

Derivative Spectrophotometric Estimation of Amoxicillin and Bromhexine Hydrochloride in Tablets

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A simple, accurate, economical and reproducible procedure for simultaneous estimation of amoxicillin and bromhexine hydrochloride in two component tablet formulations has been developed. The method was based on derivatisation of fundamental spectra in first order to eliminate the spectral interference from one of the two drugs while estimating the other and measure absorbance at two wavelengths 278.8 and 326.2 nm. Beer's law was obeyed in the concentration range of 0.0 to 375.0 mcg/mL of amoxicillin and 0.0–100.0 mcg/mL of bromhexine hydrochloride. The results of analysis obtained in triplicate of experiment with two different compositions of tablet formulation were validated statistically and by recovery studies.

Key Words: Simultaneous estimation, Amoxicillin, Bromhexine hydrochloride, Derivative spectrophotometry.

INTRODUCTION

Amoxicillin is an antibacterial agent¹ and bromhexine hydrochloride is a mucolytic and expectorant^{2,3}. The combination of amoxicillin and bromhexine hydrochloride is used in respiratory disorders. Simple spectrophotometric methods and chromatographic methods have been reported for determination of bromhexine hydrochloride⁴⁻⁸. Spectrophotometric methods, chromatographic methods and iodometric titration have been reported for analysis of amoxicillin⁹⁻¹⁵. No simple spectrophotometric method has been reported so far for the simultaneous estimation of amoxicillin and bromhexine hydrochloride in combined dosage forms. The present study illustrates simple, accurate, economical and reproducible procedures for the simultaneous spectrophotometric estimation of amoxicillin and bromhexine hydrochloride in two component tablet formulations.

EXPERIMENTAL

A Shimadzu UV 160A spectrophotometer with 10 mm matched quartz cells was employed for this work. Water is used as solvent.

Procedure

Standard stock solutions: Standard stock solutions of amoxicillin and bromhexine hydrochloride of strengths 625.0 mcg/mL and 200.0 mcg/mL were prepared in water respectively.

Preparation of sample solutions: Tablet samples from two different formulations were separately used for analysis. Twenty tablets were weighed and ground to fine powder. An accurately weighed powder sample equivalent to 25 mg of amoxicillin was dissolved in about 20 mL of water by intermittent shaking for

about 45 min; to this (in case of 1 : 31.25 bromhexine hydrochloride : amoxycillin) 16 mL standard solution of bromhexine hydrochloride (200 mcg/mL) was further added. In case of 1 : 62.5 bromhexine hydrochloride to amoxycillin, an amount of 18 mL of standard solution of bromhexine hydrochloride (200 mcg/mL) was added. The sample solution was then filtered through Whatman filter paper No. 41 in a 50 mL volumetric flask and the volume was made up to the mark.

Derivative spectrophotometry

Standard stock solutions of amoxycillin and bromhexine hydrochloride were prepared separately with concentration of 25 mcg/mL. These solutions were scanned over the range of 400–200 nm. The absorption spectra thus obtained were derivatised and derivative spectra from first to fourth order were recorded. Considering all these derivative spectra of amoxycillin and bromhexine hydro-

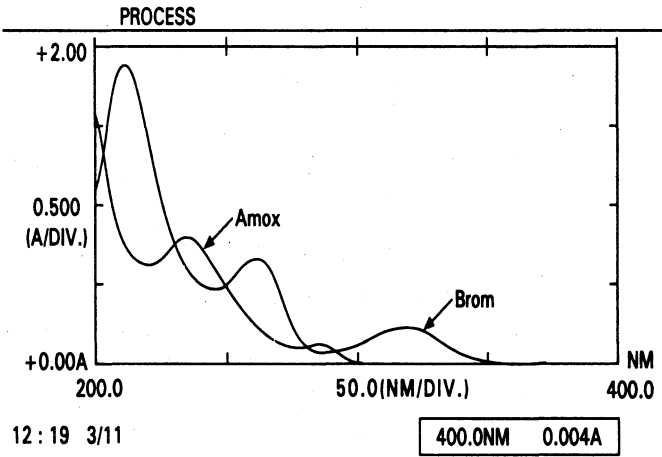


Fig. 1

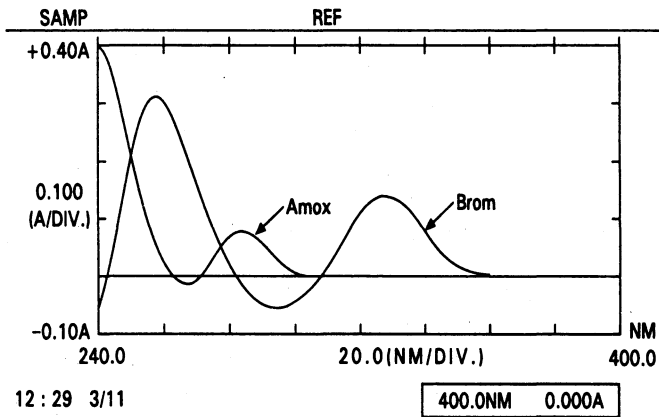


Fig. 2

chloride, the first order derivative spectra for both the drugs were selected. Five mixed standards of pure drugs containing 62.5, 125.0, 187.5, 250.0 and 312.5 mcg/mL amoxicillin and 10.0, 20.0, 30.0, 40.0 and 50.0 mcg/mL bromhexine hydrochloride were prepared. All mixed standards were scanned over the range of 400–260 nm and derivatised to measure substantial absorbance at 278.8 and 326.2 nm for amoxicillin and bromhexine hydrochloride respectively. Then working equations for both the drugs were derived.

For amoxicillin:

$$C_{\text{amox}} = 613.94 \times A_{\text{amox}} + (-0.0772)$$

For bromhexine hydrochloride:

$$C_{\text{brom}} = 278.8 \times A_{\text{brom}} + (0.0103)$$

where C_{amox} and C_{brom} are the concentrations of amoxicillin and bromhexine hydrochloride respectively, and A_{amox} and A_{brom} are the absorbances of amoxicillin (278.8 nm) and bromhexine hydrochloride (326.2 nm) respectively.

Sample solutions were scanned after suitable dilution. Concentrations of both components were calculated using these equations.

Recovery studies: In order to ascertain reproducibility of proposed method, recovery studies were carried out by adding known amount of drugs to the pre-analyzed sample solution.

RESULTS AND DISCUSSION

The result of analysis, obtained in triplicate, of experiment with two different compositions of tablet formulation was validated statistically (Table-1). The value of standard deviation co-efficient of variation was significantly low and recovery was close to 100% (Table-2) indicating the reproducibility of the method.

It is concluded that the proposed method is simple, reliable and accurate and can be successfully employed for routine simultaneous estimation of amoxicillin and bromhexine hydrochloride in two component tablet formulations.

TABLE-1
STATISTICAL ANALYSIS OF RESULTS

Method	Batch	Tablet component	Label claim (mg/mL)	% of label claim estimated* ± S.D.	Coeff. of variation
I	A	Amox.	125	98.44 ± 0.875	0.888
		Brom.	4	99.89 ± 1.5084	1.510
	B	Amox.	250	99.43 ± 0.363	0.365
		Brom.	4	100.04 ± 3.286	3.285

Amox.: Amoxicillin

Brom.: Bromhexine hydrochloride

S.D.: Standard deviation

* : Average of three estimations

A and B are two different compositions of tablet formulations.

TABLE-2
RECOVERY STUDIES

Concentration of added drug in preanalysed solution (mcg/mL)		% Recovery			
		A		B	
Amox.	Brom.	Amox.	Brom.	Amox.	Brom.
25.0	2.0	99.74	100.20	98.71	99.55
50.0	4.0	98.98	99.55	99.86	98.85
75.0	6.0	99.56	98.48	100.14	102.90

ACKNOWLEDGEMENTS

One of the authors, Arun Kumar Gupta, is thankful to Ministry of Human Resource Development for providing financial assistance and to Prof. S.C. Chaturvedi, Head of the Department for providing necessary facilities. The authors are also thankful to M/s Nicholas Piramal India Ltd, Pithampur and M/s Vostok Laboratories, Indore for providing bromhexine hydrochloride and amoxicillin respectively as a gift samples.

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(Received: 30 October 2002; Accepted: 8 January 2003)

AJC-2964