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Simultaneous estimation of amlodipine besylate and olmesartan medoxomil drug formulations by HPLC and UV-spectrophotometric methods

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Abstract:

One UV- derivative spectrophotometric and one reverse phase high performance liquid chromatography methods have been developed for the simultaneous estimation of amlodipine besylate, Olmesartan Medoxomil in tablet dosage form. The first UV derivative spectrophotometric method was a determination using the simultaneous equation method at 239.0 and 256.0 nm over the concentration range 15 and 15 µg/ml for amlodipine besylate, Olmesartan Medoxomil , respectively. In reverse phase high performance liquid chromatography analysis is carried out using 0.05 M Pot.dihydrogen phosphate : ACN (50:50 v/v), PH (6.8)as the mobile phase and C18 bonded phase i.e. CAPCELL PACK Col No. AKAD 05395 (4.6 mm X 250mm) with particle size 5µm as stationary phase with detection wavelength of 230 to 260 nm linearity was obtained in the concentration range of 5 and 20 µg/ml for amlodipine besylate, Olmesartan Medoxomil, respectively. Both UV-spectrophotometric and reverse phase high performance liquid chromatography methods were statistically validated and can be used for analysis of combined dose tablet formulation containing amlodipine besylate, Olmesartan Medoxomil.

Keywords: *Amlodipine besylate, Olmesartan Medoxomil, Reverse phase high performance liquid chromatography, Simultaneous equation method, area under curve method.*

Introduction:

Methods of multicomponent analysis using uv- visible spectrophotometer:

Simultaneous equation method, Absorption ratio or q- analysis method, Simultaneous equation using area under curve method, Derivative spectroscopy, Two-wavelength method, Using multicomponent mode, Absorbance correction method, Geometric correction method, Orthogonal polynomial method, Difference spectrophotometry.

Derivative Spectroscopy:

The UV-Visible spectra consist of increasing or decreasing absorbance as a function of wavelength, A= f (λ): Zero order. In derivative spectroscopy the first or higher derivative of absorbance or transmittance with respect to wavelength is recorded versus the wavelength.

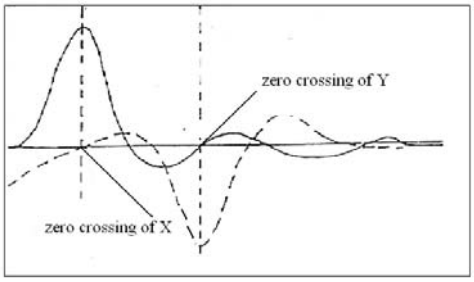


Fig: Overlain Spectra of X and Y Drugs

[dA/dλ]= f'(λ) : First order,

[d^2A / $d\lambda^2$]= f''(λ) : Second order

Advantages of derivative spectroscopy:

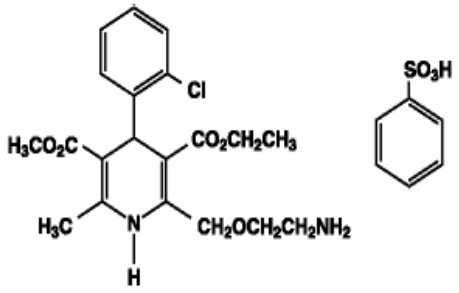
Compounds in which absorption spectra overlap and cannot be separated by conventional methods, are easily recorded. In quantitative analysis, selectivity and sensitivity are increased. High Performance Liquid Chromatography High performance liquid chromatography (HPLC) is the fastest growing analytical technique for the analysis of drugs. Its simplicity, high specificity, and wide range of sensitivity make it ideal for the analysis of many drugs in both dosage forms and biological fluids. The technique is based on the same modes of separation as classical column chromatography, i.e. adsorption, partition, ion exchange and gel permeation, but it differs from column chromatography in that the mobile phase is pumped through the packed column under high pressure.

The present study aims at UV-Visible spectrophotometric and HPLC method for the estimation of AMB and OLM in bulk and formulated tablet dosage form. A UV-Visible spectrophotometric method was developed for the estimation of OLM in pure and formulated tablet dosage form. This is a simple, sensitive, standard, reproducible method for the quality control

and assurance of AMB and OLM. The methods were validated as per ICH guidelines for Tablet assay. Precision. Accuracy (Recovery Test). Suitable statistical tools were used to compare the developed methods.

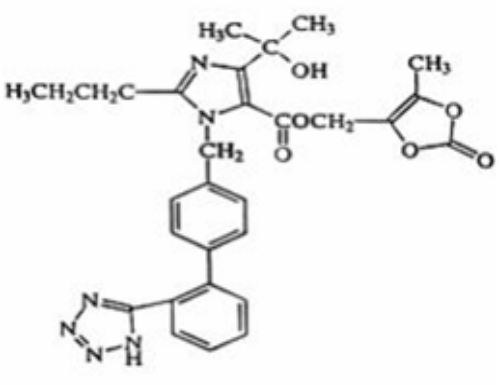
Drug Profile:

Amlodipine besylate:
It is the besylate salt of amlodipine, a long-acting calcium channel blocker.
Structure :



Molecular formula :
$C_{20}H_{25}C_lN_2O_5 \bullet C_6H_6O_3S$
Molecular weight : 408.8760

Olmesartan besylate:
It belongs to the class of medicines called angiotensin II receptor antagonists to treat high blood pressure.
Structure :



Molecular formula : $C_{29}H_{30}N_6O_6$
Molecular weight : 558.5851

Experimental Method:

1. Spectrophotometric Method:-

First Derivative Method

Materials:
Standard drugs and their Suppliers:
Amlodipine Besylate -Ajantha Phamaceutical Ltd. Aurangabad
Olmesartan Medoxomil -Ajantha Phamaceutical Ltd. Aurangabad

Tablet formulation:
Brand Name - Pinom A
Each film coated tablet contains:
Olmesartan Medoxomil ……..… 20 mg
Amlodipine Besylate ……..... 5 mg

Instrument:
A Shimadzu 1700 UV (Shimadzu, Japan) spectrophotometer with 1 cm matched quartz cells was used for the estimation.

Determination of λmax:-
Preparation of standard solutions:
AMB – 15 µg/ml in Methanol, exhibit λ_{max} at 239.0 nm.
OLM – 15 µg/ml in Methanol, exhibit λ_{max} at 256.0 nm.
The spectra display possible overlapping, hence the simultaneous estimation of AMB and OLM by conventional UV spectrophotometry becomes difficult.
The experiments showed that the first-derivative spectra of AMB and OLM were simple and gave results with suitable precision

Drug	Zero crossing point
AMB	237 nm
OLM	259 nm

The absorbance was measured after every 10 min. The solutions were found to be stable.
Table : Stability Study of Drugs in A Selected Solvent

Sr.No.	Time (Min)	Absorbance	
		AMB	OLM
1	10	0.3572	0.3820
2	20	0.3573	0.3822
3	30	0.3571	0.3821
4	40	0.3574	0.3822
5	50	0.3572	0.3820
6	60	0.3570	0.3821

Fig: zero crossing point of AMB

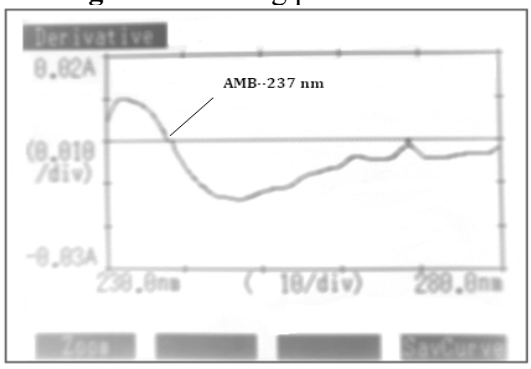


Fig: Zero crossing point of OLM

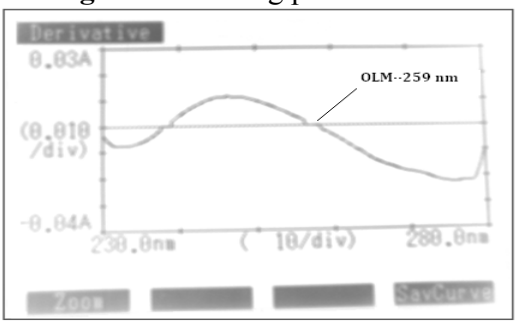
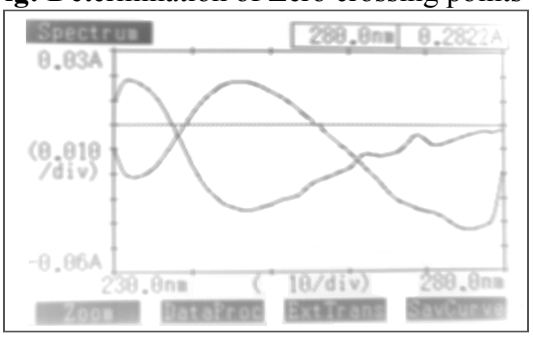


Fig: Determination of Zero crossing points



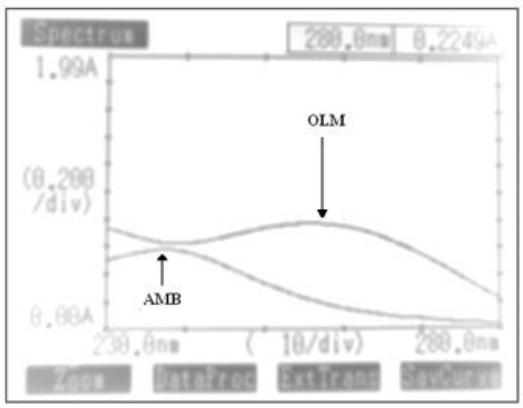
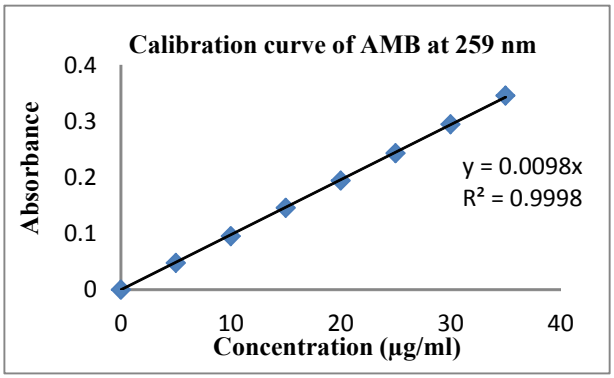


Table : Standard Calibration Table for AMB and OLM by first derivative method.

Sr. No.	Amlodipine Besylate		Olmesartan Medoxomil	
	Conc (µg/ml)	Absorbance* at 259 nm	Conc. (µg/ml)	Absorbance* at 237 nm
1	0.0	0.0	0.0	0.00
2	5.0	0.0475	5.0	0.2383
3	10.0	0.0955	10.0	0.4498
4	15.0	0.1458	15.0	0.6582
5	20.0	0.1945	20.0	0.8896
6	25.0	0.2435	25.0	1.0984
7	30.0	0.2951	30.0	1.3088
8	35.0	0.3460	35.0	1.5186
9			40.0	1.6959

*Mean of three determinations.

Fig: Optical Parameters for the Calibration Curve



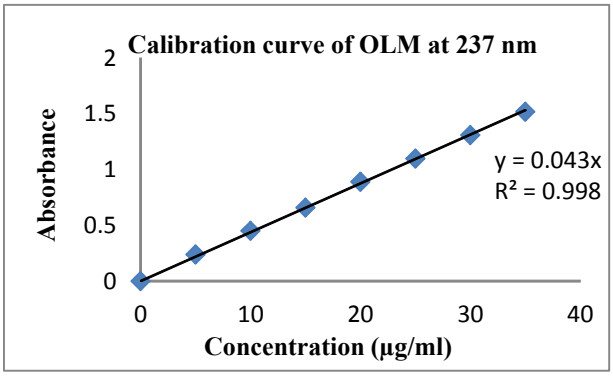


Table: Showing linerity of AMB and OLM.

Parameter	**AMB**	**OLM**
Linearity range (µg/ml)	5-35	5-40
Slope ± SD	$0.009 \pm 0.03162 \times 10^{-2}$	$0.043 \pm 0.2881 \times 10^{-2}$
Intercept ± SD	0	0
Regression coefficient (r^2) ± S.D	$0.999 \pm 0.08367 \times 10^{-2}$	$0.998 \pm 0.933 \times 10^{-2}$

Fig.: Showing linerity of AMB.

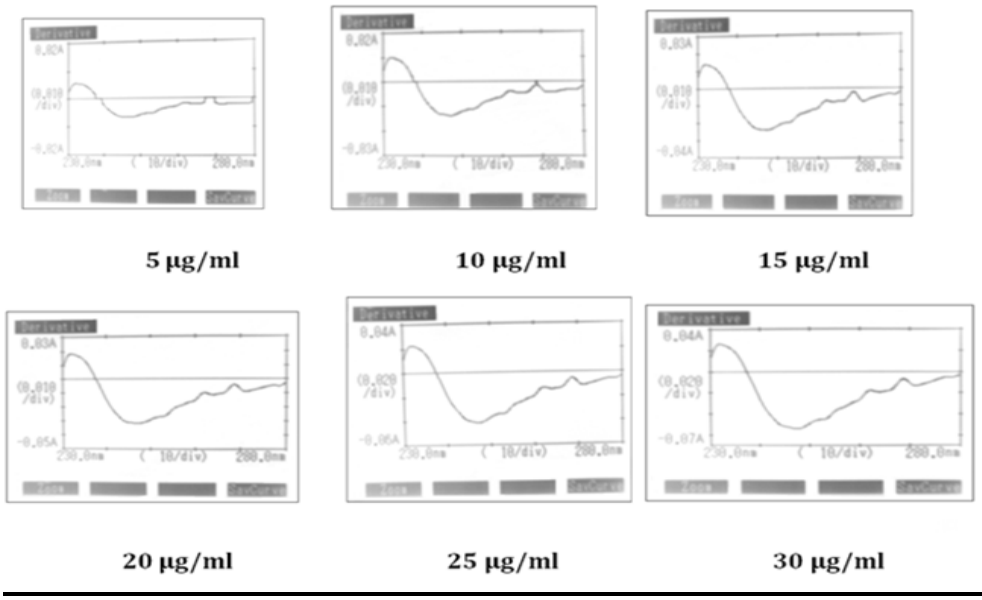


Fig.: Showing linerity of AMB and OLM.

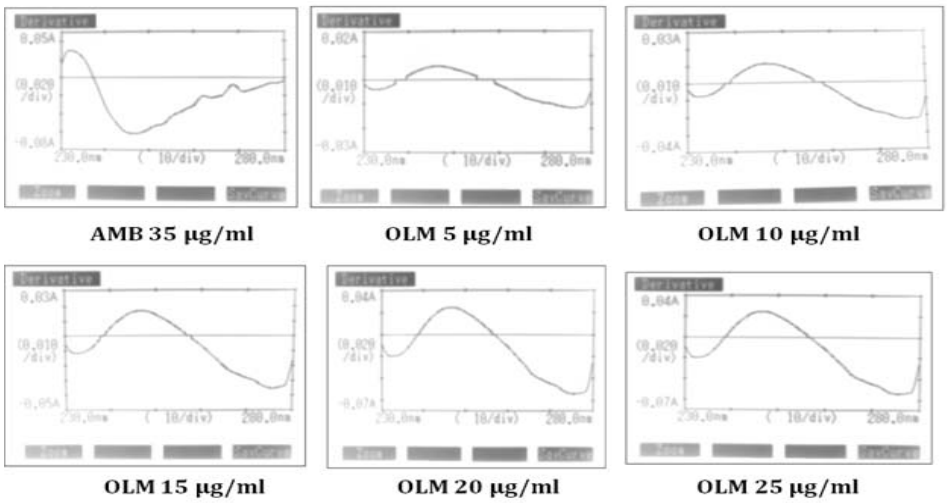


Table: The results and statistical parameters for tablet analysis

Drug	Label Claim(mg/tab)	Amount Found (mg/tab)	% of Label Claim	Mean	SD
AMB	5.00	5.05	101.00	100.13	0.5164
	5.00	5.01	100.20		
	5.00	4.99	99.80		
	5.00	4.99	99.80		
	5.00	4.98	99.60		
	5.00	5.02	99.40		
OLM	20.00	19.98	99.90	99.90	0.2569
	20.00	19.99	99.95		
	20.00	20.01	100.05		
	20.00	19.95	99.75		
	20.00	19.90	99.50		
	20.00	20.05	100.25		

Validation of proposed method:-

Estimation of drug from dosage form:
(tablet assay study)

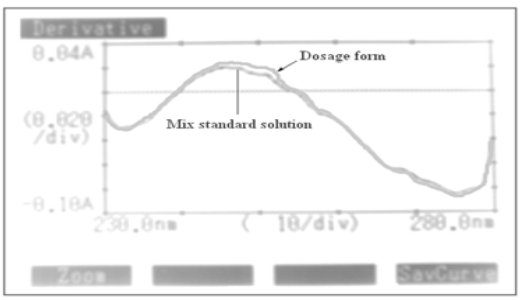
Tab: Pinom-A (Lupin Ltd., Mumbai, India)

AMB: 5 mg

OLM: 20 mg

A quantity of powder sample equivalent to 50 mg of AMB and 200 mg OLM was taken in a volumetric flask and dissolved in methanol. Further dilutions were made to get concentration of 5 µg/ml of AMB and 20 µg/ml of OLM. These concentrations were scanned at different wavelengths i.e. 259 nm and 237 nm and in derivative mode with n=2.

First derivative overlain spectrum of mix standard stock solution and drug from dosage form



Accuracy Study (Recovery Test):

Accuracy of the method was studied by recovery experiments. The recovery experiments were performed by adding known amounts to tablet. The recovery was performed at three levels, 80, 100 and 120% of AMB and OLM standard concentration. Three samples were prepared for each recovery level. The solutions were then analyzed, and the percentage recoveries were calculated by using formula;

$$\% \text{ Recovery} = \frac{\text{Observed amount of compound in Sample}}{\text{Amount of all compound present in Sample}} \times 100$$

Table: Results of accuracy parameter by first derivative method.

Drug	Level of recovery	% Recovery*	SD	CV
AMB	80	99.446	0.6605	0.6641
	100	99.506	0.6238	0.6268
	120	99.977	0.9118	0.9120
OLM	80	99.808	0.2349	0.2353
	100	99.902	0.05506	0.0506
	120	100.036	0.06337	0.0636

***Mean Three Determination**

Table: Determination of Precision by first derivative method for AMB and OLM

Sample Number	Assay Of AMB as % of labeled amount	
	Analyst-I (Intra-day precision)	Analyst-II (Intra-day precision)
1	99.76	99.83
2	99.62	100.23
3	100.12	99.16
4	99.51	99.89
5	99.02	99.18
6	99.06	100.14
Mean	99.64	99.73
SD	0.3720	0.5022
CV	0.3741	0.5035

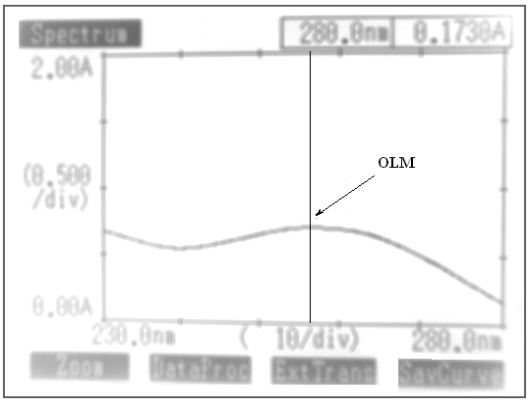
Sample Number	Assay Of OLM as % of labeled amount	
	Analyst-I (Intra-day precision)	Analyst-II (Intra-day precision)
1	99.42	99.70
2	99.72	99.32
3	99.48	99.47
4	99.10	99.88
5	99.20	99.25
6	100.12	99.98
Mean	99.50	99.60
SD	0.3713	0.3001
CV	0.3731	0.3013

UV spectrophotometric method:-
(For estimation of olmesartan medoxomil in tablet dosage forms)

Determination of λ max

1.0 ml of standard stock solution of OLM 10 ml volumetric flask and the volume was adjusted to the mark with same solvent to obtain the solution of concentration 10 µg/ml. The solution was scanned in the UV range 230 - 280 nm the λ max was found to be 256 nm. The spectrum of OLM was recorded in following Fig.

Zero order spectra of OLM



Standard stock solution of OLM 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0 ml were transferred to eight separate 10 ml volumetric flasks and volume were made up to the mark with methanol to obtain concentrations 5, 10, 15, 20, 25, 30, 35, 40 µg/ml and calibration curve was constructed.

Table: Standard Calibration Table for OLM at 256 nm.

Sr. No.	Concentration of OLM (µg/ml)	Absorbance at 256 nm
1	5.0	0.1928
2	10.0	0.3820
3	15.0	0.5663
4	20.0	0.7456
5	25.0	0.9485
6	30.0	1.0950
7	35.0	1.320
8	40.0	1.501

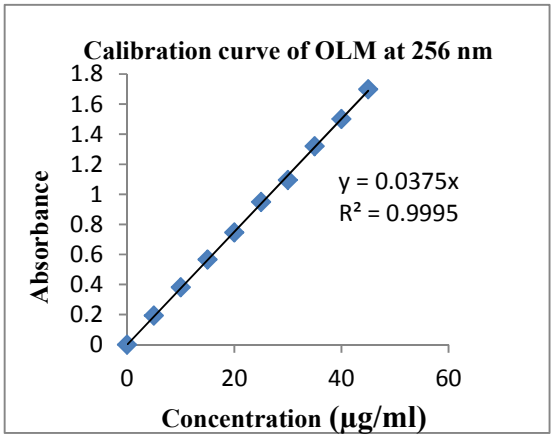


Table: Optical and regression Parameters of the Calibration Curve obtained by UV spectrophotometric method.

Parameter	OLM
Linearity range (µg/ml)	5-40
Slope ± S.D	$0.037 \pm 0.1 \times 10^{-2}$
Intercept ± SD	0
Regression coefficient (r^2) ± S.D	$0.999 \pm 0.932 \times 10^{-2}$

Validation of proposed method:-

Application of proposed method for analysis of tablet formulation

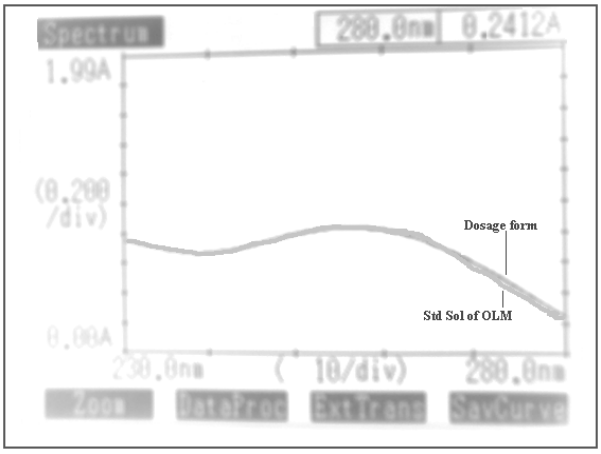
A quantity of tablet powder equivalent to 20 mg of OLM was transferred into 100 ml volumetric flask containing 30 ml methanol, shaken manually for 10 min, volume was adjusted to mark with same solvent and filtered through Whatmann filter paper no. 41. An appropriate aliquot 2 ml was transferred to 10 ml volumetric flask; volume was adjusted to the mark with same solvent (Conc. 20 µg/ml).

The absorbance of the solution was recorded at 256 nm and the concentration of the OLM was determined by linear regression equation; results are shown in following table.

Table: Assay of OLM in Tablet formulation (Analysis of Tablet formulation) for UV spectrophotometric method.

Amount Taken (µg/ml)	Amount found (µg/ml)	Amount found (%)
20.00	19.97	99.85
20.00	20.13	100.65
20.00	20.11	100.55
20.00	19.95	99.75
20.00	20.09	100.45
	Mean	100.25
	SD	0.4183
	CV	0.4172

Overlay spectrum of olm standard solution and drug from dosage form:



Accuracy Study (Recovery Test):

To the pre-analyzed sample solution a known amount of standard drug solution was added at three different levels and absorbance's were recorded. The % recovery was then calculated by using formula:

$$\% \text{ Recovery} = \frac{\text{Observed amount of compound in Sample}}{\text{Amount of all compound present in Sample}} \times 100$$

Table: Results of accuracy parameter

Drug	Level of recovery	% Recovery*	SD	CV
OLM	80	99.548	0.5037	0.5059
	100	100.304	0.3579	0.3568
	120	100.057	0.1992	0.1990

*Mean of three determinations

Table: Determination of Precision of OLM for UV spectrophotometric method.

Sample Number	Assay Of OLM as % of labeled amount	
	Analyst-I (Intra-day precision)	Analyst-II (Intra-day precision)
1	99.42	99.87
2	99.72	99.73
3	99.76	100.03
4	100.17	99.48
5	100.11	99.93
6	99.89	100.09
Mean	99.845	99.855
SD	0.2761	0.2226
CV	0.2765	0.223

2. HPLC Method

Instrument:

HPLC, Model LC-100 HPLC, CYBERLAB^{TM} 20, salo Terrace, Millbury, MAO 1527 USA, with C_{18} RP-HPLC column CAPCELL PACK Col No. AKAD 05395 (4.6 mm X 250 mm, *i.d.*) was used for the estimation.

Selection of Chromatographic Parameters

Selection of chromatographic mode: The reverse phase HPLC was selected for separation because it is convenient and rugged than other forms of the liquid chromatography and is more likely to result in a satisfactory final separation.

Selection of stationary phase: On the basis of reversed phase HPLC mode stationary phase with C18 bonded phase i.e. *CAPCELL PACK Col No. AKAD 05395* (4.6 mm X 250mm, *i.d.*) with particle size 5µm was selected.

Preparation of standard stock solution AMB : Initially 50 mg of AMB was weighed accurately and transferred to 100 ml volumetric flask, about 80 ml of methanol was added and sonicated to dissolve. The final volume was made up to mark with methanol and 10 ml of this solution transferred to 100 ml volumetric flask, volume was made up to mark with methanol to obtain 50 µg/ml of AMB solution. Finally 1 ml of this solution transferred to 10 ml volumetric flask, volume was made up to mark with methanol to obtain final concentration of AMB solution as 5 µg/ml. OLM—200 mg---20 µg/ml

Determination of λmax:-

The standard solution of AMB (5 µg/ml) and OLM (20 µg/ml) were scanned separately in the wavelength range of 200-400 nm and the λ max was found to be 239 nm and 256 nm for AMB and OLM respectively.

The overlay absorption spectrum of AMB and OLM mixture is shown in Fig.4.25 and it exhibits maxima at 238 nm (Isobestic point). Hence wavelength selected for analysis was 238 nm.

Table: Selection of mobile phase

Sr. No.	Mobile Phase Composition	PH	Remark
1	Methanol: Water (50:50)	-	No peak was found for AMB.
2	Methanol: ACN: Water (40:30:30)	-	Showed Broad Peak of both with tailing.
3	Ammonium Acetate(0.005 M): ACN (60:40)	3.0	AMB showed sharp peak but OLM showed prominent tailing and peak broading.
4	0.05 M Pot.dihydrogen phosphate : ACN (50:50 v/v)	6.8	Showed sharp, well resolved peaks with symmetry within limit having significant and reproducible results.

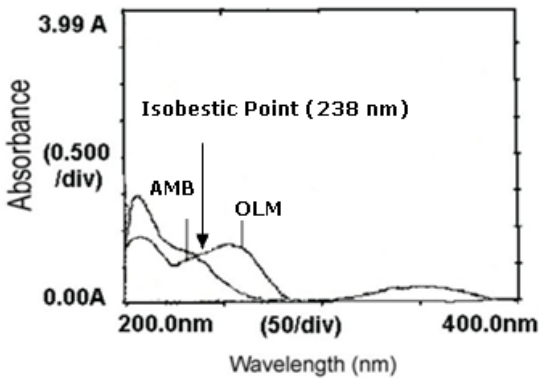


Fig: UV-Absorption overlay spectra of AMB and OLM .

Selection of mobile phase:-

The standard solutions containing AMB and OLM were injected into the HPLC system and run in different solvent systems. By studying literature survey, different mobile phases in different proportion and different pH were tried in order to find the best conditions for the separation. Each mobile phase was sonicated for 10 min. and filtered through 0.45 µ membrane filter. The mobile phase was allowed to equilibrate until steady baseline was obtained. The standard solutions containing AMB and OLM were run and combinations of solvents were tried to get a good separation and stable peak. From the various mobile phases tried, mobile phase containing 0.05 M pot. Dihydrogen phosphate (pH 6.8) and acetonitrile in the ratio of 40:60 (v/v) was selected since it gave sharp peak with symmetry and significant reproducible retention time for AMB and OLM.

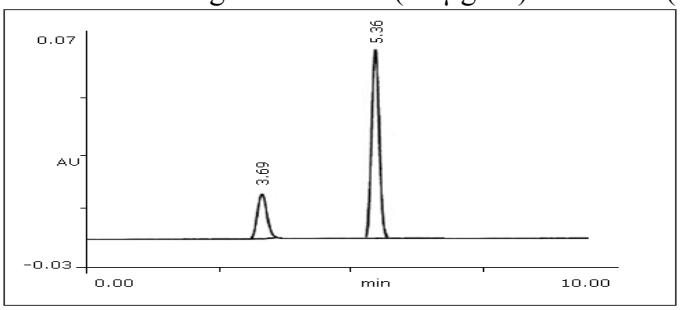
Preparation of optimized mobile phase:-

Preparation of 0.05M Pot. Dihydrogen phosphate: Dissolve 6.8 gm of pot. Dihydrogen phosphate in sufficient water to produce 1000 ml. Preparation of mobile phase: The mobile phase was prepared mixing 0.05M Pot.Dihydrogen phosphate solution (pH 6.8) and acetonitrile in the ratio 50:50 (v/v). The solution was then filtered through 0.45µm membrane filter and degassed.

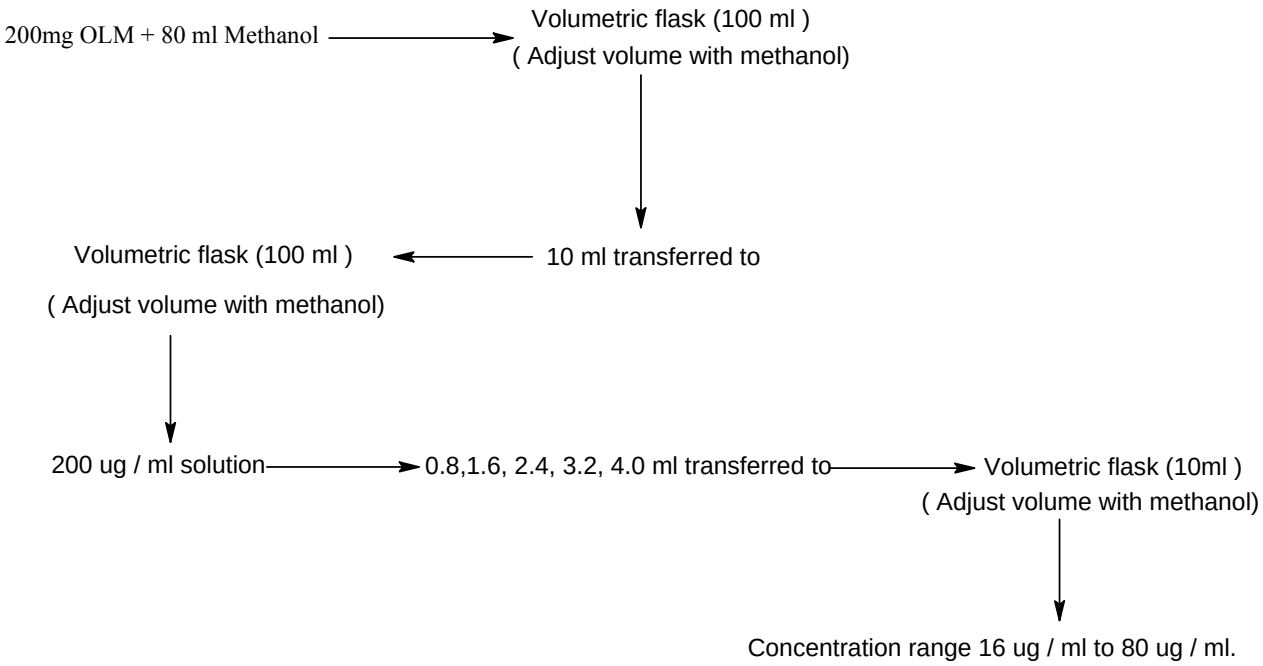
Table : Optimized chromatographic conditions.

Parameters	Method
Stationary phase (column)	C18 bonded phase i.e. CAPCELL PACK Col No. AKAD 05395 (4.6 mm X 250mm, *i.d.*) with particle size 5µm
Mobile phase	0.05M ammonium acetate solution(pH 6.8) and acetonitrile in the ratio 50:50 (v/v)
Flow rate (ml /min)	1.0
Column temperature (^{0}C)	Ambient
Volume of injection (µl)	20
Detection wavelength (nm)	238
Retention Time (min.)	AMB- 3.69 OLM -5.36

Fig. : RP-HPLC Chromatogram of AMB (20 µg/ml) and OLM (80 µg/ml).



Preparation of standard stock solution:- OLM



Preparation of standard stock solution:-AMB

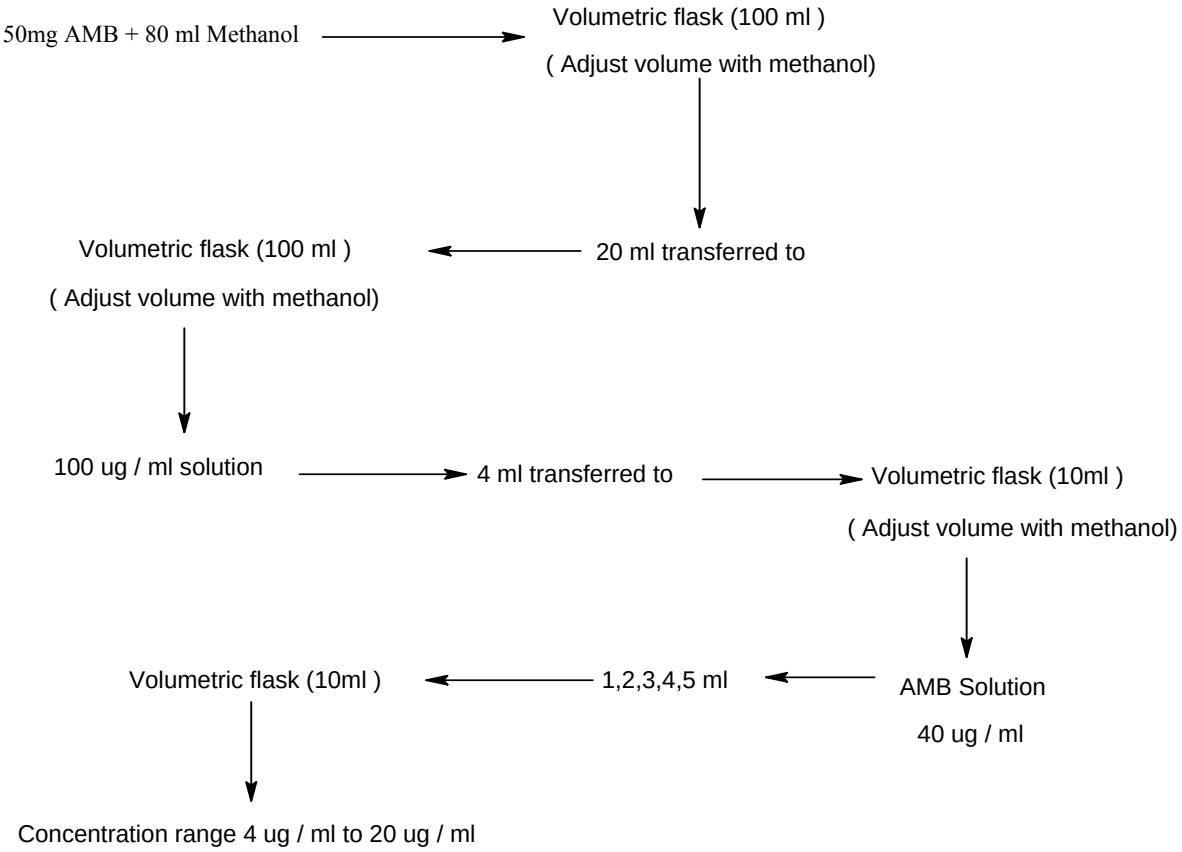


Fig. : Calibration Plot for AMB showing R^2 value 0.998

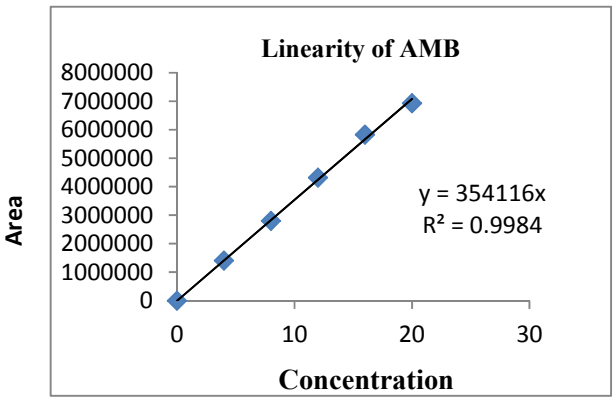


Fig. : Calibration Plot for OLM showing R^2 value 0.999

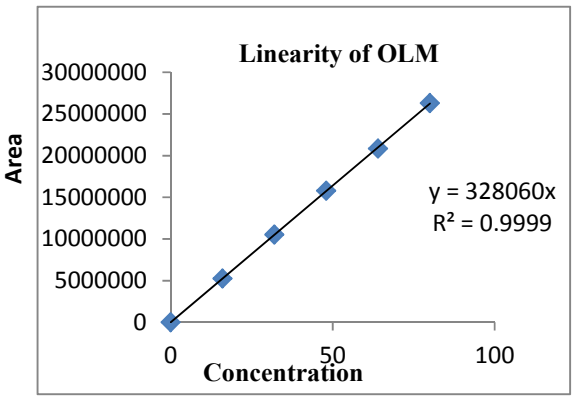


Table: Concentration to peak response of AMB

Conc. (µg/ml)	Peak Area				Statistical Analysis
	INJ-1	INJ-2	INJ-3	Mean	
4	1405990	1405893	1405845	1405909.3	Y=35411x R^2=0.998
8	2799826	2799756	27997653	2799765.3	
12	4317740	4317834	4317790	4317788	
16	5824653	5824709	5824725	5824695.6	
20	6929566	6929594	6929621	6929593.6	

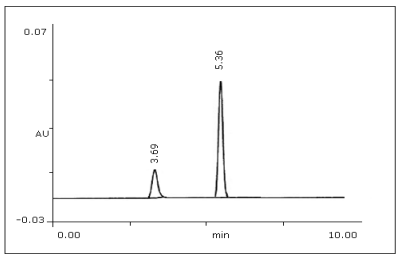
Table: Concentration to peak response of OLM

Conc. (µg/ml)	Peak Area				Statistical Analysis
	INJ-1	INJ-2	INJ-3	Mean	
16	5262940	5262892	5262902	5262911.3	Y=32806x R^2=0.999
32	10529542	10529588	10529487	10529539.0	
48	15788840	15788796	15788816	15788817.3	
64	20857624	20857689	20857612	20857641.6	
80	26314700	26314756	26314691	26314715.6	

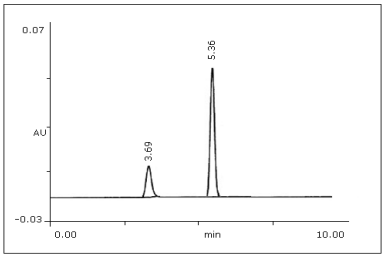
Table: Summary of linearity parameter for RP-HPLC method

Sr. No.	Statistical Analysis	AMB	OLM
1	Concentration Range	4-20 µg/ml	16-80 µg/ml
2	Regression Equation	y = 35411x	Y=32806x
3	Correlation Co-Efficient	0.998	0.999
4	Slope	35411	32806
5	Intercept	0	0

Chromatograms showing linearity of AMB and OLM

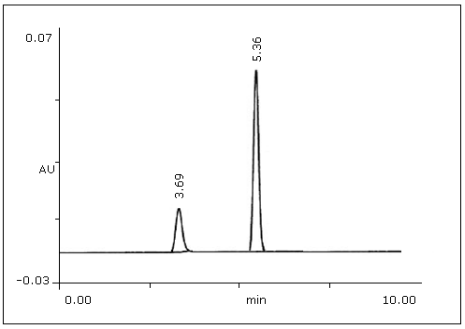


1

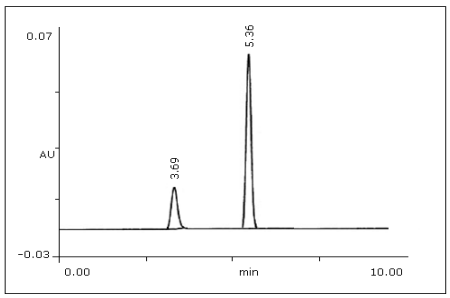


2

Fig. No.	AMB (µg/ml)	OLM (µg/ml)
1	4	16
2	8	32
3	12	48
4	16	64
5	20	80



3



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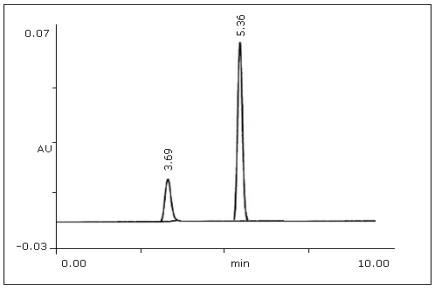

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Table: Chromatograms showing linearity of AMB and OLM.

Validation of proposed method:
Analysis of standard laboratory mixture and Tablet formulation:
Preparation of standard solution:
Weigh accurately 25 mg of AMB and 100 mg of OLM and transfer to 100 ml volumetric flask. Add 30 ml of the solvent & shake to dissolve the contents completely. Dilute to volume with same solvent. Pipette out 10ml of this & dilute to 100 ml.
This yielded a solution with nominal concentration 25 µg/ml of AMB and 100 µg/ml of OLM.

Preparation of sample solution (Solution of Tablet formulation):
Twenty tablets of brand Pinom-A (Lupin Ltd., Mumbai, India) containing 5 mg of AMB and 20 mg of OLM were weighed, and finely powdered.
A quantity of powder sample equivalent to 25 mg of AMB and 100 mg of OLM transferred to 100 ml volumetric flask.
The contents of mobile phase were filtered before use through 0.2µm millipore membrane filter and pumped from the solvent reservoir to the column at specified chromatographic conditions.
Prior to injection of the drug solutions, the column was equilibrated for at least 60 min with mobile phase flowing through the systems.
Then 20 µl of standard and sample solution were injected for five times and two times respectively.
The chromatograms were recorded to measure and peak responses of AMB and OLM in standard and sample solutions.

Fig. : RP-HPLC Chromatogram of Test Sample and marketed formulation.

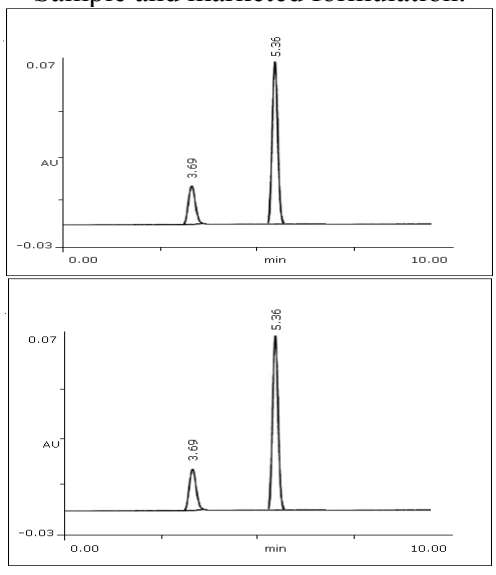

Table: Analysis of tablet formulation by RP-HPLC method.

Drug	Amount Found(mg)	% Amount Found
AMB	4.98	99.6
	4.96	99.2
	5.01	100.2
	Mean	**99.66**
	S.D.	**0.5033**
	%RSD	**0.5050**
Olmesartan medoxomil	19.91	99.55
	20.13	100.65
	20.16	100.80
	Mean	**100.33**
	S.D.	**0.6825**
	%RSD	**0.6803**

Accuracy (Recovery Studies):

Recovery studies were carried out by standard addition method at three different levels 80, 100 and 120%. The % recovery of AMB and OLM in the sample mixture was determined. The results of recovery studies obtained by proposed method were validated by statistical evaluation

Precision:

Six preparations were prepared individually using single batch of AMB and OLM working standard as per test method and injected each solutions in duplicate

Ruggedness:

Ruggedness, according to the USP, is the degree of reproducibility of the results obtained under a variety of conditions, expressed as %RSD.

These conditions include different laboratories, analysts, instruments, reagents, days, etc.

Table: Results of accuracy parameter of AMB for RP-HPLC method.

Level of % Recovery	INJ-1	INJ-2	INJ-3	Mean	SD	CV	% Recovery
80	4317740	4317512	4318587	4317946.33	368.95	0.008544	99.41
100	5396165	5397210	5396817	5396730.66	527.83	0.009780	99.44
120	6477610	6476469	6476986	6477021.66	571.33	0.008820	99.58

Table: Results of accuracy parameter of OLM for RP-HPLC method.

Level of % Recovery	INJ-1	INJ-2	INJ-3	Mean	SD	CV	% Recovery
80	15788780	15788834	15788857	15788823.3	39.52	0.000250	99.61
100	19735938	19735912	19735929	19735926.3	13.20	0.000083	100.30
120	23683148	23683163	23683213	23683174.6	34.03	0.000215	99.55

Table: Results of Method precision of AMB for RP-HPLC method.

Sr. No.	INJ-1	INJ-2	Mean
1	19639883	19849317	19744600
2	19747219	19762214	19754716.5
3	19719743	19817439	19768591
4	19685126	19730528	19707827
5	19701343	19793667	19747505
6	19658170	19805263	19731716.5
Mean	19691914	19793071.33	19742492.66
SD	39532.16	41881.24	20870.76
CV	0.2007	0.2115	0.1057

Table: Results of Method precision of OLM for RP-HPLC method.

Sr. No.	INJ-1	INJ-2	Mean
1	5395214	5386287	5390750.5
2	5376819	5363612	5370215.5
3	5382236	5396940	5389588
4	5362988	5373356	5369172
5	5364376	5386833	5375604.5
6	5343168	5365861	5354514.5
Mean	5370800.16	5378981.5	5374974.17
SD	18049.24	1307.53	13694.97
CV	0.3360	0.2436	0.2547

Table: Results of ruggedness for RP-HPLC method

	Drug	Label Claim (mg)	Recovery (mg)	Amount found (%)
Analyst I	AMB	5	4.93	98.60
	OLM	20	19.91	99.55
Analyst II	AMB	5	4.98	99.60
	OLM	20	19.75	98.75

CONCLUSION:

From the experimental studies it can be conclude that First derivative and HPLC methods are developed for the simultaneous estimation of Amlodipine Besylate and Olmesartan Medoxomil and UV spectrophotometric method is developed for estimation of olmesartan medoxomil. The Proposed methods for the selected drugs were found to be accurate and precise. The method is more reproducible.The most striking features of spectrophotometric methods is their simplicity and rapidity. RP-HPLC is also more sensitive and specific method. Result of validation parameter demonstrate that these analytical procedures are suitable for its intented purpose and meets the criteria defined in ICH Q2A/B.

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