophotometric methods and HPLC, RP-HPLC, high performance capillary electrophoresis have been reported for the estimation of amlodipine in tablet alone and in combination with other drugs[1-8]. Benazepril hydrochloride (BZ), (3S)-3-[(1-ethoxycarbonyl-3-phenypropylamino]-2,3,4,5-tetrahydro1-2-oxo-1*H*-benzazepine-2-on hydrochloride, is used as an angiotensin converting enzyme inhibitor. Literature survey of the drug revealed some spectrophotometric, HPLC, RP-HPLC, LC, TLC, HPTLC methods for it estimation. There is no single method have been developed for the simultaneous estimation of amlodipine besylate and benazepril hydrochloride from pharmaceutical dosage form by UV-Visible spectrophotometry in their combined dosage form. Hence in the present investigation simple, rapid and reproducible methods was developed for the simultaneous estimation of amlodipine besylate and benazepril hydrochloride from their combined dosage form.

Shimadzu UV-2401PC: UV-Visible recording spectrophotometer: Spectrophotometer using 1 cm quartz cell was used for the experimental purpose. Shimadzu electronic balance was used for weighing the sample. Methanol of analytical grade (S.D. Fine Chem. Limited, Mumbai) was used as a solvent. Gift samples of amlodipine besylate and benazepril hydrochloride were obtained from Ranbaxy

Laboratories Ltd., Dewas (M.P.). A combination of both drugs, amlodipine besylate 5 mg and benazepril hydrochloride 10 mg in tablet form is marketed by Systopic laboratories Ltd. Using a trade name AMACE-BP.

Preparation of standard stock solution: Standard stock solution was prepared by dissolving 10 mg of each drug in 100 mL of methanol to get a concentration of 100 µg/mL for both drugs separately. The absorbance was measured at 361 nm for amlodipine besylate and 242 nm for benazepril hydrochloride against methanol. Both drugs obey Beer's law individually and in mixture within the concentration range of 5-50 µg/mL. Fig. 1 represents the overlain spectra of both the drugs.

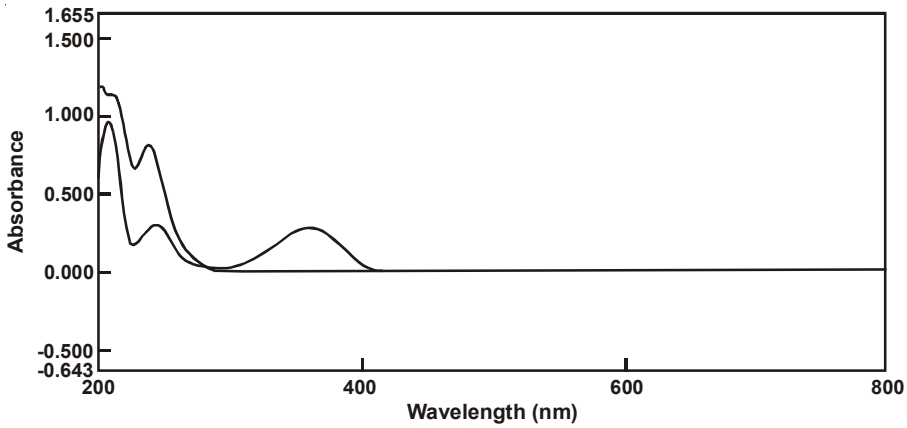

Fig. 1. Overlain graph of amlodipine besylate and benazepril hydrochloride

Preparation of sample stock solution: Sample stock solution was prepared by extracting tablet containing amlodipine besylate 5 mg and benazepril hydrochloride 10 mg. The above drugs were diluted up to 100 mL methanol in 100 mL volumetric flask. Further dilutions were made from this stock solution to get the required concentration.

Spectra of amlodipine besylate has shown absorbance at 361 nm while benazepril hydrochloride showed zero absorbance at this wavelength. A first order derivative spectrum is recorded to overcome the spectral interference from other drug. Amlodipine besylate showed $dA/d\lambda$ zero in contrast to benazepril hydrochloride that has considerable $dA/d\lambda$ at 237 nm. These 2 wavelengths were employed for the estimation of amlodipine besylate and benazepril hydrochloride without any interference. The calibration curves were plotted at these 2 wavelength using different concentrations against absorbance within the range mentioned above. The equations obtained to determine concentration of amlodipine besylate and benazepril hydrochloride is as follows respectively:

$$Y = 0.0163X + 0.0020 \quad R^2 = 0.9975 \qquad (1)$$

$$Y = 0.0022X + 0.0006 \quad R^2 = 0.9936 \qquad (2)$$

Estimation of marketed preparation: An aliquot sample stock solution (1 mL) was transferred to 100 mL standard volumetric flask and volume was made up to the mark with methanol. The solution was scanned in the range 200-400 nm against methanol as blank. Then the spectra at zero order at wavelength 361 nm and at first order derivative (n = 3) at wavelength 237 nm scanned, $dA/d\lambda$ were measured. Using the eqn. 1 and 2 the concentration was calculated.

Results of the analysis of the method are given in the Table-1, to determine the precision and accuracy of the method, recovery experiment was performed using the proposed method. A fixed volume of standard solution was added to different concentrations of the sample solutions. The total amount of drug was found by difference. The whole experiment was performed using 2 different batches of drug combination (A and B). The result of the recovery is given in Table-2. Above method was found to be accurate, simple and rapid for routine simultaneous analysis of drugs from the tablet formulations. The method is less time consuming and can easily applied to routine analysis.

TABLE-1

Batch	Amlodipine Besylate			Benazepril hydrochloride		
	Drug/label claim (mg)	Amount found	Percentage	Drug/label claim (mg)	Amount found	Percentage
A	5	4.908	98.16	10	9.515	95.15
	5	4.908	98.16	10	10.121	101.21
	5	4.989	99.80	10	9.818	98.18
B	5	4.870	97.34	10	9.520	95.15
	5	4.830	96.52	10	9.820	98.18
	5	4.870	97.34	10	9.820	98.18

TABLE-2

Batch	Drugs	Means (%)	±Standard deviation	%Coefficient variation	Standard error
A	AB	98.70	0.945	0.957	0.546
	BH	98.18	3.048	3.048	1.719
B	AB	99.16	0.472	0.486	0.273
	BH	97.17	1.741	1.800	1.010

REFERENCES

1. British Pharmacopoeia, International edition, p. 117 (2002).
2. Martindale, The Complete Drug Reference, edn. 32, p. 822.3, 827.1 (1999).
3. F. Betal, A.I. Zaagi and M.A. Asif, *IL Farmaco*, **55**, 425 (2000).
4. S.T. Hassif, Z.A. El Sharif, R.I. Elbagari and N.F. Youssef, *Anal. Lett.*, **33**, 3225 (2000).
5. A. El Glindy, N.A. Fattah and M.M. Shabana, *J. Pharm. Biomed. Anal.*, **25**, 179 (2001).
6. R.N. Rao and V. Nagaraju, *J. Pharm. Biomed. Anal.*, **33**, 335 (2003).
7. K. Lango, P.B.S. Kumar and K.S. Lakshmi, *Indian Drugs*, **39**, 497 (2001).
8. N. Rahman and N.H.S. Azami, *Anal. Sci.*,**16**, 1353 (2000).

(*Received*: 1 January 2008; *Accepted*: 25 February 2009) AJC-7295