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Method development and validation of simultaneous estimation for Amlodipine besylate and Olmesartan medoxomil by UV- VISIBLE spectrophotometric Method

Syed Arshed S N, Sonia K*, Lakshmi K S

Department of Pharmaceutical Analysis, SRM College of Pharmacy, SRM Nagar, Kattankulathur - 603 203, Chengalpattu, TamilNadu, India

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ABSTRACT

The present experiment works on routine initiation and scientific recognization of a typical, exact and meticulous UV-Visible Spectrophotometric process for the synchronous assessment of Amlodipine besylate and Olmesartan medoxomil. The working solutions of Amlodipine and Olmesartan medoxomil were scanned at 240 nanometer and 230 nanometer respectively. The regression strength of Amlodipine besylate and Olmesartan medoxomil over its absorbances were obtained as y = 0.068x-0.2182 and y = 0.067x0.0386 respectively with a correlation coefficient (r^2) of 0.9995 for Amlodipine besylate and 0.9992 for Olmesartan medoxomil. The intra-day precision in addition inter-day precision for Amlodipine besylate and its % RSD were obtained as 0.15% and 0.39% individually. The intra-day precision in addition inter-day precision for Olmesartan medoxomil and % RSD were obtained as 0.39% and 0.14%, respectively. The precise amount of tablet formulation were added which holds Alkaline (0.1 N Sodium hydroxide), Acidic (0.1 N Hydrochloric acid) reflux for 3 hours, 3% Oxydol at 50ºC, heat (60ºC), humidity (75 Relative percentage humidity) for 24 hr and after the particular time quantity was dissolved with distilled water, separated using Filter paper. From this stock solution, 5 mL part of the filtrate was isolated and further diluted by distilled water in a 100 mL standard flask (10 μg/mL). The standard solution of two drugs were compared against a label claim.

*Corresponding Author

Name: Sonia K
Phone: :+91-9884328353
Email: soniapharm68@gmail.com

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INTRODUCTION

Amlodipine besylate is a sequence portraying calcium traject stopper worn as a resistive hypertensive and in aid of angina (Karajgi and Kulkarni, 2013). 3-Ethyl 5-methyl 2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate benzenesulfonate) is the IUPAC name of Amlodipine besylate. (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl5-(2-hydroxypropan-2-yl)-2-propyl-3-[[4-[2-(2H-tetrazole 5yl) phenyl] phenyl] methyl]imidazole-4-carboxylate) is the IUPAC name of olmesartan medomoxil. The skeltal structure of both is given in Figures 1 and 2. It constrains calcium inflow over cell laminate in cardiac and vascular smooth muscle, with huge outcome surrogates on vascular smooth muscle (Patil *et al.*, 2010; Kumar *et al.*, 2009). Olmesartan medoxomil constrains the vasoconstrictor properties of angiotensin II over clogging the coupling of angiotensin II to the AT1

site in vascular smooth muscle (Patil *et al.*, 2011; Naveed *et al.*, 2016). Angiotensin II is an energetic vasoconstrictor that irrupts the blood flow in the body (Solanki *et al.*, 2013; Shah *et al.*, 2012). Sullen of irrupted blood flow aids in precluding cardiac arrest (Patel *et al.*, 2007; Sharma *et al.*, 2010). As stated by the ICH guidelines, HPTLC was utilized for routine initiation and scientific recognization (Sonia *et al.*, 2018; Parmar *et al.*, 2012).

MATERIALS AND METHODS

Instrumentation

Digital weighing machine from Shimadzu, Lab India Analytical UV 3092. Double beam UV –Visible Spectrophotometer; pH meter (Systronics model EQMK VI); a sonicator (Spectra Lab; model UCB 40); a hot air oven (Labhosp); UV chamber (Labhosp) were utilized in this analysis+.

Materials and Reagent employed

Olmesartan medoxomil and Amlodipine besylate of pharmaceutical-grade were supplied by Yarrow Chem Pvt Ltd. Methanol and water used was of Analytical grade and were bought from Spectrochem Pvt. Ltd. Mumbai, India. Formulation consisting of 5mg olmesartan and 40mg of Amlodipine besylate was purchased from the local market and utilized.

Preparation of Standard Stock Solution

Meticulous weighed and transferred into 50mL standard flasks of 10mg of each drug Amlodipine besylate and Olmesartan medoxomil in two discrete standard flasks and dissolved in 50mL of Acetonitrile, sonicated for 20 minutes to get the strength of the analytical standard solution of 100 μg/mL of both drugs.

Preparation of Sample solution

Twenty tablets weight were taken and exquisitely pulverized in a mortar. The equivalent amount of 200mg of Olmesartan medoxomil and 50mg of Amlodipine besylate was meticulous weighed and relocated into a 100mL tidy volumetric flask in which methyl alcohol was added and sonicated for 5min in which drug go into solution completely. The solution was separated by using whatmann filter paper, discarding the first few mL. It is diluted with methyl alcohol to attain a strength of 5 μg/mL of AMB and 20 μg/mL of OLM.

RESULTS AND DISCUSSION

Method development

Amlodipine and Olmesartan medoxomil analytical standard solutions were prepared in dilution 100μg/mL. Different dilution was taken from a standard stock solution and diluted with Acetonitrile in the concentration of 2μg/mL to 12μg/mL solutions at 2μg/mL interval. The working solutions of Amlodipine and Olmesartan medoxomil were scanned at 240 nanometer and 230 nanometer respectively. The absorbances were recorded and are outlined against the strength to obtain the respective calibration curves.

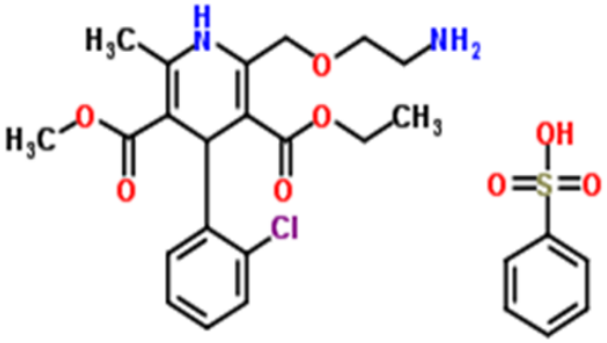

Figure 1: Chemical structures of Amlodipine besylate

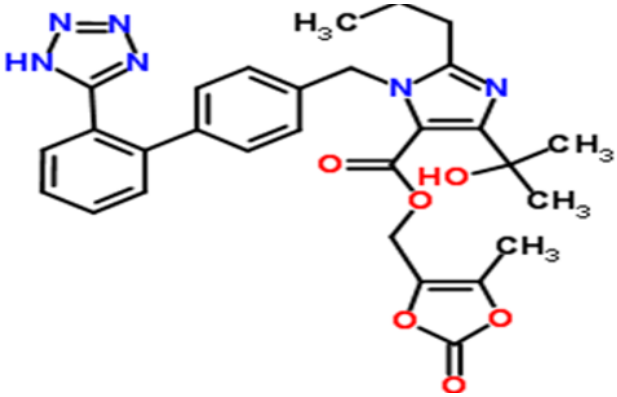

Figure 2: Chemical structures of Olmesartan medoxomil

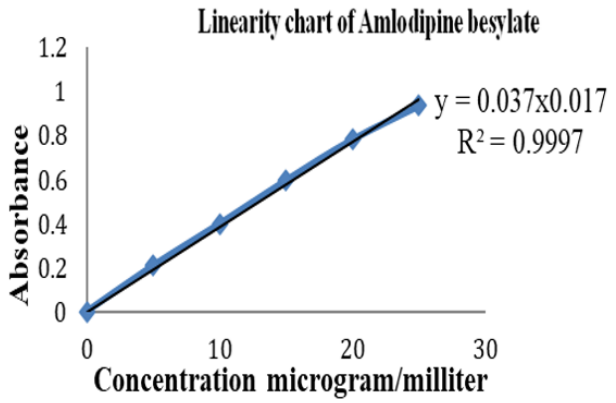

Figure 3: Linearity chart for Amlodipine besylate

Validation of the method

Table 1: Linearity data for Olmesartan medoxomil and Amlodipine besylate

S.No.	Olmesartan medoxomil		Amlodipine besylate	
	Conc(μg/mL)	Absorbance	Conc(μg/mL)	Absorbance
1	0	0	1	0
2	5	0.293	2	0.289
3	10	0.645	3	0.5295
4	15	0.994	4	0.786
5	20	1.347	5	1.047
6	25	1.679	6	1.279
7	30	2.002	7	1.502
8	35	2.452	8	1.752
Slope		0.067	Slope	0.068
Intercept		-0.0386	Intercept	-0.2182
Correlation coefficient		0.9992	Correlation coefficient	0.9995

Table 2: Intra-day and Inter-day precision results of Olmesartan and Amlodipine

S. No.	Intra-day precision			Inter-day precision		
	Time (Hours)	Olmesartan Absorbance	Amlodipine Absorbance	Time (Days)	Olmesartan Absorbance	Amlodipine Absorbance
1	0	99.65	99.76	1	99.45	99.74
2	2	99.53	99.82	2	98.99	99.69
3	4	99.67	99.98	3	99.81	99.88
4	6	99.96	99.53	4	99.57	99.97
5	8	99.78	99.89	5	98.97	99.85
6	10	99.87	99.28	6	99.88	99.58
Mean		99.74	99.71	Mean	99.445	99.785
SD		0.15743	0.259692	SD	0.3926	0.141809

Table 3: Stability study parameters for Olmesartan medoxomil and Amlodipine

Degradation Condition	Time	% Assay	
		Olmesartan medoxomil	Amlodipine besylate
Acidic degradation	24h	87.63%	99%
Basic degradation	24h	97%	99.8%
Oxidative degradation	24h	98.9%	95%
Dry Heat induced	24h	94.6%	98%
Photolytic degradation	24h	98.7%	99%
UV Radiation at 256 nm	24h	98.5%	98%

Table 4: LOD and LOQ for Amlodipine besylate and Olmesartan medoxomil

Parameter	Amlodipine besylate (μg/mL)	Olmesartan medoxomil (μg/mL)
Limit of detection	0.14	0.34
Limit of quantification	0.30	0.94

Table 5: Recovery studies forAmlodipine besylate and Olmesartan medoxomil

	Amlodipine besylate			Olmesartan medoxomil		
	80%	100%	120%	80%	100%	120%
Std. conc. (microgram/mL)	10	10	10	10	10	10
Conc. added (microgram/mL)	8	10	12	8	10	12
Conc. found (microgram/mL)	7.95	9.94	11.97	7.98	9.94	11.98
% Recovery	99.375	99.40	99.75	99.75	99.4	99.83
% Mean recovery	99.50				99.66	

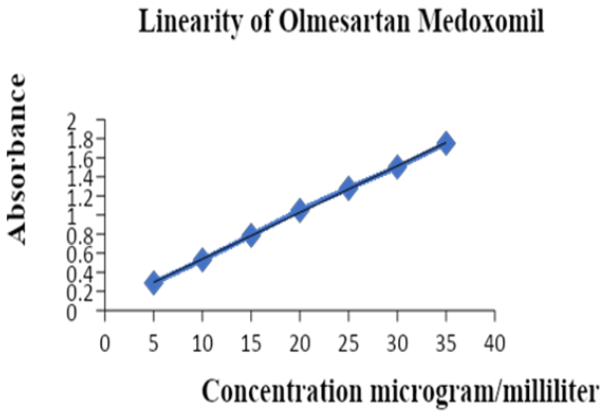

Figure 4: Linearity chart for Olmesartan medoxomil

This analysis was formalised, in accordance with ICH guidelines ICH Q2B, for linearity, Precision, Stability parameters,

Linearity

In evaluation of grined sample, propotionate to 50 mg of Amlodipine besylate and 200 mg of Olmesartan medoxomil were added in a graduated flask and reduced in methyl alcohol solvent. Farther dilutions were made to attain a strength of 5 μg/mL of Amlodipine besylate and 20 μg/mL of Olmesartan medoxomil. It was examined at various wavelengths i.e., 240 nanometer and 260 nanometer (Table 1,Figures 3 and 4).

Precision

For the intra-day calculation of precision 0-10 hours with the interval of every two hours and interday precision 1-6 days were chosen and readings were taken for every day for Olmesartan and Amlodipine tabulated in (Table 2).

Stability parameter

The precise amount of tablet formulation which is equal to 20 mg of Olmesartan medoxomil and 5 mg of Amlodipine besylate were added to 100 mL graduated flask to maintain subsequent conditions which hold Alkaline (0.1 N Sodium hydroxide), Acidic (0.1 N Hydrochloric acid) reflux for 3 hours, 3% Oxydol at 50ºC, heat (60ºC), humidity (75 percentage Relative humidity) for 24 hr and after the particular time quantity was dissolved with distilled water, separated using Filter paper. From this stock solution, 5 mL part of the filtrate was isolated and further diluted by distilled water in a 100 mL standard flask (10 μg/mL). The standard solution of two drugs were compared against a label claim and were tabulated in (Table 3).

Detection limit and quantification limit

The detection limit (LOD) and quantification limit (LOQ) for Amlodipine besylate verified to be 0.14 microgram/mL and 0.30 microgram/mL subsequently. The LOD and LOQ were examined to be 0.34microgram/mL and 0.94microgram/mL (Table 4) respectively.

Accuracy

Accuracy was determined for drugs by spiking with 80, 100 and 120 percentage of pure drug and the mean recovery of the Amlodipine besylate and Olmesartan medoxomil were to be 99.50% and 99.66% respectively (Table 5).

Assay

The assay were done and its percentage purity found to be 98% and 99.9%, respectively.

CONCLUSIONS

The extent of Amlodipine besylate another Olmesartan medoxomil bulk samples and their tablet forms were determined by the simultaneous equation method by using UV Spectrophotometer. The regression strength of Amlodipine besylate and Olmesartan medoxomil over its absorbances were obtained as y=0.068x-0.2182 and y=0.067x0.0386 respectively with a correlation coefficient (r^2) of

0.9995 for Amlodipine besylate and 0.9992 for Olmesartan medoxomil. The intra-day precision in addition inter-day precision for Amlodipine besylate and Olmesartan medoxomil % RSD were obtained as 0.15% , 0.39% , 0.39% and 0.14% subsequently. This confirms the procedure is precise. Accuracy is determined for both drugs by spiking with 80, 100 and 120% of additional pure drug and the % mean recovery of the Amlodipine besylate and Olmesartan medoxomil were obtained as 99.50 and 99.66 respectively. The percentage purity for the assay of Amlodipine besylate and Olmesartan medoxomil were obtained as 98% and 99.9%, respectively. The assay result shows that the methodology was selective for evaluation of Telmisartan and Ramipril without hindering the inactive substance used in tablet dosage form.

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