INTRODUCTION

Cefixime is a semisynthetic, oral cephalosporin that belongs to the third generation. Chemically, it is \( (6R, 7R)-7-[2-(2-amino-4-thiazolyl) glyoxylamide]-8-oxo-3-vinyl-5-thia-1-azabicyclo[4.2.0]oct-2-ene-carboxylic acid \). It is available in various dosage forms administered orally in the treatment of susceptible infections including respiratory tract infection, complicated and uncomplicated urinary tract infection, uncomplicated gonorrhea, sinusitis, etc. Cefixime is sensitive against a wide range of gram positive, gram negative and anaerobic bacteria pathogens including beta lactamase producing strains. At high concentrations, gastrointestinal side effect, headache, dizziness, and rashes can appear. Therefore, the analysis of cefixime is important for obtaining optimum therapeutic concentrations and for quality assurance in pharmaceutical formulations.

Cefixime is officially listed in the British Pharmacopoeia \(^{10}\) which describes a liquid chromatographic method for its assay in bulk form. In order to assure the quantity of cefixime in dosage forms, several methods have been reported which include spectrophotometric \(^{11,12}\), HPLC \(^{13-18}\), HPTLC \(^{19}\), voltammetric \(^{20}\), calorimetric \(^{21}\) and capillary electrophoretic methods \(^{22}\). Spectrophotometry is the best tool for determining drugs in the research laboratories, hospitals and pharmaceutical industries due to its low cost, inherent simplicity, versatility, adaptability and affordability \(^{23}\). This study therefore aimed to apply a simple, less time consuming UV spectroscopic method for the quantification and quality assessment of cefixime in pure form and in some commercially available pharmaceutical formulations in Nigerian market.

MATERIALS AND METHODS

Equipment

A double beam UV/visible spectrophotometer (PerkinElmer; lambda 35; United State) with spectrum width of 2nm was used to obtain the spectrum and measure the absorbance of all the solutions. The spectrum was automatically obtained by UV-probe system software. An analytical balance (Explorer pro analytical balance; model EP 214C, USA) and an ultrasonic sonicator (Scientz, China) were used in the study.

Reagent and Materials

Cefixime trihydrate (batch no. CFX-1411523) was purchased from Startech Labs Madinaguda, Hyderabad, India. The six commercial formulations of cefixime (400mg tablets and capsules) were purchased from the local Nigeria pharmacies. Analytical grade methanol (JHD, China) was used as solvent for the preparation of different concentrations of pure cefixime and dosage forms.

Preparation of Standard Solution

Standard solution of cefixime was prepared by dissolving accurately weighed 100mg sample of cefixime drugs substance in 100ml of methanol to give a concentration of 1000μg/ml.

Determination of Wavelength of Maximum Absorption

For selection of analytical wavelength the standard solution (1000μg/ml) was scanned in the range of 800-200nm. From the spectrum,
wavelength of maximum absorption for the analysis of cefixime was 244.9nm.

**Preparation of Working Standard Solution**

The stock solution was further diluted with methanol to get working standard solutions (5-30µg/ml). The absorbance of each solution was measured at 244.9nm against a methanol blank and the data used to construct the Beer’s plot.

**Determination of Cefixime in Pharmaceutical Formulation**

Three brands each of commercially available capsules and tablets (twenty in number) of 400mg strength cefixime were weighed. The tablets were powdered. The powder quantity (from each brand) equivalent to 100mg cefixime was accurately weighed and transferred to a 100ml capacity volumetric flask. 60ml methanol was transferred to this volumetric flask sonicated for 15 minutes. The above solution was filtered through whatmann filter paper (0.45µ). The residue was washed well with 3 x 10ml portion of methanol for complete recovery of the drug and diluted to mark with methanol. From this solution, 2 ml was transferred to a 100ml capacity volumetric flask. The volume was made up to mark to give a solution containing 20µg/ml. The absorbance of the resulting solution was read at 244.9nm and the quantification was carried out by keeping these values to the straight line equation of calibration curve 24.

**RESULTS AND DISCUSSION**

![Figure 2: Scanning for wavelength of maximum absorption for Cefixime.](image)

**Figure 3: Calibration curve for cefixime at 244.9nm.**

![Figure 3: Calibration curve for cefixime at 244.9nm.](image)

**Table 2: Optical characteristics of cefixime trihydrate.**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cefixime trihydrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analytical Wavelength</td>
<td>244.9 nm</td>
</tr>
<tr>
<td>Range</td>
<td>5 – 30 ml</td>
</tr>
<tr>
<td>Slope</td>
<td>0.0302x</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.0177</td>
</tr>
<tr>
<td>Regression Equation</td>
<td>( Y = 0.0302x + 0.0177 )</td>
</tr>
<tr>
<td>Correlation Coefficient</td>
<td>0.99974</td>
</tr>
</tbody>
</table>

**Table 3: Analytical data of brands of cefixime trihydrate.**

<table>
<thead>
<tr>
<th>Brands</th>
<th>Amount used (µg/ml)</th>
<th>Amount determined (µg/ml); ( N = 3 )</th>
<th>Label claim (mg)</th>
<th>Amount determined Per tablet/ capsule</th>
<th>Percentage (%) of label claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>MIRAL®</td>
<td>20</td>
<td>21.820</td>
<td>400</td>
<td>436.4</td>
<td>109.1</td>
</tr>
<tr>
<td>FIXIME®</td>
<td>20</td>
<td>20.945</td>
<td>400</td>
<td>418.9</td>
<td>104.7</td>
</tr>
<tr>
<td>DAXIMIN®</td>
<td>20</td>
<td>19.802</td>
<td>400</td>
<td>396.4</td>
<td>99.01</td>
</tr>
<tr>
<td>GRAMOCEF-O®</td>
<td>20</td>
<td>21.988</td>
<td>400</td>
<td>439.6</td>
<td>109.9</td>
</tr>
<tr>
<td>MAXPAN®</td>
<td>20</td>
<td>20.596</td>
<td>400</td>
<td>411.9</td>
<td>103</td>
</tr>
<tr>
<td>CEFICOX®</td>
<td>20</td>
<td>21.199</td>
<td>400</td>
<td>423.9</td>
<td>106</td>
</tr>
</tbody>
</table>

Analysis of six (6) of the commercially available brands of cefixime found in Nigerian markets was carried out with the use of an already developed and validated simple ultraviolet spectroscopic method which has been applicable for the routine estimation of cefixime in pharmaceutical dosage forms 25. The standard solution of cefixime was scanned in the uv-vis range (200-800nm). Data was recorded at an interval of 1.00nm with a scan speed of 240.0nm/min. The spectra [figure 2] showed significant absorbance at 244.9nm. The range of concentration of the standard cefixime sample was 5-30µg/ml. Their absorbance were read at 244.9nm against methanol blank and the data used in plotting the calibration graph. The coefficient of correlation obtained was 0.9974. The observations are
presented in Table 2 and Figure 3. The high level correlation coefficient indicates good linearity of the calibration curve. The regression equation obtained was \( y = 0.0302x + 0.0177 \); where x is concentration and y the absorbance. The amount of drug found per initial powder weight (µg/ml), amount found per tablet/capsule (mg) and the percentage label claim were determined (Table 3).

According to the United States Pharmacopoeia, cefixime should contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount. Uniformity in the content of cefixime trihydrate tablets and capsules is meant to ensure a constant dose between individual tablets and capsules, hence, a predictable bioavailability.

The results show that all the brands of cefixime trihydrate analyzed contain an amount of cefixime that conformed to the required amount as stated in the USP as follows: 109.1%, 104.7%, 99.01%, 109.9%, 103%, and 106% for brands 1-6 respectively. This indicates that they are all of optimum therapeutic concentration and do meet the quality requirement of a quality medicine, and thus, can be used effectively and interchangeably for their various indications.

**CONCLUSION**

There is an increase in the usage of generic drug products from multiple sources in Nigeria and other parts of the globe, of which cefixime is a common example. These generic drugs are expected to satisfy similar established standards. Spectroscopic methods have been applicable for the routine estimation of drugs in pharmaceutical dosage forms. The result of this study showed that all the brands conformed to the physical assessment and content uniformity tests and thus could be prescribed interchangeably.

**CONFLICT OF INTEREST**

Authors declare no Conflict of Interest.

**REFERENCES**


**HOW TO CITE THIS ARTICLE**