

NOTE

Visible Spectrophotometric Methods for Estimation of Ambroxol Hydrochloride from Tablet Formulation

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Two simple visible spectrophotometric methods have been developed for the estimation of ambroxol hydrochloride from tablet formulation. The developed methods were based on formation of chloroform extractable yellow coloured chromogen of drug with bromocresol green and chlorophenol red, which shows absorbance maxima at 422.0 and 371.0 nm and linearity in the concentration range of 10–120 and 200–1200 $\mu\text{g/mL}$ of drug respectively. Results of analysis for both the developed methods were validated statistically and by recovery studies.

Key Words: Spectrophotometric estimation, Ambroxol hydrochloride.

Ambroxol hydrochloride, chemically *trans*-4-[[[-2-amino-3,5-dibromophenyl]-methyl]amino] cyclohexanol hydrochloride¹, is a new semisynthetic derivative of vasicine from the Indian shrub *Adhatoda vasica*² used as an expectorant and mucolytic agent in the treatment of respiratory disorders³. For the estimation of ambroxol hydrochloride, two spectrophotometric methods have been reported in the literature^{4,5}. An attempt has been made to develop two simple visible spectrophotometric methods for the analysis of ambroxol hydrochloride from tablet formulation.

A Thermospectronic UV1, UV/Vis double beam spectrophotometer was used for all absorbance measurements. All reagents used were of analytical grade. Bromocresol green reagent (0.2% w/v) and chlorophenol red (0.2% w/v) reagent was prepared in acid phthalate buffer of pH 4.0. Both the reagents were extracted several times with chloroform so as to remove chloroform soluble impurities. Standard drug solution of ambroxol hydrochloride (2 mg/mL) was prepared in alcohol and water mixture in the ratio 1 : 2.

Standard drug solution (2 mg/mL) was diluted with alcohol and water mixture to give several dilutions in the concentration range of 10–120 $\mu\text{g/mL}$ for method

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I and 200–1200 $\mu\text{g/mL}$ of ambroxol hydrochloride for method II respectively. To 10 mL of each dilution taken in a separating funnel, 10 mL of bromocresol green reagent (method I) or chlorophenol red reagent (method II) was added. The reaction mixture was shaken gently for 5 min and 10 mL of chloroform was added, again shaken for 5 min and allowed to stand for 5 min so as to separate aqueous and chloroform layer. The chloroform layer was separated out and absorbance maxima measured at 422.0 and 371.0 nm respectively against blank. The respective calibration curves were prepared.

The ambroxol hydrochloride contents in two marketed brands of ambroxol hydrochloride tablets were determined. Twenty tablets of ambroxol HCl were taken and finely powdered. A powder equivalent to 100 mg of drug was weighed accurately and transferred to a 100 mL volumetric flask. Alcohol and water mixture (50 mL) was added to the flask and sonicated for 20 min. The resultant was filtered through Whatmann filter paper no. 41 into another 100 mL volumetric flask. The filter paper was washed several times with alcohol and water mixture. The washings were added to the filtrate and the final volume was made up to the mark with alcohol and water mixture. For method I, the filtrate (6 mL) was further diluted to 100 mL with alcohol and water mixture. For method II, the filtrate (15 mL) was diluted to 10 mL with alcohol and water mixture. Ten millilitres of the respective final dilutions were taken in a separating funnel and treated as per procedure described for the preparation of calibration curve. Absorbances were measured at their respective absorbance maxima and concentration of drug in sample solution was determined from calibration curve.

Results of analysis are presented in Table-1. Recovery studies were carried out by addition of known quantities of standard drug solution to pre-analyzed tablet sample at three different concentration levels and the determination was repeated for all the three methods. Results of recovery studies are reported in Table-1.

TABLE-I
RESULTS OF ANALYSIS AND RECOVERY STUDIES

Method	Label claim mg/tab.(as ambroxol HCl)	% of label claim estimated*	% recovery†	S.D.
I (Bromocresol green)	30	100.88	99.46	0.545000
	30	99.66	99.31	0.510032
II (Chlorophenol red)	30	99.70	100.03	0.729474
	30	100.25	99.90	0.380175

* Average of five determinations.

† Average of recovery studies at three different concentration levels.

The proposed methods are colorimetric methods for determination of ambroxol HCl from tablet dosage forms. The methods are very simple and accurate.

Reproducibility of each method was checked by recovery studies, the results of which are found to be close to 100 per cent. It was observed that the excipients did not interfere in the determination of ambroxol HCl. Hence, the proposed methods could be used for routine determination of ambroxol HCl in its dosage forms, as it is economical, convenient, precise and reproducible.

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