WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.074
Volume 8, Issue 7, 1360-1365. Research Article ISSN 2277– 7105

UV-VISIBLE SPECTROPHOTOMETRIC ESTIMATIONOFAMLODIPINE BESYLATE AND TELMISARTAN BY AUC METHOD IN BULK DRUG AND TABLET DOSAGE FORM

M. T. Mohite*[1], R. A. Bhalchakra[2] and K. V. Chandgude[2]

Department of Pharmaceutical Chemistry Dr. D.Y. Patil College of Pharmacy Akurdi, Pune-411044, Maharashtra, India.

Article Received on
27 March 2019,

Revised on 17 April 2019,
Accepted on 07 May 2019,

DOI: 10.20959/wjpr20197-15020

***Corresponding Author**
M. T. Mohite
Department of Pharmaceutical Chemistry Dr. D.Y. Patil College of Pharmacy Akurdi, Pune-411044, Maharashtra, India.

ABSTRACT

A simple, rapid, reproducible and accurate UV spectrophotometric method has been developed for the estimation of Amlodipine besylate (AML) and Telmisartan (TEL) in bulk drug form by Simultaneous and AUC method. Evaluation of tablet is determined by the multi wavelength and AUC technique, at the wavelength of 360nm and 298nm over the concentration of 5–30 µg/ml and 1–15 µg/ml with mean recovery more than 98% and area of Amlodipine besylate and Telmisartan at absorption maxima, which is 360±10 and 298±10. The results of the analysis were validated as per the ICH guidelines. Thus the developed method can be successfully used for Simultaneous and AUC determination of Amlodipine besylate and Telmisartan.

KEYWORDS: Amlodipine besylate, Telmisartan, Spectrophotometric, Simultaneous, AUC.

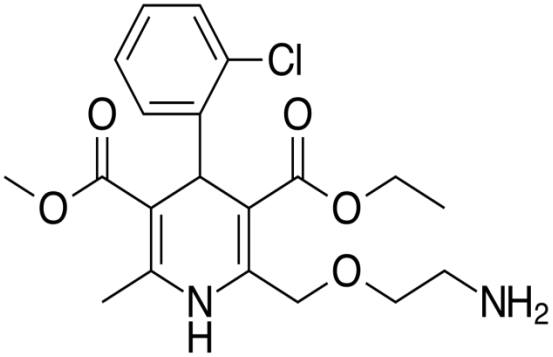
INTRODUCTION

Worldwide, hypertension is estimated to cause 7.5 million deaths, about 12.8% of the total of all deaths. The 57 million disability adjusted life years or 3.7% of total. Raised blood pressure is a major risk factor for coronary heart disease and hemorrhagic stroke. Blood pressure levels have been shown to be positive and continuous relationship with risk for stroke and coronary heart disease.

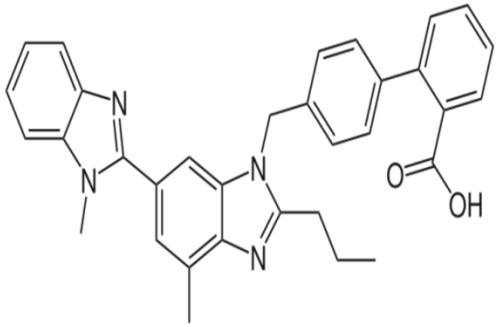
The Amlodipine besylate and Telmisartan is the antihypertensive agent belongs from the drug class calcium channel blocker and angiotensin II receptor antagonist used in the management of hypertension. Sold under the brand name of Norvasc and Micardis. Amlodipine was first

patented in 1986 with commercial scale beginning in 1990 and Telmisartan was discovered by Boehringer Ingelheim and launched in 1999.

There are few UV and HPLC methods are reported for the simultaneous analysis of Amlodipine besylate and Telmisartan in combined tablet dosage form. So a need was felt, to develop new methods to analyze the drugs simultaneously and rapidly. The present work demonstrates for the simultaneous determination of amlodipine besylate and telmisatan in tablet formulations as well as in bulk by AUC method rapidly.



Amlodipine besylate



Telmisartan

EXPERIMENTAL

Materials and methods

The pure samples of Amlodipine besylate and Telmisartan (IPCA labs ltd. India), were used in the study. Methanol and distilled water were used as a solvent. The pharmaceutical dosage form used in this study was Amlopres-TL (Cipla Ltd.) labeled claim to contain 5mg Amlodipine besylate and 40 mg of Telmisartan per tablet.

Experimental Condition

Methanol and distilled water were used as a solvent for analysis according to the solubility studies of drug. Estimation of Amlodipine besylate and Telmisartan was done by UV spectroscopy at the wavelength 238 nm and 296 nm.

Working standard solution

Amlopress-TL content Amlodipine besylate and Telmisartan in 1:16 and 1:8 ratios. Working standard solution was prepared in 1:8 ratio from the stock solution.

Preparation of standard stock solution

The 10 mg of each drug was dissolved in 100 ml of methanol for preparing standard stock solution (100 µg/ml). The working standard solutions of both drugs were obtained by dilution of the respective stock solution with distilled water.

Preparation of sample stock solution

An accurately weighed powder sample equivalent to 5mg of Amlodipine besylate and 40mg of Telmisartan fine powder of 20 tablets. Dissolved in 20ml of methanol into 100ml of volumetric flask. Sonicate the solution for 15mins. To increase the solubility of both drug in solvent after sonication make up the volume upto the mark by distilled water and filter the solution with the help of Whatmann filter paper.

Wavelength selection

The standard solution of Amlodipine besylate and Telmisartan were separately scanned at different concentration and λmax were determined at which the both drug shows maximum absorption that wavelength was selected for further study and overlain spectra for both drug was done.

Method

Area under curve

AUC method is used when the sharp peak was not obtained and broad spectra are obtained. The calculation of integrated value of area with respect to the wavelength between two selected wavelength. Calculate the area bound by the curve and horizontal axis. The AUC calculated by using zero order derivative. The calibration curve was obtained by plotting the concentration verses AUC. For AUC ranges were selected for Amlodipine besylate and Telmisartan. Both are linear at the concentration 5-30µg/ml and 2-12µg/ml at their respective λmax. Coefficient of correlation were found to be 0.999 for Amlodipine besylate and 0.998 for Telmisartan of bulk drug and in tablet it was found 0.992 for amlodipine besylate and 0.996 for telmisartan. For simultaneous estimation Amlodipine besylate and Telmisartan standard prepared in the ratio 1:8 by appropriate dilution of stock solution. The AUC of the mixed standard solution were measured at the selected wavelength intervals 235-225nm and 301-291nm.

Linearity study

Linearity study was performed on 3 different days. Amlodipine besylate and Telmisartan showed linearity in their range. Linear regression equation and coefficient correlation are given in results and discussion.

Precision

The precision study was performed by estimating the sample of both the drugs 3 times in a day and on 3 different days for different concentration of both drug for AUC and the results are reported in terms of percent relative standard deviation.

Accuracy

After the calculation of recoveries of Amlodipine besylate and Telmisartan by the 3 standard known amount of addition (80%, 100%. 120%) the accuracy of method was determined. The obtaining responses and the values are put in Y=mx+c equation of calibration curve it was help to estimate the recovery of added drug.

RESULT AND DISCUSSION

The methanol and distilled water were used as a solvent according to the solubility of Amlodipine besylate and Telmisartan. The obtained absorption spectra of both the drugs shown in fig.1 and 2 and their optical characteristics are given in table no 1,2 and 3.

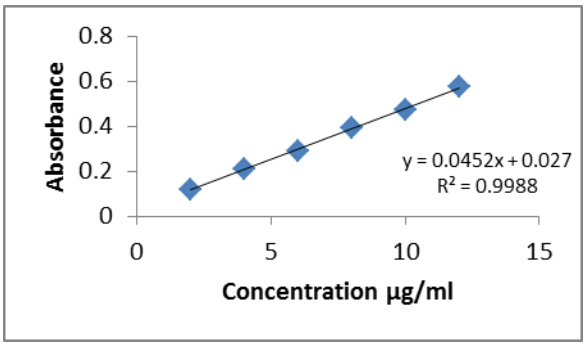


Fig. 1: Calibration curve of Telmisartan.

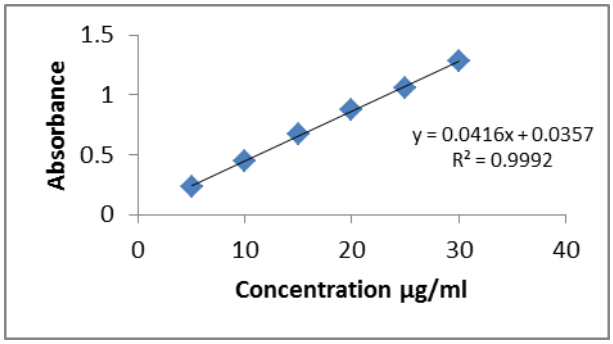


Fig. 2: Calibration curve of Amlodipine besylate.

Table no. 1: Optical characterstics of Amlodipine besylate and Telmisartan.

Parameters	Amlodipine besylate	Telmisartan
λmax (nm)	238	296
Beer lambert range (µg/ml)	5-30	2-12
Working wavelength intervals (nm)	243-233	301-291
Regression Equation	Y= mx + c	Y= mx + c
Slope	0.041	0.040
Intercepts	0.035	0.039
Coefficient correlation (r^2)	0.999	0.998
Precision* Intraday (%RSD) Interday (%RSD	 0.4322 0.5850	 0.0695 0.0712
LOD	0.2059	0.1019
LOQ	0.6259	0.2845

Stastical validationdata of bulk drug and tablet dosage form

Table no. 2: Optical characterstics of Amlodipine besylate and Telmisartan.

Component	Amount present (mg)	%amount found	SD*	%RSD*
Amlodipine besylate	1	95.06(Bulk) 98.21(Tablet)	0.006721(Bulk) 0.006901(Tablet)	0.069506(Bulk) 0.75021(Tablet)
Telmisartan	8	96.30(Bulk) 97.91(Tablet)	0.0030903(Bulk) 0.003910(Tablet)	0.03817(Bulk) 0.04210 (Tablet)

Results of Recovery (Tablet)

Table no. 3: Optical characterstics of Amlodipine besylate and Telmisartan.

Drug	Level of Recovery (%)	Amount present	Amount found	%Recovery	%RSD
Amlodipine besylate	80	4	3.9216	99.23	0.1545
	100	5	4.832	97.32	0.1751
	120	6	6.010	100	0.1905
Telmisartan	80	32	32.104	100	0.0560
	100	40	39.805	99.78	0.1375
	120	48	47.312	99.47	0.0172

CONCLUSION

The developed method is simple, precise, rapid and accurate can be employed for the routine estimation of amlodipine besylate and telmisartan in the both bulk drug and tablet dosage form.

ACKNOWLEDGEMENTS

I express my gratitude towards IPCA labs ltd. India, for the generous gift samples of pure Amlodipine besylate and Telmisartan.

REFERENCES

1. Indian Pharmacopoeia, The Indian Pharmacopoeia commission, Gaziabad, 2007, 3, 143,252,714.
2. The British Pharmacopoeia British High Commission, Landon, 2009, 1 and 2, 587-77.
3. Mishra P, Gupta Alka, Shah K., Simultaneous estimation of atorvastatin calcium and amlodipine besylate from tablets, 2007; 69: 831-833.
4. Sasmita kumara Acharjya, M. E. Bhanoji Rao, B. V. Ravi Kumar, M. Mathrusri Annapurna, UV Spectrophotometric methods for the determination of in bulk and Zolmitriptan pharmaceutical dosage forms, Journal of Advanced Scientific Research, 2011; 2(3): 0976-9595.
5. www.ich.org/products/guidelines/quality/article/qualityguidelines.html.
6. K.Shah, A.Gupta, P.Mishra; Developed Spectrophotometric Method for Estimation of Nebivolol Hydrochloride and Amlodipine Besylate in Tablets, International Journal of Pharmacy and Pharmaceutical Sciences, 2012; 4(3): 1241-1246.
7. S. Jain Pritam, H. M. Dhakad, S.J. Dhiraj Surana, Area under curve method development and validation for estimation of Amlodipine besylate in bulk drug and tablet dosage form, ACAIJ, 2014; 14(1): [01-04].
8. Varsha R. Galande, K. G. Baheti, S. Indralekha and M. H. Dehghan, Estimation of Amlodipine besylate, Valsartan and hydrochlorthiazide in bulk mixture and tablet by UV Spectrophotometry, Indian Journal of pharmaceutical sciences, 2012, Jan-Feb; 74(1): 18-23.
9. ICH-Guidelines Q2 (R1), Validation of Analytical Procedures: Text and Methodology, (2005).