SPECTROPHOTOMETRIC ESTIMATION OF CYCLOPHOSPHAMIDE IN CAPSULE DOSAGE FORM

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ABSTRACT

A spectrophotometric method for the analysis of cyclophosphamide in pure form and in capsule has been developed using 0.1N HCl as solvent. The chromogen exhibited absorption maxima at 263 nm. Beer’s law was obeyed in the concentration ranges of 10-50 μg/ml. The proposed method was successfully applied for determination of the cyclophosphamide in their pharmaceutical formulations. The method is simple, precise and accurate and not having interference in adjutants in capsules.

Keywords: Cyclophosphamide, UV spectrophotometry.

INTRODUCTION

N,N-bis(2-chloroethyl)-1,3,2-oxazaphosphinan-2-amine Cyclophosphamide (the generic name for Endoxan Cytoxan, Neosar, Procystox, Revimmune), also known as cytophosphate, is a nitrogen mustard alkylating agent, from the oxazophorines group. Cyclophosphamide also decreases the immune system's response to various diseases and conditions. Therefore, it has been used in various non-neoplastic autoimmune diseases where disease-modifying antirheumatic drugs (DMARDs) have been ineffective. Cyclophosphamide (INN, trade names Endoxan, Cytoxan, Neosar, Procystox, Revimmune), also known as cytophosphate, is a nitrogen mustard alkylating agent, from the oxazophorines group [1-3]. A survey of literature revealed a HPLC estimation in formulation [4,5]. The aim of the study was to develop a simple, precise and accurate spectrophotometric method for the estimation of cyclophosphamide in bulk drug and in pharmaceutical dosage form.

EXPERIMENTAL

Apparatus

T60 UV-Visible Spectrophotometer with 1 cm matched quartz cells were used for all spectral measurements. Digital Balance: BL-220H, Shimadzu was used.

Materials

All chemicals used were of analytical reagent grade. The chemical reagents prepared on the day of experiment.

Procedure

Accurately weighed 50 mg of cyclophosphamide was dissolved in sufficient quantity of 0.1N HCl and the solution was diluted to 100 ml with same to obtain 500 μg/ml of stock solution. From this various aliquots were accurately measured and transferred in to a series of 10 ml volumetric flasks by means of a micro burette. The volume was brought up to the mark with 0.1N HCl to get the concentration range of 10, 20, 30, 40, 50 μg/ml, mixed thoroughly and absorbance of each concentration was measured at 263 nm against 0.1N Hcl as blank. A calibration graph was constructed by plotting the absorbance against the concentration of the drug.

Procedure for pharmaceutical formulation

For analysis of capsule formulation, 20 capsules of cyclophosphamide were weighed accurately and finely powered.

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An accurately weighed portion of powdered sample, equivalent to 10 mg of cyclophosphamide was dissolved in sufficient quantity of 0.1N HCl, sonicated for 20 minutes; the resultant was filtered through whatman filter paper No. 41 and washed with same. The filtrate and washings were combined and the final volume was made to 100 ml with the same. Suitable concentration was analyzed as per the procedure given above.

**RESULTS AND DISCUSSION**

The calibration graph was plotted. The optical characteristics of this method are summarized in table 1. The drug content of the formulation and recovery studies were conducted. The results are presented in table 2. Linear regression of absorbance with concentration gave a correlation coefficient of 0.999 and RSD was found to be less than two.

### Table 1. Optical characteristics of proposed method

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>$λ_{max}$ (nm)</td>
<td>263</td>
</tr>
<tr>
<td>Beer's law limit (μg/ml)</td>
<td>10-50</td>
</tr>
<tr>
<td>Sandell’s sensitivity (μg/cm²/0.001 absorbance unit)</td>
<td>$3.3991 \times 10^{-2}$</td>
</tr>
<tr>
<td>Molar absorptivity (l/mol/cm)</td>
<td>$2.5821 \times 10^{3}$</td>
</tr>
<tr>
<td>Regression equation ($Y = a + bc$)</td>
<td></td>
</tr>
<tr>
<td>Slope (b)</td>
<td>0.0121</td>
</tr>
<tr>
<td>Intercept(a)</td>
<td>-0.0052</td>
</tr>
<tr>
<td>Correlation coefficient ($r^2$)</td>
<td>0.999</td>
</tr>
</tbody>
</table>

### Table 2. Assay and recovery of cyclophosphamide

<table>
<thead>
<tr>
<th>Dosage form</th>
<th>Labeled amount(mg)</th>
<th>*Amount found</th>
<th>Percentage recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclophosphamide capsules</td>
<td>50</td>
<td>49.98</td>
<td>99.81</td>
</tr>
</tbody>
</table>

*Each value is an average of six determinations.

**CONCLUSION**

The method developed in the present work was found to be, accurate, precise and reproducible and can be used for routine determination of Cyclophosphamide in pure and in formulation.

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**REFERENCES**