Estimation of Olmesartan Medoxomil, an angiotensin receptor blocker in pharmaceutical dosage form by U.V. Spectrophotometric method

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ABSTRACT

A simple, rapid, economical, accurate and precise method has been developed for estimation of Olmesartan medoxomil from tablet dosage form. The absorption maxima in THF solvent was found to be 265 nm and Beer’s law was obeyed in a concentration range of 5-30 mcg/ml and coefficient of correlation for Olmesartan was found to be 0.9997. The precisional accuracy of the developed method were confirmed by repeatability and recovery studies are validated statistically. The limit of detection and limit of quantitation of Olmesartan were found to be 0.23 mcg/ml and 0.77 mcg/ml respectively. The percentage recovery was found to be 99.37% for Olmesartan. The method showed good repeatability and recovery with relative standard deviation less than 2. So, this developed method can be used for the routine analysis of Olmesartan medoximil from formulations.

Key words: Olmesartan medoxomil, U.V. Spectrophotometric method, THF.

INTRODUCTION

Olmesartan medoxomil is the most recent member of Angiotensin receptor blocker1,2,3 which is chemically, (5-methyl-2-oxo-2H-1,3-dioxol-4-yl) methyl 4-(2-hydroxypropan-2-yl)-2-propyl-1-{4-[2-(2H-1,2,3,4-tetrazol-5-yl)phenyl]phenyl}methyl)-1H-imidazole-5-carboxylate. Key structural elements of Olmesartan medoxomil include a hydroxy alkyl substituent at the imidazole 4-position and a hydrolysable ester at the imidazole 5-position. Inter and Intra molecular hydrogen bonding involving these groups may contribute to the potentiation of antagonistic activity. After the oral administration, Olmesartan medoxomil is de-esterified in the intestinal tract to produce the active metabolite Olmesartan, which undergoes no additional metabolic change4. The marked anti-hypertensive efficacy of Olmesartan medoxomil may result from a unique pharmacological interaction of the drug with the AT1 receptor, resulting in a potent, long lasting, dose dependent blockade of A2. This characterizes the structural features of Olmesartan that may be responsible for its clinical efficacy5.

Literature survey reveals that Olmesartan medoxomil can be estimated by RP-LC and HPLC6, HPTLC7 methods individually or in combination with other drugs. However, there is no U.V. Spectrophotometric method reported for the estimation of Olmesartan from pharmaceutical dosage forms. Present work describes a simple, economical, accurate and precise method for the estimation of Olmesartan in tablet formulations.

MATERIALS AND METHODS:

Instrument: A double beam SYSTRONICS- U.V.-Visible spectrophotometer 2201, with spectral band width of 2nm, wavelength accuracy ±0.5nm and a pair of 1cm matched quartz cells was used to measure absorbance of the resulting solution.

Materials: Pure drug, Olmesartan was supplied as a gift sample by RANBAXY Laboratories Limited, Delhi. Tablet formulations containing Olmesartan of the brand names OLMESAR of MACLEDDS Pharmaceuticals, Mumbai and OLMECIP of CIPLA, Gujarat were purchased from local pharmacy shop.

Solvent: THF was used as the solvent.

Stock solution: Standard stock solution were prepared by weighing out 100mg of Olmesartan and transferred to 100ml volumetric flask. It was dissolved in THF (A.R grade) and made up to volume to get a concentration of 1mg/ml. Spectral characteristics of Olmesartan were studied by taking concentrations of 10, 20, 30 mcg/ml and scanned by U.V.-Visible spectrophotometer from 190-400nm and $\lambda_{max}$ of 265nm were fixed.
Calibration curve of absorbance versus Concentration were studied by taking concentrations ranging from 1-40mcg/ml and data revealed that Beer’s law was obeyed between concentration range of 5-30mcg/ml. Calibration curve of Olmesartan is given below.

Statistical evaluation of the calibration plot was done and the parameters are shown in table no 1.

### Table No.1 statistical parameters from the calibration plot

<table>
<thead>
<tr>
<th>Statistical parameters</th>
<th>Observed value</th>
</tr>
</thead>
<tbody>
<tr>
<td>The co-relation coefficient</td>
<td>0.9999</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>0.4571</td>
</tr>
<tr>
<td>Variance</td>
<td>0.2090</td>
</tr>
<tr>
<td>Standard error</td>
<td>0.0040</td>
</tr>
<tr>
<td>Coefficient of determination(r²)</td>
<td>0.9998</td>
</tr>
</tbody>
</table>

Assay of olmesartan in dosage forms:

20 tablets (OLMESAR & OLMECIP) both 20 and 40 mg were accurately weighed and average weight of the tablets were calculated. Weight equivalent to 100mg was transferred to 100ml volumetric flask and made up to volume with THF and sonicated for 15 minutes. The solution was mixed and centrifuged for excipients to settle down. The resultant 1mg/ml of the solution was further diluted to get a concentration of 100mcg/ml. Accurately pipetted out 1, 1.5 and 2ml of the above solution into three 10ml standard flasks and the volumes were made up using THF. This gave sample solution having concentration 10, 15, and 20mcg/ml. The absorbance of each concentration was measured and the results of analysis of tablet formulations were shown in table No. 2

### Table No.2 result of tablet analysis

<table>
<thead>
<tr>
<th>Brand of Drug</th>
<th>Label Claim</th>
<th>Amount of Drug Estimated</th>
<th>Percentage Label Claim</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olmesar</td>
<td>20mg</td>
<td>19.7801mg</td>
<td>98.90%</td>
<td>0.19</td>
</tr>
<tr>
<td>Olmesar</td>
<td>40mg</td>
<td>39.5078mg</td>
<td>98.76%</td>
<td>0.41</td>
</tr>
<tr>
<td>Olmecip</td>
<td>20mg</td>
<td>19.92mg</td>
<td>99.60%</td>
<td>0.01</td>
</tr>
<tr>
<td>Olmecip</td>
<td>40mg</td>
<td>39.87mg</td>
<td>99.67%</td>
<td>0.04</td>
</tr>
</tbody>
</table>

**VALIDATION**

The methods were validated with respect to linearity, accuracy, precision and LOD and LOQ.

### Accuracy:

To study the accuracy of the proposed methods, recovery studies were carried out by adding a known amount of drug to the pre analysed tablet powder and percentage recoveries were calculated. The result of recovery studies were satisfactory and are presented in table no 3.

**REFERENCES:**


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