WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 5.045
Volume 4, Issue 1, 1667-1672. Research Article ISSN 2277– 7105

UV SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF AZILSARTAN MEDOXOMIL IN BULK AND PHARMACEUTICAL FORMULATIONS

Kunal Sharad Surwade*, Ravindra Bhanudas Saudagar

KCT'S RGS College of Pharmacy, Anjaneri, Nashik, 422 213. Maharashtra, India.

Article Received on
08 Nov 2014,

Revised on 03 Nov 2014,
Accepted on 28 Dec 2014

***Correspondence for Author**
Kunal Sharad Surwade
KCT'S RGS College of Pharmacy, Anjaneri, Nashik, 422 213.
Maharashtra, India.

ABSTRACT

In this study, a simple, sensitive and highly accurate ultraviolet spectrophotometry method has been developed and validated for determination of Azilsartan medoxomil. It is an angiotensin II receptor antagonist used in the treatment of hypertension. U.S. food and Drug Administration approved for treatment of high blood pressure in adults. The method is based on the measurement of the absorbance of Azilsartan medoxomil solution in Methanol: Water (50:50 v/v) at 249 nm in the wavelength range of 200-400 nm. Beer's law was obeyed in the concentration range 2-20 µg/mL with correlation coefficient of 0.9996. The percentage recovery of Azilsartan medoxomil ranged from 99.998 to 101.857 % in Bulk. Results of analysis were validated for accuracy, precision, LOD, LOQ, and were found to be satisfactory. The proposed method in simple, rapid and suitable for the routine analysis.

KEYWORDS: Azilsartan medoxomil, Methanol: Water, Spectrophotometry and Validation.

INTRODUCTION

Azilsartan medoxomil is an angiotensin II recptor anatagonist which has chemical names (5 methyl-2-oxo-1,3-dioxol-4-yl)methyl-2-ethoxy-1-{[2'-(5-oxo-4,5-dihyro-1,2,4-oxadiazol-3 yl)biphenyl-4-yl]methyl}-1H-benzimidazole-7-carboxylate monopotassium salt. Azilsartan Medoxomil is rapidly hydrolyzed to the active moiety Azilsartan by esterase in the gestrotestinal tract and during the drug absorption.

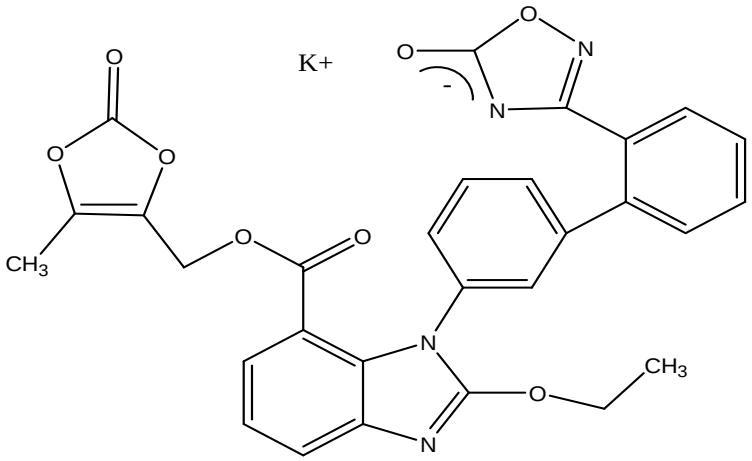

Figure 1: Structure of Azilsartan Medoxomil.

Literature survey reveals the Azilsartan Medoxomil can be estimated by several Spectrophotometer, RP-HPLC and Spectrofluorimetric methods with combination with other drugs. The scopes of present investigation were to developed and validate spectrophotometry method for Qualitative and quantification of Azilsartan Medoxomil in bulk and formulation.

MATERIALS AND METHODS

Materials: Azilsartan medoxomil working standard drug was obtained from Hetro labs ltd, Hyderabad. All analytical grade chemicals and solvents were supplied by S.D. Fine chemicals, Mumbai, India. Distilled water was used to prepare all solution. Freshly prepared solutions were always employed.

Equipment: The UV-spectrophotometry **(**Jasco V630**)** with data processing system (UV Probe Software 2.31) was used. The sample solution was recorded in 1 cm quartz cell against solvent blank over the range 200-400 nm. The citizen electronic balance (Schimadzu 220h) was used for weighing the sample. An ultrasonicator bath (PCI Analytics Pvt. Ltd) was used for sonicating the drug sample.

Method Development

Preparation of Standard Stock Solution

Azilsartan Medoxomil was accurately weighed and transferred to a 10ml volumetric flask. It was first dissolved in 5 ml methanol and sonicated with continually sonication make up the 10 ml volume using distilled water. 5ml of resulting solution is father diluted up to the 50 ml using solution of Methanol: Water (50:50 v/v). (100 µg/mL)

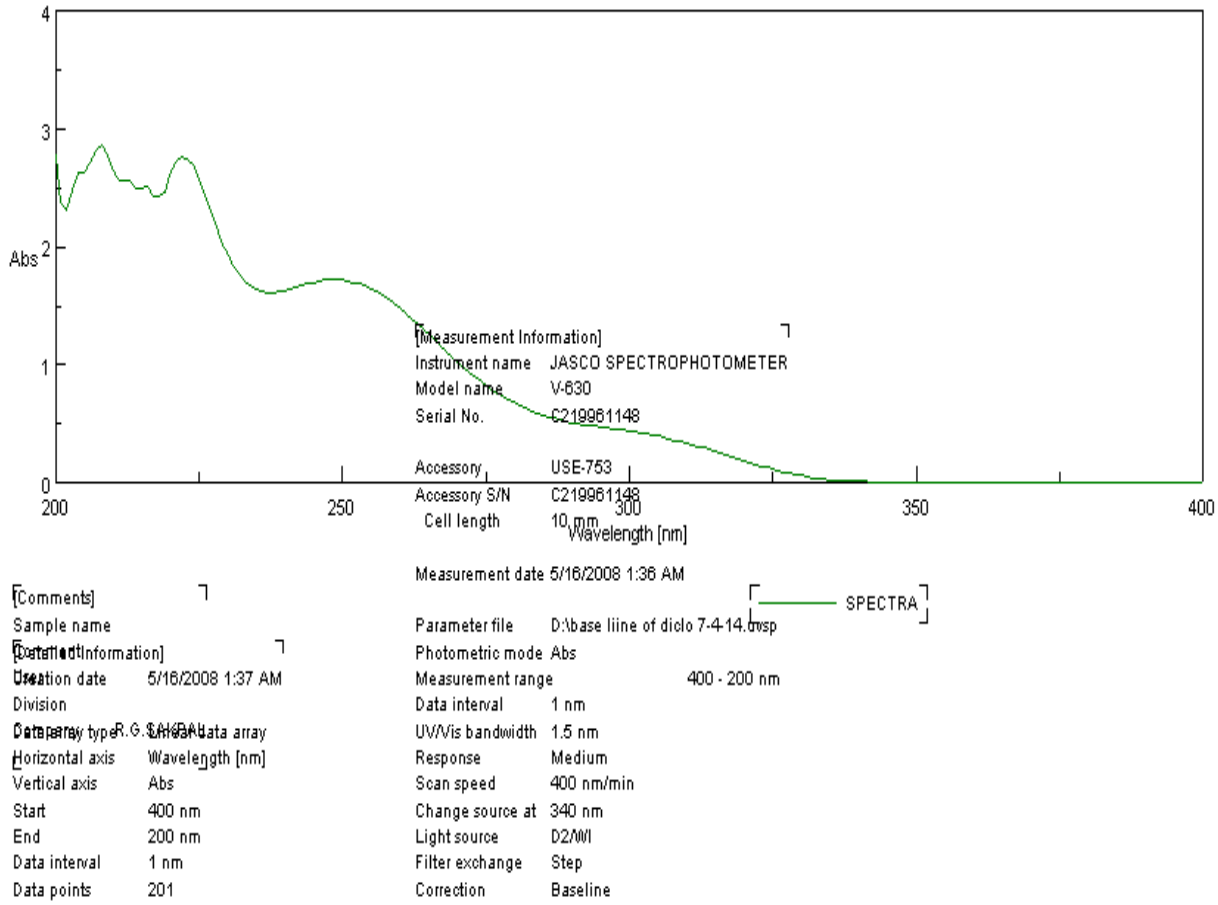

Figure 2: Spectrum of Azilsartan Medoxomil in Methanol: Water (50:50 v/v).

Preparation of Calibration Curve

From the standard stock solution fresh aliquots were pipette out and suitably diluted with Methanol: Water (50:50v/v) to get final concentration in the range of 2-20 µg/mL. The solutions were scanned under spectrum mode for 200-400 nm wavelength range and sharp peak was obtained at 249 nm. The liners relationship was observed over the range of 2-20 µg/mL. Absorbance was noted at 249 nm against methanol: water (50:50 v/v) as a blank. A calibration graph of the absorbance versus the concentration of the drug was plotted and represented in figure 2.

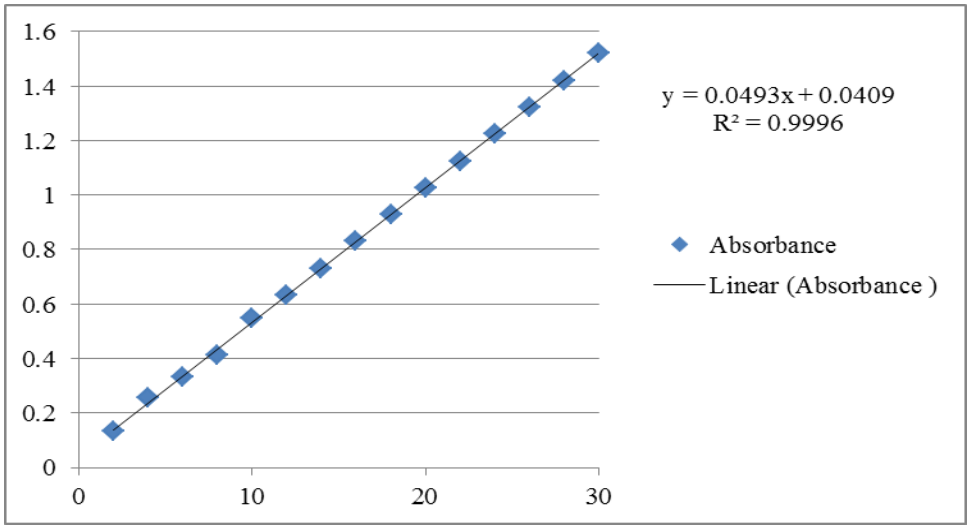

Figure 2: Calibration curve of Azilsartan Medoxomil at 249 nm.

Method Validation

Validation of the Proposed Method

The proposed method was validated according to the (ICH) guidelines.

Linearity

The developed method validates as per ICH guidelines. The plot of absorbance verses concentration is shown in figure 2. It can be seen that plot is linear in the concentration range of 2-20 µg/ml with correlation coefficient (R^2) of 0.999.

Precision

Intraday and interday precision was determined by measurement of the absorbance for three times on same day and on three different days. The relative standard deviation for replicates of sample solution was less than 2% which meet the acceptance criteria for established method. The obtained results are presented in table 1.

Table 1: Precision Study.

Concentration µg/mL	Absorbance Mean	Standard Deviation	% Relative Standard Deviation
Intraday Precision(n=3)			
80	0.42153	0.000305	0.0724
100	0.53183	0.000251	0.0473
120	0.62733	0.000115	0.0184
Interday Precision(n=3)			
80	0.4329	0.000153	0.03528
100	0.5429	0.000153	0.02813
120	0.6353	0.000265	0.04164

Accuracy

Recovery studies were carried out by adding a known quantity of pure drug to the reanalyzed drug and the proposed method was followed. From the amount of drug found, percentage recovery was calculated as per ICH guidelines. The data were presented in table 2.

Table 2: Accuracy Study.

Sample	Amount of Standard Drug Added mg	Formulation	Total Mount Recovered mg	% Recovered	Standard Deviation	% Relative Standard Deviation
80	8	10	18.179	100.9	0.041	0.225
100	10	10	20.371	101.8	0.024	0.121
120	12	10	21.999	99.9	0.044	0.202

LOD and LOQ

The limit of detection (LOD) and limit of quantification (LOQ) of the drug were separately determined based on method of the intercept and the average value of slope. (i.e. 3.3 for LOD and 10 for LOQ) ratio using the following equations designated by ICH guideline.

LOD = 3.3 σ/S LOQ = 10 σ /S.

Where, σ = the standard deviation of the response, S = slope of the calibration curve.

Table 3: Optical Parameter.

Sr. No.	Parameter	Data
1	λ-max	249 nm
2	Beer's law limit	2-20 µg/mL
3	Regression equation	$y = 0.0493x + 0.0409$
4	Correlation coefficient	$R^2 = 0.9996$
5	Slope	0.0493
6	Intercept	0.0409
7	Limit of detection	0.204 µg/mL
8	Limit of quantification	0.619µg/mL

RESULTS AND DISCUSSION

Beer's law is obeyed over the concentration range of 2-20 µg/ml, using regression analysis the linear equation y = 0.0493x + 0.0409 with a correlation coefficient of 0.9996. The limit of detection was found to be 0.204µg/mL. The limit of quantification was found to be 0.619µg/ml. Precision was calculated with intra and interday variation. Recovery study was performed on formulations and % RSD was found. The optical parameters such as Beer's law limit, slope, and intercept values were calculated and given in table 3. Method was validated for accuracy and precision. The accuracy of method was proved by performing

recovery studies in prepared formulation. The results were given in table 2 and shows relative standard deviation was observed for analysis of three replicate samples, indicating precision and reproducibility.

CONCLUSION

The simple spectrophotometric method for determination of Azilsartan Medoxomil have been developed and validated as per ICH guidelines. The developed method is found to be sensitive, accurate and reproducible and can be used for the routine quality control analysis of Azilsartan Medoxomil in pure drug.

REFERENCES

1. Q2A: Text on; Validation of Analytical Procedures. In International Conference on Harmonization. Federal Register. 1995; 60(40): 11260–11262.
2. Q2B: Validation of Analytical Procedures: Methodology, Availability. In International Conference on Harmonization. Federal Register. 1997; 62(96): 27463–27467.
3. FDA approves Edarbi to treat high blood pressure (Press release). U.S. Food and Drug Administration (FDA). February25, 2011. Retrieved 2011-03-01.
4. http://www.drugs.com/azilsartanmedoxomil.html (9th Septemberr 2014).
5. Kasimala MB, Kasimala BB. Reverse Phase-HPLC Method Development and Validation for the Simultaneous Estimation of Azilsartan Medoxomil and Chlortalidone in Pharmaceutical Dosage Form; Jam online, 2012; 2(1): 117–126.
6. Pradeepthi J. Masthanamma SK. A Validated Spectrophotometric Method for Determination of Azilsartan Medoxomil in Pharmaceutical Dosage From. Journal of Scientific Research in Pharmacy, 2013; 2(4): 7-10.
7. Masthanamma S K Pradeepthi J. Stability Indicating RP-HPLC Method for Determination of Azilsartan Medoxomil in Pharmaceutical Dosage Form; Research Journal of Pharmacy and Technology, 2014; 7(2): 168-172.
8. Walid M. Ebeid, Ehab F. Elkady. Spectrophotometric And Spectrofluorimetric Studies on Azilsartan Medoxomil and Chlorthalidone to Be Utilized in Their Determination in Pharmaceuticals; Analytical Chemistry Insights, 2014; 9(33): 33-40.