INTERNATIONAL JOURNAL OF PHARMACY AND ANALYTICAL RESEARCH

ISSN: 2320-2831

IJPAR |Vol.4 | Issue 3 | Jul-Sep-2015
Journal Home page: www.ijpar.com

Research article *Open Access*

A Simple Validated RP-HPLC Method for Quantification of Azilsartan Medoxomil in Bulk and Pharmaceutical Dosage Forms

Jampala Balaji*, Bandi Ramachandra, Niranjan and N.V.S.Naidu.

Department of Chemistry, Sri Venkateswara University, Tirupathi, India-517502

***Corresponding author: Jampala Balaji**

ABSTRACT

A simple reverse phase high performance liquid chromatography method developed for quantification of Azilsartan Medoxomil in bulk and pharmaceutical dosage forms. This method achieved by using isocratic elution with mixed phosphate buffer (pH: 6.8 ± 0.1) and acetonitrile mobile phase at 80:20 ratio, Zodiac C18 column (100 X 4.6mm, 3µm) at temperature 30ºC, flow rate 1.0mL/min and 243nm UV-Visible detector. This method validated as per ICH guidelines. This method was simple, specific, precise, linear, accurate, robust and ruggedness for analysis of Azilsartan Medoxomil.

KEYWORDS: Azilsartan Medoxomil, Reverse Phase HPLC, UV-Visible detector, Isocratic elution.

INTRODUCTION

Azilsartan Medoxomil is chemically named as (5-Methyl-2-oxo-1,3-dioxol-4yl) methyl 2-ethoxy-1-{[2'-(5-oxo-4,5-dihydro-1,2,4-oxadiazol-3-yl)biphenyl-4-yl]methyl}-1H-enzimidazole-7-carboxylate (Figure 1). It is a white crystalline powder which is practically insoluble in water, freely soluble in methanol, dimethylsulfoxide, and dimethyl formamide, soluble in acetic acid, slightly soluble in acetone, and acetonitrile and very slightly soluble in tetrahydrofuran and 1-octanol [1]. Azilsartan Medoxomil is an angiotensin II receptor antagonist used in the treatment of hypertension that was developed by Takeda. Azilsartan is an angiotensin II receptor blocker (ARB) that lowers blood pressure by blocking the action of angiotensin II, a vasopressor hormone. Azilsartan Medoxomil is used in the treatment high blood pressure (hypertension). Lowering high blood pressure helps prevent strokes, heart attacks, and kidney problems. Azilsartan belongs to a class of drugs called angiotensin receptor blockers (or ARBs). It works by relaxing blood vessels so that blood can flow more easily [2]. It is US FDA approved as Edarby tablets on 25th Feb 2011, to treat hypertension in adults. As per literature few methods are found for the determination of Azilsartan Medoxomil by using chromatography (3, 4). The developed RP-HPLC method is very simple, selective, precise, linear, accurate and robust with lower run time for the determination of Azilsartan Medoxomil in bulk and pharmaceutical dosage form.

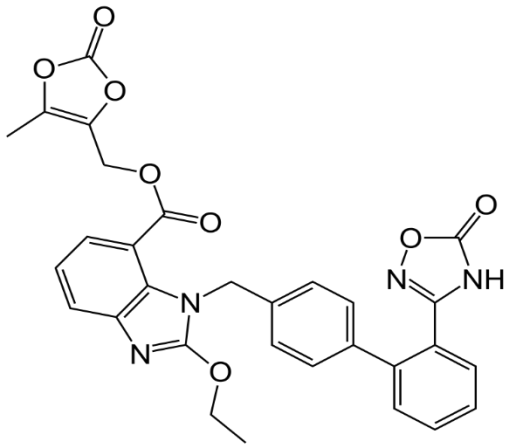

Figure 1: Azilsartan Medoxomil

MATERIALS AND METHODS

APPARATUS

HPLC (Model: Alliance 2695 separation module with UV-Visible detector, Make: Waters, Software: Empower-2), Digital pH meter (Model: LP-1393, Make: POLMAN), Sonicator (Model: Soltec, Make: Sonica), Electronic Weighing Balance (Model: ML204 Ia01, Make: Mettler Toledo).

CHEMICALS AND REAGENTS

Acetonitrile (HPLC grade, Make: Qualigens fine chemicals), Potassium dihydrogen orthophosphate (AR grade, Make: S.D Fine Chem. Ltd), Dipotassium hydrogen phosphate (AR grade, Make: S.D Fine Chem. Ltd), Water (HPLC grade), Potassium hydroxide (AR grade, Make: Rankem), Azilsartan Medoxomil (Richer Pharmaceuticals, Hyderabad, India).

CHROMATOGRAPHIC CONDITIONS

This separation of analytes achieved by isocratically using Zodiac C18 column (100 X 4.6mm, 3µm), column oven temperature 30 ◦C, flow rate 1.0mL/min, UV at 243 nm. Mobile phase was mixed phosphate buffer (pH: 6.8 ± 0.1) and acetonitrile at 80:20 ratio. Diluent was mobile phase. Run time was 10min.

PREPARATION OF MOBILE PHASE

0.3 g of potassium dihydrogen orthophosphate and 1.36 g of dipotassium hydrogen phosphate weighed and transferred to 1000 mL volumetric flask and make up to the mark with water and adjusted pH: 6.8 (±0.1)with diluted potassium hydroxide solution. This mixed buffer and acetonitrile were taken in the ratio of 80:20 and mixed well then filtered through 0.45 µm Millipore filter paper and sonicated using sonicator up to 15min.

PREPARATION OF STANDARD SOLUTION

Prepared 20mg of Azilsartan Medoxomil working standard in 100mL diluent for standard stock solution. Transferred 10mL of the standard stock solution in to 100mL volumetric flask and made up to the mark with diluent. This standard solution used to sample analysis.

PREPARATION OF SAMPLE SOLUTION

BULK AZILSARTAN MEDOXOMIL ANALYSIS

20 mg of bulk sample weighed and transferred in to 100 mL volumetric flask then made up to the mark with diluent then used as a sample stock solution. Transferred 10mL of the sample stock solution in to 100 mL volumetric flask and made up to the mark with diluent. This sample solution used to sample analysis.

PHARMACEUTICAL FORMULATIONS ANALYSIS

10 tablets of Azilsartan Medoxomil (80mg) powdered using mortar. 101 mg of this powder sample weighed and transferred in to 100 ml volumetric flask and dissolved in 50 mL diluent then made up to the mark with diluent . This sample solution filtered then used for sample analysis.

SAMPLE ANALYSIS

Injected 20µL of blank (diluent), standard solution and sample solution in HPLC for sample analysis.

METHOD VALIDATION

SPECIFICITY AND SELECTIVITY

The specificity of the method was checked by injecting blank solution and sample solution. There was no interference from blank and excipients at the retention time of analyte peak.

SYSTEM SUITABILITY

Injected the system suitability solution and checked the system suitability. The tailing factor value was less than 2.0 and theoretical plate's value was more than 2000.

LINEARITY

Linearity was checked by preparing five concentrations of the substance ranging from 50% to 200% level of the target. A concentration of 20 ppm solution was proposed in the procedure as a 100%. Hence, the test substance was prepared at concentrations of 10 ppm, 15 ppm, 20 ppm, 30 ppm and 40 ppm for determination of linearity. Estimations were carried out as per the procedure mentioned. Observations were recorded and a linearity curve was prepared using regression analysis. The correlation coefficient was 0.9999. Linearity graph was shown in Figure 4.

ACCURACY

The accuracy of the method was determined by % of recovery method for the spiked concentration levels of 10 ppm (50%), 20 ppm (100%) and 30 ppm (150%). The accuracy results were shown in table1.

PRECISION

The method precision and system precision were performed. The results were within limits**.** The results were shown in table2.

ROBUSTNESS OF THE METHOD

Changing with the flow rate (±0.1mL/minute) and column oven temperature (±2ºC) and calculated RSD. The results were within limits.

RUGGEDNESS OF THE METHOD

The ruggedness of the method was performed with different analyst and different day analysis and calculated RSD. The results were within limits.

RESULTS AND DISCUSSIONS

The developed method was validated as per ICH guidelines for specificity, linearity, accuracy, precision, robustness and ruggedness. The results were within limits.

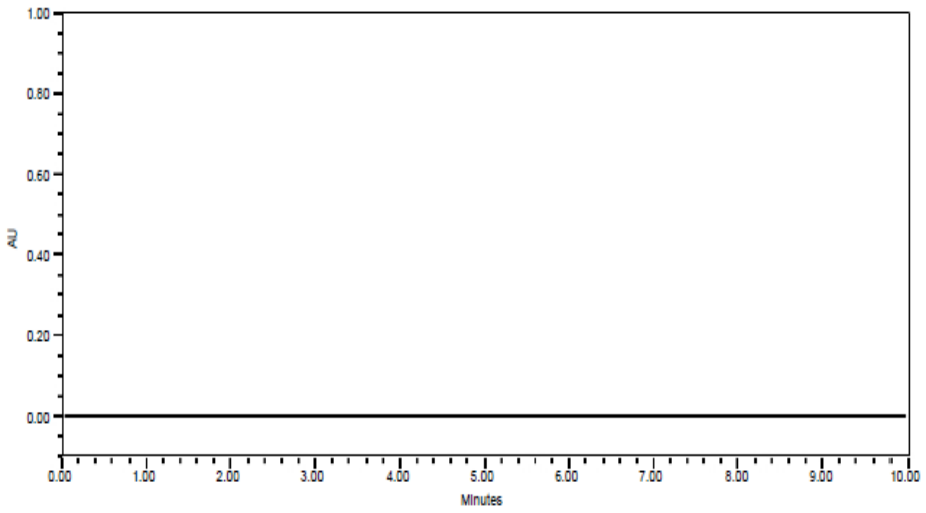

Figure 2: Chromatogram of Blank

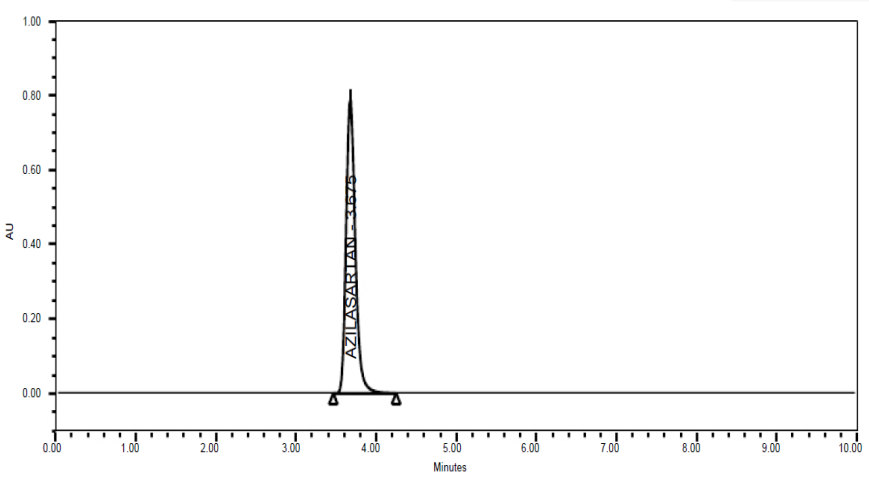

Figure 3: Chromatogram of Azilsartan Medoxomil

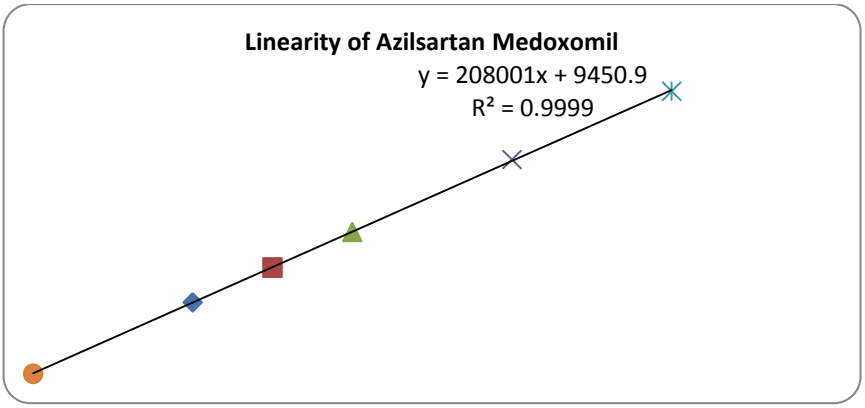

Figure 4: Linearity graph for Azilsartan Medoxomil analysis

Table1: Accuracy

Concentration Level (spike)	Recovery
50%	99.53%
100%	100.05%
150%	99.68%

Table2: Precision

Precision	%RSD
System Precision	0.05%
Method Precision	0.19%
Intermediate Precision	0.43%

CONCLUSION

The developed Reverse Phase HPLC method was very simple, selective and reproducible method for analysis of Azilsartan Medoxomil in bulk and pharmaceutical dosage forms. This method was having very low run time. It was accurate, precise, linear, robust and ruggedness method. As per best of my knowledge this method was very simple method for determination of Azilsartan Medoxomil in both bulk and pharmaceutical dosage forms.

REFERENCES

[1]. Paras P. Vekariya and Hitendra S. Joshi, "Development and Validation of RP-HPLC Method for Azilsartan Medoxomil Potassium Quantitation in Human Plasma by Solid Phase Extraction Procedure", Hindawi Publishing Corporation, ISRN Spectroscopy, Volume 2013, Article ID 572170, 2013.

[2]. Madhu Babu Kasimala, Bikshal Babu Kasimala, "Reverse phase HPLC Method Development and Validation for the Simultaneous Estimation of Azilsartan Medoxomil and Chlortalidone in Pharmaceutical Dosage Forms", Journal of Atoms and Molecules, 2(1),117–126, 2012.

[3]. S. Naazneen, A. Sridevi, "Stability indicating RP-HPLC Method for the Simultaneous Estimation of Azilsartan Medoxomil and Chlorthalidone in Solid Dosage Forms", International Journal of Pharmacy and Pharmaceutical Sciences, Volume 6, Issue 6, 2014.

[4]. P. Sravani, S. Rubesh Kumar, N. Duganath, N. Devanna, "Method Development and Validation for the Simultaneous Estimation of Azilsartan and Chlorthalidone by RP-HPLC in Pharmaceutical Dosage Form", International Journal of Pharma Sciences, Vol. 4, No. 5, 725-729, 2014.