

Research Article



A Novel Approach for Solubility and Dissolution Enhancement of Poorly Aqueous Soluble Anti-Hypertensive Drug

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ABSTRACT

Objective: Azilsartan Medoxomil is a potent antihypertensive drug belonging to Biopharmaceutical Classification System (BCS) Class II and exhibits poor aqueous solubility, resulting in low dissolution rate and limited oral bioavailability. The present study aimed to enhance the solubility and dissolution behaviour of Azilsartan Medoxomil using a mixed hydrotropy-based solid dispersion approach.

Methods: Equilibrium solubility studies were performed using different hydrotropic agents, namely sodium acetate, sodium benzoate, sodium citrate, and urea. Based on the solubility results, sodium benzoate and sodium citrate were selected for the preparation of mixed hydrotropic solid dispersions in various drug-to-hydrotrope ratios. The prepared formulations were evaluated for solubility enhancement, drug content, and in vitro dissolution performance. Compatibility studies were carried out using Fourier Transform Infrared Spectroscopy (FTIR) and Differential Scanning Calorimetry (DSC). The optimized solid dispersion formulation was further compressed into immediate-release tablets and evaluated for post-compression parameters and stability.

Results: Solubility studies demonstrated that sodium benzoate and sodium citrate significantly improved the aqueous solubility of Azilsartan Medoxomil compared with pure water. Among all formulations, F4 exhibited the highest solubility and dissolution rate. FTIR analysis confirmed the absence of significant drug-excipient interactions, while DSC studies indicated reduced crystallinity and partial amorphization of the drug in the solid dispersion system. The optimized tablet formulation showed satisfactory hardness, friability, weight variation, drug content uniformity, and rapid drug release, achieving approximately 99% drug release within 30 minutes. Accelerated stability studies indicated that the formulation remained stable without significant changes in physicochemical properties.

Conclusion: The findings demonstrate that mixed hydrotropy-based solid dispersion is an effective, economical, and safe strategy for improving the solubility and dissolution characteristics of Azilsartan Medoxomil. The developed formulation has the potential to enhance oral bioavailability and therapeutic performance of the drug.

Keywords: Azilsartan Medoxomil, Mixed Hydrotropy, Solid Dispersion, Solubility Enhancement, Dissolution Rate, Sodium Benzoate, Sodium Citrate.

INTRODUCTION

Hypertension is a common chronic cardiovascular disorder and a major risk factor for heart disease, stroke, and renal failure. Effective treatment often requires long-term use of antihypertensive drugs; however, many of these drugs belong to BCS Class II and exhibit poor aqueous solubility, resulting in low dissolution, reduced oral bioavailability, and variable therapeutic response.¹⁻³ Azilsartan Medoxomil is a potent angiotensin II receptor blocker (ARB) used in the management of hypertension. Despite its excellent antihypertensive activity, its poor aqueous solubility and low dissolution rate limit its oral bioavailability and therapeutic efficacy.^{4, 5} Therefore, improving its solubility and dissolution characteristics is essential.

Various techniques such as micronization, co-solvency, solid dispersion, complexation, and nanoparticle systems have been employed to enhance drug solubility. Among these, hydrotropy is a simple, economical, and effective approach that improves the aqueous solubility of poorly soluble drugs using hydrotropic agents.⁶⁻⁸ Mixed hydrotropy, which

utilizes a combination of two or more hydrotropic agents, offers enhanced solubilization while reducing the concentration-related drawbacks of individual agents.^{9, 10}

The present study aimed to enhance the solubility and dissolution rate of Azilsartan Medoxomil using mixed hydrotropy. The formulations were evaluated for solubility, drug content, percentage yield, dissolution behavior, stability, and drug-excipient compatibility using FTIR and DSC studies. The study highlights the potential of mixed hydrotropy as an effective strategy for improving the oral bioavailability and therapeutic performance of poorly water-soluble antihypertensive drugs.¹¹

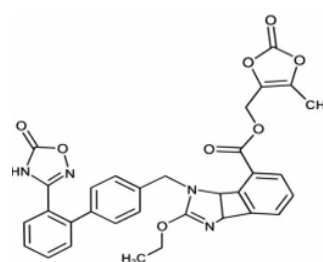


Figure 1: Structure of Azilsartan Medoxomil.



Azilsartan medoxomil is a potent antihypertensive drug of the angiotensin II receptor blocker (ARB) class. It is an orally active prodrug that is rapidly converted into azilsartan after administration. It is a benzimidazole derivative with the molecular formula $C_{30}H_{24}N_4O_8$ and a molecular weight of 568.54 g/mol. The drug is a white to off-white crystalline, odorless powder with a bitter taste. It exhibits poor aqueous solubility but is soluble in organic solvents such as methanol, ethanol, and DMSO, which may limit its dissolution and oral bioavailability. Azilsartan medoxomil has a melting point of 201–205°C, a pKa of approximately 6.1, and a log P value of 4.5–5.0, indicating its lipophilic nature. It remains stable under normal storage conditions but is sensitive to moisture and alkaline environments. Pharmacologically, it blocks angiotensin II type 1 (AT_1) receptors, resulting in vasodilation, reduced peripheral vascular resistance, decreased sodium and water retention, and effective blood pressure control. Its high receptor affinity and prolonged action provide sustained 24-hour antihypertensive efficacy with once-daily dosing.¹²

MATERIALS AND METHODS

Material

The ingredients utilised in this investigation comprised Azilsartan Medoxomil, procured from Ajanta Pharma, Mumbai. Excipients and other chemicals, including sodium benzoate, sodium citrate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, PVP K-30, and talc, were obtained from Ozone International, India. All chemicals and reagents utilised in the formulation and assessment experiments were of analytical grade and employed as obtained without additional purification.¹³

Methods

Preformulation Studies

Preformulation studies of Azilsartan Medoxomil included organoleptic characterization, melting point determination, saturation solubility studies, pH measurement, and UV spectrophotometric analysis. Drug–excipient compatibility was evaluated using FTIR spectroscopy, while DSC analysis was performed to assess thermal behaviour, melting characteristics, and crystallinity of the drug.^{14–20}

Equilibrium Solubility Studies in Different Hydrotropic Agents

Equilibrium solubility studies were carried out using 10% w/v aqueous solutions of urea, sodium benzoate, sodium acetate, and sodium citrate. Excess Azilsartan Medoxomil was added to each solution, mechanically shaken for 12 hours, and allowed to equilibrate for 24 hours. The samples were then centrifuged, filtered, diluted, and analyzed by UV spectrophotometry at 249 nm. The solubility enhancement ratio was determined by comparing the drug solubility in hydrotropic solutions with that in water.²¹

Equilibrium Solubility Studies in Mixed Hydrotropic Blends

Equilibrium solubility studies were carried out using mixed hydrotropic blends to enhance the aqueous solubility

of Azilsartan Medoxomil. Different ratios of hydrotropic agents, namely sodium benzoate and sodium citrate, were prepared and dissolved in water to obtain clear solutions. Excess amount of drug was added to each hydrotropic blend and mechanically shaken until saturated solutions were formed. The solubility of the drug in each blend was determined to optimize the ratio of hydrotropic agents for maximum solubility enhancement.²²

Table 1: Equilibrium Solubility Studies in Mixed Hydrotropic Blends

Formulation Code	Drug (Azilsartan Medoxomil)	Hydrotropic Combination (Sodium Benzoate + Sodium Citrate)
F1	500 mg	500 mg
F2	500 mg	1 g
F3	500 mg	1.5 g
F4	500 mg	2 g

Formulation of hydrotropic solid dispersions of Azilsartan medoxomil

Hydrotropic solid dispersion of Azilsartan Medoxomil was prepared using sodium benzoate and sodium citrate (1 g each). The hydrotropic blend was dissolved in approximately 5 ml of warm distilled water with magnetic stirring, followed by the addition of 500 mg of drug (1:4 drug-to-carriers ratio). The mixture was heated at 55–60°C to evaporate water and form a wet solid dispersion. The product was dried in a hot air oven at $50 \pm 2^\circ\text{C}$, pulverized, passed through sieve no. 60, and stored in an airtight glass bottle.²³

Evaluation of Hydrotropic Solid Dispersion of Azilsartan Medoxomil

DSC Analysis

DSC study was performed using Shimadzu DSC to evaluate thermal behavior, melting point, crystallinity, and drug–carrier interaction of the solid dispersion from 30°C to 300°C.

FTIR Study

FTIR analysis of pure drug and solid dispersion was carried out in the range of 4000–400 cm^{-1} to check functional groups and possible interactions between drug and hydrotropic agents.

In Vitro Dissolution Study

Dissolution was carried out using USP Type II apparatus in phosphate buffer pH 6.8 at $37^\circ\text{C} \pm 0.5^\circ\text{C}$. Samples were withdrawn every 5 minutes and analyzed at 249 nm to determine drug release profile.

Preparation of Immediate Release Tablets

Immediate release tablets of Azilsartan Medoxomil solid dispersion were prepared by direct compression method. All ingredients were sieved through 60 mesh, mixed uniformly in geometric order, and compressed using an 8



mm punch on a Karnavati mini compression machine to obtain tablets.²⁴⁻²⁷

Table 2: Formulation of Azilsartan medoxomil tablet prepared by direct compression method

Sr. No.	Ingredients	Quantity (mg)
1	HSD (Equivalent to 40 mg Azilsartan Medoxomil)	160 mg
2	Microcrystalline Cellulose (MCC)	120 mg
3	PVP K30	8 mg
4	Magnesium Stearate	4 mg
5	Talc	8 mg
6	Total Weight of Tablet	300 mg

Evaluation of Tablets (Post Compression Parameters)

Hardness: Hardness was determined using a Monsanto hardness tester by testing three tablets and expressed as kg/cm² (mean $\pm$ SD).

Friability: Friability was evaluated using a Roche friabilator operated at 25 rpm for 4 minutes (100 revolutions), and the percentage weight loss was recorded. A value below 1% was considered acceptable.

Weight Variation: Twenty tablets were weighed individually using an analytical balance and the results were compared with pharmacopeial limits.

Drug Content Uniformity: Tablets were dissolved in methanol, suitably diluted, and analyzed at 249 nm using UV spectrophotometry to determine drug content uniformity.

In Vitro Dissolution: Dissolution studies were carried out using a USP Type II apparatus containing 900 mL phosphate buffer (pH 6.8) maintained at 37°C $\pm$ 0.5°C, and the percentage drug release was determined at specified time intervals.

Stability Study: Stability studies were conducted under ICH Q1A (R2) conditions (25°C/60% RH and 40°C/75% RH), and the formulations were evaluated for physical and chemical stability over time.²⁸⁻²⁹

RESULTS AND DISCUSSION

Preformulation Study

Organoleptic Characterization

Azilsartan medoxomil was identified based on its physical appearance and sensory properties. The drug was found to be a white to off-white crystalline powder with a bitter taste and odourless nature.

Determination of Melting Point

The melting point of azilsartan medoxomil was determined by the capillary method and found to be in the range of 202°C–204°C. This value is consistent with the reported literature, indicating the purity of the drug sample.

Determination of Saturation Solubility

The solubility of azilsartan medoxomil in different solvents was evaluated. The drug showed very low solubility in water (16.1 $\pm$ 0.1 μ g/mL), whereas comparatively higher solubility was observed in phosphate buffer pH 6.8 (374 $\pm$ 0.5 μ g/mL), indicating its poorly water-soluble nature.

Determination of pH of Azilsartan Medoxomil

The pH of 0.1% w/v solution of Azilsartan Medoxomil in distilled water was measured using a calibrated digital pH meter at room temperature. The pH was found to be **6.2 $\pm$ 0.1**, indicating near-neutral nature suitable for oral formulations.

UV Characterization ($\lambda_{\max}$ Determination)

The UV-Visible spectrophotometric analysis of Azilsartan Medoxomil in methanol showed maximum absorbance at **249 nm**, which matches reported values.

Calibration Curve Preparation

A stock solution of **100 μ g/mL** was prepared and diluted to obtain standard solutions in the range of **2–20 μ g/mL**. Absorbance was measured at **249 nm** and a calibration curve of absorbance vs. concentration was plotted using UV spectrophotometry.

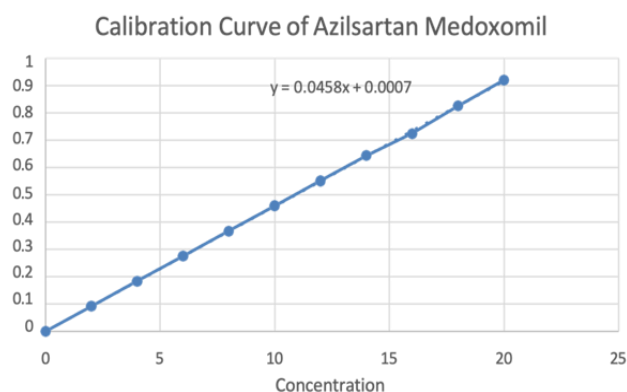


Figure 2: Calibration Curve of Azilsartan Medoxomil

Fourier Transform Infrared Spectroscopy (FTIR) Study of Azilsartan Medoxomil

FTIR analysis was performed to identify characteristic functional groups and possible drug–excipient interactions. The FTIR spectrum of Azilsartan Medoxomil (4000–500 cm⁻¹, KBr pellet method) revealed characteristic absorption peaks confirming its chemical structure. Broad peaks at 3729 and 3657 cm⁻¹ indicate O–H stretching vibrations, while the peak at 2888 cm⁻¹ corresponds to aliphatic C–H stretching. Strong absorption bands at 1822 and 1707 cm⁻¹ confirm the presence of carbonyl (C=O) groups. Peaks at 1668 cm⁻¹ and 1550 cm⁻¹ are attributed to aromatic C=C stretching and N–H bending vibrations, respectively. Fingerprint region peaks (1388–1040 cm⁻¹) correspond to C–N and C–O stretching, while peaks at 945 and 762 cm⁻¹ indicate aromatic C–H out-of-plane bending. The presence of all characteristic peaks without any significant shifts or additional peaks confirms the identity, purity, and compatibility of the drug.

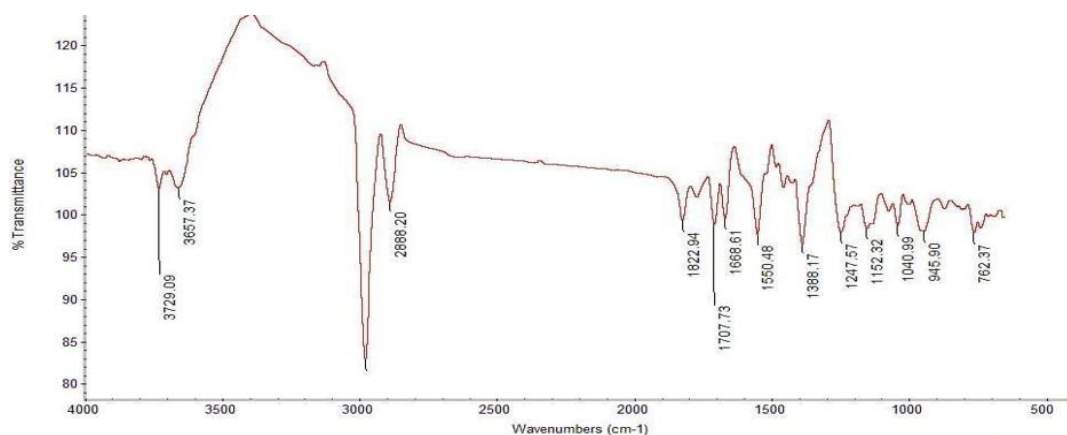


Figure 3: FTIR OF Azilsartan Medoxomil

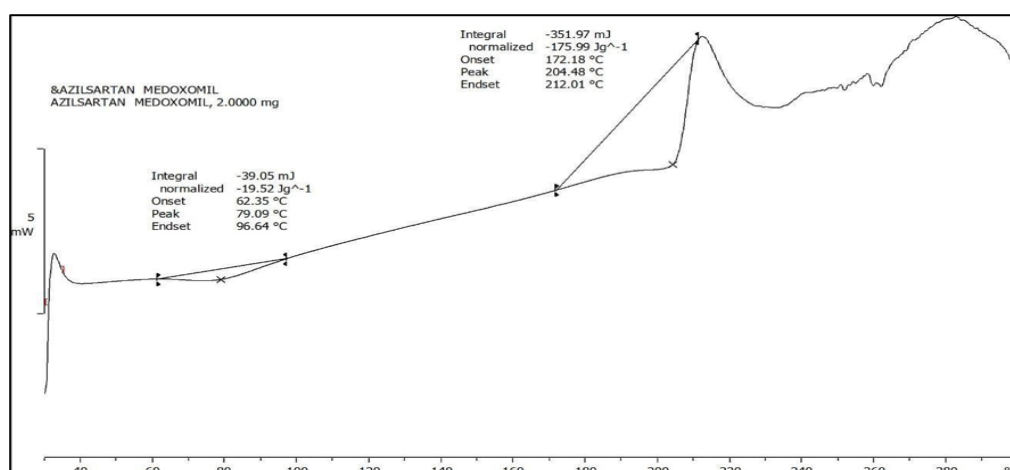


Figure 4: DSC Of Azilsartan Medoxomil

Differential Scanning Calorimetry (DSC) Study of Azilsartan Medoxomil

DSC thermograms of Azilsartan medoxomil showed two thermal events. The first broad endothermic peak at 79.09 °C ($\Delta H = -19.52 \text{ J/g}$) indicates loss of moisture or residual solvent. The second sharp endothermic peak at 204.48 °C (onset 172.18 °C, endset 212.01 °C, $\Delta H = -175.99 \text{ J/g}$) corresponds to melting of the crystalline drug, confirming its crystalline nature. No additional transitions were observed, suggesting absence of polymorphic changes and good purity. Slight irregularity after melting may indicate thermal degradation at higher temperatures.

Equilibrium Solubility Study in Different Hydrotropic Agents

The solubility of Azilsartan medoxomil was evaluated using different hydrotropic agents at 10% w/v concentration. Among all agents, sodium citrate ($160.65 \pm 0.96 \mu\text{g/mL}$) and sodium benzoate ($155.78 \pm 1.12 \mu\text{g/mL}$) showed the highest solubility enhancement. Urea showed moderate solubility ($140.31 \pm 1.05 \mu\text{g/mL}$), while sodium acetate exhibited the lowest effect ($120.42 \pm 0.84 \mu\text{g/mL}$). Overall, sodium citrate and sodium benzoate were found to be the most effective hydrotropic agents for improving solubility of the drug.

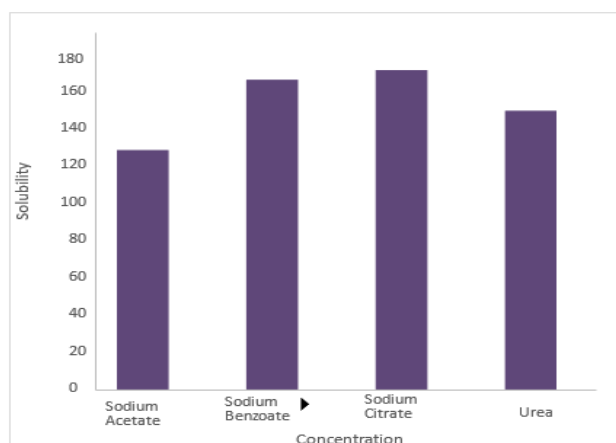


Figure 5: Equilibrium Solubility Study of AZ in Different Hydrotropic Agents

Equilibrium Solubility Study in Mixed Hydrotropic Blend

The solubility of Azilsartan medoxomil increased progressively with an increase in formulation ratio from F1 to F4. Among all formulations, F4 (1:4 ratio) showed the highest solubility ($215.38 \pm 0.98 \mu\text{g/mL}$), indicating it as the optimized batch. This improvement is attributed to better drug dispersion, enhanced wetting, and increased

interaction with the hydrotropic blend, resulting in improved solubilization of the poorly water-soluble drug.

Table 3: Equilibrium Solubility Study in Mixed Hydrotropic Blend

Sr. No.	Formulation	Ratio	Solubility ($\mu\text{g/mL}$)
1	F1	1:1	130.18 $\pm$ 0.72
2	F2	1:2	149.26 $\pm$ 0.81
3	F3	1:3	175.41 $\pm$ 0.93
4	F4	1:4	215.38 $\pm$ 0.98

Evaluation of Hydrotropic Solid Dispersion of Azilsartan Medoxomil

FTIR Study of Azilsartan Medoxomil Hydrotropic Solid Dispersion

The FTIR spectrum of Azilsartan medoxomil hydrotropic solid dispersion showed characteristic peaks confirming the presence of major functional groups. A broad peak at 3729 cm^{-1} indicates O–H stretching, while peaks at 2978 cm^{-1} and 2888 cm^{-1} correspond to C–H stretching. The peak at 1770 cm^{-1} represents C=O stretching. Peaks at 1591 cm^{-1} and 1547 cm^{-1} indicate aromatic C=C stretching and N–H bending, while 1392 cm^{-1} and 1067 cm^{-1} correspond to C–H

and C–O stretching, respectively. Peaks at 707 cm^{-1} and 678 cm^{-1} represent aromatic C–H bending. Overall, the spectrum confirms retention of functional groups without significant drug–carrier interaction.

DSC Analysis of Azilsartan Medoxomil Hydrotropic Solid Dispersion

The DSC thermogram of Azilsartan medoxomil hydrotropic solid dispersion showed a sharp endothermic peak with an onset at 161.18 $^{\circ}\text{C}$, peak at 167.34 $^{\circ}\text{C}$, and endset at 178.51 $^{\circ}\text{C}$, corresponding to the melting of sodium citrate. The absence of the characteristic drug melting peak indicates possible amorphous conversion of the drug within the solid dispersion. No additional thermal events were observed, suggesting absence of degradation or incompatibility. Overall, the results indicate reduced crystallinity and improved solubility potential of the drug in the solid dispersion.

In - Vitro Dissolution Study

All formulations show improved drug release, but F4 exhibits the highest and fastest dissolution, reaching nearly complete release within 30 minutes. This indicates superior solubility enhancement due to the hydrotropic solid dispersion.

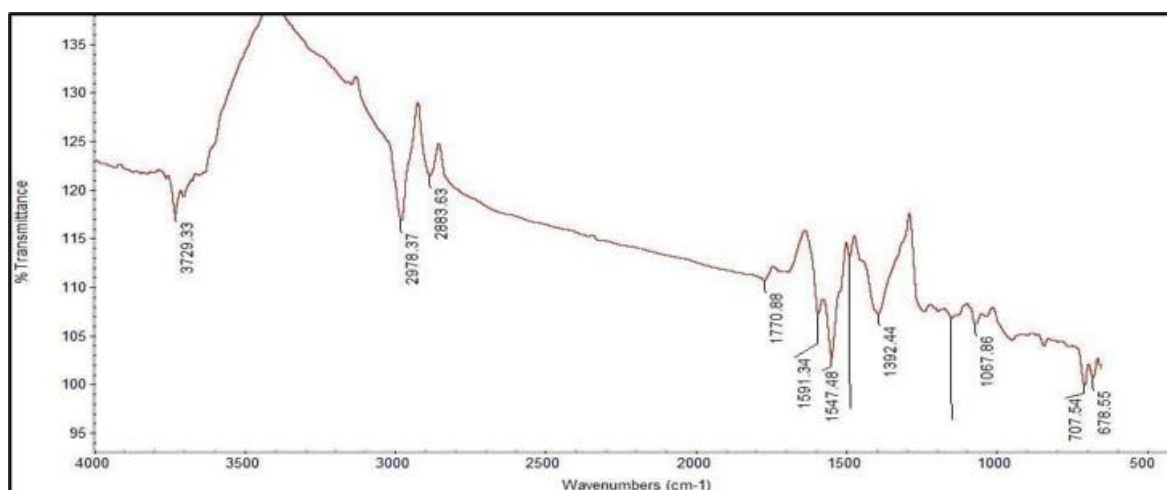


Figure 6: FTIR of Hydrotropical Solid Dispersion of Azilsartan Medoxomil

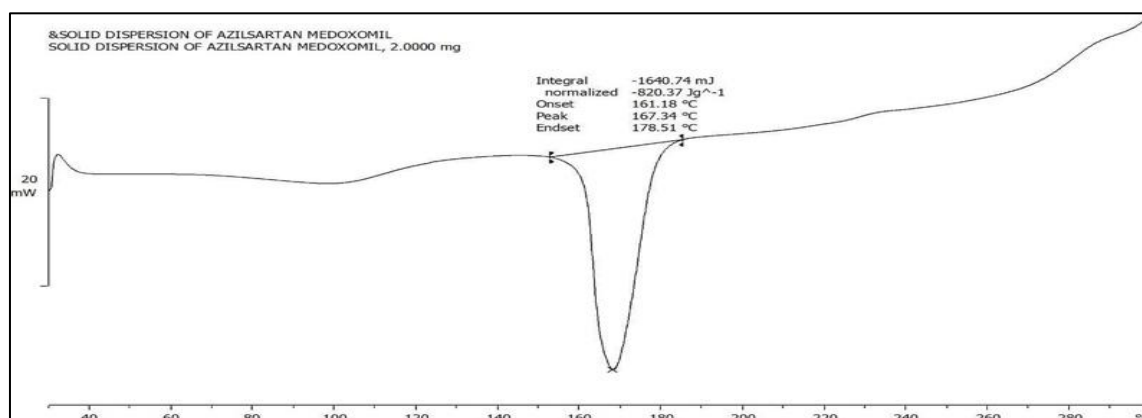
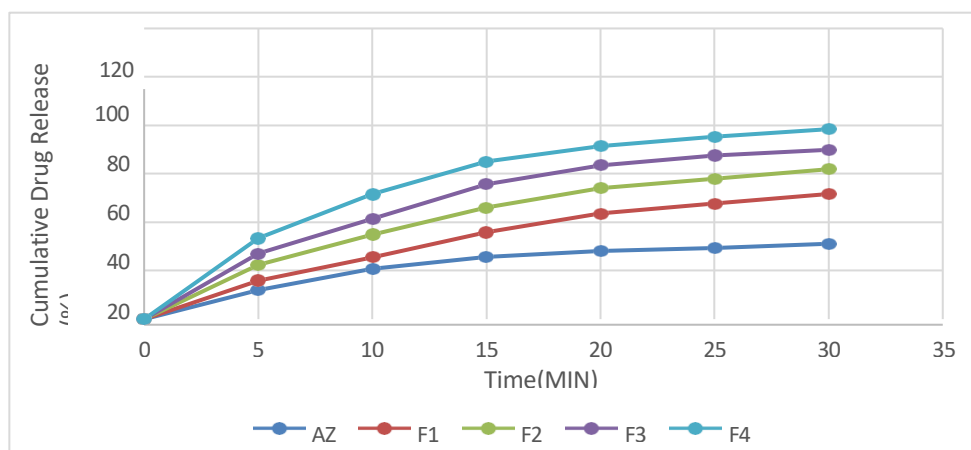


Figure 7: DSC Thermogram of Hydrotropic Solid Dispersion of Azilsartan Medoxomil

Table 4: *In-vitro* Dissolution Study Hydrotropic Solid Dispersion of AZ

Time (min)	Plain AZ	F1	F2	F3	F4
5	15.24±0.82	20.18 ±1.04	28.32 ± 1.16	34.24 ± 1.22	42.18 ± 1.34
10	26.18±1.05	32.24 ±1.18	44.16 ± 1.28	52.38 ± 1.42	65.24 ± 1.56
15	32.45±1.16	45.32 ±1.26	58.24 ± 1.36	70.42 ± 1.58	82.16 ± 1.72
20	35.62±0.94	55.18± 1.14	68.36 ± 1.42	80.24 ± 1.66	90.38 ± 1.84
25	37.18±1.02	60.24 ±1.22	73.18 ± 1.48	85.42 ± 1.72	95.16 ± 1.96
30	39.34±0.88	65.32±1.1820	78.24 ± 1.56	88.36 ± 1.84	99.12 ± 1.42

**Figure 8:** *In-Vitro* Dissolution Study HSD of Azilsartan Medoxomil**Table 5:** Evaluation of Tablet Post Compression Parameters

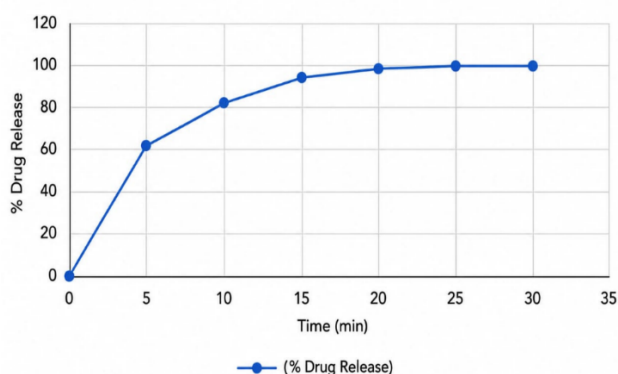
Parameters	Azilsartan Medoxomil Solid Dispersion Tablet
Hardness (kg/cm ²)	4.5 ± 0.08
Friability (%)	0.58 ± 0.03
Weight Variation (mg)	300 ± 1.8
Drug Content (%)	99.21 ± 0.37
Disintegration Time (sec)	45 ± 1
Cumulative Drug Release at 30 min (%)	99.8 ± 0.2

Stability Study

Table 6: Stability Study of Azilsartan Medoxomil

Parameter	Before Storage (0 Month)	After Storage (3 Month)
Hardness (kg/cm ²)	4.5 ± 0.08	4.3 ± 0.09
Friability (%)	0.58 ± 0.03	0.61 ± 0.03
Weight Variation (mg)	300 ± 1.8	298 ± 1.7
Drug Content (%)	99.21±0.37	98.72 ± 0.36
Disintegration Time (sec)	45 ± 1	47 ± 2
Cumulative Drug Release at 30 min (%)	99.8 ± 0.2	98.6 ± 0.4

In-vitro Dissolution Tablet

**Figure 9:** *In-Vitro* Dissolution of Azilsartan Medoxomil Tablet

CONCLUSION

The present study successfully developed a mixed hydrotrophy-based solid dispersion of Azilsartan medoxomil to enhance its solubility and dissolution. Preformulation studies and compatibility studies (FTIR and DSC) confirmed the drug's purity and compatibility with excipients. The use of sodium benzoate and sodium citrate significantly improved solubility, with formulation F4 showing the best results in terms of solubility, drug release, and dissolution profile.

The optimized F4 batch, when formulated into tablets, exhibited acceptable physical properties, uniform drug content, rapid disintegration, and enhanced dissolution. Stability studies confirmed that the formulation remained stable under accelerated conditions.

Overall, the study concludes that mixed hydrotrophy combined with solid dispersion is an effective, economical, and safe approach for improving the solubility, dissolution, and potential bioavailability of Azilsartan medoxomil.

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