

Determination of Azilsartanmedoxomil by Visible Spectrophotometry

Dr.K. Sandhyarani

Department of BS&H Avanthi institute of Engineering and Technology, Cherukupally, Tagarapuvalasa, Vizianagaram 531162.

DOI: <https://doi.org/10.51583/IJLTEMAS.2025.140400109>

Received: 16 April 2025; Accepted: 13 May 2025; Published: 20 May 2025

Abstract: A simple and reproducible spectrophotometric method has been developed for the determination of Azilsartanmedoxomil in bulk and pharmaceutical dosage forms. The method is based on the extraction of the drug into organic layer of the dye TPooo in presence of 0.1 N hydrochloric acid and the absorbances were measured at 485 nm. The method was optimized using eight parameters. The linearity range of Azilsartanmedoxomil with TPooo was found to be 0.5 – 3.0 ml; 400 µg/ml. The developed method was found to be precise and accurate from the statistical validation of the analytical data. The proposed method has been successfully applied for analysis of dosage formulations.

Keywords: Azilsartanmedoxomil, TPooo, and Spectrophotometric method.

I. Introduction

Azilsartanmedoxomil is the newest angiotensin receptor blocker marketed for the treatment of arterial hypertension. Azilsartanmedoxomil acts by antagonizing the angiotensin II type 1 receptor. Where angiotensin II is potent vasoconstrictor; which also causes synthesis and release of aldosterone. By blocking AT1 receptor it blocks the aldosterone and vasoconstrictor effects of angiotensin II.

Azilsartanmedoxomil has an ability to remain tightly bound to AT1 receptor for very long period of time. Azilsartanmedoxomil is used for treatment of essential hypertension. Azilsartanmedoxomil was found to be superior to olmesartan and Valsartan.

Azilsartan is an angiotensin II receptor blocker (ARB). It works by blocking a substance in the body that causes blood vessels to tighten. As a result, Azilsartan relaxes the blood vessels. This lowers blood pressure and increases the supply of blood and oxygen to the heart.

Azilsartan is an angiotensin II receptor antagonist used in the treatment of hypertension, developed by Takeda. Edarbi is an angiotensin II receptor blocker (ARB) that lowers blood pressure by blocking the action of angiotensin II, a vasopressor hormone.

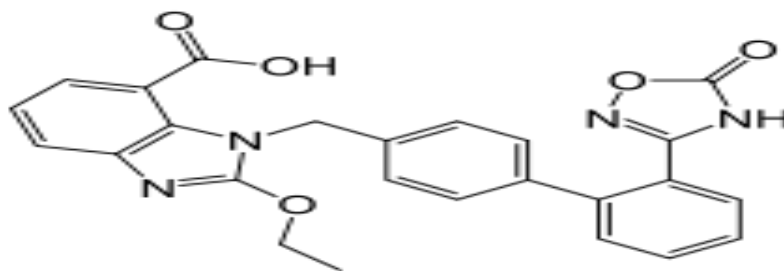


Fig1: Chemical structure of Azilsartan

Experimental

A Systronics UV-Visible double beam spectrophotometer 2203 with 1 cm matched quartz cells was used for all spectral and absorbance measurements. A Systronics digital pH meter 361 was used for pH measurements. All the chemicals used were of AR grade. Solutions of 0.2 % TPooo and 0.1 N hydrochloric acid were prepared using distilled water. AR grade chloroform was used.

Preparation of standard drug solutions:

The stock solution (1 mg/ml) of Azilsartanmedoxomil (AZS) was prepared by dissolving 100 mg of it in 100 ml of methanol. A portion of this stock solution was diluted stepwise with the methanol to obtain the working standard AZS solution of concentration 400 µg/ml.

Preparation of sample solution:

An accurately weighed portion of the powdered tablets equivalent to 100 mg of drug was dissolved in 20 ml of methanol (MeOH), shaken well and filtered. The filtrate was diluted to 100ml with MeOH to get 1 mg/ml solution of drug in formulations.

Preparation of the reagents:

All the chemicals and reagents were of analytical grade and all solutions were freshly prepared in Millipore distilled water.

Tpooo (0.2%): Prepared by dissolving 200 mg of Tropaeolinooo in 100 ml of distilled water and washed with chloroform to remove chloroform soluble impurities.

HCl solution: prepared by dissolving 8.6 ml of con HCl to 1000 ml of distilled water and Standardized.

Chloroform: AR grade chloroform was used as it is.

II. Method:

Aliquots of standard AZS solution (0.5-3.0ml, 400 $\mu\text{g/ml}$), were placed in a series of 125 ml separating funnels. 5.0 ml of 0.1M HCl, and 2.0 ml of TPOOO were added successively. The total volume of aqueous phase in each separating funnel was adjusted to 15 ml with distilled water. Then 25ml of chloroform was added to each separating funnel and the contents were shaken for 2 min and allowed to separate. The organic layer was collected through cotton plug/ filter paper and the absorbance was measured immediately at λ_{max} 485 nm against a reagent blank. The coloured species was stable for one hour. The amount of AZS in the sample solution was calculated by using Beer's law plot.

III. Results and Discussion

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar extinction coefficient, percent relative standard deviation and percent range of error were calculated for the method and the results are summarized in Table 1. The accuracy of the methods was ascertained by comparing the results of the proposed methods with that of reported method. In order to justify the reliability and suitability of proposed methods, known amounts of pure drug was added to its various pre analyzed dosage forms and were analyzed by the proposed method. The results presented in Table 2, which indicates that the proposed method can be successfully applied for the analysis of Azilsartanmedoxomil in dosage forms. The additives and excipients usually present in pharmaceutical preparations did not interfere. Thus, the proposed method was simple, sensitive, accurate and reproducible and can be used for the routine analysis of Azilsartanmedoxomil in bulk and in pharmaceutical dosage forms.

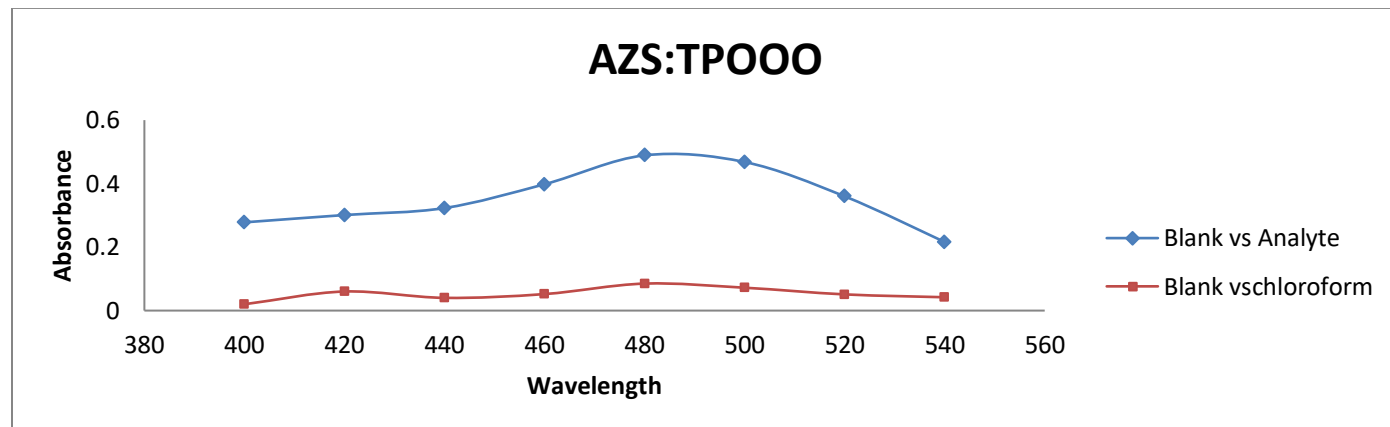


Fig2: Absorption spectra of AZS: TPOOO

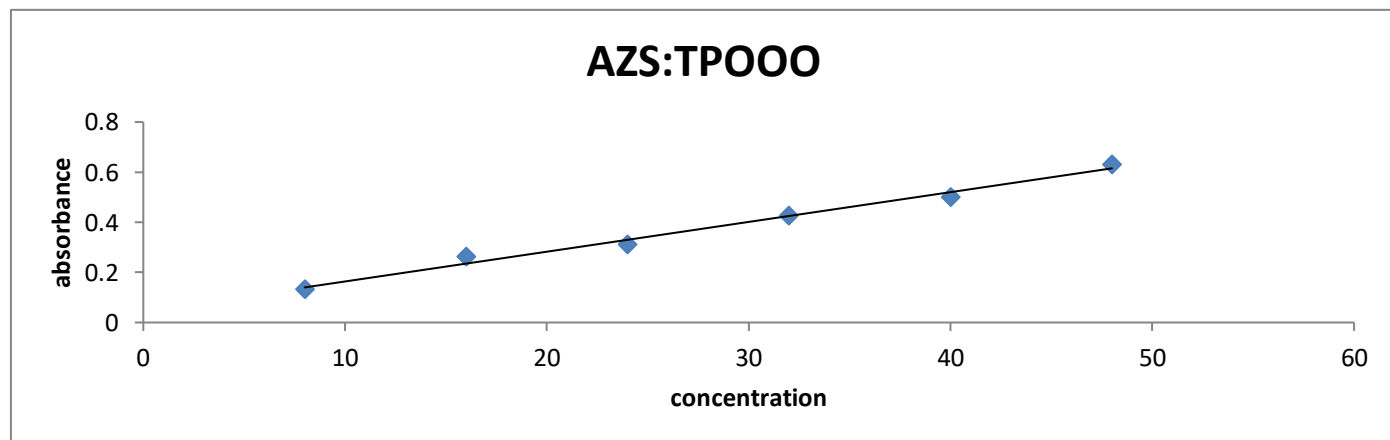


Fig3: Beer's plot of AZS: TPOOO

Table1: Optical and Regression characteristics, precision and accuracy of the proposed method for AZS

Parameter	Method
$\lambda_{\max}$ (nm)	485
Beer's law limits ($\mu\text{g ml}^{-1}$)	8-48
Detection limits ($\mu\text{g ml}^{-1}$)	10.136
Molar absorptivity (1 mole cm^{-1})	1.4264×10^5
Sandell's sensitivity ($\mu\text{g cm}^{-2}$ / 0.001 absorbance unit)	0.008
Regression equation ($Y = a + bC$) Slope (b)	0.011
Standard deviation of slope (S_b)	1.193×10^{-3}
Intercept (a)	0.045
Standard deviation of intercept (S_a)	3.716×10^{-2}
Standard error of estimation (S_e)	3.993×10^{-2}
Correlation coefficient (r^2)	0.988
Relative standard deviation (%)*	0.638
% Range of error (Confidence limits)*0.05 level	0.6696
0.01 level	1.0501
% Error in bulk samples **	0.4

Table 2: Assay of Azs In Pharmaceutical Formulations

Sample	Amount taken (mg)	Amount found by proposed methods*	Reference methods\$	Percentage recovery by proposed methods**
Tablet I	80	79.682 $\pm$ 0.114 F=1.145 t =0.48	79.738 $\pm$ 0.122	99.506 $\pm$ 0.312
Tablet II	40	39.756 $\pm$ 0.192 F=2.28 t =1.53	39.648 $\pm$ 0.127	99.457 $\pm$ 0.324

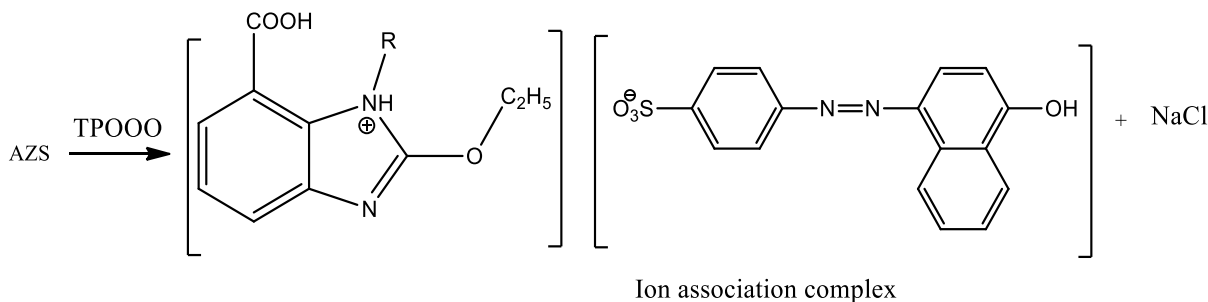
*: Average $\pm$ standard deviation of six determinations; the t- and F- values refer to comparison of the proposed method with the reference method. Theoretical values at 95% confidence limit t=2.57, F=5.05.

** : After adding 2 different amounts of the pure labelled to the pharmaceutical formulations, each value is an average of 3 determinations

\$: UV Reference method.

Chemistry of the coloured species:

Azilsartanmedoxomil possesses different functional moieties such as tertiary amino group and imidazole group proposed method are based on the reactivity of either tertiary amine (ion association complex formation with acid dyes TPOOO) complex formation with the reviews concerning the reagents used for color development by exploring appropriate functional groups in AZS are presented.



References:

1. Goodman, L.S. and Gilman, A.G., The Pharmacological Basis of Therapeutics, 9th Edn. By Hardman, J.G., Limbard, L.E., Editors in Chief, McGraw - Hill, 1996.
2. Wolff, M.E., Edt, Burger's Medicinal Chemistry, Part IV, 4th Edn., Wiley Interscience, New York, 1981.
3. Deorge, R.F., Edt., Wilson and Gisvolds Text book of Organic and Medicinal and Pharmaceutical Chemistry, 8th Edn., Lippincott Company, 1982.
4. Korolkovas, A., Essentials of Medicinal Chemistry, 2nd Edn., Wiley Interscience, New York, 1988.
5. Topliss, J.G..Edt.. Quantitative Structure - activity relationships of Drugs, Vol 19, Academic press, London, 1983.
6. Rao,N.V., Sastri, C.K., J.Ind.Chem.Soc., 1987, 64, 131.
7. Mahadevappa,D.S., Naidu, H.M.K., Talanta, 1973, 20, 349.
8. Mahadevappa,D.S., Anandamurthy,A.S., Talanta, 1970, 17, 131.
9. Rasheed et al. Asian Journal of Chemistry Vol. 22, No. 4 (2010), 2491-2494
10. MrutyunjayaRao et al. IJPCBS 2014, 4(3), 522-528
11. DC Pavithra; SS Lakshmi, Indian J Pharm. Sci.,**2006**, 68(3), 375-376.
12. J Dharuman;V Ravichandran; N Thirumoorthy; A Dharamsi,Pharmazie,**2004**, 59,720-721.
13. MM Annapurna; ME Bhanoji Rao;VV Ravikumar, E -Journal of Chemistry**2007**,4,79-82.
14. K Basavaiah; UR Anil Kumar, E- Journal of Chemistry**2006**, 3(13), 242-249.
15. K Basavaiah ; UR Anil Kumar ; K Tharpa ; KB Vinay , J. Chilean Chem. Soc., **2008**, a. 53(3), 1635-1639.
16. K Basavaiah; UR Anil Kumar; K Tharpa; RP Nagaraju; SH Ganeshbhat; KB Vinay, a. Archives of Pharmacal Research**2009**, 32(9), 1271-1279.
17. SS Zarapkar; RV Rele; VJ Doshi, Indian drugs**1987**, 24(12), 560-564.