Asian Journal of Chemistry Vol. 21, No. 2 (2009), 1633-1635

NOTE

Simultaneous Spectrophotoetric Estimation of Bromhexine Hydrochloride and Pseudoephedrine Hydrochloride in Tablet Dosages

V. GUPTA, M. VERMA, U. MISRA* and R.K. NEMA†
Faculty of Pharmacy, Integral University, Dasauli
P.O. Bas-ha, Kursi Road, Lucknow-226 026, India
E-mail: upama.misra@rediffmail.com

Two simple, precise and economical derivative spectrophotometric methods have been developed for the simultaneous determintion of bromehexine hydrochloride and pseudoephedrine hydrochloride in tablet formulations. In zero order, bromhexine hydrochloride and pseudoephedrine hydrochloride shows absorption maxima of 308 and 257 nm respectively in both methanol and distilled water. Beer's law is obeyed in the concentratrion range of 10-60 µg/mL for bromhexine hydrochloride and 75-900 µg/mL for pseudoephedrine hydrochloride at the selected wavelengths. The results of analysis validated statistically and by recovery studies.

Key Words: Bromhexine, Pseudoephedrine, Ultraviolet spectroscopy, Derivative spectrophotometric method.

Bromhexine hydrochloride (BMX), offficial in IP[1] and BP[2] has mucolytic and expectorant activity. IP describes a spectrophotometric method for its analysis in tablet formulations. A colorimetric[3], chromatrographic[4,5] and electrophoretic[6] method of estimation of bromhexine hydrochloride has also reported. Pseudoephedrine hydrochloride (PSD) is oifficial in BP[7] and has bronchodilating activity[8]. IP describes a HPLC method for the analysis of pseudoephedrine hydrochloride and its tablet formulations. A gas chromatographic[9], HPTC[10] and HPLC[11-13] method of estimation has also been reported for the analysis of pseudoephedrine hydrochloride. The literature review revealed that no spectrophotometric method is available for simultaneous determination of these drugs in pharmaceutical formulations. This paper presents two simple, precise, reproducible and economical methods for the simultaneous analysis of two components in table formulations.

Standard samples of bromhexine hydrochloride and pseudoephedrine hydrochloride were procured from IPCA Ratlam. Methanol of AR grade was purchased from Ranbaxy Fine Chemicals. A Shimadzu UV-Visible spectrophotometer 1700 was used for the development of analytical method.

†S.D. College of Pharmacy & Vocational Studies, Muzaffarnagar-251 001, India.

Derivative method: Solution of bromhexine hydrochloride (BMX) (40 µg/mL) and pseudoephedrine hydrochloride (PSD) (300 µg/mL) ware prepared separately and then scanned in the spectrum mode from 400 to 200 nm. The absorption spectra thus obtained were derivatized from first to fourth order and were recorded. From the overlain spectra, first derivative order was selected for BMX and fourth derivative order was selected for PSD. The sampling wavelengths selected from these overlain spectra were 326.0 nm for BMX and 270.0 nm for PSD.

Procedure for analysis of tablet formulations: Twenty tablets were weight and crushed to fine power. An accurately weighed powder sample equivalent to 4 mg of BMX was transferred to a 100 mL volumetric flask and was dissolved and diluted to 100 mL with distilled water. The solution was filtered through Whatmann filter paper No. 41 and was suitably diluted to obtain a concentration of 40 µg/mL of BMX. The solution was then scanned in the spectrum mode from 400 to 200 nm and the sbsorption spectra was derivatized for first and fourth order and the absorbance values were noted at 326 nm for BMX and 270 nm for PSD. The absorbance of both the drugs were then extrapolated on the standard calibration curves and concentration of both the drugs were determined (Table-1). The recovery studies were carried out by adding 10, 20 and 30 µg/mL of pure standard solution of BMX and 75, 150 and 225 µg/mL of pure standard solution of PSD in preanalyzed tablet solution containing 40 µg/mL of BMX and 75 µg/mL of PSD.

TABLE-1
RESULTS OF ANALYSIS OF COMMERCIAL TABLETS

Drug	Label claim (mg/tab)	Amount found (mg/tab)*	Result (%)		STD. Dev.		S.V.		S.E.	
			M-I	M-II	M-I	M-II	M-I	M-II	M-I	M-II
Bromhexine hydrochloride	8	8.04	100.50	100.12	0.22	0.25	0.05	0.04	0.11	0.20
Pseudoephedrine hydrochloride	60	60.12	100.20	100.53	0.15	0.09	0.02	0.05	0.30	0.10

*Average of three values.

Multicomponent method: Solution of BMX (40 mg/mL) and PSD (300 mg/mL) ware prepared separately in methanol and then scanned in the spectrum mode from 400 to 200 nm to obtain a overlain spectra the sampling wavelengths selected from this spectra were 308 nm for BMX and 257 nm for PSD.

Preparation of mixed standards: From the standard solutions five-mixed standard of pure drug containing 10-50 µg/mL of BMX and 75-450 µg/mL of PSD were prepared on the basis of their ratio in tablet formulation. All the five mixed standard were run in multicomponent mode to obtain the overlain spectra.

Procedure for analysis of tablet formulation: Twenty tablets were weighed accurately, the average weight determine and then ground to a fine powder. A quantity equivalent to 8 mg of BMX was weighed and transferred to 100 mL volumetric flask. The contents were shaken with methanol to dissolve the active ingredients.

The volume was adjusted and filtered through Whatmann filter paper No. 41. The filtrate was further diluted to a desired concentration and was run in multicomponent mode to obtain the concentration of two drugs in the sample. Thne results of the analysis of the tablet formulation are reported in Table-1.

The proposed methods for estimation of bromhexine hydrochloride and pseudoephedrine hydrochloride in combined dosage form are found to be simple, accurate and rapid. The method requires measurement of absorbance at only two wavelengths to determine the concentration of two drugs. The recovcery studies carried out to gave satisfactory results in the range of 97-100 % (Table-2). Also a satisfactory low value of standard deviation of 0.604 for BMX and 0.757 for PSD was indicative of the reproducibility of the method.

TABLE-2
RECOVERY STUDY DATA

Conc. of added drug in the final dilutrion (mg/mL)		Recovery (mg/mL)		Recovery (%)	
BMX	PSD	BMX	PSD	BMX	PHD
10	75	9.91	74.42	99.10	99.23
20	150	19.87	149.74	99.35	99.83
30	225	30.01	223.85	100.01	99.49

BMX = Bromhexine hydrochloride; PSD = Pseudoephedrine hydrochloride.

ACKNOWLEDGEMENTS

The authors are thankful to IPCA Ratlam for providing gift samples of the drugs, Vice-Chancellor and Pro Vice-Chancellor of Integral University, Lucknow for providing necessary research facilities to complete the research work.

REFERENCES

1. Indian Pharmacopoeia, Delhi, Controller of Publication, Govt. of India, Vol. 1, edn. 4, p. 111 (1996).
2. British Pharmacopoeia, Londan, British Pharmacopoeias Commission, Vol. 1, edn. 3, p. 87 (1993).
3. P. Parimoo and S. Kumar, *Indian Drugs*, **31**, 41 (1994).
4. A.P. DeLeeneer, L.M.R. Vandecosteele-Thienpont, *J. Pharm. Sci.*, **69**, 99 (1980).
5. J.L. Kumar, W.C. Mann and A.J. Razanki, *Chromatography*, **249**, 373 (1982).
6. V.G. Rodriguez, S.E. Lucangioll, *J. High Rosholt. Chromatogr.*, **19**, 703 (1996).
7. Indian Pharmacopoeia, Delhi, Controller of Publication, Govt. of India, Vol. 1, edn. 4, p. 641 (1996).
8. British Pharmacopoeia, Londan, British Pharmacopoeia Commission, Vol. 1, edn. 3, p. 180 (1993).
9. M.L. Labelle and C. Savard, *Forensic Sci. Int.*, **71**, 215 (1995).
10. J.K. Lalla, S.V. Bhat and N.R. Shashtry, *Indian Drugs*, **34**, 197 (1997).
11. L.H. Pao and D.Y.P. Hu, *Drug Dev. Indian Pharm.*, **20**, 2695 (1994).
12. S.E. Hendrikz and L.W. Brown, *J. Chromatogr. B. Biomed.*, **661**, 357 (1994).
13. I. Caraballo and A. Prenander, *Drug Dev. Indian Pharm.*, **21**, 605 (1995).

(*Received*: 7 February 2008; *Accepted*: 20 October 2008) AJC-6961