Jothieswari D. et al. / Vol 4 / Issue 5 / 2014 / 299-306.

International Journal of Pharmaceutical Research & Analysis

e-ISSN: 2249 – 7781
Print ISSN: 2249 – 779X

www.ijpra.com

DEVELOPMENT AND VALIDATION OF UV- SPECTROSCOPIC METHOD FOR AMLODIPINE BESYLATE, OLMESARTAN MEDOXOMIL, HYDROCHLOROTHIAZIDE IN PURE AND TABLET DOSAGE FORM

***Jothieswari D, Sasi Moulika G, Amulya R , Chandra Sekhar G, Nagarjun P, Ravi Chandra Kumar A, Chandraobulreddy B and Bhaskar Reddy K**

Department of Pharmaceutical Analysis, Sri Venkateswara College of Pharmacy, Chittoor, Andhra Pradesh - 508001, India.

ABSTRACT

The objective of the present study to develop and validation of Amlodipine Besylate, Olmesartan Medoxomil, Hydrochlorothiazide in bulk and in combined tablet formulation by UV Spectrophotometric method. Blood pressure lowering drugs such as Amlodipine Besylate, Olmesartan Medoxomil and Hydrochlorothiazide dissolved in methanol (1000µg/ml). The stock solutions were further diluted with distilled water to get 10 µg/ml scanned in the Double beam UV Spectrophotometer. Amlodipine Besylate estimated at 255 nm, 315 nm and 365 nm, Hydrochlorothiazide at 255 nm and 315 nm and Olmesartan Medoxomil at 255 nm were used and the absorbance corrected for interference method was applied. Hence, Hydrochlorothiazide was found at 315 nm and Olmesartan Medoxomil found at 255 nm. Calibration curve was plotted by using concentration versus absorbance. Range of Amlodipine Besylate was 1 – 5 µg/ml. The absorbance of these solutions were measured at 365 nm, 315 nm and 255 nm respectively. Hydrochlorothiazide obeys Beer's law in the range of 2.5 – 12.5 µg/ml and measured at 255 nm and 315 nm. Whereas range of Olmesartan Medoxomil was 4 – 20 µg/ml and measured at 255 nm. Correlation coefficient value of these drugs found to be 0.99992.The amount of Olmat AMH (Amlodipine Besylate, Hydrochlorothiazide and Olmesartan Medoxomil) tablets was found to be 99.78 ± 1.1367, 100.90 ± 0.7190 and 99.88 ± 0.5308 for Amlodipine Besylate, Hydrochlorothiazide and Olmesartan Medoxomil respectively. The % RSD (Relative Standard Deviation) values were found to be 1.1392, 0.7126 and 0.5315 for Amlodipine Besylate, Hydrochlorothiazide and Olmesartan Medoxomil respectively. The % RSD value of intraday and inter day analysis were found to be 1.7430 and 0.8715 for Amlodipine Besylate, 0.8361 and 0.6869 for Hydrochlorothiazide and 0.7288 and 0.6542 for Olmesartan Medoxomil. The accuracy of the method was performed by recovery studies. The percentage recovery was found to be in the range of 100.23–101.27% for Amlodipine Besylate, 99.99 – 100.10% for Hydrochlorothiazide and 99.94 – 100.05% for Olmesartan Medoxomil.

Keywords: UV Spectrophotometric Method, Amlodipine Besylate, Olmesartan Medoxomil, Hydrochlorothiazide.

INTRODUCTION

Amlodipine Besylate, Olmesartan Medoxomil and Hydrochlorothiazide are blood pressure lowering drugs used for the treatment of hypertension. Amlodipine Besylate is 3 – Ethyl – 5 – methyl (±) 2 - [(2 – amino ethoxy) methyl] – 4 - (2 – chloro phenyl) - 1, 4 – dihydro – 6 – methyl - 3, 5 – pyridine dicarboxylate, mono benzene sulphonate [1]. Olmesartan Medoxomil is 4-(1-Hydroxy-1-methylethyl)-2-propyl-1-[[2'-(1H-tetazol-5-yl) [1,1' - bip henyl] -4-yl]methyl]-1H-imidazole-5-carboxylic acid (5-Methyl-2-oxo-1,3-dioxol-4-yl) methyl ester [1]. Hydrochlorothiazide is 6 – chloro - 1, 1 – dioxo - 3, 4 – dihydro - 2H - 1, 2, 4 – benzothiadiazine – 7 – sulfonamide [1]. Most of the pharmaceutical companies are

Corresponding Author:- D. Jothieswari Email:- jothies_82@yahoo.co.in

manufacturing multiple drug formulations to meet the market demand and patient compatibility. The multiple drug formulation analysis plays an important role in the analysis method development, manufacture and therapeutic use of drugs. Most of the pharmaceutical industries do the quantitative chemical analysis to ensure that the raw material used in the final product and thus obtained meet certain specification and to determine how much of each components are present in the final product. Standard analytical procedure for multiple drug formulations may not be available in Pharmacopoeias; hence it is essential to develop newer analytical methods which are simple, accurate, precise, specific, linear and rapid. No methods available for that combination [2-16]. Estimation of multiple drug formulations has advantage that the methods are time consuming, usage of solvent is minimized and analysis of drugs without prior separation from the formulation. UV grades of solvents used for respective determinations and the solvent should be readily available and cheaper. The solvent should be completely extracting the active ingredient from formulation and the developed method validated as per ICH guidelines [17].

MATERIALS AND METHOD

Materials

Drug Samples (Raw material)

Amlodipine Besylate, Olmesartan Medoxomil and Hydrochlorothiazide were obtained as a gift samples from Caplin point, Chennai.

Formulation used

Olmat AMH tablets (Microlabs Limited Unit 3) containing Amlodipine Besylate equivalent to Amlodipine 5 mg, Olmesartan Medoxomil 20 mg and Hydrochlorothiazide 12.5 mg was procured from SSR Pharmacy, West Tambaram, Chennai.

Chemicals and solvents used

Distilled water, Methanol (AR grade), were purchased from LOBAL CHEMICALS, Chennai.

Instruments used

Shimadzu AUX- 220 Digital balance, Anlytical Spectroplus 2060 Double Beam UV-Visible spectrophotometer consists of halogen lamp and deuterium lamp as light source, with silicon photo diode detector.

Method

In the present work an attempt was made to develop and validate simple, precise and accurate method for the estimation of Amlodipine Besylate, Olmesartan Medoxomil and Hydrochlorothiazide in pure form and in combined tablet dosage form by UV spectrophotometry.

Absorbance Correction Method

If the identity, concentration and absorptivity of the absorbing interferences are known, it is possible to calculate their contribution to the total absorbance of a mixture. The concentration of the absorbing component of interest is then calculated from the corrected absorbance (total absorbance minus the absorbance of the interfering substance) in the usual way. The information required for the construction of absorbance corrected for interference is:

- The λmax of the drugs should be found out by using reference standards of the drugs.
- The calibration curve should be plotted for each drug and linearity range should be found out.
- The absorbance values of each drug at the three wave lengths should be measured and their absorptivity values should be calculated.
- At one wavelength, two of the drugs show no absorbance and one drug shows absorbance. Hence the first drug was calculated without any interference.
- In second wavelength, the absorbance corrected for first drug and the second drug was determined.
- At third wavelength, the absorbance corrected for two drugs and the third drug was determined.

The information required is:

a) the absorptivities of AMB at λ_1, λ_2, and λ_3 a_{x_1}, a_{x_2} and a_{x_3} respectively

b) the absorptivities of HCT at λ_2 and λ_3 a_{y_2} and a_{y_3} respectively

c) the absorptivities of OLE at λ_3 a_{z_3} respectively

d) the absorbances of the diluted sample at λ_1, λ_2 and λ_3 A_1, A_2 and A_3 respectively.

Let c_x, c_y and c_z be the concentrations of AMB, OLE and HCT respectively in the diluted sample. Three equations are constructed based upon the fact that at λ_1, λ_2 and λ_3 the absorbance of the mixture is the sum of the individual absorbances of AMB, OLE and HCT.

At λ_1

$$A_1 = a_{x_1} b c_x \quad (1)$$

At λ_2

$$A_2 = a_{x_2} b c_x + a_{y_2} b c_y \quad (2)$$

At λ_3

$$A_3 = a_{x_3} b c_x + a_{y_3} b c_y + a_{z_3} b c_z \quad (3)$$

For measurements in 1cm cells, b=1. Rearrange eq. (1)

$$c_x = \frac{A_1}{a_{x_1}}$$

Substituting for c_x in eq.(2) get c_y and Substituting for c_x and c_y in eq.(3) get c_z.

Selection of solvent

The solubility of drugs was determined in a variety of solvents as per Indian pharmacopoeia standards. Solubility was carried out in polar to non-polar solvents. From the solubility table the common solvent was found to be methanol and further dilutions were made up with distilled water for the analysis of AMB, OLE and HCT for proposed methods.

Preparation of standard stock solution

50mg of AMB, 50 mg OLE and 50 mg HCT raw materials were weighed and transferred into 50 ml volumetric flasks separately and dissolved in methanol and made up to the volume with more methanol. These solutions were observed to contain 1000 μg/ml.

Selection of wavelengths for estimation and stability studies

The selection of wavelengths for the estimation Amlodipine Besylate, Olmesartan Medoxomil and Hydrochlorothiazide, the stock solutions were further diluted with distilled water to get 10 μg/ml of each and the solutions were scanned between 200 – 400 nm by using distilled water as blank. From the overlain spectra, by the observation of spectral characteristics of Amlodipine Besylate, Olmesartan Medoxomil and Hydrochlorothiazide, the absorbance correction method was selected. The wavelengths selected were 255 nm, 315 nm and 365 nm. The absorbance of Olmesartan Medoxomil and Hydrochlorothiazide is zero at 365 nm. Hence, for the analysis of Amlodipine Besylate without any interference was done at 365 nm. At 315 nm, the absorbance of Olmesartan Medoxomil is zero. But Amlodipine Besylate and Hydrochlorothiazide showed absorbance from that Hydrochlorothiazide amount was found. To estimate the amount of Amlodipine Besylate at 255 nm, 315 nm and 365 nm, Hydrochlorothiazide at 255 nm and 315 nm and Olmesartan Medoxomil at 255 nm were used and the absorbance corrected for interference method was applied. Hence, the amount of Hydrochlorothiazide was found at 315 nm and Olmesartan Medoxomil found at 255 nm. The Stability was performed by measuring the absorbance of same solution at different time intervals. It was observed that Amlodipine Besylate, Olmesartan Medoxomil and Hydrochlorothiazide in methanol followed by distilled water were stable for more than 4 hours at all the selected wavelengths.

Preparation of calibration graph

The standard stock solutions of Amlodipine Besylate equivalent to Amlodipine 25 mg, 100 mg of Olmesartan Medoxomil and 62.5 mg of Hydrochlorothiazide raw materials were weighed and transferred into 50 ml volumetric flasks separately, added sufficient amount of methanol to dissolve the substance and made up to the volume with more methanol. These solutions were further diluted 10 ml to 50 ml with distilled water. These solutions were observed to contain 100 μg/ml of Amlodipine, 250 μg/ml Hydrochlorothiazide and 400 μg/ml Olmesartan Medoxomil. The aliquots of stock solution of AMB, OLE and HCT (1 – 5 ml) were transferred into 100 ml volumetric flasks and made up to the volume with distilled water. The absorbance of different concentration solutions were measured at 255 nm, 315 nm and 365 nm for AMB, 255 nm and 315 nm for HCT and 255nm for OLE. The calibration curve was plotted at their corresponding wavelengths. AMB was linear with the concentration range of 1 – 5 μg/ml, OLE showed the linearity in the range of 4 – 20 μg/ml and HCT was linear in the concentration range of 2.5 – 12.5 μg/ml at their respective wavelengths.

Quantification of formulation

Twenty tablets of formulation Olmat AMH (containing Amlodipine Besylate equivalent to Amlodipine 5 mg, Olmesartan Medoxomil 20 mg and Hydrochlorothiazide 12.5 mg) were weighed accurately. The average weight of each tablet was found and powdered. The tablet powder equivalent to 100 mg of Olmesartan Medoxomil was weighed and transferred into 50 ml volumetric flask and added a minimum quantity of methanol to dissolve the substance and made up to the volume with the same (2000 μg/ml). The solution was sonicated for 15 minutes, centrifuged for 10 minutes at 100 rpm and filtered through Whatmann filter paper No. 41. From the clear solution, further dilutions were made by diluting 10 ml to 50 ml with distilled water and further diluted 3 ml to 100 ml with distilled water to obtain 12 μg/ml solution of Olmesartan Medoxomil which is also contains 3 μg/ml of Amlodipine and 7.5 μg/ml of Hydrochlorothiazide theoretically. The absorbance measurements were made 6 times for the formulation at 255 nm, 315 nm and 365 nm. The Amlodipine Besylate can be determined at 365 nm without interference. By using absorptivity of Amlodipine Besylate at 315 nm the concentration of Hydrochlorothiazide can be determined at 315 nm. From the absorptivity values of Amlodipine Besylate and Hydrochlorothiazide at 255 nm the absorbance was corrected for interference and the amount of Olmesartan Medoxomil can be determined at 255 nm.

Recovery studies

The recovery experiment was done by adding known concentrations of Amlodipine, Olmesartan Medoxomil and Hydrochlorothiazide raw material to the preanalyzed formulation. 100 mg of Olmesartan Medoxomil, 25 mg of Amlodipine and 62.5 mg of Hydrochlorothiazide dissolved in 50 ml of methanol and further 5 ml diluted to 50 ml with water. To 100 mg equivalent of Olmesartan Medoxomil in formulation dissolved in 50 ml of methanol and the solution was

sonicated for 15 minutes. After sonication, centrifuged for 15 minutes at 100 rpm, the solution was filtered through Whatmann filter paper No. 41. From the solution, 3.0 ml of clear filtrate was transferred into a series of 100 ml volumetric flasks and added 1ml, 2 ml and 3 ml of raw material solution and made up to the volume with distilled water. The absorbances of the resulting solutions were measured at their selected wavelengths for determination of Amlodipine, Olmesartan Medoxomil and Hydrochlorothiazide respectively. The amount of each drug recovered from the formulation was calculated for all the drugs by absorbance correction method. The procedure was repeated for three times for each concentration.

Results

Linearity

A calibration curve was plotted between concentration and absorbance. Amlodipine was linear with the concentration range of 1 – 5 μg/ml at 255 nm, 315 nm and 365 nm. Olmesartan Medoxomil showed the linearity in the range of 4 – 20 μg/ml at 255 nm and Hydrochlorothiazide was linear in the concentration range of 2.5 - 12.5 μg/ml at 255 nm and 315 nm.

Accuracy (Recovery studies)

Accuracy of the method was confirmed by recovery studies. To the pre analyzed formulation, a known concentration of raw materials of Amlodipine, Olmesartan Medoxomil and Hydrochlorothiazide were added and the procedure was followed as per the analysis of formulation. The amount of each drug recovered was calculated. This procedure was repeated for three times for each concentration. The % RSD was calculated.

Precision

The repeatability of the method was confirmed by the analysis of formulation was repeated for 6 times with the same concentration. The amount of each drug present in the tablet formulation was calculated. The % RSD was calculated. The intermediate precision of the method was confirmed by intraday and inter day analysis i.e. the analysis of formulation was repeated three times in the same day and on three successive days. The amount of drugs was determined and % RSD also calculated.

LOD and LOQ

The linearity study was carried out for six times. The LOD and LOQ were calculated by using the average of slope and standard deviation of intercept.

DISCUSSION AND CONCLUSION

A simple, accurate, rapid and precise absorbance correction method was developed and validated. The solvent methanol was used to dissolve the drugs followed by further dilution with distilled water was chosen as a common solvent for the estimation of Amlodipine Besylate, Olmesartan Medoxomil and Hydrochlorothiazide.

The sample solutions of 10 μg/ml of Amlodipine Besylate equivalent to Amlodipine, Olmesartan Medoxomil and Hydrochlorothiazide in methanol followed by distilled water prepared individually and the solutions were scanned in UV region in the wavelength range from 200 to 400 nm by using distilled water as blank. The overlain spectrum of mixture of Amlodipine Besylate, Olmesartan Medoxomil and Hydrochlorothiazide was recorded as shown in Figure 1. From the spectrum, 365 nm was selected for the estimation of Amlodipine Besylate without any interference. Because of both Hydrochlorothiazide and Olmesartan Medoxomil have zero absorbance at 365 nm. At 315 nm, the absorbance of Olmesartan Medoxomil is zero. But Hydrochlorothiazide and Amlodipine Besylate showed absorbance. To estimate the amount of Hydrochlorothiazide at 315 nm by absorbance corrected for interference method was applied. Hence, the amount Hydrochlorothiazide was found. At 255 nm, these three drugs were showed the absorbance. To estimate the amount of Olmesartan Medoxomil, the absorbance of Hydrochlorothiazide and Amlodipine Besylate were corrected for interference at 255 nm.

The different aliquots of Amlodipine Besylate in methanol followed by distilled water were prepared in the concentration range of 1 – 5 μg/ml. The absorbances of these solutions were measured at 365 nm, 315 nm and 255 nm respectively. Different aliquots of Hydrochlorothiazide in methanol followed by distilled water were prepared in the concentration range of 2.5 – 12.5 μg/ml. The absorbances of solution were measured at 255 nm and 315 nm. Different aliquots of Olmesartan Medoxomil in methanol followed by distilled water were prepared in the concentration range of 4 – 20 μg/ml. The absorbance of these solutions were measured at 255 nm. The preparation of calibration curve was repeated for six times for each drug at their selective wavelengths. The optical parameters like, sandell's sensitivity, molar absorptivity, correlation coefficient, slope, intercept, LOD, LOQ and standard error were calculated. The correlation coefficient for all the three drugs at the selected wavelength was found to be above 0.999. This indicates that all the drugs obey Beer's law in the selected concentration range. Hence the concentrations were found to be linear. The optical characteristics of three drugs at their selective wavelengths were shown in Table 1 for Amlodipine Besylate, Table 2 for Hydrochlorothiazide and Table 3 for Olmesartan Medoxomil.

Olmat AMH tablets containing Amlodipine Besylate equivalent to Amlodipine 5 mg, Olmesartan Medoxomil 20 mg and Hydrochlorothiazide 12.5 mg was selected for analysis. The nominal concentration of Olmesartan Medoxomil from formulation (12 μg/ml) was prepared and also contains 3 μg/ml of Amlodipine Besylate and 7.5 μg/ml of Hydrochlorothiazide, the absorbance's of

the solution were measured at their respective wavelengths. The percentage label claim present in tablet formulation was found to be 99.78 ± 1.1367, 100.90 ± 0.7190 and 99.88 ± 0.5308 for Amlodipine Besylate, Hydrochlorothiazide and Olmesartan Medoxomil respectively. The amount present in tablet formulation was in good concord with the label claim and the % RSD values were found to be 1.1392, 0.7126 and 0.5315 for Amlodipine Besylate, Hydrochlorothiazide and Olmesartan Medoxomil respectively. The low % RSD values indicate that the method has good precision. The results of analysis are shown in Table 5.

Table 1. Optical Characteristics of Amlodipine Besylate by Absorbance Correction Method

Parameters	At 365 nm*	At 315 nm*	At 255 nm*
Beer's law limit (µg/ ml)	1 - 5	1 – 5	1 – 5
Molar absorptivity ($L\ mol^{-1}\ cm^{-1)}$	11976.6119	8527.6537	10562.9126
Sandell's sensitivity (µg/ cm^2/ 0.001 A.U)	0.048203	0.071243	0.055874
Correlation coefficient (r)	0.99992	0.999262	0.999875
Regressionequation (y = mx + c)	y = 0.021114 x + 0.000048	y = 0.015057 x + 0.001629	y = 0.018624 x + 0.000024
Slope (m)	0.021114	0.015057	0.018624
Intercept (c)	0.000048	0.001629	0.000024
LOD (µg/ ml)	0.023535	0.079596	0.027601
LOQ (µg/ ml)	0.071319	0.241199	0.083638
Standard Error	0.000049	0.000287	0.000041

* Mean of six observations

Table 2. Optical Characteristics of Hydrochlorothiazide By absorbance Correction Method

Parameters	At 315 nm*	At 255 nm*
Beer's law limit (µg/ ml)	2.5 – 12.5	2.5 – 12.5
Molar absorptivity ($L\ mol^{-1}\ cm^{-1)}$	5076.277959	8172.915740
Sandell's sensitivity (µg/ cm^2/ 0.001 A.U)	0.060447	0.036546
Correlation coefficient (r)	0.999951	0.99999
Regressionequation (y = mx + c)	y = 0.017072 x - 0.000230	y = 0.02745 x - 0.000016
Slope (m)	0.017072	0.02745
Intercept (c)	-0.000230	-0.000016
LOD (µg/ ml)	0.108194	0.02005
LOQ (µg/ ml)	0.327860	0.06075
Standard Error	0.000219	0.000071

* Mean of six observations

Table 3. Optical Characteristics of Olmesartan Medoxomil By Absorbance Correction Method

Parameters	At 255 nm*
Beer's law limit (µg/ ml)	4 - 20
Molar absorptivity (L mol-1 cm-1)	16388.4099
Sandell's sensitivity(µg/ cm2/ 0.001 A.U)	0.0342
Correlation coefficient (r)	0.999996
Regressionequation (y = mx + c)	y = 0.029338 x + 0.000008
Slope (m)	0.029338
Intercept (c)	0.000008
LOD (µg/ ml)	0.030567
LOQ (µg/ ml)	0.092627
Standard Error	0.0001

* Mean of six observations

Table 4.Quantification of Formulation (OLMAT AMH) By Absorbance Correction Method

Drug	Sample No.	Labeled amount (mg/ tab)	Amount found (mg/ tab)*	Percentage Obtained*	Average (%)	S.D	% R.S.D.	S.E.
AMB	1	5	4.98	99.53	99.78	1.1367	1.1392	0.4641
	2	5	4.90	98.02				
	3	5	5.05	101.04				
	4	5	5.05	101.04				
	5	5	4.98	99.53				
	6	5	4.98	99.53				
HCT	1	12.5	12.56	100.46	100.90	0.7190	0.7126	0.2935
	2	12.5	12.72	101.78				
	3	12.5	12.49	99.93				
	4	12.5	12.69	101.50				
	5	12.5	12.66	101.25				
	6	12.5	12.56	100.46				
OLE	1	20	19.94	99.72	99.86	0.5308	0.5315	0.2167
	2	20	19.89	99.46				
	3	20	20.14	100.70				
	4	20	19.88	99.42				
	5	20	19.91	99.53				
	6	20	20.07	100.33				

* Mean of six observations

Table 5. Intra Day and Inter Day Analysis of Formulation (OLMAT AMH) by Absorbance Correction Method

Drug	Sample No.	Labeled amount (mg/ tab)	Percentage obtained*		S.D		% R.S.D.	
			Intra day	Inter day	Intra day	Inter day	Intra day	Inter day
AMB	1	5	98.02	101.04	1.7436	0.8718	1.7430	0.8715
	2	5	101.04	99.53				
	3	5	101.04	99.53				
Mean			**100.03**	**100.03**				
HCT	1	12.5	99.93	100.46	0.8436	0.6955	0.8361	0.6869
	2	12.5	101.50	101.78				
	3	12.5	101.25	101.50				
Mean			**100.89**	**101.25**				
OLE	1	20	99.46	99.72	0.7277	0.6539	0.7288	0.6542
	2	20	100.70	99.46				
	3	20	99.42	100.70				
Mean			**99.86**	**99.96**				

* Mean of Three Observations

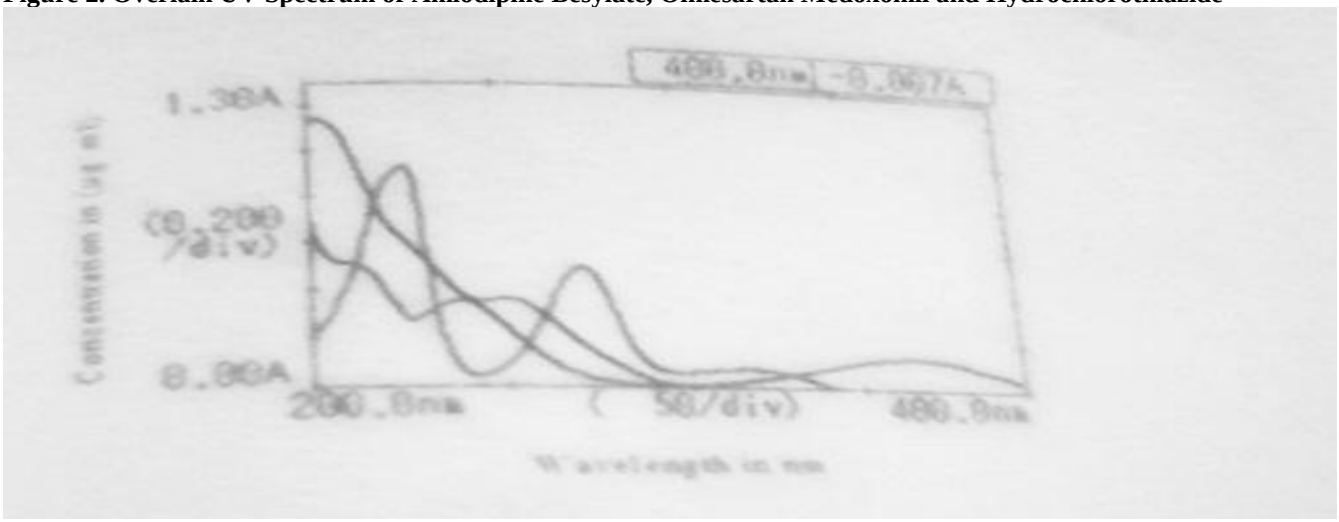
Table 6. Recovery Analysis of Formulation (OLMAT AMH) By Absorbance Correction Method

Drug	Sample No.	Amount present (µg/ ml)	Amount added (µg / ml)	Amount estimated* (µg / ml)	Amount recovered (µg / ml)	% Recovery*	S.D	% R.S.D	S.E.
AMB	1	2.9935	0.5110	3.5110	0.5175	101.27	0.5205	0.5168	0.3005
	2		1.0012	4.0011	1.0076	100.63			
	3		1.5021	4.4992	1.5057	100.23			
					Mean	100.7170			
HCT	1	7.5677	1.2573	8.8249	1.2572	99.99	0.0606	0.0605	0.0350
	2		2.5081	10.0785	2.5108	100.10			
	3		3.7512	11.3196	3.7519	100.01			
					Mean	100.0395			
OLE	1	11.9836	2.0043	13.9891	2.0055	100.05	0.0602	0.0602	0.0347
	2		4.0061	15.9873	4.0037	99.94			
	3		6.0014	17.9854	6.0018	100.01			
					Mean	100.0033			

* Mean of Three Observations

Figure 1. Chemical structure of Amlodipine Besylate, Olmesartan Medoxomil and Hydrochlorothiazide

Figure 2. Overlain UV Spectrum of Amlodipine Besylate, Olmesartan Medoxomil and Hydrochlorothiazide



Further the precision of the method was confirmed by Intraday and Inter day analysis. The analysis of formulation was carried out for three times in the same day and one time in the three consecutive days. The % RSD value of intraday and inter day analysis were found to be 1.7430 and 0.8715 for Amlodipine Besylate, 0.8361 and 0.6869 for Hydrochlorothiazide and 0.7288 and 0.6542 for Olmesartan Medoxomil. The results of analysis are shown in Table 6. The results showed that the precision of the method was confirmed.

The accuracy of the method was performed by recovery studies. To the pre analyzed formulation, a known quantity of Hydrochlorothiazide, Olmesartan Medoxomil and Amlodipine Besylate raw material solutions were added at different levels. The absorbance of the solutions was measured and the percentage recovery was calculated. The percentage recovery was found to be in the range of 100.23– 101.27% for Amlodipine Besylate, 99.99 – 100.10% for Hydrochlorothiazide and 99.94 – 100.05% for Olmesartan Medoxomil. The low % RSD value for three drugs indicates that this method is very accurate.

The present study concluded that one simple, rapid, precise and accurate spectrophotometric method was developed and validated for the estimation of Amlodipine Besylate, Olmesartan Medoxomil and Hydrochlorothiazide in pure form and in tablet dosage form.

ACKNOWLEDGMENTS

The authors are grateful to management, Sri Venkateswara College of Pharmacy, Chittoor providing facilities to carry out this work. Also thank to Caplin point, Chennai providing the gift samples.

REFERENCES

1. www.Rx list.com/www.Drug profile.com
2. Anandakumar K, Jayamariappan M. Absorption correction method for the simultaneous Estimation of Amlodipine Besylate, Olmesartan and hydrochlorothiazide in bulk and in combined tablet dosage form. .*International Journal of Pharmacy and Pharmaceutical Sciences*, 3 (1), 2011, 23-27.

3. Bhatt LR, Vora AT, Godge RK, Damle MC. Simultaneous Estimation of Nebivolol Hydrochloride and Amlodipine Besylate in Bulk and Combined Tablet Dosage form by Ultraviolet Spectrophotometry. *Indian Drugs*, 44 (12), Dec 2007, 915 - 919.
4. Bhusari KP, Khedekar PB, Seema Dhole, Banode VS. Derivative andQ - analysis spectrophotometric methods for estimation of hydrochlorothiazide and olmesartan medoxomil in tablets. *Indian Journal of Pharmaceutical Sciences*, 71 (5), Dec 2009, 505 - 508.
5. DP Kardlie, HH Patel and M R Patel. Simultaneous Estimation of Amlodipine Besylate and Olmesartan Medoxomil Drug Formulations By HPLC And UV-Spectrophotometric Methods. *International Journal of Pharmaceutical and Applied Sciences*, 2 (1), 2011, 23-34.
6. GopalGarg, ShailendraSaraf, SwarnlataSaraf. Development and Validation of Simultaneous Estimation of Enalapril Maleate and Amlodipine Besylate in Combined Dosage Forms. *Trends in Applied Sciences Research*, 3(3), 2008, 278-284.
7. Bagyalakshmi J, Sincy Mary Philip, TK Ravi. Development of UV spectroscopic method for the estimation of s(-) Amlodipine and Hydrochlorothiazide in dosage forms by simultaneous equation method. *Scholars Research Library* Der PharmaChemica, 3(3), 2011, 246-252 *Available* from: www.derpharmachemica.com.
8. Kakde RB, Kotak VH, Barsagade AG, Chaudhary NK, Kale DL. Spectrophotometric Method for Simultaneous Estimation of Amlodipine Besylate and BisoprololFumarate in Pharmaceutical Preparations. *Research Journal of Pharmacy and Technology*, 1 (4), 2008, 513- 515.
9. MehulkumarRamesh, Vinaykumar, R Srinivas, and Prakash V Diwan. Simultaneous Spectroscopic Estimation of Amlodipine Besylate and Olmesartan Medoximil in Tablet Dosage Form. *Asian J. Research Chem*, 2(2), 2011, 127-131.
10. Neela Manish Bhatia, Snehal Jawaharlal Deshmane, HarinathNivrutti More, PrafullaBalkrishnaChoudhari. Simultaneous Spectrophotometric Estimation of the Amlodipine Besylate and Hydrochlorothiazide. *Asian Journal of Research in Chemistry*, 2 (4), Oct – Dec 2009, 393 - 397.
11. Pallavi Salve, DeepaliGharge, RupaliKirtawade, PandurangDhabale, KishorBurade. Simple Validated Spectroscopic Method for Estimation of Amlodipine Besylate from Tablet Formulation. *Asian Journal of Research in Chemistry*, 2 (4), Oct – Dec 2009, 553 - 555.
12. Pandurang N Dhabale and Sunita R Bhagade. Simultaneous UV Spectrophotometric Methods for Estimation of Amlodipine Besilate and Olmesartan Medoxomil in Tablet Dosage Form. *Journal of Chemical and Pharmaceutical Research*, 3(2), 2011, 650-656.
13. PatilPournima S, ChivateNiranjan D, Shindeshubhangi S, More harinath N, Pishwikarsachin A. Simulteneous determination of olmesartan medoxomil and amlodipine Besylate from tablet formulation by multiwavelength method. *International Journal of ChemTec Research*, 3(1), 2011, 267-273.
14. PermenderRathee, SushilaRathee, Shyama Thakur, Vikash Kumar. Simultaneous Estimation of Amlodipine Besylate and Atenolol as A.P.I. and in Tablet Dosage Forms by Vierodt's Method using UV Spectrophotometry. *International Journal of Chem Tech Research*, 2 (1), 2010, 62 - 68.
15. Pournima S Patil, Pramodini D Kulkarni, Mallappa S Burkul, Harinath N More, Sachin A Pishawikar.Simultaneous estimation of Amlodipine Besylate and Olmesartan medoxomil by First order Derivative Spectroscopy from Tablet. *International Journal of PharmTech Research*, 3(2), 2011, 668-675.
16. Sonali P Mahaparale1, Yogesh S Andhale1, Vishwajeet H Sonawane1, Indrajeet D Gonjari. Simultaneous estimation of olmesartan medoxomil and hydrochlorothiazide in tablet dosage form by UV- spectrophotometric method. *International journal of pharmaceutical research and development*, 3(6), 2011, 242 – 247.
17. Code Q2A, Text on Validation of Analytical Procedures. ICH Harmonized Tripartite Guidelines, Geneva, Switzerland, 27th October, 1994, 1 - 5.