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Research Article

A New Method Development and Validation for Quantitative Estimation of Olmesartan Medoxomil in Pharmaceutical Dosage form by UV spectrophotometry

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Abstract: A Simple, Sensitive,Precise,Accurate and Linear Spectroscopic Method has been Developed and Validated for the Estimation of Olmesartan Medoxomil in Tablet Dosage form. The λmax of Olmesartan Medoxomil was Determined by using Acetonitrile : Methanol(1:1) as Solvent and Absorption Maxima of Olmesartan was found to be 257nm.The Linearity was obtained in the Range of 5-15 ug/mL and Coefficient of Correlation was found to be 0.9997.The %RSD was found to be below 2.0 for Repeatability and Interday Precision indicated that the Method was highly Precise. The LOD and LOQ were found to be 0.26 & 0.8ug/ml revealed that the method was Sensitive. The percentage recovery value was found to be 100.12% to 101.87 %, indicating the accuracy of the method and absence of interference of the excipients present in the formulation. The proposed method was simple, fast, Specific, accurate, precise, Rugged and reproducible and hence can be applied for routine quality control analysis of Olmesartan Medoxomil pharmaceutical formulations.
Keywords: Olmesartan, UV Spectroscopy, Estimation, Validation.

INTRODUCTION

The Chemical Name for Olmesartan [1,2] is 2,3-Dihydroxy-2-Butenyl 4(1-Hydroxy-1-Methylethyl)-2-Propyl-1-[P-(O-1H-Tetrazol-5-Ylphenyl)Benzyl] Imidazole5-Carboxylate, Cyclic 2,3-Carbonate. The Molecular Formula for Olmesartan was $C_{29}H_{30}N_6O_6$ and Molecular Weight [3] was 558.59**.** Olmesartan Medoxomil, a Prodrug, is hydrolyzed to Olmesartan during Absorption from The Gastrointestinal Tract. Olmesartan [4,5] is a Selective AT1 Subtype Angiotensin II Receptor Antagonist. Olmesartan is reported to Have P^{ka} Values 5.57 for the Strongest Basic and 0.91 for the Strongest Acidic Group. It is White to Light Yellowish-White Powder or Crystalline Powder and other Brand Names for Olmesartan are Azor (Combination), Benicar, Benicar HCT, Olmetec, Votum, Tribenzor (20mg, 40mg, 80mg). Olmesartan is an Antihypertensive Agent and Angiotensin II Type 1 Receptor Blockers. Some Literature Reports Reveal that Olmesartan can be Estimated by RPLC- HPLC[9], RP- HPLC[10], UPLC[11] and HPTLC[12] Methods Individually or in Combination with Other Drugs. Few Spectrophotometric Methods were reported for Estimation of Olmesartan in Tablet Dosage forms[8]. The development of a method followed according to ICH guidelines [6-7].

The Objective of The Present Investigations Was to Develop a Simple, Specific, Accurate, Rugged and Robust Spectrophotometric Method For Estimation of Olmesartan Medoxomil in Tablet Dosage Form.

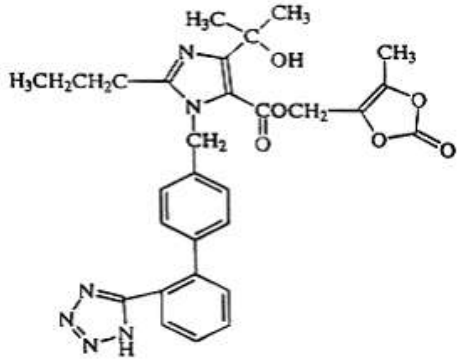

Fig-1: Structure of Olmesartan

MATERIALS AND METHODS

Chemicals and Reagents:

Standard Olmesartan Was Received as a gift Sample from M.S.N Pharmaceuticals Ltd Hyderabad. The Commercially available Olmesartan Medoxomil Tablets claimed to contain 10mg of active ingredients

were procured from local market. Analytical grade Acetonitrile: Methanol (1:1) was used as Solvents.

Instruments:

UV-Visible double beam Spectrophotometer (ELICO SL-210 PC) With Spectrum Treats as a Software, Digital electric balance, Rotary Shaker (Remi Instruments Ltd).

Selection of Wavelength:

In order to ascertain the Wavelength of Absorption maximum (λmax) of the Olmesartan Medoxomil, different solutions of the drugs (5-15 ug/ml) prepared in Acetonitrile: Methanol (1:1) Were Scanned using Spectrophotometer within the Wavelength range 200-400nm against Blank. The resulting spectra were shown in Figure 2 and the Absorption curve showed characteristic absorption maxima at 257nm for Olmesartan Medoxomil.

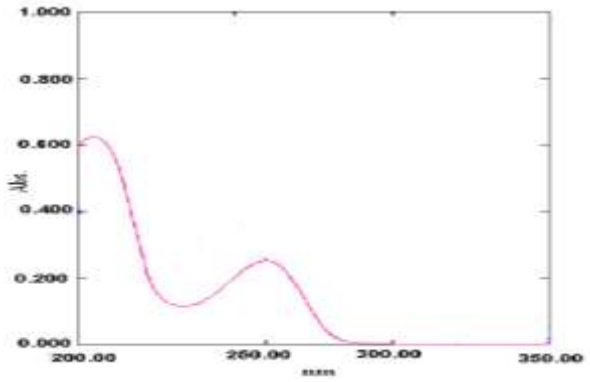

Fig- 2: UV spectrum of Olmesartan medoxomil in Acetonitrile: methanol (1:1) Diuent used: Acetonitrile : methanol (1:1)

Preparation of Standard Stock Solution for Calibration Curve:

Accurately weighed quantity 100 mg of Olmesartan Medoxomil were transferred to 100 ml volumetric flask dissolved in diluent and volume was made up to the mark to diluent further dilute 5ml of this solution in to 50ml volumetric flask volume make up with diluents to produce a stock solution of 100ug/ml . Appropriate aliquots in the range 2.0 – 6.0 ml of olmisartan stock solution were transferred to five separate 20 ml volumetric flasks. The volume was adjusted to the mark with diluent to obtain concentrations of 5, 7.5, 10, 12.5 and 15 µg/ml and was used for the construction of calibration curve.

Preparation of Sample Solution:

Twenty tablets were weighed and ground to fine powder. An accurately weighed quantity of powder equivalent to 100 mg of olmisartan was transferred to 100 ml volumetric flask containing 70 ml of diluent, sonicated for 10 min and volume was made up to the mark with same solvent. The resulting solution was filtered through Whattsmann filter paper (no. 41). Appropriate volume 5ml was transferred to 50 ml volumetric flask and the volume was made up to the mark with same solvent and again further dilute 5ml in to 50ml with same solvent and the Absorbance was Recorded at 257nm.

RESULTS AND DISCUSSION:

Specificity:

Specificity was conducted by Observing Absorption Maximum of Blank, Placebo, and Sample. By Observing Concluded That there is no interference between Drug and Excipients, hence the proposed method was Specific.

Linearity:

Linearity of this Method was determined by using six concentration levels ranging from 5ug/ml to 15ug/ml.The plot of Absorbance Vs Concentration (Fig-3) of Olmesartan was found to be linear in the range of 5-15ug/ml.Beers law found to be obeyed for this concentration range. The regression equation was found to be Y=0.0428x-0.0024 and the Correlation coefficient of the Standard curve were found to be 0.9997(Table-1).

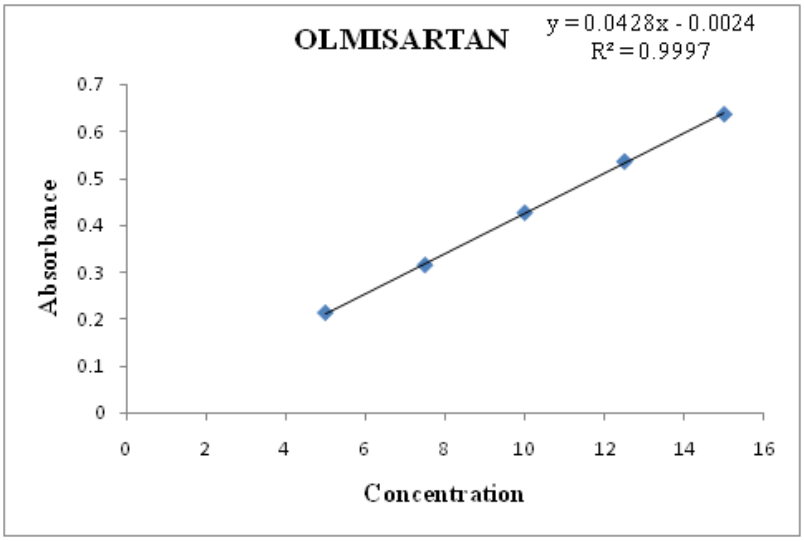

Fig-3: Linearity/Calibration Graph of olmisartan

Precision:

The Precision of the Proposed Method Was Determined by Repeatability (Intra-day) and Intermediate Precision (inter-day) and Reported as %RSD. Repeatability was determined by analyzing 10 µg/ml of olmisartan concentration of drug solutions for six times. Inter-day precision was determined by analyzing the 10µg/ml of Olmesartan Medoxomil solution using two different systems by different analysts analyzed under Day1 and Day2 similar conditions as per the test method and then %RSD was Calculated. The Precision Results showed (Table-1) good Reproducibility with % Relative Standard Deviation (%RSD) was below 2%. This indicates that method was highly Precise.

Recovery Studies (Accuracy):

Recovery Studies were performed to find the accuracy of the method. To The Preanalysed sample solution a known amount of standard solutions of the pure drug (Olmesartan Medoxomil) were added. Recovery studies were carried out at three different levels 50%, 100%, 150% for the formulation concentration of 10ug/ml. The %Recovery values (Table-2) was found to be higher than 100%, So that the proposed method was Accurate.

Sensitivity:

Limit of Detection (LOD) and Limit of Quantification (LOQ) were calculated based on the standard Y- intercept and slope of calibration curve method. The LOD &LOQ for Olmesartan was were found to be 0.184 and 0.558 ug/ml respectively in (Table1) this concluded that the method is sensitive.

Ruggedness:

Ruggedness of the proposed method was determined by analysis of aliquot from homogenous slot by two analyst using same operational and environmental conditions and the results are reported in Table 3.

Robustness:

Robustness of the analytical method for assay of olmesartan Medoxomil was determined under deliberate condition of wavelength at lower and higher sides of the value. Results are reported in Table 4.

Table-1 Validation Parameters

Parameter	Result	
Absorption Maxima(nm)	257	
Linearity Range(ug/mL)	5-15	
Standard Regression Equation	Y= 0.0428x-0.0024	
Correlation Coefficient	0.9997	
LOD(ug/ml)	0.26	
LOQ(ug/ml)	0.8	
Precision	Intra-day(%RSD)	Inter-day(%RSD)
	0.19	0.11

Table-2 Recovery Study

S.no	Recovery	Addition of pure drug (in mg)	Amount found (in mg)	%Recovery	%Mean Recovery	S.D	%RSD
1	50%	50.05	50.062	100.02	100.70	0.18	0.17
2	100%	100.09	100.954	100.86	100.75	0.11	0.10
3	150%	150.10	150.707	100.40	100.66	0.05	0.04

Table-3 Ruggedness

S.no	%Amount foundin olmesartan(n=6)	%RSD
Analyst-1	96.79	0.19
Analyst-2	97.05	0.07

Table-4 Robustness

Sample name	Actual at 257nm	Wavelength + at 260nm	Wavelength -at 254nm
Standard	0.4844	0.4767	0.4790
Sample	0.4670	0.4575	0.4635
%Assay	96.52%	96.08%	96.87%

Table-5 Determination of active ingredient in Tablets

Sample	Label claimed	Amount found	%Label claim
Olmesartan Medoxomil	10mg/Tab	10.01mg	100.10

Stability:

The Stability of the solutions (Both Standard and Sample) was checked by measuring the Absorbance over a period of 24hrs at Room Temperature (Unstressed condition) and 105°c (Stressed condition). It was observed that for both solutions the Absorbance and Spectrum of Olmesartan almost similar in both conditions so that the proposed method was highly stable and results shown in Table-6.

Table-6 Stability Data

Sample Name	Absorbance of Olmesartan(10ug/ml) Standard at 257nm	Absorbance of Olmesartan(10ug/ml) Sample at 257nm
Initial	0.4788	0.4596
24 hr at RT	0.4717	0.4515
%Difference	0.55%	0.61%

CONCLUSION

From the above discussion an efficient UV Method was developed and validated for estimation of Olmesartan Medoxomil in Pharmaceutical Dosage form. It was concluded that The Proposed method was Specific, Sencitive, Stable and Reliable with good Precision and Accuracy and Robust. The Proposed method was applied for the assay of Olmesartan Medoxomil in Tablet formulation and the results were in good. (Table-5).Hence this method can be used for routine determination of Olmesartan Medoxomil in Pure sample and in Tablet formulation.

ACHKNOELEDGEMENT

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