RESEARCH ARTICLE

Enhancement of Solubility and Dissolution of Azilsartan using Liquisolid Technology: Formulation, Optimization and Evaluation

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ABSTRACT
The Liquisolid technique was employed to enhance the solubility and dissolution of Azilsartan, an angiotensin II receptor blocker with poor aqueous solubility. A 2^2 full factorial design was utilized to optimize the formulation parameters, particularly focusing on FUJ and Croscarmellose Sodium concentrations. Solubility studies conducted in non-volatile solvents (Labrasol, Captisol, Transcutol HP, and Capryol) identified Labrasolas the most effective solvent (96.37± 0.82mg/mL), while Fujicalin exhibited the highest solubility enhancement (0.42 ± 0.02 mg/mL) among different carriers. The optimized formulation, containing 50mg FUJ and 5% Croscarmellose Sodium, demonstrated significantly improved drug release compared to the pure drug. FTIR analysis confirmed no significant drug-excipient interactions, ensuring the stability of the formulation. Pre-compression and post-compression parameters, including Carr's Index (13.85 ± 0.30%), Hausner's Ratio (1.16 ± 0.01), hardness (5.6 ± 0.2 kg/cm²), friability (0.78 ± 0.03%), and disintegration time (65.2 ± 2.1 sec, n=3), confirmed the formulation's suitability for tablet manufacturing. Stability studies conducted per ICH guidelines demonstrated that the optimized formulation remained stable for three months.The study confirms that the Liquisolid technique significantly improves the solubility and dissolution of Azilsartan.
Keywords: Azilsartan, Liquisolid technique, Solubility Enhancement, Fujicalin, Labrasol, Dissolution, Drug Release, Factorial Design
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INTRODUCTION

The Liquisolid system represents a promising and innovative drug delivery approach designed to enhance the solubility and dissolution rate of poorly water-soluble drugs[1,2]. In this technique, liquid medications—comprising either liquid drugs or solutions/suspensions of hydrophobic drugs in non-volatile solvents—are converted into dry, free-flowing, and directly compressible powders through the incorporation of suitable carrier and coating materials[3-7]. Typically, porous carriers such as microcrystalline cellulose or Fujicalin are employed to absorb the liquid formulation, while fine coating agents like colloidal silicon dioxide facilitate surface adsorption, thereby ensuring acceptable flow and compressibility characteristics[8,9]. Azilsartan (Figure 1) is an antihypertensive drug of the ARB class. Its physicochemical profile reveals poor solubility in aqueous media but favorable solubility in methanol and ethanol, making it a candidate for solubility enhancement strategies[10]. It is characterized by its crystalline nature and moderate lipophilicity, contributing to its effective oral bioavailability. The mechanism of action (MOA) involves selective blockade of the angiotensin II type 1 (AT_1) receptor, leading to vasodilation, reduced aldosterone secretion, and a decrease in blood pressure[11]. Compared to other ARBs, Azilsartan demonstrates a longer duration of action and greater affinity for AT_1 receptors, resulting in superior antihypertensive efficacy. It is commonly prescribed for the management of essential hypertension, either as monotherapy or in combination with other antihypertensive agents, improving cardiovascular outcomes in patients at risk[12].

The Liquisolid compact strategy remains unexplored for enhancing the solubility and dissolution of Azilsartan. This study evaluates the impact of non-volatile solvents and carrier effect on drug release using a 2^2 full factorial design to optimize dissolution in the Liquisolid compact formulation.

MATERIALS AND METHODS

Cipla Pharmaceuticals, Mumbai, supplied Azilsartan as a gift sample. Excipients such as Fujicalin, Starch, and MCC were purchased from Merck Chemicals. All other materials used were of analytical grade and suitable for pharmaceutical formulation studies

Preparation of Calibration Curve in pH 7.8 Buffer

Exactly 10 mg of Azilsartan was taken and solubilized in a small volume of phosphate buffer (pH 7.8), followed by dilution to 10 mL in a volumetric flask, yielding a 100 µg/mL stock solution. Standard solutions ranging from 5 to 25 µg/mL were prepared, and their absorbance was

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Table 1: Independent variables with their levels and Response variables of Azilsartan Liquisolid compacts using 2^2 Factorial Design

Independent Factors	Name	Units	Level 1 (-1)	Level 2 (+1)	Response	Units
A	FUZ	mg	60	95	Drug Release	%
B	Croscarmellose sodium	mg	5	15	at 30 min.	

Table 2: Linearity Data for Azilsartan

Conc. (µg/mL)	Absorbance (254 nm)
5	0.158
10	0.331
15	0.472
20	0.649
25	0.788

Table 3: Solubility of Azilsartan

Solvent	Solubility (Mean ± SD) (mg/mL)
Transcutol HP	86.33 ± 0.85
Capryol	79.43 ± 0.87
Labrasol	96.37 ± 0.82
Captisol	88.57 ± 0.85

measured at 254 nm using a UV-Vis spectrophotometer to construct the calibration curve.

Screening of Solubilizing Agents for Azilsartan

To screen potential solubilizers for Azilsartan, its solubility was tested in Transcutol HP, Capryol, Labrasol, and Captisol. Each solvent (10 mL) was saturated with the drug and shaken for 48 hours at room temperature. Samples were centrifuged, filtered using 0.45 µm membranes, and analyzed at 254 nm via UV-Vis spectroscopy. All solubility measurements were carried out in triplicate.

Selection of Carrier

A 1:0.5 ratio of Azilsartan and selected carriers (Microcrystalline Cellulose, Neusilin, Fujicalin, Starch, Lactose, Mesoporous Silica, and Syloid XDP 3035) was prepared in separate containers. Each mixture was subjected to continuous agitation at 37°C ± 1°C for 24 hours to reach equilibrium, then samples were filtered (0.45 µm), and drug content in the filtrates was measured at 254 nm using UV spectroscopy, with blanks containing only the carriers used for calibration.

Precompression Study

Powder Flow Property Evaluation

Table 4: Solubility of Azilsartan in Different Carriers

Excipient	Solubility (mg/mL) (Mean ± SD)
Microcrystalline Cellulose (MCC)	0.27 ± 0.02
Neusilin	0.36 ± 0.02
Fujicalin	0.42 ± 0.02
Starch	0.19 ± 0.01
Lactose	0.31 ± 0.01

Table 5: Pre-Compression Studies of the Liquisolid powder blend

Parameter	1	2	3	Mean ± SD
Bulk Density (g/mL)	0.55	0.56	0.57	0.56 ± 0.01
Tapped Density (g/mL)	0.64	0.66	0.65	0.65 ± 0.01
Carr's Index (%)	13.50	14.00	14.05	13.85 ± 0.30
Hausner's Ratio	1.15	1.16	1.17	1.16 ± 0.01
Angle of Repose (°)	29.50	30.00	30.50	30.0 ± 0.5

Flow behaviour was studied by analyzing how the powder settled (bulk density), how it compacted after tapping (tapped density), and the difference between these two values to assess compressibility and cohesiveness[13]. The powder's natural flow tendency was also evaluated by measuring the angle of repose.

Interaction Study

The compatibility between Azilsartan and excipients was assessed using FTIR Spectroscopy (IRAffinity-1s, Shimadzu).

Accurately weighed amounts of Azilsartan and the Liquisolid Compact mixture were analyzed for possible physicochemical interactions. By scanning the samples in the 4000–400 cm^{-1} range, possible interactions or structural shifts between Azilsartan and the excipients were evaluated.

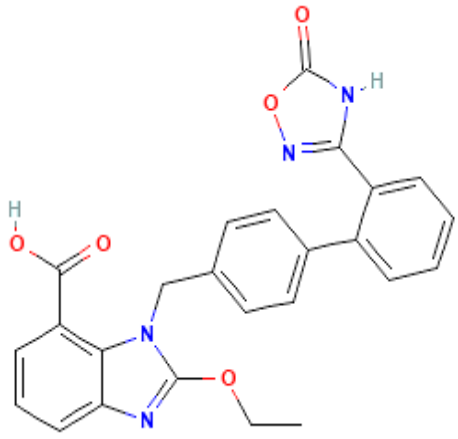

Figure 1: Chemical Structure of Azilsartan

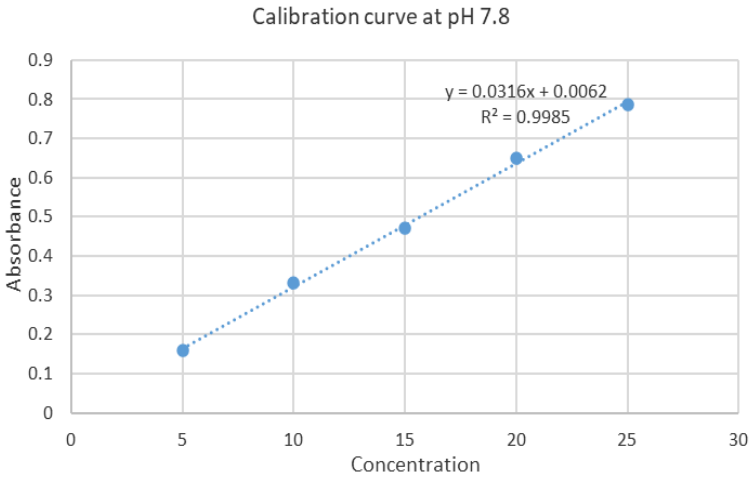

Figure 2: Calibration curve of Azilsartan

Preparation of Liquisolid Tablet

Azilsartan was dissolved in the measured quantity of Labrasol to yield a consistent liquid solution. This solution was then gradually added to Fujicalin (the carrier material) in a mortar and pestle, with continuous mixing until complete absorption occurred, resulting in a non-greasy, free-flowing powder. The Liquisolid powder was then blended with Aerosil, Microcrystalline Cellulose, and Magnesium Stearate. The final blend was compressed into tablets using a tablet press equipped with a suitable punch and applied compression force.

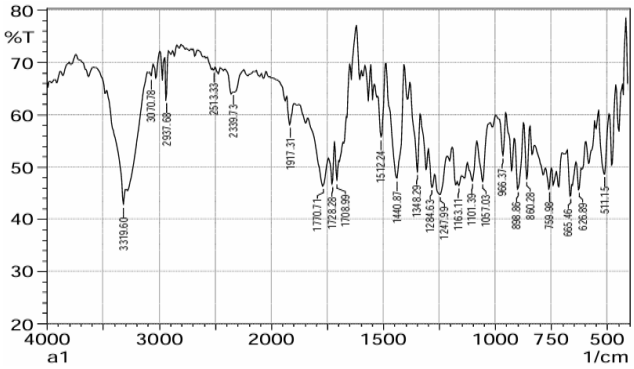

Figure 3: FT-IR of Azilsartan

Design Summary

The formulation was optimized using a 2^2 full factorial design to systematically study the effects of AZL-FUJ and Croscarmellose sodium on the dissolution efficiency of Azilsartan from Liquisolid compacts. The design included two independent variables, each at two levels, resulting in eight experimental runs conducted in duplicate. The design facilitated the identification of significant factors influencing drug dissolution while maintaining minimal experimental runs[14-16].

Post Compression Parameters

Weight Variation

The weight variation test was conducted using an Analytical Balance (Model: Sartorius ENTRIS224-1S). Twenty tablets were individually weighed, and the weights were recorded. The mean value was calculated and compared against Pharmacopoeial limits, which specify that the variation should not exceed ±5% for tablets weighing ≥250 mg.

Hardness

Hardness testing was performed using the Monsanto Hardness tester on ten randomly selected tablets. The force needed to break each tablet was noted, and the mean value

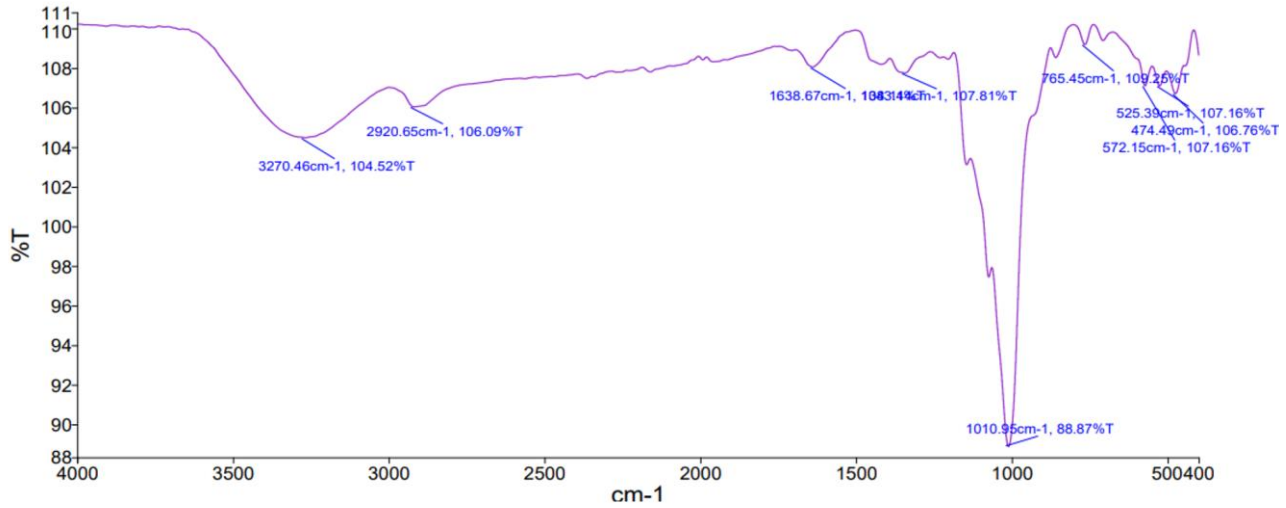

Figure 4: FTIR of optimized Formulation

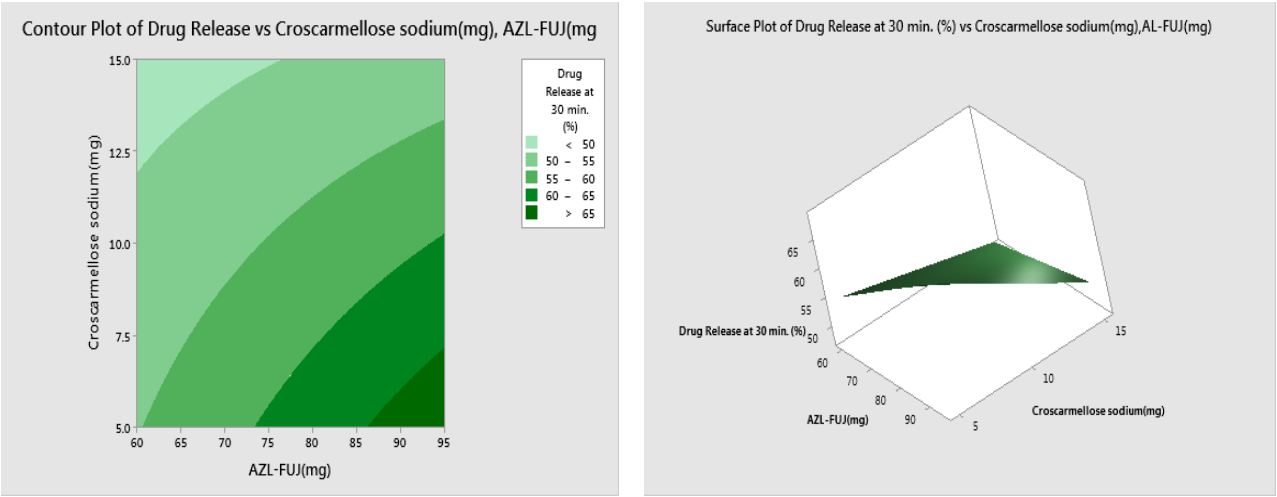

Figure 5: Contour Plot of Drug Release and Surface Plot of Drug Release

was calculated to evaluate their resistance to mechanical stress during handling and storage.

Friability

Electrolab EF-2 Friabilator was used to the friability of twenty tablets. Tablets were weighed, rotated at 25 rpm for 100 revolutions, and weighed again. The percentage loss in weight indicated the friability of the batch.

Thickness

Tablet thickness was measured using a Vernier Calipers (Model: Mitutoyo 530-312). Ten tablets were randomly chosen, and the thickness of each one was measured separately. The average thickness was then calculated to ensure dimensional uniformity.

Drug Content Uniformity

For drug content analysis, ten tablets were randomly chosen, finely powdered, and an amount equivalent to 40 mg of Azilsartan was accurately weighed[17]. The sample was dissolved in ethanol, diluted, and analyzed using a Shimadzu UV-1900 spectrophotometer. Individual and average drug content values were calculated to verify uniformity as per the Pharmacopoeial standards

In-vitro Drug Release

To determine the release kinetics of Azilsartan, a USP paddle apparatus was employed with 900 mL of phosphate buffer (pH 7.8) at 37 ± 0.5°C. Samples were withdrawn at defined intervals and replenished with fresh buffer. The filtered samples (0.45 µm) were analyzed at 254 nm[18,19].

Disintegration Time

Disintegration was evaluated in purified water (37 ± 2°C) at 29–32 cycles/min. Time was noted when no residue remained. Each formulation was tested thrice, and the mean disintegration time ± SD was calculated.

Stability Study

In accordance with ICH Q1A(R2), the optimized Azilsartan formulation was stored at 40 ± 2°C/75 ± 5% RH for three months. At 0, 1, 2, and 3 months, tablets were evaluated for physical and performance parameters to monitor any changes affecting stability[20].

RESULTS AND DISCUSSION

Standard Curve of Azilsartan in Phosphate Buffer (pH 7.8)

The calibration curve (Figure 2) for Azilsartan was constructed by measuring absorbance at 254 nm for different concentrations (5–25 µg/mL). A linear increase in absorbance was observed, indicating a direct correlation between drug concentration and UV absorbance, confirming the method's suitability for quantification (Table 2).

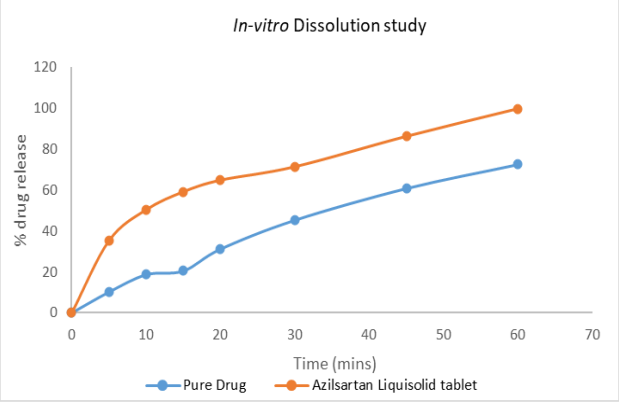

Figure 6: Drug release profile for pure drug and Liquisolid tablet

Table 6: Post-Compression Parameters for Optimized Formulation

Test Parameter	1	2	3	Mean ± SD
Weight Variation (mg)	298	300	302	300 ± 2.0
Hardness (kg/cm²)	5.4	5.6	5.8	5.6 ± 0.2
Friability (%)	0.77	0.80	0.73	0.78 ± 0.03
Thickness (mm)	4.1	4.2	4.3	4.2 ± 0.1
Drug Content Uniformity (%)	97.2	98.5	99.8	98.5 ± 1.3
Disintegration Time (sec, N=3)	64.0	66.5	65.2	65.2 ± 2.1

Screening of Solubilizing Agents for Azilsartan

As presented in Table 3, Labrasol showed the highest solubilizing capacity among the tested solvents, followed closely by Captisol and Transcutol HP. Capryol demonstrated comparatively lower solubility. These findings suggest that Labrasol may serve as the most effective solvent system for enhancing the solubility of Azilsartan in formulation development.

Selection of Carrier

The solubility of Azilsartan was evaluated in various commonly used pharmaceutical carriers to identify the most effective excipient for enhancing drug solubilization. As summarized in Table 4, Fujicalin exhibited the highest solubility for Azilsartan among the tested carriers, followed by Neusilin and Lactose. Microcrystalline Cellulose (MCC) showed moderate solubility, while Starch demonstrated the lowest solubilizing potential. These findings suggest that Fujicalin may be a promising carrier for improving the solubility of Azilsartan in solid dosage forms.

Pre-compression Parameters

The pre-compression studies were conducted to evaluate the flow properties and compressibility of the Liquisolid powder blend. The Carr's Index (13.85 ± 0.30%) and Hausner's Ratio (1.16 ± 0.01) indicate good flow properties, while the Angle of Repose (30.0 ± 0.5°) suggests acceptable powder flowability. The bulk and tapped densities confirm the blend's suitability for direct compression (Table 5).

Post-compression Parameters

Post-compression studies (Table 6) confirmed that the optimized tablets demonstrated excellent physical and pharmaceutical properties. All critical attributes were within standard limits, ensuring dose uniformity and reliable disintegration.

FTIR

The FTIR spectrum of the Azilsartan Liquisolid compact formulated with Fujicalin and Labrasol confirmed the presence of key functional groups without significant shifts, indicating no major interactions. The N–H stretch at 3270.46 cm-¹ confirmed the presence of amine groups, while the C–H stretch at 2920.65 cm^{-1} suggested aliphatic chains, indicating compatibility with Labrasol[21-23]. The C=N stretch at 1638.67 cm^{-1} corresponded to the tetrazole

Table 7: Effect of FUJ and Croscarmellose Sodium on Drug Release

Std Order	Run Order	Center Pt	Blocks	AZL-FUJ (mg)	Croscarmellose Sodium (%)	Drug Release at 30 min (%)
1	1	1	1	50	2	53.85
2	2	1	1	100	2	48.67
3	3	1	1	50	5	71.35
4	4	1	1	100	5	63.53
5	5	1	1	50	2	54.25
6	6	1	1	100	2	49.89
7	7	1	1	50	5	471.35
8	8	1	1	50	5	62.28

Table 8: ANOVA for Drug Release at 30 Minutes

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Model	3	572.249	190.750	475.26	0.003
Linear Effects	2	565.496	282.748	704.47	0.001
Fujicalin (mg)	1	87.318	87.318	217.55	0.002
Croscarmellose Sodium (mg)	1	478.178	478.178	1191.39	0.003
2-Way Interaction	1	6.753	6.753	16.82	0.015
Fujicalin(mg) Croscarmellose Sodium	1	6.753	6.753	16.82	0.015
Error	4	1.605	0.401		
Total	7	573.854			

Table 9: ICH-Based Stability Evaluation of the Optimized Formulation

Month	Physical Appearance	Hardness (kg/cm^2)	Friability (%)	Disintegration Time (sec)	Dissolution (%)
0	No Change	5.6 ± 0.2	0.78 ± 0.03	65.2 ± 2.1	99.8 ± 0.2
1	No Change	5.5 ± 0.3	0.80 ± 0.04	66.1 ± 2.3	99.7 ± 0.4
2	No Change	5.4 ± 0.3	0.82 ± 0.05	69.5 ± 2.5	99.6 ± 0.3
3	No Change	5.3 ± 0.4	0.85 ± 0.06	71.8 ± 2.7	99.4 ± 0.6

ring, a crucial pharmacophore of Azilsartan, while the C=C stretch at 1538.41 cm^{-1} confirmed the aromatic ring structure. Additionally, the C–O stretch at 1010.95 cm^{-1} highlighted the carboxylic acid group, indicating no chemical interaction with Fujicalin (Figure 3 and 4)[24-26].

Effect of -FUJ and Croscarmellose Sodium on Drug Release at 30 Minutes

The contour plot (Figure 5) illustrates the interactive effect of Fujicalin (mg) and Croscarmellose sodium (%) on the drug release at 30 minutes. The plot clearly shows that drug release increases with higher concentrations of Croscarmellose sodium, whereas Fujicalin exerts a comparatively moderate influence. At lower levels of Croscarmellose sodium (2%), drug release remained below 55% even with increased Fujicalin content, while at higher levels (5%), drug release exceeded 70%, particularly when combined with lower amounts of Fujicalin (50 mg). These findings confirm that Croscarmellose sodium is the critical factor governing rapid drug release, with the best performance observed at low Fujicalin and high roscarmellose sodium concentrations

Effect of Formulation Variables on Drug Release

The surface plot (Figure 5) depicts the combined influence of Fujicalin (mg) and Croscarmellose sodium (%) on the percentage of drug release at 30 minutes. The rising plane in the plot indicates that drug release improves substantially with higher concentrations of Croscarmellose sodium, while the effect of Fujicalin is comparatively less pronounced. At lower levels of Croscarmellose sodium (2%), drug release remained closer to 50–55%, whereas at higher levels (5%), the release values exceeded 70%, particularly when Fujicalin content was maintained at 50 mg. This 3D plot thus reinforces the contour plot findings, confirming that Croscarmellose sodium is the primary factor enhancing drug release, while Fujicalin plays a secondary role in modulating the response.

Analysis of Variance (ANOVA) for Drug Release at 30 Minutes

The ANOVA results are presented in Table 8, which depicts the relative contribution of formulation factors on drug release at 30 minutes. Among the variables studied, Croscarmellose sodium (%) had the most significant impact, with the highest F-value (1191.39), indicating that it is the primary factor governing drug release. Fujicalin (mg) also showed a statistically significant effect (F =217.55), though its influence was less pronounced compared to Croscarmellose sodium. The interaction between Fujicalin and Croscarmellose sodium was significant ($F = 16.82$, $p = 0.015$) but contributed minimally to the overall variability. These findings confirm that the dissolution performance of the optimized formulation is predominantly controlled by the concentration of Croscarmellose sodium, with Fujicalin playing a secondary role and their interaction exerting only a minor effect.

Comparison of Drug Release Profiles

The drug release profiles of pure Azilsartan, Azilsartan Liquisolid tablet were evaluated over 60 minutes. The results indicate that the Liquisolid tablet significantly

enhances drug release, reaching 99.8% at 60 minutes, compared to 72.5% for the pure drug. The initial dissolution rate (first 30 minutes) was also higher for the Liquisolid formulation, confirming its potential to improve solubility (Figure 6)Effect of AZL-FUJ and

Stability Studies

As summarized in Table 9, the tablets retained their physical integrity with no observable changes in appearance throughout the study period. A slight but consistent trend of marginal decrease in hardness and increase in friability and disintegration time was observed, yet these changes did not significantly impact the dissolution profile, which remained above 99% at all-time points. These findings confirm the formulation's stability, robustness, and suitability for long-term storage.

CONCLUSION

In conclusion, the Liquisolid technique effectively addressed the solubility challenges associated with Azilsartan. Enhanced drug release from the optimized formulation confirmed the approach's potential, with FTIR studies ensuring chemical stability. Comprehensive pre- and post-compression evaluations established the formulation's physical robustness, while accelerated stability studies validated its long-term integrity.

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