NEW VISIBLE SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF ITOPRIDE HYDROCHLORIDE FROM TABLETS FORMULATIONS USING METHYL ORANGE REAGENT

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ABSTRACT
A simple, economical, precise and fast visible spectrophotometric method has been developed for the determination of Itopride hydrochloride in tablet dosage form. Developed method is based on the formation of extractable colored complex of drug with coloring agent Methyl orange. A wavelength maximum was found to be 418.5 nm. Linearity was observed in the concentration range of 10-50 μg /ml. The result of analysis have been validated statistically and also by recovery studies.

Keywords :

INTRODUCTION
Itopride hydrochloride is chemically an anti-emetic drug and used in the management of gastrointestinal symptoms like nausea, vomiting, non-ulcer dyspepsia, emesis and chronic gastritis1. Literature survey reveals spectrophotometric2, HPLC3-4 and HPTLC5 methods for the estimation of Itopride hydrochloride from pharmaceutical formulation has been developed. Visible Spectrophotometric estimation of drug is based on the formation of coloured complex of drug with methyl orange. In present research work a colorimetric method has been developed for estimation of Itopride hydrochloride from its tablet formulations.

MATERIALS AND METHOD
Shimadzu 1700 spectrophotometer was used for the present work. The chemicals used were of analytical grade.
Methyl orange solution of concentration 0.5% w/v was prepared in double distilled water. Commercially available tablets of itopride hydrochloride were procured from local market. Gift sample of standard itopride hydrochloride drug was procured from Abbott India Ltd.

**Preparation of calibration curve**

Standard drug solution (100µg/ml) was prepared in double distilled water and was diluted with same, so as to give several dilutions in concentration range 10-50 µg/ml of drug. To 10 ml of each dilution taken in separating funnel, 10 ml of methyl orange solution was added and shaken gently. Then 5 ml of chloroform was added reaction mixture was shaken gently and allowed to stand so as to separate aqueous and chloroform layer. The chloroform layer was separated out and transferred to 10 ml of volumetric flask. Reaction mixture was extracted further with 3 ml and 2 ml of fresh chloroform and combined it with previously extracted chloroform layer containing complex. Absorbance of this final extracted chloroform layer was measured at wavelength maxima 418.5 nm against blank (Fig: 1). Calibration curve was plotted between concentration of drug and measured absorbance.

![Fig.1: Spectra of Itopride hydrochloride](image)

Absorbance

<table>
<thead>
<tr>
<th>Wavelength (nm)</th>
<th>350</th>
<th>450</th>
<th>550</th>
<th>650</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absorbance</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>
Analysis of tablet formulations
Twenty tablets were accurately weighed and average weight per tablet was determined. Tablets were crushed to fine powder and tablet powder equivalent to 10 mg of Itopride hydrochloride was accurately weighed, extracted four times with 20 ml portions of water and filtered through Whatman filter paper no. 41. Filter paper was washed with water. Washings were added to the filtrate and volume was made 100 ml with water. From this solution, 2 ml was taken in another 10 ml volumetric flask and volume was made with water so as to give concentration of 20 µg/ml and treated as per the procedure for calibration curve. The absorbance of extracted complex was measured at wavelength maxima 418.5 nm. Concentration of drug in sample was calculated from respective calibration curve. The analysis procedure was repeated five times for both marketed formulations.

RESULTS AND DISCUSSION
In present research work a colorimetric method has been developed for determination of Itopride hydrochloride from its tablet formulations. The developed method was based on formation of chloroform extractable complex of drug with methyl orange in double distilled water. Wavelength maxima of Itopride hydrochloride was found to be at 418.5 nm and linearity was observed in concentration range of 10-50 µg/ml. Percentage label claim estimated for tablet formulation was found to be in the range of 98.00-98.02 % and respective values of standard deviation were found in the range of 0.5413-0.8803 for two different batches of tablet formulations of Itopride hydrochloride (Table 1).

Table 1 : Results of analysis of commercial formulations

<table>
<thead>
<tr>
<th>Formulations</th>
<th>Label claim estimated*</th>
<th>% Recovery**</th>
<th>Std. Deviation</th>
<th>Rel. Std. Deviation</th>
<th>Coeff. of Variance</th>
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<tbody>
<tr>
<td>A</td>
<td>49.01</td>
<td>98.02</td>
<td>99.05</td>
<td>0.5413</td>
<td>0.00546</td>
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<tr>
<td>B</td>
<td>49.0</td>
<td>98.00</td>
<td>100.59</td>
<td>0.8803</td>
<td>0.00875</td>
</tr>
</tbody>
</table>

*Average of five determinations, **Average of recovery studies at three different concentration levels
ACKNOWLEDGMENT
The authors thank Abbott India limited, Goa for providing the gift sample of Itopride hydrochloride.

REFERENCES