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Research Article

Method Development, Validation And Stability Indicating Studies Of Olmesartan Medoxomil In Bulk And Pharmaceutical Dosage Form By UV-Spectroscopy

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ABSTRACT

Development of UV spectrophotometric method for the estimation of Olmesartan medoxomil was done by Q-Absorbance ratio method and area under curve method and stability indicating studies using methanol as solvent. In the present research, we have made an attempt to develop a simple, specific, accurate, precise and reproducible method for the estimation of Olmesartan medoxomil in dosage form by UV spectrophotometric method. The method includes area under curve method (Method I) and Q- absorbance Ratio method (Method II). The wavelength is 243 nm of the drug were selected for Method I, and for Q- absorbance Ratio method (Method II) 250 nm an iso-absorptive wavelength were selected for estimation of Olmesartan medoxomil. The drug follow Beer's law over the concentration range of 1-6 µg/ml. The % recovery of the drug was found to be nearly 100 % representing the accuracy of the proposed methods. LOD and LOQ values of Olmesartan medoxomil was found to be 0.400,0.403,0.407,0.400,0.403,0.407 at different wavelengths 272nm, 250nm, 242nm and validation of the proposed methods was carried out for its accuracy, precision, specificity and ruggedness according to ICH guidelines. The present validated method was successfully applied for determination of Olmesartan medoxomil in bulk and pharmaceutical dosage form.

INTRODUCTION

Olmesartan medoxomil was an anti - hypertensive drug chemically it was named as (5-Methyl- 2-oxo-1, 3-dioxol-4-yl) methyl5- (2-hydroxypropan-2-yl) - 2-propyl-3- [4- [2- (2H-tetrazol-5-yl) phenyl] methyl] imidazole-4-carboxylate. Olmesartan medoxomil is also one of several angiotensin II receptors blocking agent. Olmesartan medoxomil has been shown to have a longer half -life and a greater effect on systolic

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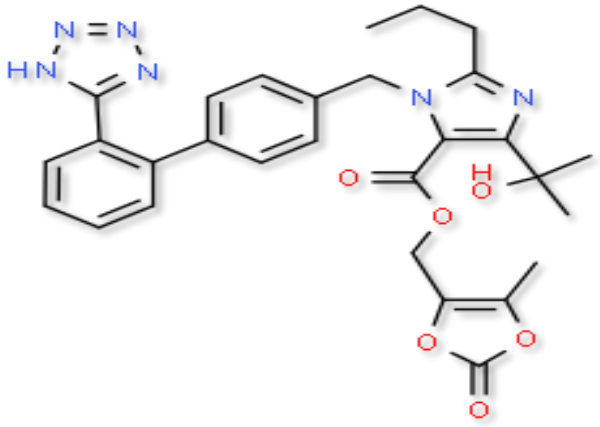
blood pressure than other Angiotensin receptor blocking agents, making it widely prescribed for the management of hypertension. Olmesartan medoxomil is an inactive ester prodrug, which is quickly bio activated by hydrolysis in the gut wall to the pharmacologically active the Olmesartan drug.



Olmesartan Medoxomil (OLM)

MATERIALS AND METHODS [1-7]:

Chemicals and reagents:

Olmesartan Medoxomil was procured from the KP laboratories, Hyderabad. Commercial pharmaceutical preparation Olmesartan Medoxomil, manufactured by INTA pharmaceuticals, containing 10mg, 20mg, and 40mg of Olmesartan, 20mg of drug was collected from local market, methanol analytical grade was procured from Quietens India Pvt Ltd.

Instrumentation:

The proposed method was carried on a shimadzu UV-Visible Spectrophotometer (UV-1800 series). All the products were weighed on digital balance (Shimadzu), a fast clean ultra sonicator was used for degassing the solvent.

Selection of Solvents: On the basis of the solubility studies methanol was selected as solvent for method development.

UV-SPECTROSCOPY:

Preparation of Standard Solutions:

Weigh accurately 10mg of Olmesartan medoxomil into a 100ml volumetric flask, add 10ml of solvent and shake well to dissolve the drug completely. Make up the volume to 100ml with solvent to get 100µg/ml of Olmesartan medoxomil.

Preparation of Sample Solution:

20 Tablets were taken, crushed into fine powder. Accurately weighed powder sample equivalent to 10mg of Olmesartan medoxomil powder and transferred to 100ml volumetric flask, dissolved in sufficient solvent and filtered through whatman filter paper. The filtrate was made up to volume of 100ml with solvent get 100µg/ml of Olmesartan medoxomil.

Determination of λmax:

Standard solutions of Olmesartan medoxomil was prepared and scanned in UV- spectrophotometer in the range of 200-400nm to determine the λmax. The λmax of Olmesartan medoxomil was found to be 250nm.

METHOD DEVELOPMENT)(8-12):

1. Q-Absorbance ratio method: According to Q-absorption ratio method, at selected wavelength was used for the ratio of absorption. One was at iso-absorptive point and other one was at the λmax, the concentrations were calculated by using the equation.

   Cx = {(Qm-Qy)/ (Qx-Qy)}* (A1/ax1)

   Cy = {(Qm-Qx)/ (Qy-Qx)}* (A1/ay1)

2. Area Under the Curve Method: Olmesartan medoxomil was scanned between 200-400nm and found 243nm as λmax for estimation using area under curve method. Aliquotes of 1-6 µg/ml solutions was prepared using methanol as solvent and measured absorbance of drug at λmax.

CM = XNλ1-λ2 AUCλ3-λ4 - XNλ3-λ4 AUCλ1-λ2 / XNλ1-λ2 = XMλ3-λ4 - XNλ3-λ4 XMλ1-λ2

CN = XMλ1-λ2 AUCλ3-λ4 - XMλ3-λ4 AUCλ1-λ2 / XNλ1-λ2 = XMλ3-λ4 - XNλ3-λ4 XMλ1-λ2

Validation of the Method (13-15):

Validation was done by UV-VIS Spectroscopic method according to International Conference on Harmonization (ICH) guidelines. Different parameters were studied for validation: they are linearity, precision, accuracy, limit of detection (LOD) and limit of quantification (LOQ).

Linearity:

The methods were validated according to International conference on Harmonization guidelines for validation of analytical procedures in order to determine the linearity, sensitivity, precision and accuracy for each analyte. Calibration curve was generated with appropriate volume of working standard solution for UV and with the range of 1-5 respectively. The linearity was determined by using unweighted data in the least square regression method.

Accuracy and Precision:

The precision of the product was validated by intermediate precision (inter-day) and repeatability (intra-day) and reported as %RSD for a statistically remarkable number of replicate measurements. The intermediate precision was carried out by comparing the assay in three different days and the results were reported as standard deviation and %RSD. Accuracy was the percent of analyte recovered from assay by addition known amount, for the measurement of accuracy data from nine determinations over three concentration levels covering the specified range were validated.

Robustness:

Robustness of the method was validated by making minute changes in the chromatographic conditions, such as composition mobile phase ratio, flow rate and wavelength.

LOD and LOQ:

Limit of quantification and limit of detection were predicted by plotting linearity curve for different nominal concentration of Olmesartan medoxomil. The LOD and LOQ values were calculated by using the following formula:

$$LOD = 3.3 \times \sigma/S$$

$$LOQ = 10 \times \sigma/S$$

Where σ = the standard deviation of the response

S = Slope of calibration curve.

RESULTS AND DISCUSSION:

Table 1: Q-Absorbance Ratio Method Values Of Olm

Concentration(µg/mL)	OLM 250nm	OLM 272nm
1	0.12	0.105
2	0.229	0.231
3	0.301	0.321
4	0.432	0.404
5	0.543	0.557

Table 2: Area Under Curve Of Olm

Concentration(µg/mL)	OLM 242nm
1	0.05456
2	0.11942
3	0.19421
4	0.25421
5	0.29940
6	0.35761
Mean	0.1536
SD	0.1311

Linearity:

A series of solutions in the concentration range of 1-6µg/mL of OLM stock solutions were prepared.

These solutions were scanned in the range of 200-400 nm and the absorbance was noted at the λmax of 242 nm.

Table 3: Linearity Of Olm

Concentration (µg\ml)	Absorbance
1	0.0865
2	0.1625
3	0.234
4	0.3185
5	0.410
6	0.482

Table 4: Intraday Precision

Concentration	272nm	250nm	242nm
3	0.994	0.226	0.672
3	0.995	0.225	0.673
3	0.996	0.221	0.674
3	0.997	0.221	0.675
3	0.998	0.219	0.676
Mean	0.996	0.222	0.674
SD	0.0014	0.0027	0.0014
%RSD	0.1420	0.0894	0.2747

Table 5: Inter Day Precision

Concentration	272nm	250nm	242nm
3	0.994	0.226	0.672
3	0.995	0.225	0.673
3	0.996	0.221	0.674
3	0.997	0.221	0.675
3	0.998	0.219	0.676
Mean	0.996	0.222	0.674
SD	0.0014	0.0027	0.0014
%RSD	0.1420	0.0894	0.2747

Table 6: Robustness Of Olm

Drug	Changes in wavelengths	Absorbance
OLM	243	0.0866
	244	0.0867
	245	0.0868
	246	0.0869
	247	0.0869

Table 7: LOD and LOQ of OLM

Parameter	Olmesartan		
	Methods -A		Method -B
	272nm	242nm	252nm
LOD	0.146	0.136	0.201
LOQ	0.422	0.488	0.407

Accuracy:

Table 8: Accuracy Of Olm

Methods	Amount taken	Amount found	%Recovery
Method A	50	0.139	99.7
	100	0.147	99.8
	150	0.235	100.1
Method B	50	0.142	99.**9**
	100	0.145	99.9
	150	0.232	100.2

Table 9: Forced Degradation Studies

Stress Degradation Condition	Area Under Curve	% Degradation	Active drug process after degradation (%)
Standard drug	3.866	0	100
Acid Degradation	1.723	64.26732673	57.73267327
Base degradation	0.832	79.9669967	30.0330033
Oxidative degradation	0.25	61.50825083	44.49174917
Photo stability degradation	0.26	85.80858086	14.19141914

CONCLUSION:

The proposed UV Spectrophotometric methods are simple, fast, sensitive, accurate, precise, less time-consuming and economic. All the parameters were observed within the limits, validation of the proposed methods was carried out for its accuracy, precision, specificity and ruggedness according to ICH guidelines. The stability studies have been developed for the estimation of Olmesartan medoxomil. The use of this method has proved to be a smart strategy to provide both environmental and economic benefits. The proposed methods successfully applied in routine work for determination of Olmesartan dosage form.

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CONFLICT OF INTERESTS: The authors declare that there exist no conflicts of interests regarding the publication of this manuscript.

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