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SIMULTANEOUS ESTIMATION OF OLMESARTAN MEDOXIMIL AND AMLODIPINE BESYLATE USING DERIVATIVE SPECTROSCOPY

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ABSTRACT

A simple, accurate, economical and precise spectroscopic method was developed for simultaneous determination of olmesartan medoximil and amlodipine besylate in tablets using first derivative spectra. Olmesartan showed zero crossing at 257 nm while amlodipine showed zero crossing at 239 nm. Beer's law is obeyed in the concentration range of 4-36 µg/mL for olmesartan medoximil and 5-50 µg/mL for amlodipine besylate in ethanol. Intra-day and inter-day variations showed coefficient of variation (CV%) values less than 1.5% for both drugs. The results of the analysis were validated stastically and found to be satisfactory. The method was successfully applied for simultaneous determination both these drugs in tablet dosage form.

Key words: Olmesartan medoximil, Amlodipine besylate, Ethanol, Derivative spectroscopy.

INTRODUCTION

Olmesartan medoxomil (OM) is 5-methyl-2-oxo-1, 3-dioxol-4-yl-methyl ester. It is an angiotensin II receptor antagonist and used in the treatment of hypertension. This drug contains a medoxomil ester moiety and is cleaved rapidly by an endogenous esterase to release the active metabolite olmesartan[1]. Methoxy-4-(1-hydroxy-1-methylethyl)-2-propyl-1-{4-[2-(tetrazol-5-yl)-phenyl]phenyl}methylimidazol-5-carboxylate, is a potent and selective angiotensin AT1 receptor blocker[2].

Amlodipine besylate (AM), 2-(aminoethoxy) methyl] 4-(2-chlorophenyl) 3-ethoxy-carbonyl-5-methoxycarbonyl-6-methyl-1, 4-dihydropyridine, is a benzene sulphonate (besylate) salt of amlodipine, which is a dihydropyridine calcium channel blocker. AM is a calcium antagonist that inhibits the trans membrane influx of calcium ions into vascular

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smooth muscles and cardiac muscles, which in turn affects their contractile process and results in reduced blood pressure. It is used in the treatment of hypertension and angina.

To the best of knowledge, no spectroscopic method has been developed for the simultaneous determination of both these drugs in tablets. Derivative spectroscopy provides a greater selectivity than common spectroscopy and offers a powerful approach for resolution of band overlapping quantitative analysis of multi-component mixture. The aim of the present study is the development of a simple, accurate and sensitive derivative spectroscopic method for the determination of amlodipine and olmesartan in tablet dosage form.

EXEPERIMENTAL

Instrumentation

Spectroscopic analysis was carried out on a double beam Shimadzu UV/Visible spectrophotometer. The zero order absorption spectra were recorded over the wavelength range of 200 to 400 nm, against solvent blank, in quartz cuvetts with 1 cm diameters. For all solutions, the derivative spectra were obtained over 200–400 nm. All the measurements were made using Shimadzu UV visible spectrophotometer with 1 cm matched quartz cells. All the solutions were freshly prepared with distilled water.

Preparation of standard stock solution

Standard and calibration solutions

Standard stock solutions of amlodipine and olmesartan were prepared separately using ethanol. Appropriate volume of standard stock solution was diluted with ethanol to get concentration of 100 μg/mL of both the drugs. Further dilutions were made from these solutions in distilled water to get mixed standard linearity concentrations in the ratio of (4 : 1) 4-36 μg/mL for olmesartan and amlodipine.

Sample preparation

A total number of 20 tablets were accurately weighed and powdered in a mortar. Quantities of the powdered tablets equivalent to average of one tablet were accurately weighed and transferred in a 50 mL volumetric flask. Weighed powder was dissolved in 30 mL of ethanol. Then the volume made up to 50 mL with ethanol, mixed thoroughly and shaken for 15 minutes. Solution obtained was filtered through Whatman filter paper No. 42 and diluted with the distilled water (solvent) to get the required concentration.

Method

Calibration curves were constructed by analysis of working mixed standard solutions of olmesartan and amlodipine with at least 9 different concentrations in the ratio (4 : 1) 4-36 µg/mL. Each concentration was analysed in triplicate. First derivative values (D1) of olmesartan and amlodipine were measured at 257 and 239 nm, respectively. Calibration curve was plotted by taking first derivative values (D1) on Y-axis and concentrations on X-axis. The relation between drug concentration (x) and its corresponding D1 value (y) is expressed by the equation) Y= mx + b, where m is slope and b is the intercept.

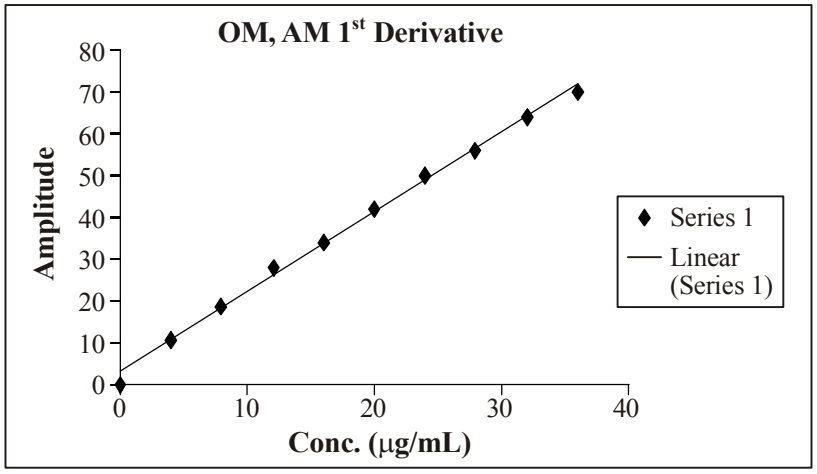

Fig. 1: Standard calibration curve

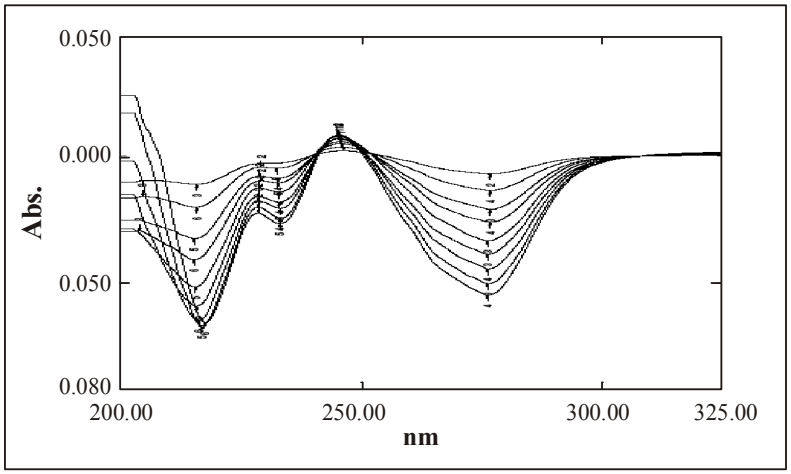

Fig. 2: Overlay spectrum first derivative

Sample analysis

Applicability of the proposed methods for the simultaneous estimation of amlodipine besylate (AM) and olmesartan medoximil (OM) was studied by assay of commercial tablets (Labeled to contain 5 mg of AM and 20 mg of OM). The results obtained are given in Table 2.

RESULTS AND DISUSSION

The optical characteristics such as absorption maxima, Beer's law limits, and regression characteristics like slope (b), intercept (a), correlation coefficient (r), and standard error were calculated and the results are summarised in Table 1.

Recovery experiments were carried out to study the accuracy and reproducibility of the proposed method, by adding a known amount of drug to pre-analysed sample and the percentage recovery was calculated. The results are furnished in Table 2. The results obtained are in good agreement with the labeled contents.

A rapid, simple and specific UV first derivative spectroscopic method has been developed for the simultaneous determination of amlodipine and olmesartan. This method is also successfully applied for determination of both the drugs in tablet dosage forms. This can be useful for the routine drug analysis in quality control laboratories.

Table 1: Optical characteristics

Parameters	Derivative spectroscopy
Wave length (nm)	257 - OM / 239 - AM
Beer's law limits (µg/mL)	0-36 µg/mL-OM 0-50 µg/mL-AM
Slope (m)	1.0909
Intercept (c)	3.0363
Regression (y = mx + c)	1.0909X + 3.0363
Correlation coefficient (r)	0.9970
Standard error	1.5608

Table 2: Assay and recovery

Tablet	Label claim	Amount found by proposed method	% Recovered by the proposed method
Olmeasrtan	**20 mg**	**20.86 mg**	**99**
Amlodipine	**5 mg**	**4.76 mg**	**100**

*Average of three determinations

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