A UV SPECTROPHOTOMETRIC ASSAY METHOD FOR AVAILABLE BRANDS OF ONDANSETRON HYDROCHLORIDE

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ABSTRACT
A simple, reliable, rapid and a novel method have been developed for determination of ondansetron hydrochloride. The method is truly based on measuring UV absorbance maximum of 210 nm using universal solvent i.e. double distilled water (DDW). Three different brands of ondansetron were purchased from market for the analysis. A standard solution of drug was initially prepared by dissolving 10 mg of standard drug in double distilled water to get concentration of 100 μg/ml. The different aliquots of solution of three different brands were prepared in the range of 2-10 μg/ml. The percentage assay of each brand was calculated and their regression analysis was also performed. Among the three brands (Emeset, Zofer and ondem) Emeset showed high percentage assay value of 100.77 and remaining two brands showed same percentage assay value of 97.22. All the brands were found to be within the limit as per Indian pharmacopeia. The regression coefficient was with in tolerable limit i.e. 0.999.

KEYWORDS: Ondansetron Hydrochloride, UV Spectrophotometry, Emeset, Zofer, Ondem, percentage assay.

INTRODUCTION
The IUPAC name of Ondansetron is 9-methyl-3-[(2-methylimidazol-1-yl) methyl]-2, 3-dihydro-1H-carbazol-4-one; hydrochloride. It is used in cancer chemotherapy, radiation therapy and surgery to prevent nausea and vomiting.¹ It elicits its response in gastro enteritis and has a very little effect on motion sickness.²³ Ondansetron availability is limited in the form of tablet, intramuscular and intravenous infusions.⁴ It is a best 5-HT₃ serotonin receptor and has no effect on dopamine or muscarinic receptors.⁵ It was first used medically...
in 1990. WHO prescribes in its essential medical list that ondansetron is one among the best effective and safe medicines needed in the health care system.\(^6\) It is one of the most whole sale selling medicines in USA.\(^7\) Ondansetron is an effective anti-emetic agent. Compared to other drugs it is less sedating than cyclizine and more responsive than metoclopramide. It plays very important role in cyclic vomiting syndrome.\(^8\) It is expected that ondansetron antiemetic action is mediated via antagonism of vagal afferents with a small contribution from antagonism of central receptors.\(^9\) Ondansetron (marketed under the brand name Zofran) was developed in the mid-1980s by GlaxoSmithKline in London. It was granted US patent protection in September 1987\(^{10}\) received a US patent in June 1988\(^{11}\) and was approved by the US FDA in January 1991. It was granted another divisional patent in November 1996.\(^{12}\) Finally, owing to GlaxoSmithKline’s research on paediatric use, ondansetron patent protection was extended until December 2006. Finally in the year 2006, Zofran had become the 20th highest-selling brand-name drug in the United States, with sales of US$1.3 billion in the first 9 months of 2006 (80% from the US). Literature survey reveals that a derivative spectrophotometric method,\(^{13}\) UV spectrophotometric method for determination of Ondansetron using Saline\(^{14}\) and a RP-HPLC method\(^{15},^{16}\) has also been described. Each method has its own demerit like derivative methods require long time for analysis; while HPLC method requires expensive columns, trained personnel for running analysis, using saline as an medium may incur some stability issues so a simple attempt was made for analysing such an effective drug using UV spectrophotometric method proves to be beneficial since the amount of solvent required will be less and very economical due to its ease in its operation, a part from that it is very least time consuming and worthful for analysing all the brands at a time in one single medium. Some methods explain the quantification of ondansetron in combination with other techniques. Hence it is very important to develop a simple cost effective and least time consuming method for quantification of ondansetron in all the three brands which paves the way for common health professionals and quality control department.

\[\text{Fig. 1: Drug structure of ondansetron Hydrochloride Dihydrate}\]
MATERIALS AND METHODS

Instrumentation
SHIMADZU UV-2600 double beam UV Spectrophotometer was used for measuring absorbance of standard and sample solutions. A SHIMADZU AUX-220 electronic balance for weighing and an Ultra sonicator are being used for sonication of sample solutions. A Millipore Q distillation apparatus was used to prepare DDW freshly for the entire analysis.

Materials and Reagents
The standard drug of ondansetron Hydrochloride was obtained from TCI Chemicals, Chennai, Tamil Nadu, India. Throughout the analysis freshly prepared double distilled water (DDW) was used.

Selection of wavelength
About 5 μg/ml Standard solution of ondansetron was prepared using DDW and scanned in a range of 200-400 nm. The wavelength of maximum absorbance was found to be at 210 nm and this wavelength was being used for analysis of sample solutions. Figure 2 represents the UV spectrum of ondansetron.

![Fig. 2: UV Spectrum of ondansetron Hydrochloride (5μg/ml)](image)

Preparation of standard solution
Stock solution containing 100μg/ml was prepared by dissolving 10 mg of standard in 100 ml standard flask. Further dilution was done to get final concentration of 5μg/ml.
Preparation of sample solutions

Three different brands (Emeset, Zofer and Ondem) were purchased from local pharmacy in Trichy and are labelled to contain 4 mg of Ondansetron hydrochloride per tablet and have a shelf life of two years. 20 tablets of each brand were accurately weighed and crushed uniformly with the help of Mortar and pestle. Weight equivalent to 10 mg of each brand was measured and transferred into series of 100ml standard flasks. Nearly 50 ml of DDW was added to each flask and the contents were subjected to sonication for nearly fifteen to twenty minutes for the maximum solubility of the drug, then the sample solutions were filtered using whatman no 1 filter paper. First ten ml of the filtrate was discarded and finally make up with DDW to get concentration of 100μg/ml. From this different aliquots were prepared ranging from 2-10μg/ml.

Procedure

After dilutions preparation of standard solution, sample solutions and their, absorbance was measured at the wavelength of maximum absorbance i.e. 210 nm using a double beam UV spectrophotometer and blank solution of DDW. Calculate the quantity in mg of ondansetron per tablet.

RESULTS AND DISCUSSIONS

Pharmaceutical Assay of three different brands of ondansetron has been carried out successfully using UV Spectrophotometry. Table 1 represents the absorbance of three different brands. The method exhibits good linearity in the range of 2-10 μg/ml of each brand. The method is cost effective since the amount of solvent being used is very little. The values of correlation co-efficient were found to be in acceptable range i.e. ≤1. The % Assay and regression data predicts further availability of the drug. Table 2 represents the regression data of different brands. The regression analysis was carried out and graphs were linear with good adjusted R² values. From figures 3-6 it is evident that absorbance is directly proportional to concentration and hence the Beers law is obeyed. This method plays a useful role for routine quality control analysis of drugs. The assay can be beneficial to pharmacists and health professionals. The optimization studies showing effect of dilution medium, time and temperature were studied and results were depicted.
Table 1: Absorbance of different brands

<table>
<thead>
<tr>
<th>Concentration (μg/ml)</th>
<th>Emeset</th>
<th>Zofer</th>
<th>Ondem</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>0.242</td>
<td>0.22</td>
<td>0.16</td>
</tr>
<tr>
<td>4</td>
<td>0.435</td>
<td>0.39</td>
<td>0.32</td>
</tr>
<tr>
<td>6</td>
<td>0.627</td>
<td>0.57</td>
<td>0.49</td>
</tr>
<tr>
<td>8</td>
<td>0.833</td>
<td>0.74</td>
<td>0.65</td>
</tr>
<tr>
<td>10</td>
<td>1.019</td>
<td>0.93</td>
<td>0.82</td>
</tr>
</tbody>
</table>

Table 2: Regression data of different brands

<table>
<thead>
<tr>
<th>Brands</th>
<th>Regression Equations</th>
<th>R²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emeset</td>
<td>y = 0.0976x + 0.0456</td>
<td>0.9998</td>
</tr>
<tr>
<td>Zofer</td>
<td>y = 0.0885x + 0.039</td>
<td>0.9996</td>
</tr>
<tr>
<td>Ondem</td>
<td>y = 0.0825x - 0.007</td>
<td>0.9999</td>
</tr>
</tbody>
</table>

Table 3: % Assay of different brands

<table>
<thead>
<tr>
<th>Brands</th>
<th>Absorbance</th>
<th>% Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emeset</td>
<td>0.518</td>
<td>100.77</td>
</tr>
<tr>
<td>Zofer</td>
<td>0.50</td>
<td>97.22</td>
</tr>
<tr>
<td>Ondem</td>
<td>0.50</td>
<td>97.22</td>
</tr>
</tbody>
</table>

Fig 3: Linearity plot of Emeset

Fig 4: Linearity plot of Zofer
CONCLUSION
The % Assay values of all the three brands were found to be as per Indian pharmacopeia and United States pharmacopeia limit that is it should not be less than 90% or not more than 110 % for ondansetron hydrochloride tablets. The developed assay is within the quality control range. This method of analysis is proved to be inherent, time saving, Economical, simple and accurate.

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REFERENCES


