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QUANTITATIVE ANALYSIS OF AMLODIPINE BESYLATE AND VALSARTAN IN TABLET DOSAGE FORM BY ABSORPTION FACTOR SPECTROPHOTOMETRY METHOD

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ABSTRACT

This study aimed to develop a spectrophotometry method by absorption factor using methanol solvent to get the levels of amlodipine besylate and valsartan in the tablet. This method is very simple, to find the levels of valsartan was substracted the absorption of amlodipine besylate at 247.2 nm using an experimentally calculated absorption factor. The maximum wavelengths of amlodipine besylate and valsartan were obtained 358.0 nm and 247.2 nm, respectively. The average % recoveries were obtained in 100.16% and 99.71% for amlodipine besylate and valsartan to 5/80 mg tablet dosage form and 100.29% and 99.64% for amlodipine besylate and valsartan, respectively to 10/160 mg tablet dosage form. This method is successfully applied to determine amlodipine besylate and valsartan in tablet preparation without interference from excipients as shown in recovery studies and fulfill the validation requirements.

Keywords: Amlodipine besylate, Valsartan, Spectrophotometry, Absorption Factor.
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INTRODUCTION

There are more than 50% of patients with hypertension may use two or more drug components to decrease their blood pressure.[1] Patient is more convenient using a single tablet than two or more tablets.[2] The Exforge tablet from Novartis is used in the treatment of blood pressure, they contain two components (amlodipine besylate and valsartan) in one tablet preparation, 5 mg/80 mg (A Tablet) and 10 mg/160 mg (B Tablet).

Amlodipine (AML) with chemical name, 3-ethyl-5-methyl(±)-2-[(2-aminoethoxy)methyl]-4-(o-chlorophenyl)-1,4-dihydro–6-methyl 3,5-pyridinedicarboxylate, monobenzenesulfonate,[3] is a calcium channel blocker that is used in the control the blood pressure and chronic stable angina pectoris.[4,5]

Valsartan (VAL) with chemical name, N-(1-oxopentyl)-N-[[2′-(1Htetrazol-5-yl) [1,1′-biphenyl]-4-yl] methyl]-L-valine, is a specific and potent competitive angiotensin receptor blocker that used for control hypertension, post-myocardial infarction and heart failure.[6,7]

UV spectrophotometric methods,[8-11] HPLC,[12-14] HPTLC,[15,16] infrared,[17] LC-MS/MS[18] and LC-ESI-MS/MS,[19] potentiometric and voltammetry,[20] simultaneous UV spectrophotometry,[21] were obtained to analyze AML and VAL alone or in combination.

The absorption factor (AF) is a simple, accurate and precise spectrophotometric method that can be applied to determine a combination of drugs with no any separation, without complicated calculations, without derivatization first and can be applied to determine levels of pharmaceutical formulation without interference from excipients.[22-25] Based on the explanation, AML and VAL levels in the tablet can be determined using the AF spectrophotometric method.

EXPERIMENTAL

Measurement operated by UV visible spectrophotometer Shimadzu 1800 with UV-Probe 2.42 software. Raw materials of AML and VAL were obtained from the Indonesian Food and Drug Administration. Exforge tablets (contains 5 mg AML/ 80 mg VAL and 10 mg AML/ 160 mg VAL, Novartis, Indonesia) were obtained from a local pharmacy.

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Standard Solution of AML and VAL with concentration 100 µg/ml were prepared with methanol as a solvent. The maximum wavelength was selected by measuring at 200 to 400 nm with a concentration of AML (4-12 µg/ml) and VAL (6-18 µg/ml). Method validation was validated based on linearity, accuracy, precision, LOD and LOQ refer to ICH guidelines.[26-33]

Prepare sample solution of AML (8 µg/ml) and VAL (12 µg/ml) in the methanol solvent. AML and VAL solution were measured by spectrophotometer and the absorption factor value was obtained 1.510. Quantitative analysis of the AML and VAL were measured by using the following equation.

Absorption VAL at 247.2 nm:

$$\text{Abs 247.2 nm (AML+VAL)} - \frac{\text{Abs 247.2 nm (AML)}}{\text{Abs 358 nm (AML)}} \text{X Abs 358 nm (AML+VAL)}$$

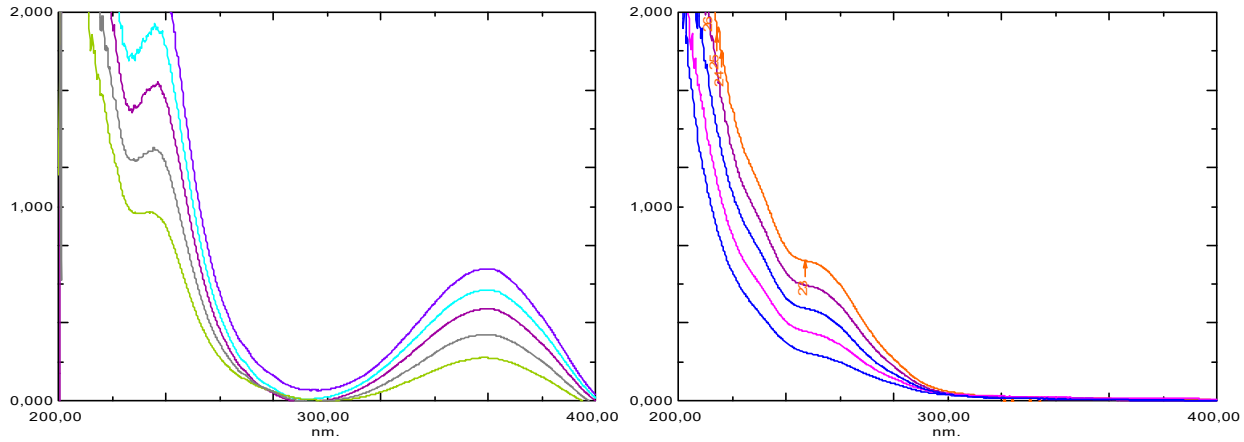
Abs: Absorption value

AML: Amlodipine besylate

VAL: Valsartan

RESULTS AND DISCUSSION

Maximum wavelength was selected by finding the AF value of each spectrum with different concentrations. Based on Fig.-1, AML shows linear response at its λmax 358.0 nm and VAL has been measured at 247.2 nm. The correlation coefficient value indicates the best linear relationship between the AF value and its concentration, as shown in Table-1.



(a) (b)

Fig.-1: Spectrum of (a) AML (358.0 nm) and (b) VAL (247.2 nm)

Based on Fig.-1, AML and VAL are measured at 358.0 nm and 247.2 nm respectively. AML was also found in absorbance at 247.2 nm, as shown in Figure 2 and interfere with the determination of VAL. Therefore, quantitative analysis of VAL is calculated by subtracting AML interference using AF value calculation.

Method Validation

The validation parameters used to validate the method are linearity, accuracy, precision, LOD and LOQ.

Table-1: Method Validation of AML and VAL with AF method

Parameters	A Tablet		B Tablet	
	AML	VAL	AML	VAL
Linearity	0.9994	0.9998	0.9996	0.9998
Accuracy (%)	100.16	99.71	100.29	99.64
Precision (%)	0.04	0.12	0.42	0.67
LOD (µg/ml)	0.5397	0.4489	0.4462	0.4117
LOQ (µg/ml)	1.6355	1.3605	1.3522	1.2477

The results showed that the simultaneous analysis of AML and VAL give good method validation results on tablet A and tablet B for each parameter and conform to the requirements of the ICH guidelines, as shown in Table-1. Several studies using absorption factor spectrophotometry have been reported and had good method validation results.

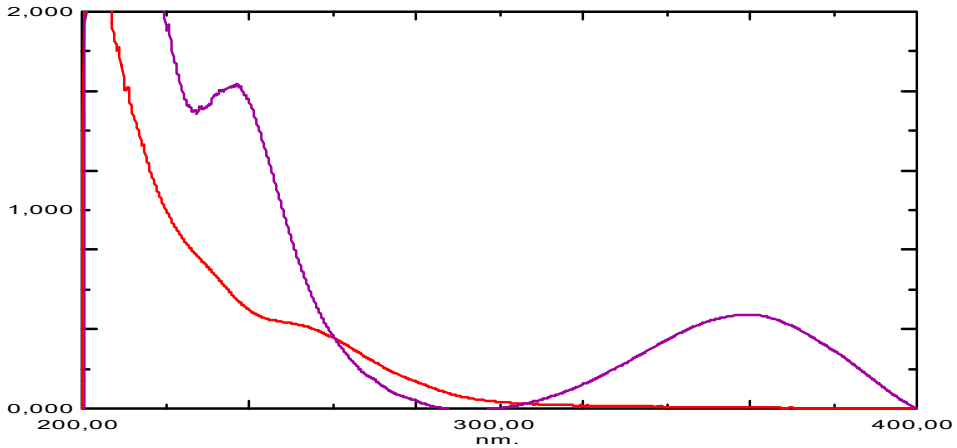


Fig.-2: Overlain Spectrum of (—) AML and (—) VAL

CONCLUSION

The AF spectrophotometry method is a simple, accurate, precise, sensitive and easy to apply spectrophotometric method. This method can be applied to simultaneously analysis of AML and VAL in combined tablet preparation and conform to the requirements of validation and can be applied in routine analysis of AML and VAL.

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