Extractive spectrophotometric methods for the determination of Escitalopram

T.Ashok*, B.Sandeep, and G.Devala Rao

K.V.S.R Siddhartha College of Pharmaceutical sciences, Pinnamaneni Polyclinic Road, Siddhartha Nagar, Vijayawada-520 010, AP, India.

ARTICLE INFO

Article history:
Received: 30 March 2012;
Received in revised form: 19 November 2012;
Accepted: 28 November 2012;

Keywords
Sensitive,
Extractive,
Bulk.

ABSTRACT

Two simple and sensitive extractive spectrophotometric methods (Method A and Method B) have been developed for the determination of Escitalopram in bulk and pharmaceutical preparation which are based on the formation of coloured complex of the drug with dyes namely bromothymol blue (BTB) and methyl orange (MO). The ion pair complexes formed was quantitatively extracted into chloroform under the experimental conditions. All the variables have been optimized and the concentration measurements are reproducible with a relative standard deviation of 1.98 and the recoveries are 99-100.7%.

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Introduction

Escitalopram (ETP) is chemically s(+)-1-[3-(dimethyl amino) propyl]-1-(p-flurophenyl)-5-pthalancarbonitrile. It is a newer antidepressant used for treatment of panic disorders. As it is not official in any pharmacopoeia, there is no official methods for its estimation. A few methods appeared in the literature for the determination ETP in biological fluids and pharmaceutical formulations. The techniques used in this connection include HPLC and spectrophotometric methods.

As only very few spectrophotometric methods (visible) reported for the determination of ETP the authors have made an attempt to establish two colorimetric methods for its estimation. The proposed extractive spectrophotometric methods are based on the formation of ion-pair complexes with Bromothymol blue (BTB) and Methyl orange (MO) and these complexes are maximum absorbance at 415 nm and 426 nm respectively.

Experimental:

A Elico SL 150 UV-VIS spectrophotometer with 1cm matched quartz cells was used for absorbance measurements. All the chemicals used were of analytical reagent grade and double distilled water was used throughout. 0.2% aqueous solution of BTB and MO were prepared. Analytical grade chloroform used in the investigation.

Standard and sample solution:

The required quantity of standard ETP or formulation (tablets) was dissolved in water to get a stock solution of 1mg/ml and the stock solution was further diluted with 0.1N HCl for Method A and Method B.

Assay Procedure:

Aliquots of the ETP (0.2 - 1ml, 100 µg/ml) for Method A or (0.2 – 1ml, 100 µg/ml) for Method B were transferred into a series of 125 ml separating funnels, 2 ml of 0.1N HCl added to each method, 2 ml of BTB (Method A) or 2 ml of MO (Method B) solution werevadded to each separating funnels and total volume of aqueous phase was made up to 10 ml with distilled water. 10 ml of chloroform was added and contents were shaken for 2 min. The two phases were allowed to separate and the absorbance of the chloroform layer was measured at 415 nm for Method A and 426 nm for Method B against a reagent blank. The amount of ETP was computed from its calibration curve.

Results And Discussion:

The optical characteristics such as absorption maxima, beer’s law limits, molar absorptivity and Sandell’s sensitivity are presented in table 1.

Table 1: Optical Characteristics and Precision

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Method A</th>
<th>Method B</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \lambda_{\text{max}} ) (nm)</td>
<td>415</td>
<td>426</td>
</tr>
<tr>
<td>Beer’s law limits( µg/ml)</td>
<td>2 - 10</td>
<td>2 – 10</td>
</tr>
<tr>
<td>Sandell’s sensitivity (µg/cm²/0.001 absorbance unit)</td>
<td>0.0192</td>
<td>0.0158</td>
</tr>
<tr>
<td>Molar absorptivity (litre .mole⁻¹.cm⁻¹)</td>
<td>2.154x10⁴</td>
<td>2.6148x10⁴</td>
</tr>
<tr>
<td>Correlation coefficient (r)</td>
<td>0.9986</td>
<td>0.9998</td>
</tr>
<tr>
<td>% RSD*</td>
<td>1.98</td>
<td>1.97</td>
</tr>
<tr>
<td>% Range of Error (0.05 confidence limits)</td>
<td>1.656</td>
<td>1.647</td>
</tr>
<tr>
<td>% Range of Error (0.01 level of significance)</td>
<td>2.449</td>
<td>2.347</td>
</tr>
</tbody>
</table>

Table 2: Estimation of Escitalopram in pharmaceutical formulation

<table>
<thead>
<tr>
<th>Formulation (Tablets)</th>
<th>Labelled amount(mg)</th>
<th>Amount found* by the proposed methods (mg)</th>
<th>% Recovery** by proposed method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Method A</td>
<td>Method B</td>
</tr>
<tr>
<td>Tablet 1</td>
<td>5.00</td>
<td>4.68</td>
<td>4.88</td>
</tr>
<tr>
<td>Tablet 2</td>
<td>10.00</td>
<td>9.99</td>
<td>9.97</td>
</tr>
<tr>
<td>Tablet 3</td>
<td>20.00</td>
<td>19.98</td>
<td>19.96</td>
</tr>
</tbody>
</table>

* Average of 6 determination.

** Recovery of amount added to the pharmaceutical formulation (Average of 3 determinations).

The stochiometric relationship of drug: dye in each case obtained by slope analysis method is given in table 1. The results showed that the methods have reasonable precision. A comparison of the results obtained with the proposed and reference methods for dosage forms.

T.Ashok et al./ Elixir Pharmacy 53 (2012) 11707-11708

Available online at www.elixirpublishers.com (Elixir International Journal)

Pharmacy

Elixir Pharmacy 53 (2012) 11707-11708

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The other active ingredients and excipients usually present in pharmaceutical dosage forms did not interfere.

The proposed methods are found to be simple, rapid, sensitive and accurate and can be used for the determination of ETP and their pharmaceutical dosage form in a routine manner.

**Acknowledgements:**

The authors are grateful to Siddhartha Academy General and Technical Education, Vijayawada for providing the necessary facilities to carry out the present investigation.

**References:**