Simultaneous UV Spectrophotometric Estimation of Ambroxol Hydrochloride and Levocetirizine Dihydrochloride

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A novel, simple, sensitive and rapid spectrophotometric method has been developed for simultaneous estimation of ambroxol hydrochloride and levocetirizine dihydrochloride. The method involved solving simultaneous equations based on measurement of absorbance at two wavelengths 242 nm and 231 nm, the \( \lambda_{\text{max}} \) of ambroxol hydrochloride and levocetirizine dihydrochloride, respectively. Beer’s law was obeyed in the concentration range 10–50 \( \mu \text{g/ml} \) and 8–24 \( \mu \text{g/ml} \) for ambroxol hydrochloride and levocetirizine dihydrochloride respectively. Results of the method were validated statistically and by recovery studies.

Key words: Ambroxol hydrochloride, levocetirizine dihydrochloride, \( \lambda_{\text{max}} \), spectrophotometric method

Ambroxol hydrochloride (AMB) is chemically, trans-4-((2-amino-3,5-dibromobenzyl) amino) cyclohexanol hydrochloride. Levocetirizine dihydrochloride (LEVC) is chemically, (RS)-2-{4-[(R)-p-chloro-α-phenylbenzyl]-1-piperazinyl} ethoxyacetic acid dihydrochloride. AMB reduces bronchial hyper-reactivity and acts as a mucolytic and cough suppressant. LEVC is usually used in allergic conditions including rhinitis. Combination of AMB and LEVC is used for the treatment of bronchitis. These two drugs are not official in any pharmacopoeia; hence no official method is available for the simultaneous estimation of AMB and LEVC in formulations. Capillary electrophoresis, spectrometry, gas chromatography, LC with potentiometric detection, MS detection and UV detection methods have been reported for the estimation of AMB. However, no references have been found for simultaneous determination of AMB and LEVC in pharmaceutical formulations. A successful attempt has been made to estimate these two drugs simultaneously by spectrophotometric analysis.

A Shimadzu UV/Vis spectrophotometer, model-1601 (Japan) was employed with spectral bandwidth of 0.1 nm and a wavelength accuracy of ±0.5 nm with automatic wavelength correction with a pair of 3 mm quartz cells. AMB and LEVC (Aristo Pharma Ltd.), methanol (Merck India Ltd., Mumbai) and distilled water were used in the present study.

Stock solutions (500 \( \mu \text{g/ml} \)) of AMB and LEVC were prepared by dissolving separately in 20 ml of water in a 100 ml clean volumetric flask, and the volume was made up to 100 ml with distilled water. The maximum absorbance of AMB and LEVC was obtained at 244 nm (\( \lambda_{1} \)) and 231 nm (\( \lambda_{2} \)), respectively. AMB and LEVC showed linearity with absorbance in the range of 10–50 \( \mu \text{g/ml} \) and 8–24 \( \mu \text{g/ml} \) at their respective maxima, which were validated by least square method. Coefficients of correlation were found to be 0.9992 for AMB and 0.9993 for LEVC. For simultaneous estimation of AMB and LEVC, a series of standard solutions in concentration range of 2 to 24 \( \mu \text{g/ml} \), were prepared by diluting appropriate volumes of the standard stock solutions. The scanning of solutions of AMB and LEVC were carried out in
A set of two simultaneous equations were framed using the mean of absorptivity values, given as $A_{\lambda_1} = 211 C_1 + 312 C_2$ and $A_{\lambda_2} = 263 C_1 + 71 C_2$, where, $C_1$ and $C_2$ are the concentrations of AMB and LEVC, respectively in simple solution ($\mu g/ml$). $A_{\lambda_1}$ and $A_{\lambda_2}$ are the absorbance of the sample solution measured at 231 and 244 nm, respectively.

Twenty tablets were weighed accurately. The average weight was determined and then ground to a fine powder. A quantity equivalent to 75 mg of AMB and 5 mg of LEVC were transferred to a 100 ml volumetric flask. The contents were sonicated for 10 min with 50 ml of distilled water and the volume was made up with distilled water. The solution was then filtered through a Whatman filter paper No. 40. The solution was further diluted with distilled water, to give concentrations of 30 and 2 $\mu g/ml$ of AMB and the range of 200 to 400 nm against water as blank for obtaining the overlain spectra that are used in the analysis (fig. 1). Absorbance and absorptivities of series of standard solutions were recorded at selected wavelengths $\lambda_1$ and $\lambda_2$.

The absorptivity values for AMB and LEVC are shown in Table 1. The optical characteristics and regression values for the calibration curve are presented in Table 2. The method employed simultaneous equations using Cramer’s rule and matrices ($C_1 = \lambda_1 \epsilon_2 \times A_{\lambda_2} - \lambda_2 \epsilon_2 \times A_{\lambda_1}$ and $C_2 = \lambda_1 \epsilon_1 \times A_{\lambda_1} - \lambda_2 \epsilon_1 \times A_{\lambda_2}$). A set of two simultaneous equations were framed using the mean of absorptivity values, given as $A_{\lambda_1} = 211 C_1 + 312 C_2$ and $A_{\lambda_2} = 263 C_1 + 71 C_2$, where, $C_1$ and $C_2$ are the concentrations of AMB and LEVC, respectively in simple solution ($\mu g/ml$). $A_{\lambda_1}$ and $A_{\lambda_2}$ are the absorbance of the sample solution measured at 231 and 244 nm, respectively.

![Overlain spectra of AMB and LEVC](image)

Overlain spectra of ambroxol hydrochloride (AMB) and levocetiricine dihydrochloride (LEVC) in water. X axis depicts wavelength and Y axis depicts absorbance.

<table>
<thead>
<tr>
<th>Drug in standard mixture solution (µg/ml)</th>
<th>% Recovery</th>
<th>Coefficient of variance (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMB</td>
<td>LEVC</td>
<td>AMB</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>99.28±0.341</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>99.52±0.254</td>
</tr>
<tr>
<td>8</td>
<td>6</td>
<td>99.13±0.205</td>
</tr>
</tbody>
</table>

AMB and LEVC stands for ambroxol hydrochloride and levocetiricine dihydrochloride, respectively. The results are mean of three readings (n=3). % Recovery is expressed as mean ± standard deviation.
LEVC, respectively. The absorbance of the resulting solution was measured at 231 and 244 nm.

To study accuracy, reproducibility, and precision of the proposed methods, recovery studies were carried out at three different levels by addition of standard drug solution to preanalysed samples. Results of recovery studies were found to be satisfactory which are presented in Table 3.

The proposed method for simultaneous estimation of AMB and LEVC in combined sample solutions was found to be simple, accurate and reproducible. Beer’s law was obeyed in the concentration range of 10–50 µg/ml and 8-24 µg/ml for AMB and LEVC, respectively. Co-efficient of variation was found to be 0.9992 and 0.9993 for AMB and LEVC, respectively. The percentage recovery studies were found to be in the range of 99.13 to 99.52% and 98.88 to 99.42% for AMB and LEVC, respectively. Once the equations are determined, analysis requires only the measuring of the absorbance of the sample solution at two wavelengths selected, followed by a few simple calculations. It is a method that can be employed for routine analysis in quality control laboratories.

REFERENCES


Antibacterial Potential Assessment of Jasmine Essential Oil against E. coli

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