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Original Research Article
Simultaneous Spectrophotometric Estimation of Telmisartan and Amlodipine Besylate in Tablet Dosage Form

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ABSTRACT
A simple, accurate and reproducible spectrophotometric methods have been developed for the simultaneous estimation of Telmisartan (TEL) and Amlodipine Besylate (AML) in combined tablet dosage forms. The method involves determination using the simultaneous equation method, the sampling wavelengths selected are ‘TLM’ = 297nm and ‘AML’ =238nm, over the concentration ranges of 8-48µg/ml for ‘TEL’ and 1-6 µg/ml for ‘AML’ respectively. The method was validated for linearity, accuracy, precision, robustness and application for assay as per ICH guidelines. The proposed method is simple, economical, accurate and precise, and could be successfully employed in routine quality control for the simultaneous analysis of Telmisartan (TEL) and Amlodipine Besylate (AML).

Introduction
Telmisartan, 4-[[2-n-propyl-4-methyl-6-(1-methyl benzimidazol-2-yl)-benzimidazol-1-yl] methyl]–bi phenyl-2-carboxylic acid is a new highly selective, nonpeptide angiotensin II type 1 (AT1)-receptor antagonist. Telmisartan lowers blood pressure through blockade of the rennin-angiotensin-aldosterone system (RAAS) and is widely used in the treatment of hypertension[1-2]. Literature survey reveals several spectroscopic, HPLC and HPTLC methods for the estimation of Amlodipine individually as well as in combination with other drugs[15-22].

Materials and methods

TLM’ and ‘AML’ were received as gift samples from Tirupati Drugs, Paonta sahib (H.P.), India. Double distilled water was used for cleaning of borosil laboratory glassware and methanol of analytical grade used as solvent of both drugs. Whatman filter papers (41) were used for filtering of solutions.

Experimental

Instrumentation
Varian Cary 50 UV-Visible spectrophotometer. Dual beam, Czerny-Turner monochromator, 190–1100 nm wavelength range, approximately 1.5 nm fixed spectral bandwidth, Wavelength accuracy (nm) ± 0.07 at 541.94 nm, ± 0.24 at 260.54 nm. Wavelength reproducibility (nm) ± 0.01, Photometric accuracy (Abs) Using NIST 930D filters at 1 Abs ± 0.0007.

Simultaneous equation method
For the simultaneous equation method, 297nm, and 238 nm were selected as the two sampling wavelengths for Telmisartan and Amlodipine besylate respectively. Fig.1 represents the overlain UV spectra of Telmisatan and Amlodipine besylate exhibited linearity with absorbances in the range of 8-48 µg/ml and 1-6 µg/ml at their respective selected wavelengths. Coefficients of correlation were found to be 0.999 and 0.999 for TLM and AML respectively. The optical characteristics and regression values for the calibration
curves are presented in Table 1. For simultaneous estimation of TLM and AML, mixed standards containing TLM and AML in a concentration ratio of 8:1 µg/ml each were prepared by appropriate dilution of the standard stock solutions with distilled water. The absorbances of the mixed standard solutions were measured at the selected wavelengths[15-17].

**Preparation of standard stock solution**

The equivalent of 50mg each of Telmisartan (TLM) and Amlodipine (AML) were accurately weighed and transferred to the 100ml volumetric flasks separately and dissolved in 25ml of Methanol after the dissolution, the volume was made up to mark with Methanol. These standard stock solutions were observed to contain 500µg/ml of ‘TLM’ and ‘AML’. Further dilution of standard stock solutions of 500 µg/ml, to prepare the stock solutions of 50µg/ml of ‘TML’ and ‘AML’ with Methanol[18-19].

**Selection of sampling wavelengths**

By appropriate dilution of the above prepared standard stock solutions of 50µg/ml with solvent, solutions containing 20µg/ml of ‘TLM’ and 20µg/ml of ‘AML’ were prepared separately. Both the solutions were scanned over the range of 400nm to 200nm in the spectrum mode at slow speed (480nm/min) and the overlain spectra of both the drugs were recorded Fig.1 and the individual spectra of ‘TLM’ and ‘AML’ are given in Fig. 2 and-3.

![Fig.1: Overlain Spectra of ‘TLM’ And ‘AML’](image1)

![Fig.2: Spectra of ‘TLM’](image2)
**Analysis of tablet formulation**

Twenty tablets were taken and their average weight was determined. The tablets were crushed to fine powder containing equivalent of 40mg Telmisartan and 5mg Amlodipine were taken in 100ml volumetric flask. The Amlodipine, present in tablet powder was 5mg that could not be found accurately due to low absorbance. Hence, to increase the accuracy, 25mg of Amlodipine in pure form of drugs was added directly to already weighed powdered tablet that
increased the amount of ‘AML’ to 30mg. It was then dissolved in 75ml of Methanol by intermittent shaking for 4-5 minutes. The supernatant liquid was transferred to a 100ml of volumetric flask through a Whatman filter paper (No.41). The residue was washed with Methanol and to volume was made up to mark with Methanol. The filtrate was further diluted to get final concentration of 20µg/ml of ‘TLM’ and 15µg/ml of ‘AML’. These diluted samples were scanned over the range of 400nm to 200nm at sampling wavelength 297 and 238nm. The absorbances at these wavelengths for each sample were then used for the calculation of both the drugs by using simultaneous equations for ‘TLM’ and ‘AML’ respectively. The results of the statistical validations are recorded in Table no.1

**Table 1: Results of statistical validation of tablet formulation**

<table>
<thead>
<tr>
<th>S. No</th>
<th>Drugs</th>
<th>Mean%</th>
<th>± Standard Deviation</th>
<th>%Coefficient Variation</th>
<th>Standard Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TLM</td>
<td>100.11</td>
<td>0.5482</td>
<td>0.5475</td>
<td>0.2447</td>
</tr>
<tr>
<td>2</td>
<td>AML</td>
<td>99.90</td>
<td>0.5449</td>
<td>0.5454</td>
<td>0.2432</td>
</tr>
</tbody>
</table>

**Table 2: Optical Characteristics and Validation Data of Telmisartan and Amlodipine Besylate**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Telmisartan</th>
<th>Amlodipine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working wavelengths</td>
<td>297nm</td>
<td>238nm</td>
</tr>
<tr>
<td>Beer-Lamberts Law</td>
<td>8-48</td>
<td>1-6</td>
</tr>
<tr>
<td>Regression Values:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I. Slope*</td>
<td>0.055</td>
<td>0.036</td>
</tr>
<tr>
<td>II. Intercept*</td>
<td>0.010</td>
<td>0.003</td>
</tr>
<tr>
<td>III. Regression</td>
<td>0.999</td>
<td>0.999</td>
</tr>
<tr>
<td>Coefficient (r²)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Precision*</td>
<td>0.4096</td>
<td>0.4483</td>
</tr>
<tr>
<td>Intraday (%RSD)</td>
<td>0.3686</td>
<td>0.4937</td>
</tr>
<tr>
<td>Recovery</td>
<td>100.06</td>
<td>100.41</td>
</tr>
<tr>
<td>LOD (µg/ml)</td>
<td>0.0674</td>
<td>0.2163</td>
</tr>
<tr>
<td>LOQ (µg/ml)</td>
<td>0.2044</td>
<td>0.666</td>
</tr>
</tbody>
</table>

**Results and discussion**

The experimental conditions described, calibration curve, assay of tablets and recovery studies were performed. The developed methods were validated as per ICH guidelines for linearity, repeatability, intermediate precision (inter-day and intra-day precision studies), LOD, LOQ as shown in Table 2. The mean % content of TLM and AML in tablet formulation by the developed methods were 100.11% and 99.90% respectively (Table 1). The mean % recoveries of TLM and AML were found to be 100.06% and 100.41 % respectively (Table 2)

**Conclusion**

Telmisartan and Amlodipine besylate are available in combined tablet dosage form for the treatment of hypertension. So many methods has been reported individually of both the drugs and also in the combined tablet dosage form but the author try to make it simple, precise reproducible, versatile and economical. The standard deviation, RSD, %Coefficient Variation and standard error calculated for the method are low, indicating high degree of precision of the methods. The RSD is also less than 2% as required by ICH guidelines. The % recovery was between 99-101% indicating high degree of accuracy of the proposed methods. The method can be successfully used for routine analysis of TEL and AML in bulk drugs and pharmaceutical dosage forms without interference.

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**Conflict of interest**: We declare that we have no conflict of interest.
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