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Research Article

Analytical Method Development and Validation for the Simultaneous Estimation of Amlodipine and Valsartan in Bulk and Pharmaceutical Dosage Form by RP-HPLC Method

Ratti Bhavani*, Dr. P. V. Madhavi Latha, K. Suvarna, Dr. P. Uma Devi

Viswanadha Institute of Pharmaceutical Sciences.

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ABSTRACT

A rapid, sensitive and accurate RP-HPLC method was developed for the identification and quantification of Amlodipine and Valsartan using a Waters HPLC system equipped with a PDA detector. Chromatographic separation was achieved on an Inertsil ODS-C18 column (150 × 4.6 mm, 5 µm particle size) with a flow rate of 1.0 mL/min. The mobile phase consisted of degassed and filtered Water and Triethylamine (1000: 10) with pH of 2.8 adjusted with phosphoric acid (Solution-A) and Methanol:Acetonitrile (700: 300) (Solution-B). Detection was performed at 240 nm, providing reliable resolution and measurement of both analytes.

INTRODUCTION

Amlodipine (6-7) is a long-acting dihydropyridine calcium channel blocker widely prescribed for the management of hypertension and angina pectoris. It exerts its therapeutic effect by inhibiting the entry of calcium ions into vascular smooth muscle cells, resulting in vasodilation. This mechanism reduces blood pressure and improves oxygen supply to the myocardium.

Valsartan (8-9) is an angiotensin II receptor blocker (ARB) commonly used to treat hypertension, heart failure, and to enhance survival following a heart attack. It works by blocking the effects of angiotensin II, thereby preventing blood vessels from constricting and decreasing the release of aldosterone, a hormone that causes salt and fluid retention. This leads to a reduction in blood pressure and alleviates strain on the cardiovascular system.

MATERIALS AND METHODS

Preparation of Stock solution: Precisely weighed 50 mg of Amlodipine and 60 mg of Valsartan were transferred into 100 ml volumetric flasks. Approximately 60 ml of methanol was added to flasks and the solutions were sonicated for about 5 minutes. After sonication, the volumes were adjusted to the mark to give 500µg/ml of Amlodipine and 600µg/ml of Valsartan.

***Corresponding Author:** Ratti Bhavani
Address: Viswanadha Institute of Pharmaceutical Sciences
Email ✉: rattibhavani7@gmail.com

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Preparation of working standard solution: From the stock solutions of both standards, each 4 ml was pipetted out and transferred into 50ml volumetric flasks, then diluted up to the mark to get 40µg/ml of Amlodipine and 48µg/mlof Valsartan.

RESULTS AND DISCUSSION

Method validation: Validation parameters include specificity, linearity, range, accuracy, precision, limit of detection, limit of quantification, robustness and assay (1-5).

Specificity: Specificity is the ability to assessing equivocally the analyte in the presence of components which may be expected to be present. Typically, these components include impurities, degradants, matrix etc. Blank solution and standard solutions of Amlodipine and Valsartan were injected into the HPLC system. The peak purity data of Amlodipine and Valsartan were compared. There should not be any interference at the retention time of the main peaks.

Linearity: Linearity for the drugs Amlodipine and Valsartan (10-13) was determined by preparing the standard solutions at five concentrations levels in range of 20 to 60µg/ml of Amlodipine and 24 to 72µg/ml of Valsartan from stock solution. The linearity charts of Amlodipine and Valsartan was shown in the figure no 2&3. The correlation coefficient was found to be 0.9985 and 0.9990 for Amlodipine and Valsartan respectively. Linearity results were tabulated in table 2.

Accuracy: Accuracy was performed by spiking known amounts of standard solution to sample solution at three different concentrations levels (50%, 100%, 150%) and there by analyzed for %RSD which should not be more than 2.0.The% recovery was calculated and the results was reported in table no. 3 & 4.

Precision: The precision (14-18) of the analytical method was studied by injecting six replicates of standard containing 40µg/ml of Amlodipine and 48µg/ml of Valsartan which were injected into HPLC system. The % RSD was calculated and the results were reported in the table no.5

Limit of Detection (LOD) and Limit of Quantification (LOQ): The limit of detection was defined as the concentration which yields a signal - to – noise ratio 3:1 whereas the limit of quantification was calculated to be the lowest concentration that could be measured with signal - to – noise ratio10:1. LOD and LOQ were calculated from slope and standard deviation. The results were tabulated in table no 6.

Robustness: The smallest deliberate changes in method like change in flow rate are made but there were no predictable changes in the results and are in the range as per ICH guidelines. Conditions like decrease in flow rate (0.8 ml/min), increase in flow rate (1.2 ml/min) was maintained and samples were injected in duplicate manner. System suitability parameters were not much affected and all the parameters were passed. % RSD was found to be within the limits and results were tabulated in table no 7.

Assay: Assay was conducted on marketed formulation and mean % assay was found. The results were tabulated in table no. 8.

Table 1: Optimised Chromatographic Conditions

Parameter	Method
Stationary Phase (column)	C18 (150mm*4.6mm, 5µm particle size)
Mobile Phase	Solution-A Water and Triethylamine (1000:10). pH was adjusted to 2.8 with phosphoric acid. Solution-B Methanol and Acetonitrile (700:300)
Flow rate (ml/min)	1.0 ml/min
Run time (minutes)	25 min
Temperature in the column (°C)	Ambient
Volume of injection loop (∟l)	20
Wavelength of detection (nm)	240nm
Drug RT (min)	8.443 for Amlodipine and 12.449 for Valsartan

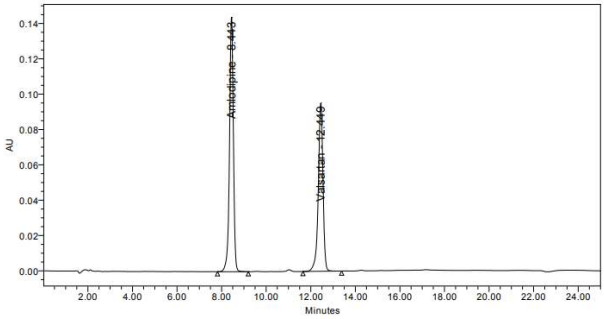

Figure 1: Optimized Chromatogram

Table 2: Linearity Data of Amlodipine and Valsartan

Amlodipine		Valsartan	
Conc (µg/ml)	Peak area	Conc (µg/ml)	Peak area
20	888591	24	721408
30	1356985	36	1098781
40	1746613	48	1408815
50	2109076	60	1723935
60	2614104	72	2106470

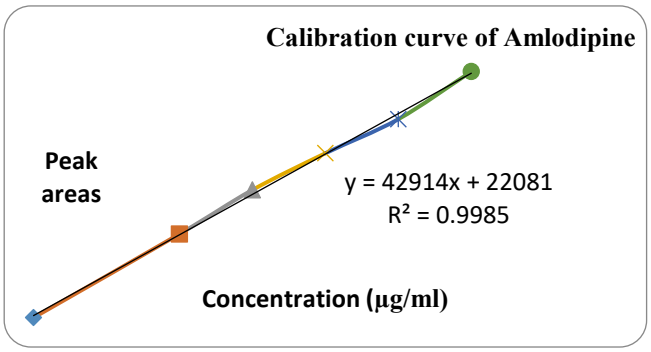

Figure 2: Calibration Curve of Amlodipine

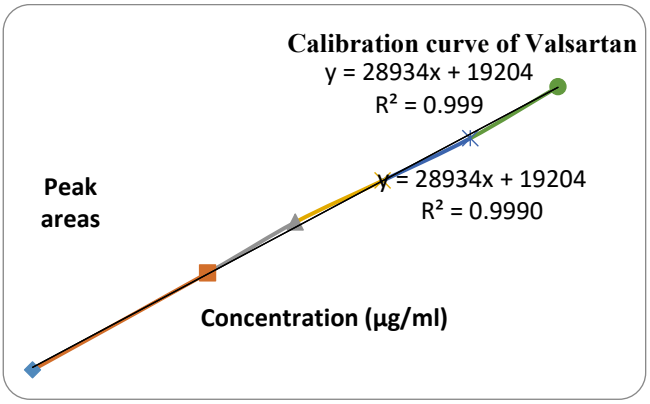

Figure 3: Calibration Curve of Valsartan

Table 3: Accuracy Data of Amlodipine

Concentration % of spiked level	Area	RT	Statistical Analysis of % Recovery	
50% - 1	889021	8.564	**MEAN**	99.71
50% - 2	890265	8.569	**%RSD**	0.37
50% - 3	888582	8.575		
100 % - 1	1729390	8.585	**MEAN**	98.95
100 % - 2	1738662	8.593	**%RSD**	0.45
100% - 3	1733234	8.603		
150% - 1	2609502	8.627	**MEAN**	99.54
150% - 2	2618749	8.629	**%RSD**	0.11
150% - 3	2619105	8.633		

Table 4: Accuracy Data of Valsartan

Concentration % of spiked level	Area	RT	Statistical Analysis of % Recovery	
50% - 1	716252	12.510	**MEAN**	100.20
50% - 2	718548	12.513	**%RSD**	0.49
50% - 3	718909	12.512		
100 % - 1	1395764	12.527	**MEAN**	99.28
100 % - 2	1395472	12.530	**%RSD**	0.30
100% - 3	1397934	12.538		
150% - 1	2104116	12.556	**MEAN**	99.97
150% - 2	2111406	12.559	**%RSD**	0.29
150% - 3	2113274	12.561		

Table 5: Precision Data for Amlodipine and Valsartan

S. No	Peak areas of Amlodipine	Peak areas of Valsartan
1	1729390	1395764
2	1738662	1394572
3	1733234	1397934
4	1733634	1393957
5	1742369	1404417
6	1736777	1397576
Mean	99.4	99.5
SD	0.79	0.54
% RSD	0.8	0.5

Table 6: LOD and LOQ Data of Amlodipine and Valsartan

Drug Name	LOD (µg/ml)	LOQ (µg/ml)
Amlodipine	2.507	7.598
Valsartan	2.448	7.419

Table 7: Robustness Data of Amlodipine and Valsartan

S No	Drug Name	Condition	Peak area	% RSD	
1	Amlodipine	Decreased Flow rate of 0.8 ml/min	1731325	1.1164	
2		Increased Flow rate of 1.2 ml/min	1739657	0.5756	
3	Valsartan	Decreased Flow rate of 0.8 ml/min	1400532	0.3439	
4		Increased Flow rate of 1.2 ml/min	1397228	0.6241	

Table 8: Assay Data of Amlodipine and Valsartan

S. No	Peak area of Amlodipine	% Assay	Peak area of Valsartan	% Assay
Sample- 1	1700946	98.87	1401224	99.16
	1747661		1402139	
Sample- 2	1728954		1385187	
	1747661		1402139	

CONCLUSION

The developed RP-HPLC method was successfully validated in accordance with ICH guidelines. All system suitability parameters were found to be within the acceptable limits specified by ICH. No interfering peaks were observed in the blank, standard or sample chromatograms, demonstrating the specificity of the method. The proposed method exhibited satisfactory characteristics in terms of simplicity, precision, accuracy, sensitivity, specificity and robustness. Therefore, the developed and validated RP-HPLC method is suitable for routine analytical applications and can be effectively employed in pharmaceutical quality control laboratories.

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