

SIMULTANEOUS SPECTROPHOTOMETRIC ESTIMATION OF VALSARTAN AND AMLODIPINE BESYLATE BY DUAL WAVELENGTH METHOD IN TABLET DOSAGE FORM

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ABSTRACT

A simple and rapid spectrophotometric dual wavelength method has been developed for simultaneous estimation of amlodipine besylate and valsartan in tablet dosage form. Two wavelengths selected were 227 and 244nm, for estimation of valsartan and 360 nm for amlodipine besylate using methanol as a solvent. Both the drugs obeyed Beer-Lambert's law over the concentration range 5-100µg/ml and 5-50µg/ml for valsartan and amlodipine besylate. The r^2 for valsartan and amlodipine besylate were 0.9982 and 0.9973 with mean percent recovery of 100.23 and 99.66 respectively. The Relative standard deviations for validation parameters were found to be less than the 5%.

Keywords: *Amlodipine Besylate; Valsartan; Tablet; Spectrophotometric method.*

INTRODUCTION

Valsartan (VAL), *N*-(1-Oxopentyl)-*N*-[[2'-(1*H*-tetrazol-5-yl) [1,1'-biphenyl]-4-yl]methyl]-L-valine is used as anti-hypertensive drug. It acts by blocking the action of angiotensin receptor there by dilates blood vessels and reduces blood pressure¹. Amlodipine besylate (AM), 3-Ethyl 5-methyl(4 RS)-2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate benzene sulphonate is long-acting calcium channel blocker. It blocks the transport of calcium into the smooth muscle cells, lining the coronary arteries thus relaxing artery muscles and lowering the blood pressure². Literature survey reveals that various methods are available for the determination of amlodipine besylate alone or in combination with other drugs by UV spectrophotometry^{3,4}. Similarly methods such as derivative spectrophotometry⁵ and HPLC⁶ are available for valsartan. To our knowledge simultaneous estimation of both drugs by dual wavelength method is not available. In the present work, an attempt has been made to develop dual wavelength method for simultaneous estimation of both the drugs in pharmaceutical dosage form. Using dual wavelength method, we can calculate the unknown concentration of component of interest in the mixture. The method is based on the principal that "The absorbance difference between two points on the mixture spectra is directly proportional to the concentration of component of interest independent of the interfering component". The method was validated statistically as per ICH Guidelines⁷ for parameters like accuracy, precision, linearity and range.

EXPERIMENTAL

Instrument

A Shimadzu-1700 UV-Visible double beam spectrophotometer with matched pair of quartz cell (1.0 cm path) was employed for absorption measurements.

Materials

Gift samples of valsartan and amlodipine besylate were obtained from Torrent Pharmaceuticals Ltd. and Ranbaxy Pvt. Ltd., Indore, respectively. Methanol used was of analytical grade. Marketed tablet containing 10 mg of AM and 160 mg of VAL was procured from the open market.

PROCEDURE

Preparation of standard stock solution

Standard stock solution A (1000 µg/ml) was prepared by taking 10 mg of AM and VAL separately into 10 ml volumetric flask and dissolved in 5 ml of methanol, sonicated for 10 min and final volume was made up to the mark with the solvent. 2.5 ml of stock solution A of amlodipine besylate and valsartan each were taken separately in 25ml volumetric flask and volume was made up to mark with the solvent to give concentration of 100µg/ml (Stock-B) for both drugs.

Selection of Wavelength

Standard stock solutions were scanned between the range 200 to 400nm and the overlain spectrum was recorded. As there was no absorbance at 360nm for valsartan, this wavelength was selected for estimation of amlodipine besylate. The wavelengths selected for

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Estimation of Valsartan and Amlodipine Besylate

estimation of valsartan are 227 and 244 nm, as drug showed significant difference in absorbance and amlodipine besylate showed same absorbance. Overlain spectra of amlodipine besylate and valsartan is shown in [Fig. 1].

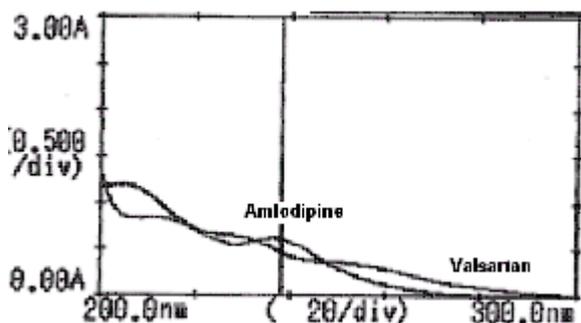


Fig. 1. Overlain spectra of Amlodipine Besylate and Valsartan

Preparation of binary mixtures

A series of standard binary mixtures of amlodipine besylate and valsartan in the ratio of 1:10 containing 5:50, 6:60, 7:70, 8:80 and 9:90 $\mu\text{g/ml}$ solutions were prepared in methanol.

Preparation of calibration curves

For valsartan, calibration curve was prepared by plotting difference between absorbance at 227nm (λ_1) and 244nm (λ_2) against the concentration used. In this case valsartan was the component of interest and amlodipine besylate was the interfering component. Similarly for amlodipine besylate, calibration curve was prepared by plotting absorbance at 360nm against the concentration used. Different dilutions ranging from 5-50 $\mu\text{g/ml}$ and 50-100 $\mu\text{g/ml}$ for amlodipine besylate and valsartan were prepared from stock solution-B for analysis. The linearity of the developed method was statistically confirmed. The linear equations were found to be:

$$Y (\text{AM}) = 55.53 C + 1.41$$

$$Y (\text{VAL}) = 93.70 C + 4.94$$

Where Y is detector response and C is the concentration of drugs in $\mu\text{g/ml}$, with correlation coefficients 0.9998 and 0.9994 for amlodipine besylate and valsartan respectively, indicating good linearity.

Analysis of tablet formulation

Twenty tablets were taken; average weight was determined and crushed to fine powder. Amount equivalent 10 mg Amlodipine and Valsartan was taken in 10 ml volumetric flask. This was dissolved in 10 ml methanol. The volume was made up to mark and filtered through 0.4 μ whatman filter paper. Aliquots of this solution were diluted to obtained a final concentration of 5, 6, 7 $\mu\text{g/ml}$ and 80, 96, 112 $\mu\text{g/ml}$ of amlodipine besylate and valsartan. The responses of final dilutions were observed at selected wavelengths and the concentrations were obtained from regression equation. The results of analysis and the statistical data for tablet analysis are given in Table 1.

Table 1. Results of analysis of tablet formulation by proposed method

Drug	% Mean	S.D.	% Coefficient variation	Standard error
AM	100.16	0.246	0.964	1.29
VAL	100.10	0.205	0.911	1.58

Recovery study

To study the accuracy, reproducibility and precision of the proposed method, recovery study was carried out by addition of standard drug solutions to pre-analyzed sample and the % recovery was estimated to be 100.4 and 100.1 for amlodipine besylate and valsartan respectively.

RESULT AND DISCUSSION

The proposed method for simultaneous estimation of amlodipine besylate and valsartan in their combined pharmaceutical dosage form was found to be simple, accurate, economical and rapid. The interference of interfering components was neglected by selecting the proper λ_1 and λ_2 for the components of interest. The standard deviation by proposed method in tablet for amlodipine besylate and valsartan were 0.246 and 0.205.

The methods were validated statistically as per ICH guidelines for parameters like accuracy, precision, repeatability, linearity and range. The values of coefficient of variation were satisfactorily low. The recovery for amlodipine besylate and valsartan were found to be 100.08 and 100.23 respectively. The recovery studies and statistical data for the method were found to be satisfactory and therefore the method can be used for routine analysis.

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