

Development and Characterization of Posaconazole Solid Dispersion Using Polymeric Carriers

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ABSTRACT

Posaconazole, a second-generation triazole antifungal agent, is hindered by poor aqueous solubility, which critically limits its oral bioavailability and therapeutic effectiveness. This study aimed to overcome this challenge by developing solid dispersions of Posaconazole using Soluplus® as a hydrophilic polymeric carrier through the solvent evaporation technique. A 3² factorial design was employed to evaluate the influence of the drug-to-polymer ratio (X₁) and methanol volume (X₂) on solubility (Y₁) and % CDR at 12 minutes (Y₂). Nine formulations (PS1–PS9) were prepared and evaluated for flow properties, drug content, solubility, and in vitro drug release. Preformulation studies confirmed the drug's identity, purity, and excipient compatibility. All batches exhibited satisfactory flow properties and acceptable drug content (93.23–99.24%), with significantly improved solubility over pure drug. Response surface analysis established that higher methanol volume and an optimized polymer ratio were key drivers of enhanced performance. Batch PS8 (1:3.5 ratio in 100 mL methanol) emerged as an optimized formulation, achieving the highest solubility (1.89 mg/ml) and near-complete drug release of 99.85% within 12 minutes. Accelerated stability studies confirmed PS8 remained stable under stressed conditions, validating solid dispersion technology as an effective strategy to enhance Posaconazole's oral bioavailability.

Keywords: Solid Dispersion, Posaconazole, Soluplus®, Solubility enhancement.

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INTRODUCTION

Fungal infections pose a significant challenge in both immunocompromised and immunocompetent individuals. Antifungal agents comprise a broad class of drugs used to treat or prevent fungal infections by acting on specific fungal structures or metabolic pathways. These infections vary from mild superficial conditions, such as candidiasis and dermatophytosis, to severe and life-threatening systemic diseases like aspergillosis and cryptococcosis. Fungal diseases affect more than one billion people globally and are responsible for over 1.5 million deaths each year. The increasing incidence of opportunistic infections, driven by conditions such as HIV/AIDS, organ transplantation, cancer chemotherapy, and extensive use of antibiotics, has greatly enhanced the need for effective antifungal

treatments. Although modern antifungal agents have broadened therapeutic options, challenges such as drug resistance, potential drug–drug interactions, and poor solubility of certain drugs (e.g., posaconazole) continue to limit their effectiveness.^{1,2}

Solubility is an important physicochemical property that influences the overall performance and characteristics of a drug substance. Over the years, various strategies have been developed to address solubility-related challenges, including the use of surfactants, co-solvents, inclusion complexes, self-emulsifying systems, prodrugs, and micro environmental buffering techniques. Among these, solid dispersion technology has emerged as a well-established and effective method for enhancing the solubility of poorly water-soluble drugs. This approach has been widely reported in pharmaceutical

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research for improving the solubility of a large number of hydrophobic drugs, although it is sometimes considered a conventional or older technique.³

MATERIALS AND METHODS

Materials

Soluplus[®] was provided by Chemdyes Corporation, Rajkot. Methanol was procured from Finar Chemicals.

Method

Posaconazole solid dispersions were prepared by the Solvent evaporation method using Soluplus[®] as the hydrophilic carrier and methanol as the solvent. A 3² factorial design was applied to evaluate combined effect of Posaconazole: Soluplus[®] (X₁) and quantity of methanol (X₂) taken as independent variables & Solubility (Y₁) and % CDR at 12 mins (Y₂) were selected as dependent variables, where each variable was evaluated at three different levels -1, 0 and +1. Nine formulations (PS1–PS9) were developed by varying the drug-to-polymer ratio as 1:3, 1:3.5, and 1:4, and methanol volumes of 50 mL, 75 mL, and 100 mL were used. For each batch, accurately weighed quantities of Posaconazole and Soluplus[®] were taken as per the specified ratio (Table 1). Soluplus[®] was first dissolved in the required volume of methanol under continuous magnetic stirring, followed by gradual addition of Posaconazole to obtain a clear and homogeneous solution. The solution was transferred to a glass dish and the solvent was allowed to evaporate at room temperature. The resulting solid mass was further dried to constant weight, pulverized, passed through a suitable sieve, and stored in a desiccator until further evaluation.⁴⁻⁵

Table 1: Formulation of Solid dispersion using 3² Factorial design

Formulation Code	Posaconazole : Soluplus [®] (gm)	Methanol (ml)
PS1	1.0 : 3.0	50
PS2	1.0 : 3.5	50
PS3	1.0 : 4.0	50
PS4	1.0 : 3.0	75
PS5	1.0 : 3.5	75
PS6	1.0 : 4.0	75
PS7	1.0 : 3.0	100
PS8	1.0 : 3.5	100
PS9	1.0 : 4.0	100

Pre-formulation study

Determination of melting point of Posaconazole:

The melting point of Posaconazole was determined using a melting point apparatus (Bhawana, India). A small quantity of the drug was filled into a thin-

walled, one-end-closed capillary tube, which was then placed in the melting point apparatus equipped with a thermometer to record the temperature range at which Posaconazole melts. The measurements were performed in triplicate.⁶

Estimation of Posaconazole by UV-Visible Spectrophotometry:

A primary stock solution of Posaconazole was prepared at a concentration of 100 µg/ml by accurately dissolving 10 mg of the drug in 100 ml of distilled water. To establish the wavelength of maximum absorption (λ_{max}), the stock solution was subjected to a full spectrum scan over the ultraviolet range of 200–400 nm using a UV-Visible spectrophotometer (Shimadzu UV-1900, Japan), with distilled water serving as the blank reference. The λ_{max} of Posaconazole was identified at 262 nm, which was subsequently employed for all further quantitative analyses. Working standard solutions spanning a concentration range of 3–15 µg/ml were prepared by transferring aliquots of 0.3, 0.6, 0.9, 1.2, and 1.5 ml from a freshly prepared intermediate stock solution of 100 µg/ml into individual 10 ml volumetric flasks, each made up to volume with distilled water. The absorbance of each working solution was recorded in triplicate at 262 nm against a distilled water blank, and the mean absorbance values were plotted against the corresponding concentrations to construct a calibration curve, which was used for the quantitative estimation of Posaconazole in all subsequent analytical measurements.⁶

FTIR: FTIR was performed for determination of Posaconazole and was estimated for standard FTIR peaks. FTIR spectroscopy of pure drug and physical mixture of drug and excipients was carried out to check the compatibility of drug and excipients.⁶

Evaluation parameters of Solid Dispersion

Determination of solubility: Solid dispersion containing drug equivalent to 1 gm of Posaconazole was added to 100 ml of water in a beaker. The mixture was stirred for 6 hours at 37 ± 0.5 °C using a mechanical stirrer at 1000 rpm. After stirring, it was allowed to equilibrate for 12 hours at the same temperature. The solution was then filtered through a 0.45 µm membrane filter, and the filtrate was analysed using a UV spectrophotometer at 262 nm.⁷

% Drug Content: The drug content in 1 gm equivalent of solid dispersion was determined by dissolving it in 25 ml of water, diluting appropriately, and measuring the UV absorbance at 262 nm. The drug concentration was then calculated using a standard calibration graph.⁸

% Cumulative Drug Release Studies: The prepared solid dispersions was performed using a USP Type II (paddle) dissolution apparatus. An accurately weighed quantity of solid dispersion was placed in 500 mL of Water, maintained at 37 ± 0.5 °C and the paddle was rotated at a constant speed of 50 rpm. At predetermined time intervals, 5 mL samples were withdrawn, filtered through a 0.45 µm membrane filter, and replaced with an equal volume of fresh preheated medium to maintain sink conditions.⁹

Stability study of optimized batch: In this study, the stability of the optimized batch was evaluated under accelerated conditions at 40 ± 2 °C and $75 \pm 5\%$ RH for 1 month. The formulation was wrapped in aluminium foil to protect it from light, following ICH guidelines for accelerated stability testing.^{10,11}

RESULTS AND DISCUSSION

Melting point of Posaconazole: Melting point determination was performed as a preliminary step to confirm the identity and purity of the procured Posaconazole sample. Using a calibrated melting point apparatus by the open capillary method, the melting point of Posaconazole was experimentally determined and found to be in the range of 168–173°C, which corresponded closely with the reported literature value of 170–171°C. The slight deviation observed between the two values is well within the acceptable range and could be attributed to minor instrumental variations or the inherent polymorphic characteristics of the drug. The close agreement between the experimental and reported melting point values satisfactorily confirmed the identity and purity of Posaconazole, establishing its suitability for use in subsequent formulation studies.

Identification of drug by UV Spectroscopy Method: The overlay spectra obtained by scanning Posaconazole solutions across concentrations of 3, 6, 9, 12, and 15 µg/ml consistently demonstrated maximum absorbance at 262 nm (Figure 1), which was in complete agreement with the reported λ_{max} of 262 nm for Posaconazole, thereby confirming the identity of the drug sample. The calibration curve constructed by plotting absorbance against concentration over the range of 3–15 µg/ml (Figure 2) exhibited a well-defined linear relationship, expressed by the regression equation $y = 0.0618x - 0.0431$, with a correlation coefficient of $R^2 = 0.9991$. The exceptionally high R^2 value reflects excellent linearity across the studied concentration range, confirming that the developed UV spectrophotometric method is reliable, precise, and well-suited for the quantitative estimation of Posaconazole in all subsequent

analytical evaluations. (Table 1)

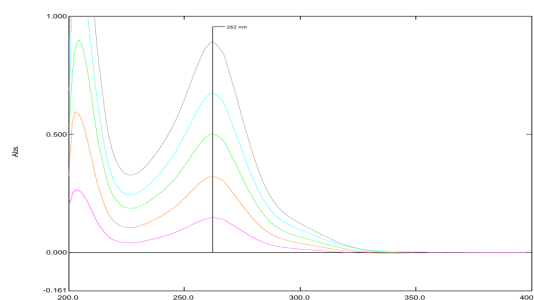


Figure 1: Overlay Spectra of Posaconazole

Table 2: Absorbance of different concentration of Posaconazole

Sr.	Concentration (ppm)	Absorbance			Mean Absorbance ± S. D.
		I	II	III	
1.	3	0.147	0.148	0.146	0.147 ± 0.001
2.	6	0.321	0.320	0.322	0.321 ± 0.001
3.	9	0.519	0.521	0.517	0.519 ± 0.002
4.	12	0.686	0.685	0.687	0.686 ± 0.001
5.	15	0.891	0.892	0.890	0.891 ± 0.001

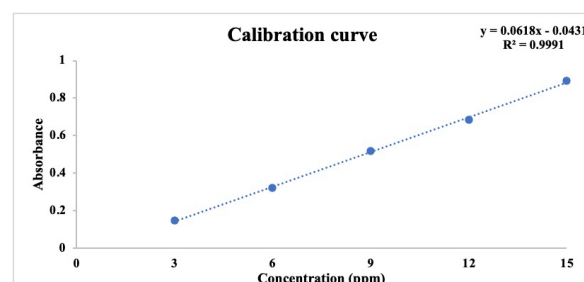


Figure 2: Calibration curve of Posaconazole in Water

FTIR Study of Posaconazole & Drug-Excipients Compatibility study

FTIR spectroscopy was carried out to confirm the identity of Posaconazole, and the resulting spectrum displayed all the key absorption bands typical of its functional groups, which matched well with the reference standard. This gave a clear confirmation that the drug was genuine and correctly identified. To check whether any of the excipients could potentially interact with the drug, physical mixtures of Posaconazole with excipients was analysed by FTIR. On comparing these spectra with that of the pure drug, it was reassuring to find that all the major peaks

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remained intact at their original positions, with no meaningful changes in their shape, intensity, or location. No new peaks appeared in the mixture spectra, which is a strong indication that none of the excipients triggered any unwanted chemical reaction with Posaconazole. Overall, these results build confidence that Posaconazole is well compatible with the chosen excipients in the development of stable and effective tablet formulations.

Results of Solid Dispersion formulated by 3² Factorial Design

The flow properties of the prepared powder blends (PS1–PS9) were assessed using bulk density, tapped density, Carr's index, Hausner's ratio, Angle of repose and Percentage porosity to determine their suitability for further processing.

The bulk density of all batches ranged from 0.58 ± 0.06 to 0.64 ± 0.02 g/ml, and tapped density ranged from 0.69 ± 0.08 to 0.74 ± 0.02 g/ml, indicating good packing characteristics. Carr's index values were $12.66 \pm 1.96\%$ to $16.32 \pm 1.96\%$, suggesting fair to good flow, while Hausner's ratio ranged from 1.11 ± 0.06 to 1.21 ± 0.04 , further confirming acceptable flowability of the powder blends.

Angle of repose values for all batches were within the range of $26.47 \pm 0.16^\circ$ to $29.60 \pm 0.21^\circ$, indicating good flow behaviour. Among all batches, PS7 showed the lowest angle of repose (26.47°), suggesting comparatively better flow, whereas PS6 showed a slightly higher value (29.60°), though still within acceptable limits.

The percentage porosity was found between $18.34 \pm 1.52\%$ and $34.76 \pm 1.09\%$. PS7 exhibited the highest porosity (34.76%), indicating a more porous structure, while PS4 showed the lowest porosity (18.34%), suggesting better packing (Table 3)

Table 3: Flow Properties of Solid Dispersions

Batch	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Carr's Index (%)	Hausner's Ratio (%)	Angle of Repose ($^\circ\Theta$)	% Porosity
PS 1	0.62 ± 0.02	0.72 ± 0.03	12.9 ± 1.70	1.18 ± 0.06	27.8 ± 0.47	30.27 ± 2.04
PS 2	0.59 ± 0.04	0.71 ± 0.06	16.3 ± 1.96	1.20 ± 0.02	28.1 ± 0.20	26.14 ± 1.03
PS 3	0.58 ± 0.06	0.69 ± 0.08	15.4 ± 2.51	1.16 ± 0.07	27.1 ± 0.11	25.61 ± 2.36

PS 4	0.59 ± 0.03	0.70 ± 0.05	15.5 ± 1.85	1.19 ± 0.02	28.4 ± 0.21	18.34 ± 1.52
PS 5	0.61 ± 0.04	0.70 ± 0.03	14.0 ± 2.07	1.11 ± 0.06	28.7 ± 0.14	25.31 ± 1.14
PS 6	0.64 ± 0.02	0.74 ± 0.02	12.6 ± 1.96	1.18 ± 0.05	29.6 ± 0.21	26.08 ± 2.67
PS 7	0.62 ± 0.04	0.74 ± 0.04	15.6 ± 1.36	1.21 ± 0.04	26.4 ± 0.16	34.76 ± 1.09
PS 8	0.59 ± 0.04	0.71 ± 0.04	16.0 ± 0.71	1.21 ± 0.03	28.1 ± 0.35	28.90 ± 1.44
PS 9	0.59 ± 0.06	0.70 ± 0.06	15.7 ± 1.94	1.19 ± 0.03	28.1 ± 0.19	28.80 ± 1.45

% Practical yield, Drug content and Solubility of Various Solid Dispersions

The prepared batches (PS1–PS9) were evaluated for percentage practical yield, amount of drug soluble, and drug content to assess process efficiency, solubility enhancement, and uniformity of drug distribution. The percentage practical yield of all batches was found in the range of $90.58 \pm 0.51\%$ to $98.56 \pm 1.26\%$, indicating good recovery of the product with minimal loss during processing. Among all batches, PS3 showed the highest yield ($98.56 \pm 1.26\%$), while PS5 exhibited comparatively lower yield ($90.58 \pm 0.51\%$). The amount of drug soluble varied from 0.87 ± 0.03 mg/ml to 1.89 ± 0.08 mg/ml. PS8 showed the highest solubility (1.89 ± 0.08 mg/ml), followed by PS7 (1.56 ± 0.03 mg/ml) and PS5 (1.44 ± 0.12 mg/ml), indicating significant enhancement in drug solubility in these formulations. In contrast, PS6 showed the lowest solubility (0.87 ± 0.03 mg/ml). Drug content across all batches was found to be within the range of $93.23 \pm 1.16\%$ to $99.24 \pm 0.24\%$, indicating uniform distribution of the drug within the formulations. PS8 exhibited the highest drug content ($99.24 \pm 0.24\%$), while PS7 showed slightly lower but acceptable drug content ($96.64 \pm 0.61\%$). Based on the results of the evaluation parameters, all batches demonstrated satisfactory practical yield and drug content. However, based on solubility enhancement, PS8 was found to be the optimized batch, showing maximum drug solubility along with acceptable yield and drug content. (Table 4)

Table 4: % Practical yield, Drug content and Solubility of Various Solid Dispersions

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Batch	% Practical Yield	Amount of Drug Soluble (mg/ml)	Drug Content (%)
PS1	93.55 ± 1.00	0.98 ± 0.01	96.71 ± 0.82
PS2	94.99 ± 2.68	1.32 ± 0.06	95.69 ± 1.29
PS3	98.56 ± 1.26	0.92 ± 0.02	97.97 ± 0.46
PS4	94.73 ± 0.34	1.22 ± 0.02	99.00 ± 0.51
PS5	90.58 ± 0.51	1.44 ± 0.12	98.24 ± 0.33
PS6	95.57 ± 2.08	0.87 ± 0.03	93.23 ± 1.16
PS7	95.22 ± 1.06	1.56 ± 0.03	96.64 ± 0.61
PS8	97.46 ± 1.82	1.89 ± 0.08	99.24 ± 0.24
PS9	96.93 ± 2.10	1.11 ± 0.11	98.92 ± 0.82

Time (min.)	PS 1	PS 2	PS 3	PS 4	PS 5	PS 6	PS 7	PS 8	PS 9
0	0	0	0	0	0	0	0	0	0
3	22.0	31.5	18.9	30.6	36.2	23.0	37.5	38.5	27.9
6	42.9	54.5	38.8	51.3	59.8	44.2	62.8	65.3	48.7
9	57.4	70.9	53.4	67.4	78.3	59.5	81.4	84.4	63.2
12	80.3	92.0	77.4	90.2	95.4	82.1	96.9	99.5	87.1
15	84.2	97.1	82.0	96.5	97.4	95.2	98.7	-	95.7
18	95.9	-	95.2	-	-	-	-	-	-

% Cumulative drug release study:

The *in vitro* drug release profiles of batches PS1–PS9 were evaluated over a period of 18 minutes to assess the dissolution behavior and effectiveness of the formulations. All batches exhibited a rapid increase in drug release with time, indicating enhanced dissolution characteristics as demonstrated in table 5 and figure 3. At 3 minutes, drug release ranged from 18.29% (PS3) to 38.75% (PS8), showing an initial burst release, particularly in batches containing higher solubility-enhancing components. The release further increased significantly at 6 and 9 minutes, with PS8 (65.32% and 84.24%) and PS7 (62.88% and 81.74%) showing comparatively higher drug release. At 12 minutes, most batches exhibited substantial drug release, ranging from 77.94% (PS3) to 99.85% (PS8). PS8 showed nearly complete drug release within 12 minutes, indicating superior dissolution performance. Similarly, PS7 (96.49%) and PS5 (95.84%) also demonstrated rapid and high drug release. At 15 minutes, PS2 and PS7 achieved drug release of 97.31% and 98.74%, respectively, while PS8 had already reached near-complete release earlier. By 18 minutes, PS1 and PS3 also showed high drug release of 95.39% and 95.32%, respectively, indicating eventual completion of drug dissolution across all batches. Overall, all formulations showed significantly improved drug release; however, PS8 emerged as the optimized batch, exhibiting the fastest and highest drug release, followed by PS7 and PS5.

Table 5: % CDR Profile of Solid Dispersions

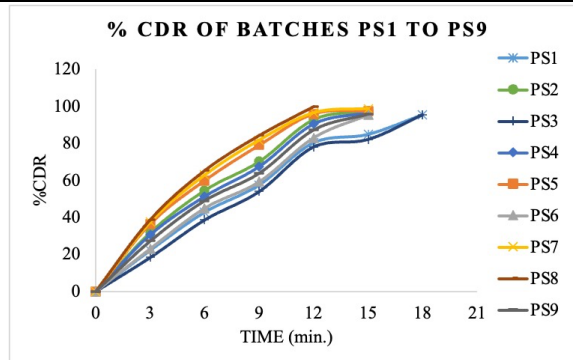


Figure 3: % CDR of Batches PS1 to PS9

STATISTICAL ANALYSIS

Statistical Analysis for Solubility: The response surface analysis of solubility (Y_1) revealed a significant dependence on both formulation variables, namely the ratio of Posaconazole: Soluplus® (X_1) and methanol volume (X_2), as described by the polynomial equation: $Y_1 = 1.47 - 0.1433X_1 + 0.2233X_2 - 0.0975X_1X_2 - 0.4400X_1^2 + 0.1200X_2^2$. The positive coefficient of X_2 (+0.2233) indicates that methanol has a pronounced enhancing effect on solubility, whereas the negative coefficient of X_1 (-0.1433) suggests that increasing polymer concentration beyond an optimal level slightly reduces solubility. The presence of quadratic terms confirms curvature in the response, with the strong negative effect of X_1^2 (-0.4400) indicating a critical optimum for polymer ratio, while X_2^2 (+0.1200)

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suggests a moderate curvature effect for methanol. The interaction term (-0.0975) reflects a mild antagonistic interaction between the variables. The contour (figure 4a) and 3D surface plots (figure 4b) demonstrate that maximum solubility is achieved at intermediate levels of polymer and higher methanol concentrations, whereas lower methanol levels result in reduced solubility across all compositions. Furthermore, the predicted versus actual plot (figure 4c) shows close alignment of data points along the diagonal, confirming excellent model predictability and validity. Overall, the results indicate that optimized solubility is achieved by maintaining a balanced Posaconazole: Soluplus[®] ratio with relatively higher methanol content, ensuring improved formulation performance.

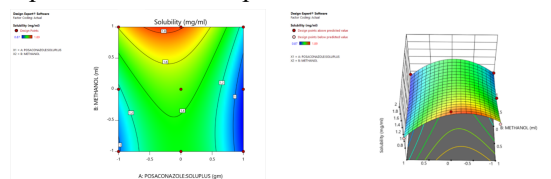


Figure 4a: Contour plot showing the effect of Posaconazole: Soluplus[®] (X₁) and Methanol (X₂) on Solubility

Figure 4b: 3D surface plot showing the effect of Posaconazole: Soluplus[®] (X₁) and Methanol (X₂) on Solubility

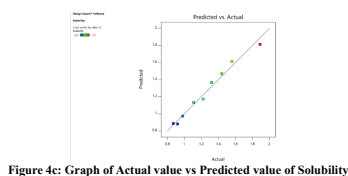


Figure 4c: Graph of Actual value vs Predicted value of Solubility

Statistical Analysis for % CDR: The response surface analysis for % CDR (Y₂) demonstrated a significant influence of both formulation variables, Posaconazole:Soluplus[®] ratio (X₁) and methanol concentration (X₂), as represented by the polynomial equation: $Y_2 = 96.59 - 3.21X_1 + 5.40X_2 - 1.76X_1X_2 - 10.30X_1^2 - 0.6417X_2^2$. The positive coefficient of X₂ (+5.40) indicates that methanol markedly enhances drug release, whereas the negative coefficient of X₁ (-3.21) suggests that increasing polymer concentration retards drug release due to the formation of a stronger matrix system. The negative quadratic terms for both X₁² (-10.30) and X₂² (-0.6417) confirm a nonlinear relationship, with a pronounced curvature effect for polymer concentration, indicating a critical optimum region. The interaction term (-1.76) reflects a slight antagonistic interaction between the variables. The contour (figure 5a) and 3D surface plots (figure 5b) illustrate that maximum drug release was achieved at lower levels of polymer and higher levels of methanol, as indicated by the red region, while higher polymer concentrations significantly decrease drug release due to increased matrix

density. Furthermore, the predicted versus actual plot (figure 5c) shows a strong linear correlation, confirming the reliability and predictive accuracy of the model. Overall, the results suggest that optimized % CDR can be achieved by maintaining a lower polymer ratio with a higher methanol concentration, ensuring effective and controlled drug release performance.

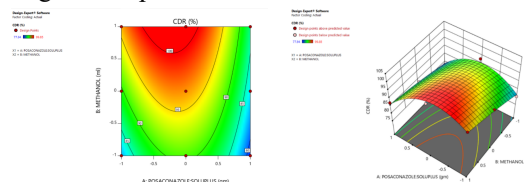


Figure 5a: Contour plot showing the effect of Posaconazole: Soluplus[®] (X₁) and Methanol (X₂) on % CDR

Figure 5b: 3D surface plot showing the effect of Posaconazole: Soluplus[®] (X₁) and Methanol (X₂) on % CDR

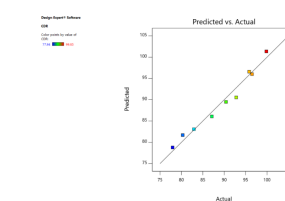


Figure 5c: Graph of Actual value vs Predicted value of % CDR

RESULTS OF STABILITY STUDY

Based on all the evaluated parameters of the factorial design batches, PS8 was identified as the optimized batch, exhibiting good flow properties and the highest solubility. Moreover, it showed 99.85 % of drug release in just 12 minutes, its solubility was 1.89 mg/ml which was highest as compared to all other batches. Thus, batch PS8 was selected as an optimized batch. A stability study of the optimized batch solid dispersion was conducted at $40 \pm 2^\circ\text{C}$ and $75 \pm 5\% \text{RH}$ for one month. After 1 month, the flow properties, solubility, and % CDR of the batch were evaluated.

Table 6: Results of stability study

Evaluation parameter	Results of optimized batch	Result after 1 month at $40 \pm 2^\circ\text{C}$ and $75 \pm 5\% \text{RH}$
Amount of Drug Soluble (mg/ml)	1.89	1.93
Drug Content (%)	98.48	98.04

Table 7: % CDR Study of Stability Batch

Time (Min.)	% CDR of Optimized Batch (%)	% CDR of batch After Time Period of 1 Month (%)
0	0	0
3	38.75	37.39
6	65.32	63.19
9	84.24	83.25
12	99.85	97.62

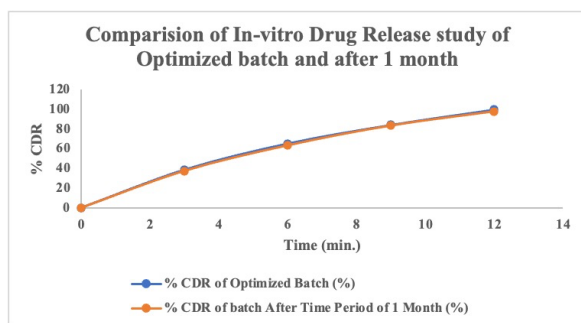


Figure 6: Comparison of % CDR study of Optimized batch and Stability batch

CONCLUSION

The study aimed to improve solubility and dissolution of Posaconazole using solid dispersions. Preformulation confirmed drug purity, low solubility, and reliable analytical methods. Solid dispersions prepared by solvent evaporation showed good flow properties, with solvent evaporation giving better yield and uniform drug content. Solubility. Optimization (3^2 factorial design) identified PS8 as the best formulation, showing highest solubility (1.89 mg/ml) and rapid drug release (~99.85% in 12 minutes). Stability studies confirmed that PS8 remained stable under accelerated conditions. Overall, solid dispersion especially using solvent evaporation with Soluplus® is an effective method to enhance solubility, dissolution, and bioavailability of Posaconazole.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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