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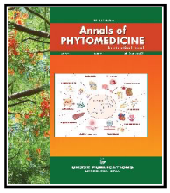

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Validated RP-HPLC method for estimation of azilsartan medoxomil in bulk and tablet dosage form: A green analytical approach

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Abstract

An efficient, sensitive, and eco-friendly reverse-phase high-performance liquid chromatography (RP-HPLC) method has been developed and validated for the quantification of azilsartan medoxomil, a widely used antihypertensive drug. Azilsartan medoxomil, known for its distinctive molecular structure and pharmacological efficacy in treating hypertension, necessitates a robust analytical approach for its accurate determination in bulk and tablet formulations. The proposed method was validated in compliance with ICH guidelines. The chromatographic separation was achieved using an Intersil C18 column (250 mm × 4.6 mm, 5 µm particle size) and a mobile phase comprising acetate buffer (pH 6.0) and acetonitrile in an 80:20 (v/v) ratio, operated at a flow rate of 1.0 ml/min. Detection was performed at 248 nm using a UV detector. The method exhibited linearity within the concentration range of 10-30 µg/ml, with a correlation coefficient of 0.999. Precision was confirmed through low relative standard deviations (RSD) for both intra- and inter-day analyses. Robustness testing demonstrated the method's reliability under minor variations in chromatographic conditions. The validated RP-HPLC method was effectively applied for the analysis of azilsartan medoxomil in commercial tablet formulations. This method represents a reliable, eco-friendly, and efficient tool for routine quality control of azilsartan medoxomil in the pharmaceutical industry.

1. Introduction

The importance of pharmaceutical quality control is underscored by the growing global demand for accurate and reliable analytical methods. One key parameter in quality control is the estimation of active pharmaceutical ingredients (APIs) in finished products. Hypertension, commonly known as high blood pressure, is a significant global health concern due to its role as a leading risk factor for cardiovascular diseases, including stroke, heart attack, and kidney failure. Effective management of hypertension is critical to reducing the associated morbidity and mortality (Carey *et al.*, 2022). Azilsartan medoxomil, an angiotensin II receptor blocker (ARB), is widely used for the treatment of hypertension as it helps lower blood pressure by blocking the effects of angiotensin II, a hormone responsible for vasoconstriction. Azilsartan's potent antihypertensive action, long duration of effect, and favorable safety profile make it a valuable option in the management of hypertension. Azilsartan medoxomil, an angiotensin II receptor antagonist, is widely prescribed for the treatment of hypertension (Angeloni, 2016). As with all pharmaceutical compounds, it is vital to ensure the content of azilsartan medoxomil in formulations complies with the standards set by regulatory agencies. Therefore, precise analytical methods are essential to ensure drug efficacy and safety (Akabari *et al.*, 2023; Shah *et al.*, 2024).

In recent years, the development of green analytical methods has gained considerable attention. The green analytical chemistry principles aim to minimize the environmental impact by reducing or eliminating hazardous reagents, energy, and waste. This can be achieved by evaluating the greenness of analytical methods using tools such as the national environmental index (NEMI), analytical greenness (AGREE) scale and analytical eco-scale. These evaluations help in selecting environmentally friendly techniques that align with sustainable development goals (Akabari *et al.*, 2023; Shah *et al.*, 2024; Ga³uszka *et al.*, 2012; Pena-Pereira *et al.*, 2020; M. Shah *et al.*, 2024).

A review of the literature reveals that a few UV spectrophotometric (Gawai *et al.*, 2018; Thangadurai *et al.*, 2019), HPLC (Kher *et al.*, 2020; Mantena *et al.*, 2014; Masthanamma and Jahnavi, 2014), and HPTLC (Khorshed *et al.*, 2024; Prajapati *et al.*, 2020; Solanki *et al.*, 2023) methods have been reported for the estimation of azilsartan medoxomil in pharmaceutical formulations. While these methods provide some insight into the compound's analysis, many of them lack the sensitivity, precision, or eco-friendliness required for modern analytical needs. In our research, we aimed to bridge this gap by developing a highly sensitive, robust, and eco-friendly HPLC method for the estimation of azilsartan medoxomil in formulations. This method was designed not only to meet the stringent regulatory requirements outlined in ICH guidelines but also to align with the principles of green analytical chemistry, reducing environmental impact while ensuring accuracy and reliability. This novel approach

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underscores the importance of sustainable practices in pharmaceutical analysis without compromising analytical performance.

HPLC provides significant advantages over UV spectrophotometry and HPTLC in pharmaceutical analysis (Anuradha *et al.,* 2023; Biswas *et al.,* 2023). While UV spectrophotometry measures the absorbance of analytes, it lacks the ability to separate components, making it more prone to interference from excipients or impurities present in complex mixtures. In contrast, HPLC ensures precise separation and quantification of analytes, enabling accurate analysis even in multi-component formulations or stability studies. Its superior sensitivity and selectivity also allow for the detection and quantification of compounds at lower concentrations, with exceptional linearity and lower detection limits compared to UV methods (Archana *et al.,* 2024; Sumithra and Surya, 2024).

Compared to HPTLC, HPLC excels in resolution, reproducibility, and quantitative accuracy. HPTLC is beneficial for preliminary screening or analyzing multiple samples simultaneously; however, its results can be affected by variability in plate quality, manual application errors, and environmental factors. HPLC, with its automated processes and precise control over flow rates, temperature, and mobile phase composition, eliminates these inconsistencies. Additionally, HPLC is more effective for stability-indicating methods, as it can accurately separate and quantify degradation products alongside the active pharmaceutical ingredient (Prasanthi *et al.,* 2023; Vimal raj and Sumithra, 2023). HPLC's compliance with ICH guidelines, reliability, and robustness make it the preferred technique for pharmaceutical quantification in quality control and regulatory environments. Its versatility and precision ensure that it meets the rigorous demands of modern pharmaceutical analysis (Archana *et al.,* 2024; Nivetha *et al.,* 2023; Sumithra and Surya, 2024).

Azilsartan medoxomil physicochemical properties make it suitable for analysis by reverse-phase high-performance liquid chromatography (RP-HPLC). Its solubility, stability, and high selectivity in chromatographic conditions make HPLC an ideal method for routine pharmaceutical analysis. The aim of this study was to develop and validate an RP-HPLC method for the quantitative analysis of azilsartan medoxomil in bulk and tablet formulations, ensuring compliance with ICH guidelines and greenness assessment using NEMI, AGREE and analytical eco-scale.

2. Materials and Methods

2.1 Chemicals and reagents

The azilsartan medoxomil sample was provided by Globela Pharma Pvt. Ltd., Gujarat, India. The Eddzaar 40 tablet, manufactured by Torrent Pharmaceutical Ltd. (containing 40 mg of azilsartan medoxomil 40 mg) was used for assay. For the study, water and HPLC-grade methanol were acquired from Merck in Mumbai, India.

2.2 Instrument and chromatographic conditions

A Shimadzu HPLC system (Model: LC-20AD) with a UV-visible detector (Model: SPD-20A) was used to do the chromatographic analysis. The separation was carried out using an Inertsil C18 column (250 mm × 4.6 mm, 5 µm). Acetate buffer, pH 6.0, and acetonitrile in an 80:20 (v/v) ratio were used as the mobile phase. The detection was performed at 248 nm while the flow rate was kept constant at 1.0 ml/min. The temperature of the column was fixed at 30°C. The injection volume of the sample was 20 µl.

2.2.1 Preparation of acetate buffer with a pH of 6.0

To prepare an acetate buffer with a pH of 6.0, approximately 2.9 g of sodium acetate trihydrate and dissolve it in 100 ml of distilled water in a beaker. Next, prepare acetic acid by diluting concentrated acetic acid (glacial) with distilled water to achieve the desired concentration. Slowly add the acetic acid solution to the sodium acetate solution while monitoring the pH using a pH meter. Adjust the pH to 6.0 by adding more acetic acid or sodium acetate as needed. After the pH is adjusted, transfer the solution to a 250 ml volumetric flask and dilute it to the final volume with distilled water. The resulting acetate buffer solution at pH 6.0 is now ready for use.

2.2.2 Mobile phase preparation

The 800 ml of acetate buffer with a pH of 6.0 and 200 ml of acetonitrile were combined to create a solution. The resultant mixture was filtered through a 0.45 µm nylon filter and then sonicated for 10 min.

2.2.3 Detection wavelength selection

The azilsartan medoxomil standard solution was scanned between 200 and 400 nm using a UV spectrophotometer. The optimal detection wavelength for the analysis was determined to be 248 nm, where the greatest absorbance was detected.

2.2.4 Diluent

Mixed acetate buffer with a pH of 6.0 and acetonitrile, in proportions of 800:200. After passing through a nylon filter (0.45 µm), the solution underwent sonication for 10 min.

2.3 Preparation of standard solutions

A standard solution of azilsartan medoxomil was prepared by accurately weighing 20 mg of the pure drug, which was then transferred into a 10 ml volumetric flask. Acetonitrile was added as a suitable solvent to dissolve the drug, and the solution was diluted up to the mark to achieve a concentration of 2000 µg/ml. From this stock solution, 1 ml was taken and further diluted in a 10 ml volumetric flask using the diluent to prepare a working standard solution of 200 µg/ml.

2.4 Method validation

2.4.1 System suitability

System suitability testing was carried out by analyzing six replicate injections of a standard azilsartan medoxomil solution (20 µg/ml). Parameters such as peak area, tailing factor, retention time, and theoretical plates were evaluated by calculating the standard deviation (SD) and percentage relative standard deviation (%RSD) to ensure the system met the required performance criteria.

2.4.2 Linearity and range

The linearity of the developed method was assessed using serial dilutions of the azilsartan medoxomil stock solution within a concentration range of 10-30 µg/ml. A calibration curve was constructed by plotting peak area against concentration, and regression statistical analysis was performed using MS excel. The correlation coefficient (R^2) was calculated to confirm the linear relationship between concentration and peak area.

2.4.3 Accuracy

Accuracy was determined by spiking known amounts of azilsartan medoxomil into the sample matrix and calculating the percentage recovery. Sample solutions (10 µg/ml) were spiked with standard azilsartan medoxomil at three levels: 80% (8 µg/ml), 100% (10 µg/ml), and 120% (12 µg/ml). The percentage recovery and %RSD were calculated to confirm the method's accuracy.

2.4.4 Precision

The method's precision was evaluated through intra-day and inter-day variability tests. Standard solutions of azilsartan medoxomil at concentrations of 5, 15, and 30 µg/ml were analyzed three times on the same day (intra-day) and across three consecutive days (inter-day). The %RSD values were calculated to assess the method's repeatability and reproducibility.

2.4.5 Robustness

The robustness of the method was tested by introducing minor, deliberate changes to chromatographic parameters, such as flow rate (± 0.2 ml/min), injection volume, detection wavelength, and mobile phase composition (± 5%). A working solution of 20 µg/ml azilsartan medoxomil was analyzed under these altered conditions to evaluate the method's reliability.

2.4.6 Limit of detection (LOD) and limit of quantification (LOQ)

The sensitivity of the method was determined by calculating the LOD and LOQ based on the standard deviation of the response and the slope of the calibration curve. These values established the minimum concentrations of azilsartan medoxomil that could be detected and quantified reliably.

2.5 Assay of marketed dosage form

The validated RP-HPLC method was applied to estimate azilsartan medoxomil in commercially available tablets. For the sample solution, 20 Eddzaar 40 Tablets (containing 40 mg of azilsartan medoxomil each) were crushed, and an accurately weighed amount of the powder was dissolved in a diluent in a 100 ml volumetric flask. The mixture was thoroughly shaken and sonicated for 15 min to ensure complete dissolution. The solution was filtered using Whatman filter paper (0.45 µm). A 0.5 ml aliquot of this stock solution was transferred to a 10 ml volumetric flask and diluted with the diluent to obtain a 20 µg/ml solution. The azilsartan medoxomil content in the tablets was determined by comparing the sample's peak area with that of the standard solution.

3. Results

3.1 Optimization of chromatographic condition

The chromatographic conditions for the analysis of azilsartan medoxomil were meticulously optimized to achieve a sharp, symmetric peak with minimal tailing and excellent resolution. Acetate buffer at pH 6.0 was chosen to optimize the ionization of azilsartan medoxomil, ensuring effective separation and a sharp, symmetric peak. Its mild and environmentally benign nature further supports the method's alignment with green analytical practices, reducing the use of more hazardous buffering agents. The mobile phase consisting of acetate buffer (pH 6.0) and acetonitrile in an 80:20 (v/v) ratio was selected after evaluating several combinations for optimal peak characteristics and reproducibility. This unique mobile phase composition, emphasizing the eco-friendly use of acetate buffer, enhances the method's sustainability and reduces reliance on harsher chemicals. The flow rate was maintained at 1.0 ml/min, ensuring efficient separation without compromising peak resolution. The detection wavelength was set at 248 nm, corresponding to the maximum absorbance of azilsartan medoxomil, to ensure high sensitivity and accuracy in quantification.

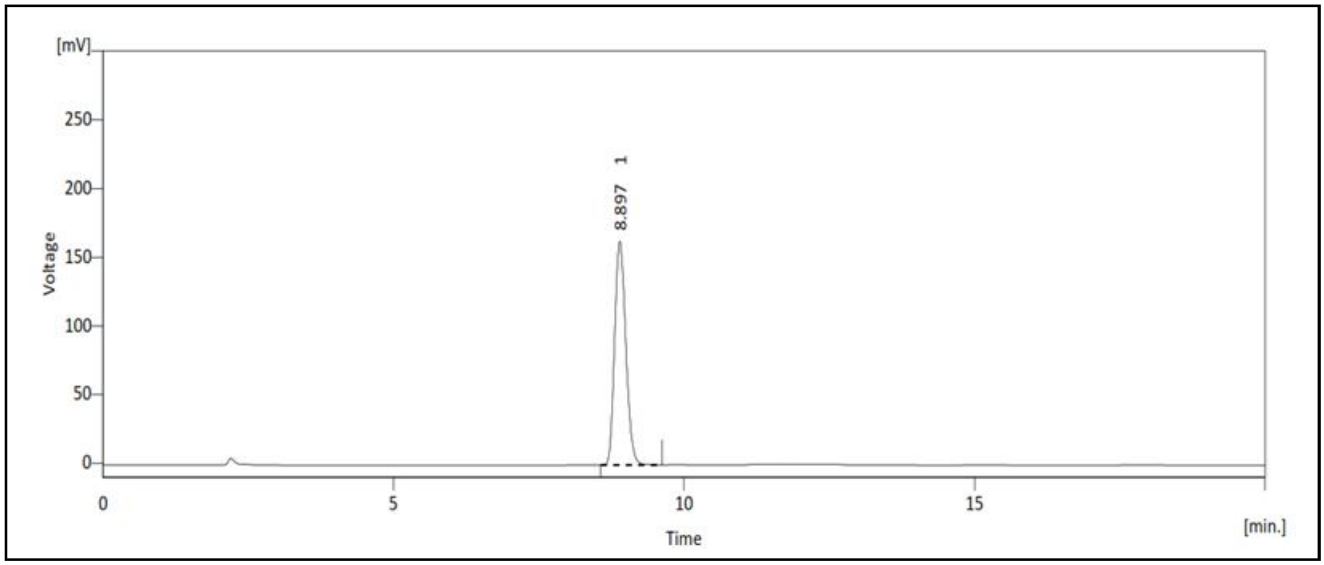


Figure 1: Chromatogram of azilsartan medoxomil under optimized chromatographic condition.

Under these conditions, the retention time was observed at 8.79 min demonstrating the method's reliability and reproducibility for routine analysis (Figure 1). The well-defined peak with minimal interference and baseline noise highlights the robustness of the optimized chromatographic conditions. This method's novelty lies in the specific use of acetate buffer at pH 6.0, which not only ensures effective ionization of the analyte but also contributes to the greenness of the method. This approach offers an efficient, accurate, and environmentally sustainable solution for the analysis of azilsartan medoxomil in bulk and dosage forms, making it a significant advancement in pharmaceutical quality control and method development.

3.2 Method validation

The analytical method was optimized and validated in accordance with the latest ICH guidelines to ensure compliance with key parameters, including accuracy, linearity, precision, and robustness.

3.2.1 System suitability

System suitability testing was performed by analyzing azilsartan medoxomil at a concentration of 10 µg/ml. The acceptance criteria included a %RSD of less than 2% for peak area and retention time, theoretical plates exceeding 2000, and a tailing factor of d"2.0. The results confirmed that all parameters met the predefined acceptance criteria, ensuring the system's reliability for analysis.

3.2.2 Linearity and range

The linearity of azilsartan medoxomil was assessed over a concentration range of 5-30 µg/ml and chromatogram shown in Figure 2. The regression coefficient (R^2) was found to be 0.9997, indicating excellent linearity, and the calibration curve is shown in Figure 3. The regression data is presented in Table 1.

Table 1: Linearity data of azilsartan medoxomil

Sr. No.	Conc. (µg/ml)	Mean peak area ± S.D. (n = 6)	% R.S.D.
1	5	596.28 ± 7.07	1.19
2	10	1096.1 ± 18.56	1.69
3	15	1627.48 ± 30.85	1.90
4	20	2185.58 ± 35.21	1.61
5	25	2695.04 ± 43.12	1.60
6	30	3262.02 ± 48.02	1.47

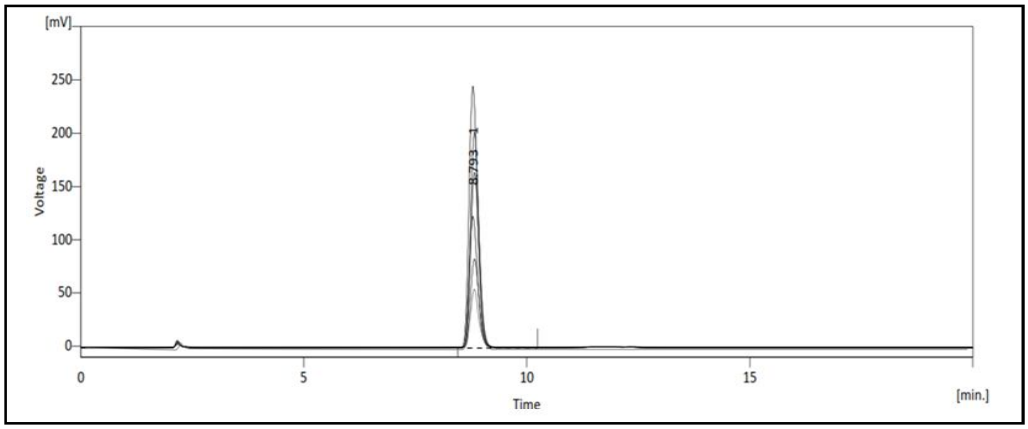


Figure 2: Chromatogram of azilsartan medoxomil over the linearity 5-30 µg/ml.

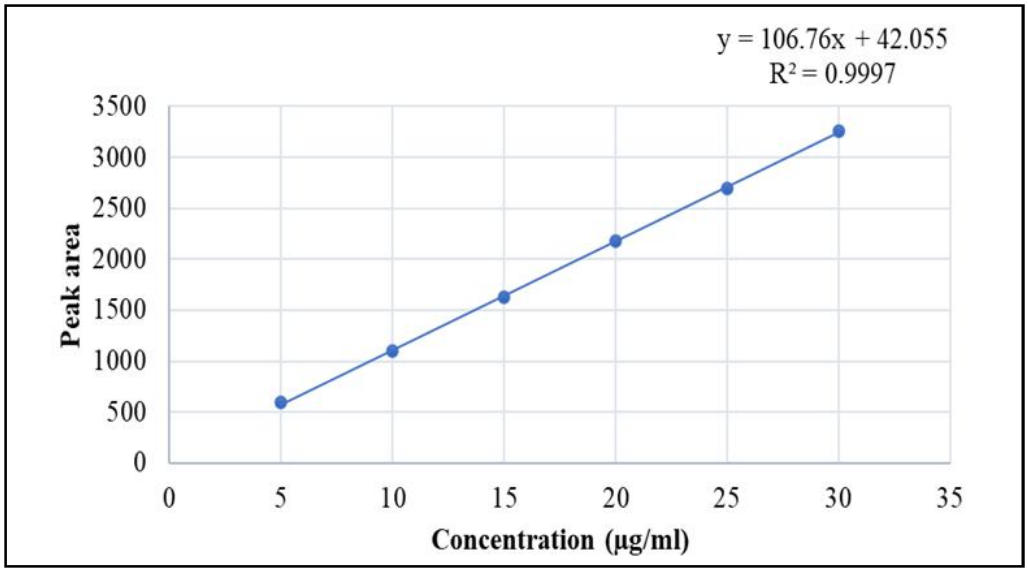


Figure 3: Calibration curve of azilsartan medoxomil over the linearity 5-30 µg/ml.

3.2.3 Accuracy

The accuracy of the developed HPLC method was evaluated by calculating the percentage recovery of azilsartan medoxomil. Spiking was performed at three levels: 80%, 100%, and 120%. The percentage recovery ranged from 99.50% to 101.20%, demonstrating the method's reliability. Chromatograms and response data are presented in Table 2.

Table 2: Recovery data of azilsartan medoxomil

Level	Conc. of azilsartan medoxomil from synthetic mixture (µg/ml)	Amount of std. azilsartan medoxomil added (µg/ml)	Total amount of azilsartan medoxomil (µg/ml)	Total amount of azilsartan medoxomil recovered (µg/ml) mean ± SD	% Recovery
0	10	0	10	10.12 ± 0.15	101.25
80%	10	8	18	17.91 ± 0.48	99.50
100%	10	10	20	20.13 ± 0.48	100.65
120%	10	12	22	22.19 ± 0.26	100.86

3.2.4 Precision

Precision was assessed by analyzing azilsartan medoxomil solutions at concentrations of 5, 15, and 30 µg/ml. Intraday precision involved three analyses within a single day, while interday precision involved analyses on three different days. The %RSD ranged from 0.62% to 1.18% for intraday precision and 1.42% to 1.54% for interday precision, all within the acceptable limit of ± 2.0%, confirming the method's precision (Table 3).

Table 3: Intraday and interday precision data for estimation of azilsartan medoxomil

Conc. (µg/ml)	Intraday precision		Interday precision	
	Mean peak area ± SD	% RSD	Mean peak area ± SD	% RSD
5	591.71 ± 4.23	0.71	593.89 ± 8.45	1.42
15	1622.68 ± 10.07	0.62	1638.72 ± 24.85	1.52
30	3218.31 ± 37.85	1.18	3207.87 ± 49.54	1.54

3.2.5 Robustness

The robustness of the method was determined by introducing small, deliberate variations in chromatographic conditions, such as flow rate, detection wavelength, and buffer ratio. Azilsartan medoxomil at 15 µg/ml was analyzed under these modified conditions, and the relative standard deviation for peak area remained below 2%, demonstrating the method's robustness. The robustness of the developed HPLC method was thoroughly assessed by introducing small, deliberate variations in key chromatographic parameters, including flow rate (± 0.2 ml/min), injection volume, detection wavelength, and mobile phase composition (± 5%). These variations ensured that the method remained reliable and reproducible under slightly altered conditions. This validation step demonstrates the method's stability and reliability, which is crucial for practical application. Results are summarized in Table 4, showing that these small changes did not significantly impact the outcome.

Table 4: Robustness data of azilsartan medoxomil

Parameters	Change in condition	Azilsartan medoxomil	
		Mean peak area ± SD	%RSD
Mobile phase compositionacetate	Acetate buffer (pH 6.0) and acetonitrile 75:25 (v/v)	1643.12 ± 15.49	0.94
buffer (pH 6.0) and acetonitrile	Acetate buffer (pH 6.0) and acetonitrile 80:20 (v/v)	1631.22 ± 22.12	1.36
in an 80:20 (v/v)	Acetate buffer (pH 6.0) and acetonitrile 85:15 (v/v)	1638.7 ± 21.19	1.29
Detection wavelength	245 nm	1618.67 ± 17.28	1.07
	247 nm	1631.22 ± 22.12	1.36
	249 nm	1631.67 ± 14.98	0.92
Flow rate changed	0.9 ml/min	1638.34 ± 16.21	0.99
	1.0 ml/min	1631.22 ± 22.12	1.36
	1.1 ml/min	1619.27 ± 23.38	1.44

3.2.6 Limit of detection (LOD) and limit of quantification (LOQ)

The LOD and LOQ were determined using the signal-to-noise ratio method, adhering to ICH guidelines. A signal-to-noise ratio of 3:1 was used for LOD, and a ratio of 10:1 was used for LOQ. The LOD and LOQ for azilsartan medoxomil were calculated as 0.56 µg/ml and 1.70 µg/ml, respectively.

3.2.7 Assay of marketed dosage form

The developed HPLC method was applied to the estimation of azilsartan medoxomil in an oral tablet dosage form. The percentage assay was determined to be 98.71 ± 1.02%, indicating high recovery and no interference from formulation excipients. The drug's retention time was consistent, affirming the method's selectivity and suitability for estimating azilsartan medoxomil in tablet formulations.

4. Greenness evaluation of the developed HPLC methods

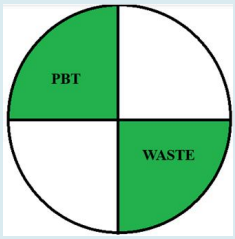
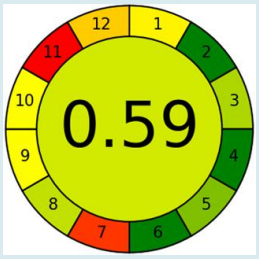
The environmentally sustainable aspects of the newly developed HPLC methods were evaluated using three prominent tools: the analytical eco-scale (AES), the national environmental method index (NEMI), and the software-based analytical greenness metric (AGREE). These tools collectively offer a thorough assessment of the environmental footprint associated with the proposed analytical techniques.

The NEMI tool offers a straightforward approach, with results represented visually using a pictogram. It evaluates methods against four criteria: persistent, bioaccumulative, and toxic (PBT), hazardous, corrosive, and waste (Akabari *et al.*, 2023; Prajapati *et al.*, 2023). Each criterion is indicated by a green or blank quadrant; a green quadrant signifies compliance with the respective environmental standard. The proposed HPLC method passed two quadrants due to the absence of PBT-listed chemicals like acetonitrile and waste generation being below 50 g or ml per sample, highlighting its eco-friendliness.

The analytical eco-scale, a semi-quantitative evaluation tool, assigns penalty points based on factors such as the quantity and toxicity of chemicals used, energy consumption, and waste generation (Ga³uszka *et al.,* 2012). A score of 79, as presented in Table 5, indicates a high level of environmental friendliness, surpassing the "excellent green" benchmark of 75. This score emphasizes the method's minimal environmental impact and alignment with green analytical principles (Akabari *et al.,* 2023; Ga³uszka *et al.*, 2012).

The AGREE metric provided a numerical assessment of the method's greenness. A score closer to 1 signifies a greener method, while lower values identify areas for improvement (Pena-Pereira *et al.,* 2020). The developed HPLC method achieved a score of 0.54, reflecting its moderate adherence to green analytical chemistry principles. Though not highly green, it demonstrates significant efforts to reduce hazardous chemicals, minimize waste, and optimize energy consumption. This commitment to sustainability underscores the method's alignment with the broader goals of environmentally conscious analytical practices (Pena-Pereira *et al.*, 2020; Prajapati, *et al.,* 2023).

Table 5: Assessment of greenness values of proposed analytical method by analytical eco-scale, NEMI, GAPI and AGREE tools

Assessment tool	HPLC method
Analytical eco scale	**Reagents** Acetonitrile (m) - 4 Ammonium acetate - 4 Acetonitrile (s) - 4 Energy used - 1Waste - 5 Occupational hazard - 3 Total penalty points 21 **Analytical eco-scale 79**
NEMI assessment	
AGREE score	

5. Discussion

The validation of the developed HPLC method for azilsartan medoxomil demonstrated its reliability, precision, and suitability for routine pharmaceutical analysis. System suitability results confirmed that all parameters, including %RSD, theoretical plates, and tailing factor, met the acceptance criteria, ensuring the system's optimal performance. Linearity over the range of 5-30 µg/ml showed an excellent correlation coefficient (R^2 = 0.9997), establishing the method's ability to provide accurate results across a wide concentration range.

Accuracy studies revealed percentage recoveries between 99.50% and 101.20%, highlighting the method's reliability in quantifying azilsartan medoxomil without interference. Precision, evaluated through intraday and interday analyses, resulted in %RSD values well below 2%, confirming the method's reproducibility under varied conditions. Robustness testing demonstrated that minor changes in chromatographic parameters did not significantly affect the results, with %RSD values remaining within acceptable limits. This indicates the method's resilience and adaptability for different analytical setups.

The calculated LOD and LOQ values (0.56 µg/ml and 1.70 µg/ml, respectively) underscore the method's high sensitivity for detecting and quantifying azilsartan medoxomil at low concentrations. The assay of marketed tablet formulations yielded a recovery of 98.71 ± 1.02%, reflecting the method's selectivity and efficacy in analyzing commercial products. Overall, the developed HPLC method is accurate, precise, and robust, making it suitable for quality control and regulatory compliance.

The greenness evaluation of the developed HPLC method highlights its moderate environmental impact and alignment with green analytical chemistry principles. While the method demonstrates significant efforts to minimize hazardous chemicals, waste, and energy consumption, the AGREE score of 0.54 suggests room for further improvement to achieve a higher level of sustainability. These findings underscore the method's potential as a more eco-friendly alternative for pharmaceutical analysis.

The developed method demonstrates superior sensitivity, with LOD and LOQ values of 0.56 µg/ml and 1.70 µg/ml, respectively, compared to previously reported methods. Additionally, the use of an acetate buffer (pH 6.0) and reduced acetonitrile content highlights its eco-friendly approach, aligning with green analytical chemistry principles and minimizing the environmental impact.

6. Conclusion

The developed HPLC method for the estimation of azilsartan medoxomil in pharmaceutical formulations has been successfully validated in accordance with ICH guidelines. This method demonstrates exceptional accuracy, precision, linearity, robustness, and sensitivity, making it suitable for routine analysis and quality control. The linearity range of 5-30 µg/ml with an R^2 value of 0.9997 confirms the method's reliability across a wide concentration spectrum. Accuracy, reflected by percentage recoveries between 99.50% and 101.20%, and precision, with %RSD values below 2% for both intraday and interday tests, further validate its robustness. Additionally, low LOD (0.56 µg/ml) and LOQ (1.70 µg/ml) values underline the method's sensitivity for detecting trace levels of azilsartan medoxomil. The method also emphasizes sustainability by integrating green analytical chemistry principles. The greenness assessments using tools like NEMI, analytical eco-scale, and AGREE demonstrate its eco-friendly features, with minimized hazardous chemical usage, reduced waste generation, and optimized energy consumption. An eco-scale score of 79 and an AGREE score of 0.54 highlight the method's substantial adherence to environmentally conscious practices. Overall, this work contributes a reliable, eco-friendly, and regulatory-compliant method for azilsartan medoxomil analysis, supporting pharmaceutical quality control while promoting sustainability in analytical processes.

Conflict of interest

The authors declare no conflicts of interest relevant to this article.

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