SHORT COMMUNICATION

SPECTROPHOTOMETRIC ESTIMATION OF AMBROXOL AND CETIRIZINE HYDROCHLORIDE FROM TABLET DOSAGE FORM

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ABSTRACT

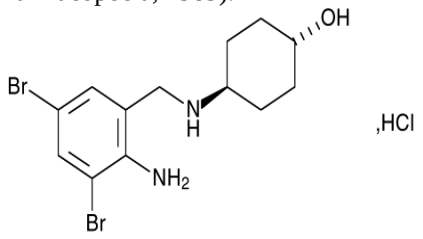
Fixed dose combination tablets containing ambroxol HCl and cetirizine HCl are clinically used as mucolytic and antiallergic. Several spectrophotometric and HPLC methods have been reported for simultaneous estimation of these drugs with other drugs.

The drugs individually and in mixture obeys Beer's law over conc. range 1.2-4.4 µg/mL for cetirizine HCL and for ambroxol HCL 15-52 µg/mL at all five sampling wavelengths (correlation coeff. well above 0.995). The mean recoveries from tablet by standard addition method were 100.18% (±2.4) and 100.66 % (±2.31). The present work reports simple, accurate and precise spectrophotometric methods for their simultaneous estimation from tablet dosage form.

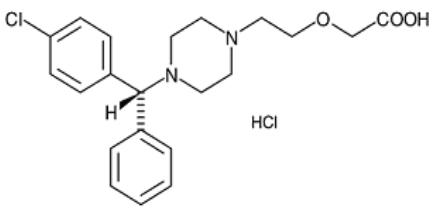
Keywords: Ambroxol HCl, cetirizine HCl, spectrophotometric, HPLC.

INTRODUCTION

Ambroxol HCl (AMB) is a expectorant and mucolytic agent. It is a metabolite of bromohexine. Chemically it is 4-[(2-Amino-3, 5-dibromobenzyl) amino] cyclohexanol hydrochloride (The Merck Index, 1989). Cetirizine HCl (CTZ) is histamine H_1-receptor antagonist. It is a piperazine derivatives and metabolite of hydroxyzine .Chemically it is 2-[2- [4(4chlorophenyl) phenyl methyl] piperazin-1-yl] ethoxy] acetic acid dihydrochloride (British Pharmacopoeia, 1989).



Ambroxol HCl



Cetirizine HCl

Literature survey reveals that several methods such as UV spectrophotometric (Narayan Rao *et al*., 1998; Indrayanto and Handayani 1993) and chromatographic (Indrayanto and Handayani 1994; Koundourellis *et al*., 2000; Uboh *et al*., 1991; Li *et al*., 1999; Nemes *et al*., 2000; Noblis *et al*., 1992) have been reported for estimation of ambroxol in pharmaceutical formulation. However several methods like spectrophotometric (Badwe *et al*., 1995; Mathwe *et al*., 1995; Nothenberg and Simon 1998; Prakash *et al*., 2000) and HPLC (Suryanarayana *et al*., 1992; Moncriff 1992; Rossel and Lefetvre 1991; Baltes and Gobert, 1998) were reported for estimation of cetirizine but for the estimation of combination of these two drugs is not available yet.

EXPERIMENTAL

The multicomponant spectrophotometric mode of estimation is based on comparing spectral data of mixed standard solutions with that sample at selected wavelengths (one less than total number of standards). The necessary requirements of the method, obeyance of Beer's law and additively of absorbance at all selected wavelengths were followed by the drugs. Six mixed standard solutions were prepared containing CTZ (1.2-4.4 µg/mL) and AMB (15-52 µg/mL) in 1:12 ratio. Tablet powder extracted with methanol and appropriately diluted to contain about 1.2µg/mL of AMB. In the scanning range 200-270 nm, five wavelengths (220, 231, 240, 245, 250 nm) were selected in multicomponent mode of spectrophotometer and the conc. of each component of all six standards were entered in it. The mixed standards were then scanned followed by samples over the scanning range. The conc. of samples were directly displayed after due processing. The results are summarized in table 1.

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Table 1: Results of estimation in Tablet by multicomponent spectrophotometric method.

S.N.	Sample	% Labeled claim*		% Recovery*	
		CTZ	AMB	CTZ	AMB
1.	Std. lab. mix.	100.59 (±1.93)	99.71 (±1.48)	---	---
2.	Tablet sample	100.21 (±1.47)	99.73 (±1.18)	100.18 (±2.4)	100.66 (±2.31)

*Mean of five observations

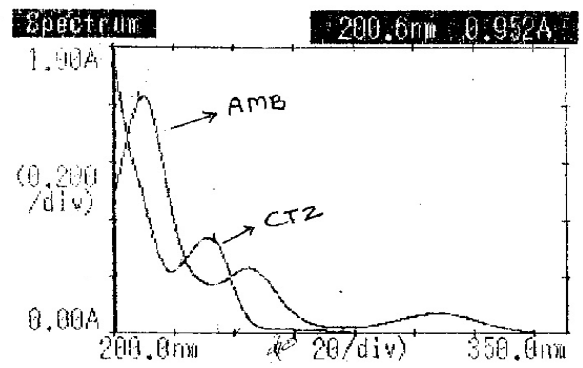

Fig. 1: Overlain spectrum of AMB and CTZ.

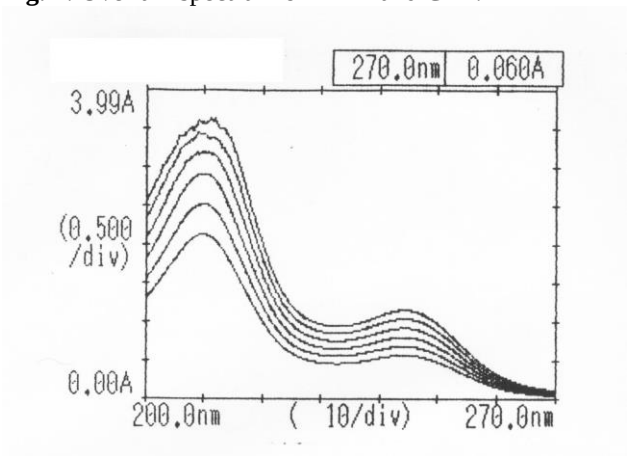

Fig. 2: Overlain spectrum of six mixed standards of AMB and CTZ.

RESULT AND DISCUSSION

The spectrophotometric method has been based on exploitation of multicomponant mode of double beam spectrophotometer Shimadzu UV-1601. Methanolic mixed standard and sample solutions were scanned over 200-270 nm range (with sampling wavelengths 220, 231, 240, 245, 250 nm). The drugs individually and in mixture obey Beer's law over conc. range 1.2-4.4 µg/mL for cetirizine HCl and for ambroxol HCl 15-52 µg/mL at all five sampling wavelengths (correlation coeff. well above 0.995). The mean recoveries from tablet by standard addition method were 100.18% (±2.4) and 100.66 % (±2.31). The method is suitable for simultaneous estimation of cetirizine HCl and ambroxol HCl from tablet dosage form.

CONCLUSION

The proposed spectrophotometric method is accurate, precise and also simple, rapid and economic and may be adopted for routine simultaneous estimation of cetirizine hydrochloride and ambroxol hydrochloride.

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