Method Development & Validation for the Estimation of Olmesartan Medoxomil from Pure & Tablet Dosage Forms By UV- Visible Spectroscopy

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***Abstract*—A simple, accurate, precise, sensitive, and economical UV-spectrophotometric method was developed and validated for the estimation of Olmesartan medoxomil in bulk drug and tablet dosage form. Olmesartan medoxomil, a poorly water-soluble angiotensin II receptor blocker, was analysed using ethanol as a solvent. The analysis was carried out on an Analytical Technologies Ltd. 2080N UV-Visible spectrophotometer using 1 cm quartz cells, and the drug exhibited maximum absorbance at 256 nm. Linearity was observed over the concentration range of 2–12 µg/mL with a correlation coefficient (r^2) of 0.9971. The method was validated according to ICH Q2(R1) guidelines. Precision studies showed %RSD values below 2% for both intraday and interday analysis. Accuracy studies demonstrated satisfactory recovery values in the range of 99.91–100.3%. The limit of detection and limit of quantification were found to be 0.0405 µg/mL and 0.123 µg/mL, respectively. The method was found to be robust with no significant interference from tablet excipients. The proposed method is rapid, reproducible, and suitable for routine quality control analysis of Olmesartan medoxomil in bulk and pharmaceutical dosage forms.**

***Index Terms*—Olmesartan medoxomil, UV-spectrophotometric method, method validation, ICH Q2(R1), bulk drug, tablet dosage form.**

I. INTRODUCTION

Olmesartan medoxomil, classified as an angiotensin receptor blocker, is approved by the USFDA for the treatment of hypertension. From a chemical standpoint, its structure can be defined as [5-methyl-2-oxo-1,3-dioxol-4-yl) methyl] 4-{1-hydroxy-1-methylethyl}-2-propyl-1-[2-(1H-tetrazol-5-yl) [1,1'-biphenyl]-4-yl) methyl]-1H-imidazole-5-carboxylate [Figure 1].

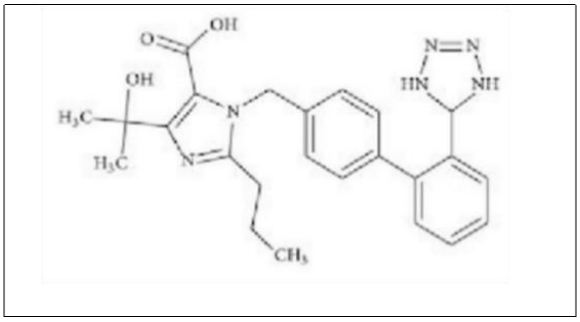


Figure 1: Structure of Olmesartan Medoxomil

Olmesartan medoxomil, has the formula $C_{29}H_{30}N_6O_6$ and a molecular weight of 558.59, is a white or light yellowish-white powder or crystalline solid that is essentially insoluble in water but slightly soluble in ethanol. Olmesartan medoxomil is taken orally, the medication is de-esterified in the colon to yield Olmesartan, the active form. Angiotensin II (AT-II) cannot bind to smooth muscle tissue's AT-II receptors when Olmesartan is taken. Olmesartan decreases the negative feedback of renin release by preventing angiotensin II from binding to its receptors; as a result, vasoconstriction is decreased along with a corresponding decrease in aldosterone. Chemical compounds are used to promote vasodilation.

II. MATERIALS & METHODS

Reagents & source: Ethanol was used for the study were procured from Merck Specialties Private Ltd., Mumbai. Distilled water was obtained from SP Chemicals, Bellary Road, Kurnool.

Instruments: In the present scientific study, a weighing balance Atom (Model A123) was used for weighing purpose and a sonicator Digital Pro (S-9650) was used during the analysis. A UV-Vis

spectrophotometer Analytical Technologies Limited (Model 2080N) was employed for analysis of the drug.

III. METHODOLOGY

Preparation of Working Solvent: To prevent contamination, a 100 mL volumetric flask was thoroughly cleaned and dried in an oven. First, a measuring cylinder was used to transfer roughly 50 mL of analytical reagent-grade ethanol into the volumetric flask. To guarantee even mixing and eliminate any trapped air bubbles, the solvent was gently swirled. Finally, ethanol was added to bring the volume up to the 100 mL mark after ensuring the ethanol was clear and free of suspended particles. After that, the flask was securely sealed and repeatedly inverted to produce a uniform ethanol solvent. This prepared ethanol served as both the blank for UV-visible spectrophotometric analysis and the diluent for the creation of standard and sample solutions.

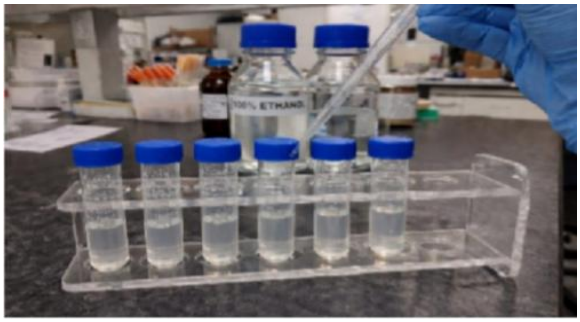


Figure 2: preparing of dilutions

Preparation of Standard Stock Solution (Olmesartan Medoxomil): 0.1 g (100 mg) of pure Olmesartan Medoxomil was accurately weighed using an analytical balance, and the contents were transferred into a 100 mL volumetric flask that had been cleaned and dried. The medication was dissolved by adding 50 mL of working solvent (ethanol) to the flask, which was then shaken gently. The solution was sonicated for five to ten minutes. After complete dissolution, working solvent was added to bring the volume up to the 100 mL mark. A consistent solution was obtained by placing the flask inverted and then stoppered. This prepared solution, with a concentration of 100 µg/mL, was identified as the standard stock solution.

Preparation of Sample Solution (Tablet Dosage Form): Twenty tablets of Olmesartan Medoxomil were precisely weighed and ground into a fine powder. A 100 mL volumetric flask was cleaned and dried thoroughly. A quantity of tablet powder equivalent to 0.1 g (100 mg) of Olmesartan Medoxomil was taken and transferred to the 100 mL volumetric flask. The flask was filled with 50 mL of ethanol, and the contents were shaken to distribute the powder. The solution was sonicated for ten to fifteen minutes to guarantee full drug extraction from the tablet matrix. Following sonication, the solution was allowed to cool to room temperature, and ethanol was added to bring the volume up to 100 mL. The solution was mixed thoroughly and then filtered through Whatman filter paper and 0.45 µm membrane filter to remove all insoluble excipients. The sample stock solution was obtained through the filtrate, which contained a concentration of approximately 100 µg/mL.

IV. VALIDATION OF THE METHOD

The performance parameters like linearity, accuracy, precision, ruggedness, limit of detection, limit of quantification, and robustness were considered for validating this method.

Linearity: The study required a serial dilution from the standard working solution (100 µg) to create different drug concentrations ranging from 2 to 12 µg/ml through solvent dilution. The solution underwent filtration through Whatman filter paper NO-41. Then a calibration curve was constructed, which displayed absorbance values on the Y-axis and concentration values on the X-axis according to the data from Table No. 5.2.

Precision: The precision of the analyzed method was assessed by the analysis of multiple samplings of a homogeneous sample. The precision of the method is defined as standard deviation or relative standard deviation. The precision of the method was proved by intraday or interday variation studies.

(a) Intraday: The standard solutions (6 µg/ml) were prepared, and absorbances during different times throughout the day were noted. The results were shown in Table No. 5.3, and the percentage relative standard deviation was calculated.

(b) Inter-day: The standard solutions (6 µg/ml) were prepared, and absorbances during different days were noted. The results were shown in Table No. 5.4, and the percentage relative standard deviation was calculated.

Accuracy: The accuracy of the standard solution was performed by adding three different purity levels of Olmesartan medoxomil standard at 80, 100, and 120% for the experiments, and the % R.S.D. results were calculated and shown in Table No. 5.5.

Sensitivity: The LOD and LOQ of olmesartan medoxomil were also measured to assess the sensitivity of the method. LOD and LOQ of olmesartan medoxomil were calculated from the equations LOD = 3.3σ /s and LOQ = 10σ/ s, where σ is the standard deviation of response and S is the slope of the curve, under the Table No. 5.10 & 5.11.

Robustness: Robustness is the degree to which the method is unaffected by small but deliberate variations in the method conditions, and it is an indicator of the reliability of the method. In order to find the robustness of this method, the experimental conditions were intentionally changed at three different conditions to evaluate the results. The variation in wavelength (254 nm and 258 nm) had very little impact on the absorbance of the 6 µg/ml solution, showing that the method is robust and shown in the Table No. 5.12 to 5.15.

V. RESULTS AND DISCUSSION

UV spectroscopy method

Table No. 5.1: Characteristic parameters of Olmesartan Medoxomil for the proposed UV spectroscopy method:

Parameters	UV Spectroscopic method
Calibration concentration (µg/ml)	2-12(µg/ml)
Wavelength (λmax)	256 nm
Regression equation (y*)	0.1052x+0.0107
Slope	0.1052
Correlation coefficient (r^2)	0.9971
LOD (µg/ml)	0.0405(µg/ml)
LOQ(µg/ml)	0.1230(µg/ml)

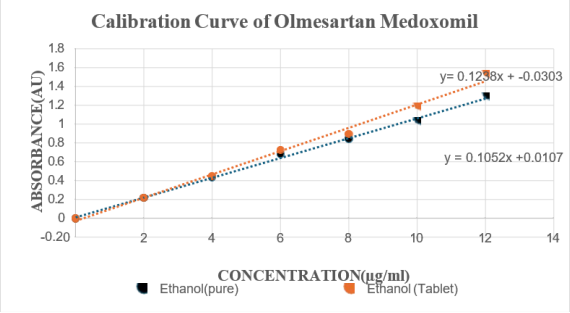
Y*=bx+a, where x is the concentration of Olmesartan medoxomil in µg/ml and Y is the absorbance at the respective wavelength.

Validation of the analytical method: Validation of the analytical method is the process to establish by laboratory studies that the performance characteristics of the method meet the requirement for the intended analytical application. Performance characteristics are expressed in terms of analytical parameters.

Linearity: A calibration graph was plotted using absorbance of standard drug on the y-axis versus concentration of standard drug solution (µg/ml) on the x-axis. Linear regression data showed a good relationship over a concentration range of 2-12 (µg/ml).

Table No. 5.2: Calibration curve of Olmesartan medoxomil

S. No.	Concentration(µg/ml)	Absorbance1 [pure form]	Absorbance2 [tablet form]
1	2(µg/ml)	0.2159	0.2189
2	4(µg/ml)	0.4357	0.4485
3	6(µg/ml)	0.6828	0.7238
4	8(µg/ml)	0.8463	0.8953
5	10(µg/ml)	1.0236	1.1765
6	12(µg/ml)	1.2878	1.5233



Observation:

- The correlation coefficient for olmesartan medoxomil was found to be 0.9971.
- The linearity concentration for olmesartan medoxomil was found to be 2-12 (µg/ml).

Precision: The precision of the analytical method was studied by analysis of multiple samplings of a homogenous sample. The precision results were expressed as standard deviation or relative standard deviation.

Table No. 5.3: Intraday precision for Olmesartan Medoxomil Absorbance

S. No	conc. µg/ml	1	2	3	4	5	6	AVG	SD	%RSD
1	2	0.2167	0.2143	0.2189	0.2134	0.2171	0.2163	0.2161	0.0019	0.8792
2	4	0.4355	0.4363	0.4379	0.4328	0.4364	0.4358	0.4358	0.0016	0.3854
3	6	0.6873	0.6841	0.6852	0.6859	0.6837	0.6851	0.6852	0.0012	0.1888
4	8	0.8462	0.8437	0.8475	0.8428	0.8434	0.8476	0.8452	0.0021	0.2554

5	10	1.0451	1.0563	1.0623	1.0541	1.0593	1.0493	1.0544	0.0063	0.6037
6	12	1.2102	1.2095	1.2059	1.2087	1.2078	1.2067	1.2081	0.0016	0.1365

Acceptance criteria: The %RSD of the six replicate samples should not be more than 2.0%.

Table No. 5.4: Inter-day precision for Olmesartan Medoxomil

Absorbance

S.no	Conc. (µg/ml)	1	2	3	4	5	6	AVG	SD	%RSD
1	2	0.2153	0.2137	0.2168	0.2124	0.2153	0.2143	0.2146	0.0015	0.7082
2	4	0.4342	0.4342	0.4363	0.4276	0.4351	0.4349	0.4337	0.0030	0.7133
3	6	0.6861	0.6835	0.6846	0.6847	0.6824	0.6847	0.6843	0.0012	0.1835
4	8	0.8451	0.8421	0.8465	0.8419	0.8423	0.8466	0.8441	0.0022	0.2653
5	10	1.0437	1.0542	1.0602	1.0501	1.0492	1.0452	1.0504	0.0060	0.5773
6	12	1.1856	1.1842	1.2064	1.1863	1.1862	1.2087	1.1929	0.0113	0.9553

Acceptance criteria: %RSD of the six replicate samples should not be more than 2.0%

Accuracy:

Table No. 5.5: Observation for accuracy standard (6 µg/ml)

S. No.	Conc. (µg/ml)	Absorbance
1	Set-1	0.6828
2	Set-2	0.6754
3	Set-3	0.6938
4	Set-4	0.6852
5	Set-5	0.6793
6	AVG	0.6833
7	SD	0.0069
8	%RSD	1.0153

Table No. 5.6: Observation for accuracy standard 80% (4.8 µg/ml)

S. No.	Conc. (µg/ml)	Absorbance
1	Set-1	0.5342
2	Set-2	0.5421
3	Set-3	0.5485
4	AVG	0.5416
5	Result	4.762
6	%Rec	99.21
7	SD	0.0072
8	%RSD	1.3294

Table No. 5.7: Observation for accuracy standard 100% (6 µg/ml)

S. No.	Conc. (µg/ml)	Absorbance
1	Set-1	0.6732
2	Set-2	0.6772
3	Set-3	0.6843
4	AVG	0.6782
5	Result	5.955
6	%Rec	99.25
7	SD	0.0056
8	%RSD	0.8257

Table No. 5.8: Observation for accuracy standard 120% (7.2 µg/ml)

S. No.	Conc. (µg/ml)	Absorbance
1	Set-1	0.6846
2	Set-2	0.6822
3	Set-3	0.6896
4	AVG	0.6854
5	Result	6.018
6	%Rec	100.3
7	SD	0.0052
8	%RSD	0.7633

Table No. 5.9: For Accuracy Summary

Sample (%)	Initial Amount (µg/ml)	Amount added (µg/ml)	Amount recovered (µg/ml)	%Recovery ± SD*	%RSD
80	6	0.6	0.5953	99.21±0.0072	1.3709
100	6	0.6	0.5955	99.25±0.0056	0.8288
120	6	0.6	0.6018	100.3±0.0052	0.7633

*Average of three determinations

Acceptance criteria: %Recovery should be within the range of 98-102%.

%RSD should not be less than 2.

Sensitivity: The limit of detection and limit of quantification were determined from the standard and slope method as per ICH guidelines. For olmesartan medoxomil, LOD was found to be 0.0405 and LOQ was found to be 0.1230.

Table No. 5.10: Observation of Limit of Detection

S. No.	Slope	SD of precision	LOD((µg/ml)
1	0.1052	0.0012	0.0405

Table No. 5.11: observation of limit of quantitation

S. No	Slope	SD of precision	LOQ(µg/ml)
1	0.1052	0.0012	0.1230

Acceptance criteria: The %RSD of the five replicate samples should not be more than 2.0%.

Robustness

Table No. 5.12: For Robustness Summary, 254 nm and 258 nm wavelengths

S. No	Condition	Modification	Mean absorbance ± SD	%RSD for absorbance
1	Wavelength(nm)	254	0.63388±0.00573	0.9043
2	Wavelength(nm)	258	0.66476±0.00455	0.6854

*Average of three determinations

Acceptance criteria: The %RSD of the five replicate samples should not be more than 2.0%.

Table No. 5.13: For Robustness Summary, at +50°C and -5^{0}C Temperature

S. No.	Concentration	Modification	Mean absorbance ± SD	%RSD for absorbance
1	Temperature	500C	0.6625± 0.01001	1.5094
2	Temperature	-500C	0.6346±0.01170	1.8446

*Average of three determinations

Acceptance criteria: The %RSD of the five replicate samples should not be more than 2.0%.

VI. DISCUSSION

In the present work an attempt was made to develop a simple, accurate, precise, sensitive, and low-cost UV-spectrophotometric method was estimated for Olmesartan medoxomil. The determination of Olmesartan medoxomil in the pharmaceutical preparations was successfully applied in the formulations.

The optimum wavelength of detection was found to be 256 nm, at which a better drug response was obtained employing ethanol as the solvent. The calibration curve was linear in the concentration range of 2-12 µg/ml for Olmesartan medoxomil.

The sensitivity of the drug was calculated, and the LOD and LOQ values of Olmesartan medoxomil were found to be 0.0405 & 0.1230. The low values of the %RSD indicated that the method was precise and accurate; the mean recoveries were found to be in the range of 99-101%.

Robustness of the proposed method was performed by changing slight variations in the wavelength (λmax = 254 nm and 258 nm) and temperature (+5°C and -5°C) during the preparation of the linearity data. The %RSD was found to be less than 2%.

The proposed method was validated in accordance with the ICH guidelines, and the results of all methods are very close to each other as well as to the label value of the commercial pharmaceutical formulations. Therefore, there is no significant difference in the results achieved by the proposed method. Hence, it is suggested that the proposed UV-spectrophotometric method can be effectively applied for the routine analysis of Olmesartan medoxomil in bulk form.

VII. CONCLUSION

A simple, accurate, and economical UV-spectrophotometric method was developed and validated for Olmesartan medoxomil in pure form and tablet form. The drug showed maximum absorbance at 256 nm in ethanol, with excellent linearity (Beer-Lambert's law) over 2–12 µg/ml.

Validation per ICH guidelines confirmed precision (%RSD low for intra/inter-day), accuracy (via recovery studies), robustness, LOD, and LOQ—all within limits, with no excipient interference.

This rapid, sensitive, reproducible method suits routine quality control, assays, and stability studies in pharma labs.

ACKNOWLEDGEMENT

We express our deep sense of gratitude to Dr. K.V. Subba Reddy, Chairman of Dr. K.V. Subba Reddy Group of institutions and Smt. K. Vijayalakshmamma Correspondent of Dr. K.V. Subba Reddy Group of institutions supporting us in providing all equipments and required chemicals and reagents. Finally, we would like to thank to principal Dr. B. V. Ramana sir, all department HODS and all the teaching staff for their support during the project work.

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