FORCED OXIDATIVE DEGRADATION STUDY OF CEFUROXIME AXETIL BY UV SPECTROPHOTOMETRY METHOD

V. Niraimathi\(^1\), G. Mahesh Kumar\(^1\), A. Jerad Suresh\(^2\).

\(^1\)Department of Pharmaceutical Chemistry, College of Pharmacy, Madras Medical College, Chennai-600003.
\(^2\)Email id vnmpg2@gmail.com

Received on 18-12-2013
Accepted on 15-01-2014

Abstract

Forced degradation is a process whereby the natural degradation rate of a product is increased by the application of additional stress. A forced oxidative degradation study of Cefuroxime axetil in bulk and tablet form was performed. The study was conducted based on available guidelines and main reference. Cefuroxime axetil has a cepham ring in its structure. It can easily undergo oxidative degradation and the degraded products were analyzed by using UV spectrophotometry. The assay values of degraded products in different time intervals were analyzed by using UV spectrophotometry. Forced degradation was performed in bulk and tablet form using 30% Hydrogen peroxide solution. Cefuroxime axetil was subjected to oxidative degradation at different time intervals based on reference. The assay value of standard and sample was found to be 63.1% and 76.8% respectively at the end of the 90 mins. The assay value of standard and sample was found to be 56.1% and 60.6% respectively at the end of the 1\(^{st}\) day degradation. Complete degradation of Cefuroxime axetil was shown at the end of 3\(^{rd}\) day onwards. It was concluded that Cefuroxime axetil was found unstable under oxidative condition.

Keywords: Cefuroxime axetil, Hydrogen peroxide, Oxidative degradation

Introduction

Forced Degradation studies are used to identify reaction which may occur to degrade a processed product; usually conducted before final formulation, forced degradation uses external stresses to rapidly screen material stabilities. Cefuroxime axetil is indicated for the prophylaxis and treatment of infections caused by bacteria susceptible to this particular form of antibiotic. There are very few reported methods for analysis of degradation product and impurities of Cefuroxime axetil are selected for the study. Forced Degradation study is carried out to demonstrate the specificity...
when developing stability indicating method and to help identify reaction that causes degradation of pharmaceutical product [2-4]. Cefuroxime axetil was found to be a ring opening degradation product because of presence of lactam and amide linkage [5]. A forced degradation study of Cefuroxime axetil has been carried out under alkali condition using 0.1N NaOH by UV spectrophotometry [1].

Materials and Methods

Material and Reagents

Hydrogen peroxide was purchased from Merck. Distilled water was used throughout the experiment. Cefuroxime axetil was obtained as a gift sample from well reputed pharma company. The determinations were carried out at room temperature. All absorption spectra were measured by using Shimadzu UV-1650PC (UV-Visible) spectrophotometer with a scanning speed of 200nm/min and band width of 2.0nm, equipped with matched quartz cells.

Experimental/Methodology

Standard preparation

Cefuroxime axetil was transferred to volumetric flask and dissolved in ethanol to achieve a concentration of 1mg/mL; an aliquot solution was diluted with distilled water to get a final concentration of 10mcg/mL. The solution was scanned in the UV region and the maximum absorbance was recorded at 278nm [6].

Intraday study

Standard preparation (stress)

Cefuroxime axetil was transferred to volumetric flask and dissolved in 10 mL of ethanol to dissolve the drug substance, and then 30% Hydrogen peroxide was added to achieve a concentration of 1mg/mL. After 30mins, an aliquot solution was diluted with distilled water to get a final concentration of 10mcg/mL. The solution was scanned in the UV region and the maximum absorbance was recorded at 278nm. The same procedure was repeated for 60mins, and 90mins time interval

Sample preparation (stress)

Cefuroxime axetil tablets were crushed weighed and transferred to volumetric flask; dissolved in 10 mL of ethanol to dissolve the drug product, and then 30% Hydrogen peroxide was added to achieve a concentration of 1mg/mL. The solution was scanned in the UV region and the maximum absorbance was recorded at 278nm. The same procedure was repeated for 60mins, and 90mins time interval.
Blank preparation

A blank solution of Hydrogen peroxide solution was prepared in a similar manner.

The procedure was repeated thrice. After the stipulated time, the absorption of the resulting solution showed maxima 278nm (Table 1) against reagent blank treated in the same way. Three such determinations were made and the assay value was estimated the obtained values were concurrent.

Table: 1 Forced Degradation Study of Cefuroxime axetil (Intraday)-Assay.

<table>
<thead>
<tr>
<th>Stress condition (Oxidation)</th>
<th>Time</th>
<th>Standard</th>
<th>Sample</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Degradation observed</td>
</tr>
<tr>
<td>30mins</td>
<td></td>
<td>83.3%</td>
<td>89.9%</td>
<td></td>
</tr>
<tr>
<td>30% Hydrogen peroxide</td>
<td>60mins</td>
<td>76.6%</td>
<td>82.5%</td>
<td>Degradation observed</td>
</tr>
<tr>
<td></td>
<td>90mins</td>
<td>63.1%</td>
<td>76.8%</td>
<td>Degradation observed</td>
</tr>
</tbody>
</table>

*Each value is the mean of three determinations

Inter day study

Standard preparation

The standard preparation was prepared in a similar manner which was mentioned in an intraday preparation

Standard preparation (stress)

Same method was followed, but the final solution was scanned and absorption was recorded at the following time intervals 1<sup>st</sup>, 3<sup>rd</sup>, and 5<sup>th</sup> day.

Sample preparation (stress)

Same method was followed, but the final solution was scanned and absorption was recorded at the following time intervals 1<sup>st</sup>, 3<sup>rd</sup>, and 5<sup>th</sup> day.

Blank preparation

Similar to intraday preparation
The procedure was repeated thrice. After the stipulated time, the absorption of the resulting solution showed maxima 278nm (Table 2) against reagent blank treated in the same way. Three such determinations were made and the assay value was estimated the obtained values were concurrent.

**Table: 2 Forced Degradation Study of Cefuroxime axetil (Interday)-Assay.**

<table>
<thead>
<tr>
<th>Stress condition</th>
<th>Time</th>
<th>Standard</th>
<th>Sample</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Oxidation)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt; day</td>
<td>56.1%</td>
<td>60.6%</td>
<td></td>
<td>Degradation observed</td>
</tr>
<tr>
<td>30% Hydrogen peroxide</td>
<td>3&lt;sup&gt;rd&lt;/sup&gt; day</td>
<td>0%</td>
<td>0%</td>
<td>Complete Degradation</td>
</tr>
<tr>
<td></td>
<td>5&lt;sup&gt;th&lt;/sup&gt; day</td>
<td>0%</td>
<td>0%</td>
<td>Complete Degradation</td>
</tr>
</tbody>
</table>

*Each value is the mean of three determinations

**Results and discussion**

Cefuroxime axetil was unstable under oxidative condition. In intraday drug standard and sample showed extensive degradation. Compared to sample, standard underwent more degradation. The assay values of standard and sample were 63.1% and 73.8% respectively at end of the 90mins degradation. In inter-day degradation study on 1<sup>st</sup> day standard and sample have undergone maximum degradation. The assay values of standard and sample were 56.1% and 60.6% respectively. Complete degradation was seen on 3rd day onwards.

**Conclusion**

The forced oxidative degradation of Cefuroxime axetil was studied by UV spectroscopy at various time intervals (30mins, 60mins, 90mins; 1st, 3<sup>rd</sup>, 5<sup>th</sup> day ;) it was established that the drug Cefuroxime axetil is vulnerable to alkali hydrolytic condition.

**References**


For Correspondence
V.Niraimathi*,
Email: vnmpg2@gmail.com