Asian Journal of Chemistry Vol. 20, No. 3 (2008), 1957-1960

Two UV-Spectrophotometric Methods for Simultaneous Determination of Levofloxacin and Ambroxol in Tablets

O.D. AGRAWAL, A.A. SHIRKHEDKAR* and S.J. SURANA
Department of Pharmaceutical Chemistry, R.C. Patel College of Pharmacy
Shirpur-425 405, India
E-mail: atul_shirkhedkar@yahoo.com

Two simple, rapid, accurate and precise UV-spectrophotometric methods have been developed for simultaneous estimation of levofloxacin and ambroxol from tablets. Method **1** involves formation and solving of simultaneous equations, while method **2** multicomponent mode of analysis. In distilled water, the absorbance maxima for levofloxacin and ambroxol was found to be 226 and 244 nm, respectively. The linearity was observed in the concentration range of 4-20 µg/mL for levofloxacin and 4-40 µg/mL for ambroxol. The results of both the methods have been validated statistically and by recovery studies.

Key Words: Levofloxacin, Ambroxol, Spectrophotometry.

INTRODUCTION

Chemically, levofloxacin hemihydrate is (-)-(S)-9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl)-1-piperazinyl)-7-oxo-7*H*-pyrido[1,2,3-de]-1,4-bezooxazine-6-carboxylic acid hemihydrate[1] and used as antibacterial agent[1,2]. Ambroxol hydrochloride, chemically is *trans*-4-[(2-amino-3,5-dibrombenzyl)amino]cyclohexanol hydrochloride[3] and used as broncho-secretolytic and expectorant[4].

Various spectrophotometric[5,6], chormatographic[7,8] methods are reported for estimations of levofloxacin and ambroxol alone and in its combination with other drugs[9,10]. At present no spectrophotometric method is reported for Simultaneous estimation of both these drugs in combined tablet dosage form. So, attempt has been made to develop two UV-spectrophotometric methods for simultaneous estimation of both these drugs.

EXPERIMENTAL

For method **1**, UV-Visible spectrophotometer (2450 Shimadzu with spectral bandwidth 1 nm) was employed for all spectroscopic measurements, using a pair of 10 mm matched quartz cells. Standard stock solutions of levofloxacin and ambroxol were prepared separately in distilled

water and diluted to different concentrations. The linearity was studied at respective absorbance maximas, *i.e.* 226 and 244 nm. Beer's law is obeyed in the concentration range 4-20 µg/mL for levofloxacin and 4-40 µg/mL for ambroxol. The optical characteristics and statistical data of regression equation for the calibration curve are presented in Table-1.

TABLE-1
OPTICAL CHARACTERISTICS AND STATISTICAL DATA OF THE REGRESSION EQUATION

Parameters	Levofloxacin	Ambroxol
λ_{max} (nm)	226.0	244.0
Beer's law limit (µg/mL)	4-20	4-40
Slope	0.0482	0.0247
Y-Intercept	- 0.0157	-0.001
Correlation coefficient	0.9989	0.9991

Method **1** is based on solving simultaneous equation[9] and utilizes corresponding absorbance maximas for quantification. The mean absorptivity coefficients of both the drugs at each wavelength were determined from different dilutions (six independent determinations) within linearity range. Using these, a set of two simultaneous equations was framed;

$$A_1 = 472.36 \times C_1 + 210.89 \times C_2 \quad (1)$$

$$A_2 = 386.88 \times C_1 + 244.83 \times C_2 \quad (2)$$

where, C_1 and C_2 are the concentration of levofloxacin and ambroxol in g/100 mL in sample solution. By rearranging eqns. 1 and 2, concentrations C_{LEV} and C_{AMB} can be obtained as;

$$C_1 = A_1 \times 210.67 - A_2 \times 244.83 / -34143.8 \quad (3)$$

$$C_2 = A_2 \times 386.88 - A_1 \times 472.36 / -34143.8 \quad (4)$$

In method **2**, multicomponent mode of analysis utilizes multicomponent mode of UV spectrophotometer (Shimadzu 1700 with spectral bandwidth 1 nm). Seven mixed standard solutions with concentration of levofloxacin and ambroxol in the ratio of 40:0, 0:40, 4:20, 5:25, 6:30, 7:35, 8:40 (mcg/mL) were prepared in distilled water. All the mixed standard solutions were scanned over the range of 400-200 nm, in the multicomponent mode of UV-spectrophotometer, using two sampling wavelength 226 nm (λ_{max} of levofloxacin) and 244 nm (λ_{max} of ambroxol). The spectral data from these scans was used to determine the concentration of two drugs in tablet sample solutions.

20 Tablets were weighed and ground to fine powder. An accurately weighed powder sample equivalent to 250 mg of levofloxacin and 15 mg of ambroxol was transferred to 100 mL volumetric flask; 40 mL of

distilled water was added and sonicated for 10 min. The solution was filtered through Whatmann filter paper no. 41 and volume was made up to the mark with same solvent. From it, 0.2 mL solution was transferred to 25 mL volumetric flask; to it 2.8 µg/mL of standard ambroxol was added (to obtain 5:1 ratio of levofloxacin and ambroxol) and volume was made up to the mark. The absorbance of resulting solutions was recorded, at 226 and 244 nm. And, the concentrations of two drugs in sample were determined by using eqns. 3 and 4.

Also, these solutions were subjected to analysis in multicomponent mode of instrument. The solutions were scanned over the range of 400-200 nm wavelength and concentration of each drug was determined by analysis of spectral data of the sample solution with reference to the mixed standard. The analysis procedure was repeated five times with tablet formulations and results of both the methods are reported in Table-2.

TABLE-2
TABLET FORMULATION ANALYSIS

Label claim (mg/tab)		Method **1**				Method **2**			
		Label claim* ± SD (%)		Recovery ± SD (%)		Label claim* ± SD (%)		Recovery ± SD (%)	
LEV	AMB	LEV	AMB	LEV	AMB	LEV	AMB	LEV	AMB
500	30	98.92 ± 0.14	98.10 ± 0.95	99.45 ± 0.14	99.10 ± 1.07	99.65 ± 0.60	99.83 ± 0.62	99.86 ± 0.39	99.40 ± 1.45

*Mean of five estimation; LEV = Levofloxacin; AMB = Ambroxol

The recovery studies were carried out by adding known amount of standard solution of levofloxacin and ambroxol to pre-analyzed tablet solutions. The resulting solutions were then analysed by proposed methods. The results of recovery studies were found to be satisfactory and results are reported in Table-2.

RESULTS AND DISCUSSION

The proposed methods were found to be simple, accurate, economical and rapid for routine simultaneous estimation of levofloxacin and ambroxol in tablets. The accuracy of the methods was determined by calculating mean percentage recovery.

ACKNOWLEDGEMENT

The authors are thankful to M/s Glenmark Pharmaceuticals, M.I.D.C., Satpur, Nashik for providing gift samples of drugs.

REFERENCES

1. The Merck Index, Merck & Co. Inc., Whitehouse Station, NJ, edn. 13 p. 6800, 67 (2001).
2. A.C. Moffat, M.D. Osselton and B. Widdop, Clarke's Analysis of Drugs and Poisons, The Pharmaceutical press, Great Britain, Vol. 2, edn. 3, p. 1172 (2004).
3. British Pharmacopoeia, London: The Stationary Office Medicinal and Pharmaceutical Substances (A-I), Vol. 1, p. 106 (2005).
4. J.E.F. Reynolds, In Martindale the Extra Pharmacopoeia, The Pharmaceutical Press, London, edn. 30, p. 1084 (1993).
5. L. Sivasubramanian, V.K. Sankar, V. Sivaraman, K.S. Kumar, A. Muthukumaran and T.K. Raja, *Indian J. Pharm. Sci.*, **66**, 799 (2004).
6. S. Bottcher, H.V. Baum, T. Hoppe-Tichy, C. Benz and H.G. Sonntag, *J. Pharm. Biomed. Anal.*, **25**, 197 (2001).
7. Z. Dincer, H. Basan and N.G. Goger, *J. Pharm. Biomed. Anal.*, **31**, 867 (2003).
8. P.U. Patel, B.N. Suhagia, C.N. Patel, M.M. Patel, G.C. Patel and G.M. Patel, *Indian J. Pharm. Sci,* **67**, 356 (2005).
9. S.B. Chepurwar, A.A. Shirkhedkar, S.B. Bari and S.J. Surana, *Asian J. Chem.*, **19**, 1628 (2007).
10. S.B. Chepurwar, A.A. Shirkhedkar, S.B. Bari and S.J. Surana, *Indian Drugs*, **43**, 803 (2006).

(*Received*: 19 March 2007; *Accepted*: 8 November 2007) AJC-6066