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Enhancement of Tadalafil Solubility and Dissolution through Solid Dispersions for Fast-Dissolving Tablet Development

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ABSTRACT

This study aimed to enhance the solubility and dissolution of Tadalafil using solid dispersions and to develop fast-dissolving tablets to improve patient compliance. Solid dispersions were prepared with PEG 6000 (1:0.5, 1:1, 1:1.5) by the fusion method and used to formulate F1–F12 fast-dissolving tablets. A 3^2 factorial design studied the combined effect of crospovidone (X1) and Kyron T-314 (X2) on disintegration time (Y1), wetting time (Y2), and drug release in 8 minutes (Y3). Tablets were evaluated for pre- and post-compression parameters. PEG 6000 (1:1.5) solid dispersion significantly improved tadalafil solubility. Fast-dissolving tablets with **2% Kyron T-314 and 1% Crospovidone** showed the fastest disintegration and highest drug release. Combining superdisintegrants proved superior to using them individually.

Keywords: Tadalafil, PEG 6000, Kyron T-314, Crospovidone

I. INTRODUCTION

Solubility is crucial for ensuring a drug dissolves properly and reaches the bloodstream in effective amounts. Drugs that dissolve poorly in water often absorb slowly, may cause inconsistent effects, and can irritate the digestive tract. For BCS Class II drugs those with low solubility but good permeability boosting solubility and dissolution rate is essential for better performance.

Solid dosage forms like tablets and capsules are popular due to their low cost, accurate dosing, and convenience. However, many people, especially children and the elderly, struggle to swallow them, making dysphagia a common concern. People who struggle to swallow pills such as children, the elderly, or those without easy access to water benefit from medicines that are easier to take. To address this, scientists developed Orodispersible Tablets (ODTs), which dissolve in saliva within seconds without needing water. This allows the drug to be absorbed faster, often leading to quicker and more effective action than regular tablets. According to the USFDA, ODTs are solid dosage forms that break down rapidly on the tongue, usually within a few seconds to a minute. They are also known as orodispersible tablets, mouth-dissolving tablets, fast-disintegrating tablets, rapid-melts, and porous tablets. Solid dispersion is a technique where one or more drugs are mixed with a solid carrier to improve the solubility of poorly water-soluble medicines. Since nearly 40% of new drugs are not water-soluble, enhancing solubility is a major challenge in drug development. Solid dispersions offer an effective way to increase dissolution rate and boost bioavailability. In this method, the drug is distributed within a water-soluble carrier either as molecules or tiny particles in crystalline or amorphous form. By combining hydrophobic drugs with hydrophilic carriers, the carrier dissolves quickly in the stomach and helps the drug dissolve faster, leading to better absorption and improved effectiveness. Tadalafil is a PDE-5 inhibitor and a BCS Class II drug, meaning it is well absorbed but poorly soluble in water, so improving its solubility is important. Techniques like solid dispersions, surfactants, and film-coating are often used to enhance its dissolution and bioavailability. It has about 80% oral bioavailability and a long half-life of around 17.5 hours, making once-daily or on-demand dosing possible. Tadalafil is mainly metabolized in the liver by CYP3A4, is moisture-sensitive and needs protective packaging, and is mostly excreted in the feces.

MATERIALS

Tadalafil API was procured from Ami Life Sciences Pvt. Ltd., Baroda. The formulation utilized pharmacopoeial-grade excipients, including Kyron T-314, Crospovidone, Croscarmellose Sodium, Sodium Starch Glycolate, Microcrystalline Cellulose (MCC), Mannitol, Magnesium Stearate, Talc, PVP K-90, and PEG-6000, carefully selected to ensure optimal

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disintegration, binding, lubrication, and solubility properties of the final dosage form.

METHODS

Fusion Method. Weight accurately 10 mg polymer and placed it into a china dish and heat it on a water bath with continuous stirring until the polymer is dissolved. Add 10 mg Aprepitant (drug) in dissolved polymer solution with continuous stirring to form a homogenous mixer. After complete mixing of drug and polymer rapidly transfer into the ice bath to solidified with vigorous stirring. Then, the final solid mass is crushed, pulverized, and sieved. Different optimized combinations of solid dispersion with different polymers were prepared and evaluated for different evaluation parameters.

Characterization of Solid Dispersion

Solubility Studies

Tadalafil from solid dispersions was estimated using a UV-Visible spectrophotometer (Shimadzu-1800, Japan) at its λmax in water. An accurately weighed amount of the solid dispersion, equivalent to the desired dose, was dissolved in 2 mL water. Stock solutions were prepared by successive dilutions, and a blank was made from the carrier. All solutions were filtered, and the absorbance was measured to quantify tadalafil accurately.

Identification Test of Tadalafil

Preparation of Standard Curve

A stock solution of Tadalafil (100 µg/ml) was prepared by dissolving the drug in a mixture of 10 ml of methanol and Phosphate buffer pH6.8. A 10 µg/ml dilution of this solution was then placed in a cuvette. The UV spectrum was recorded using a double beam UV-VIS spectrophotometer across a wavelength range of 200 nm to 400 nm. The drug's maximum absorption (λmax) was found to occur at 284.80 nm.

Fourier Transform Infrared (FTIR) spectroscopy

Identification of Tadalafil was done to ensure that available sample was of Tadalafil or not. Fourier Transform Infrared (FTIR) spectroscopy of pure drug was performed using the Bruker Alpha II spectrometer equipped with an ATR (Attenuated Total Reflectance) accessory. In the present study A small amount of Tadalafil powder was placed directly on the ATR crystal. The spectrum was recorded over the range of 4000–400 cm^{-1} with a resolution of 4 cm^{-1} using 32 scans. The crystal was cleaned with isopropyl alcohol before and after each scan.

PRELIMINARY SCREENING OF SOLID DISPERSION

Preparation of Tadalafil Solid Dispersion

A review of literature says that PEG 4000, PEG 6000, PVP K-90 are widely used carriers in fast dissolving tablets because of their non-toxic, fast disintegrating and the hydrophilic nature.

Dispersion Is Prepared By Fusion Method

Method two carriers are heated in two different chaina dishes at a temperature just above their points and then the drug is incorporated into the matrix. Different Proportion of the drug and PEG6000 used. Then the melt is solidified on an ice bath under vigorous stirring. The mass obtained because was then crushed, pulverized, and then shifted to the 80# mesh. All the solid dispersion prepared in a well-closedglass container 1till further use.

Table 1. Preliminary Batch of Solid Dispersion

Method	Carrier	Drug:Carrier	Code
Fusion Method	PEG6000	1:1	SE1
	PEG6000	1:0.5	SE2
	PEG6000	1:1.5	SE3

Table 2. Preliminary Formulation Batch Code

Ingredients (mg)	Preliminary Formulation Batch Code											
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Drug(20mg)+ Solid dispersion (1:1.5)	50	50	50	50	50	50	50	50	50	50	50	50

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Microcrystalline Cellulose	152	140	128	152	140	128	152	140	128	152	140	128
PVPK-90	9	15	21	9	15	21	9	15	21	9	15	21
Mannitol	24	24	24	24	24	24	24	24	24	24	24	24
Crospovidone	6	12	18	-	-	-	-	-	-	-	-	-
SodiumStarch Glycolate	-	-	-	6	12	18	-	-	-	-	-	-
Croscarmellose Sodium	-	-	-	-	-	-	6	12	18	-	-	-
KyronT-314	-	-	-	-	-	-	-	-	-	6	12	18
Talc	6	6	6	6	6	6	6	6	6	6	6	6
Magnesium Stearate	3	3	3	3	3	3	3	3	3	3	3	3
Total weight	250	250	250	250	250	250	250	250	250	250	250	250

3^2 full factorial design

To develop an ideal pharmaceutical formulation in minimal time and with minimal use of resources, it is important to use statistical tools rather than the traditional "one-variable-at-a-time" method, which ignores interactions between factors. Factorial design is an efficient approach that studies multiple factors simultaneously at different levels to understand both individual and interactive effects. Based on preliminary studies evaluating combinations of superdisintegrants, a 3^2 full factorial design was selected to optimize the formulation. This design evaluates two factors at three levels each, resulting in nine experimental trials and allowing construction of a second-order polynomial model. In this study, the quantities of crospovidone (X_1) and Kyron T-314 (X_2) were chosen as independent variables. The dependent variables were disintegration time (Y_1), wetting time (Y_2), and drug release at 5 minutes (Y_3). Each factor was studied at low (−1), medium (0), and high (+1) levels. The polynomial model used was:

$$Y = b_0 + b_1X_1 + b_2X_2 + b_{12}X_1X_2 + b_{11}X_1^2 + b_{22}X_2^2$$

Main effects (X_1, X_2) show the influence of each factor individually, while interaction terms show how the response changes when both factors vary together.

Table 3. Selection of Independent and Dependent Variables

Independent Variables		**Dependent Variables**		
X1	**X 2**	**Y1**	**Y2**	**Y3**
Concentration of Crospovidone	Concentration of Kyron T-314	Disintegration Time (Sec)	Wetting Time (Sec)	Drug Release At 5 Minute

Table 4. Selection of Level For Independent Variables

Coded Value	**X1 (Concentration of Crospovidone)**	**X2 (Concentration of KyronT-314)**
-1	1	1
0	2	2
+1	3	3

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Table 5. Actual Value and Coded Value for Factorial Design

Batches	Coded Value		Actual Value (%)	
	X1	X2	X1	X2
E1	-1	-1	1	1
E2	-1	0	1	2
E3	-1	+1	1	3
E4	0	-1	2	1
E5	0	0	2	2
E6	0	+1	2	3
E7	+1	-1	3	1
E8	+1	0	3	2
E9	+1	+1	3	3

Table 6. Formulation of 3^2 Factorial Design Batches

Ingredients(mg)	Formulation Batch Code								
	E1	E2	E3	E4	E5	E6	E7	E8	E9
Drug(20mg) +Solid dispersion (1:1.5)	50	50	50	50	50	50	50	50	50
Micro Crystalline Cellulose	152	149	146	149	146	143	146	143	140
PolyVinylPyrridone K-90	9	9	9	9	9	9	9	9	9
Mannitol	24	24	24	24	24	24	24	24	24
KyronT-314	3	6	9	3	6	9	3	6	9
Crospovidone	3	3	3	6	6	6	9	9	9
Talc	6	6	6	6	6	6	6	6	6
Magnesium Stearate	3	3	3	3	3	3	3	3	3
Total Weight	250	250	250	250	250	250	250	250	250

Evaluation of post compression parameter
Weight Variation

Weigh 20 tablets individually and calculate the average weight. Then, compare the weight of each tablet to the average. The batch passes the U.
S.P. test if no more than two tablets fall outside the acceptable percentage range and if no tablet deviates more than twice the allowed limit in percentage.

Friability

Friability can be tested in the laboratory using a Roche Friabilator. This device consists of a plastic chamber that rotates at 25 rpm, allowing the tablets to fall through a six-inch gap into the Friabilator, which operates for 100 rotations. Afterward, the tablets are reweighed. A tablet is considered acceptable if it loses no more than 0.5 to 1.0 percent of its original weight during the test.

W1= Initial tablet weight
W2 = Weight after processing

Disintegration Test

In-vitro disintegration time of six tablets from was determined by using disintegration test apparatus. To test for disintegration time 1 tablet was dropped in each glass tube, and the basket rack assembly was set in a 1L beaker of water at 37±2°C.

In-vitro dissolution studies

The drug release from Solid dispersion tablets is assessed using the dissolution test apparatus, specifically the USP type II (paddle). At predetermined time intervals (5, 10, 15, 20, 25, 30, 45, and 60 minutes), 5 mL aliquots of the sample are withdrawn and replaced with fresh medium. After withdrawing the sample, it is filtered, and the concentration is measured by an appropriate

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analytical method, using a standard calibration curve for analysis.

Uniformity of Drug Content

The drug content is determined by triturating a sufficient number of tablets, then dissolving an amount equivalent to the average tablet weight in 100 mL of an appropriate buffer solution. After stirring for
30 minutes, the solution is diluted as necessary, and the absorbance is measured using spectrophotometry.

Wetting Time

It is closely related to the inner structure of the tablet and the hydrophilicity of the excipients. To measure the wetting time, five circular tissue papers of 10cm diameter are placed into the petri dish with 10cm diameter. 10 ml of water containing water soluble dye is then added to petri dish. A tablet is carefully placed on the tissue paper the time required for water to reach the upper surface of the tablet is noted as the wetting time

II. RESULT AND DISCUSSION

Characterization of Tadalafil

It is a white, odourless crystalline powder, poorly soluble in water, with a melting point of about 288 ± 1 °C.

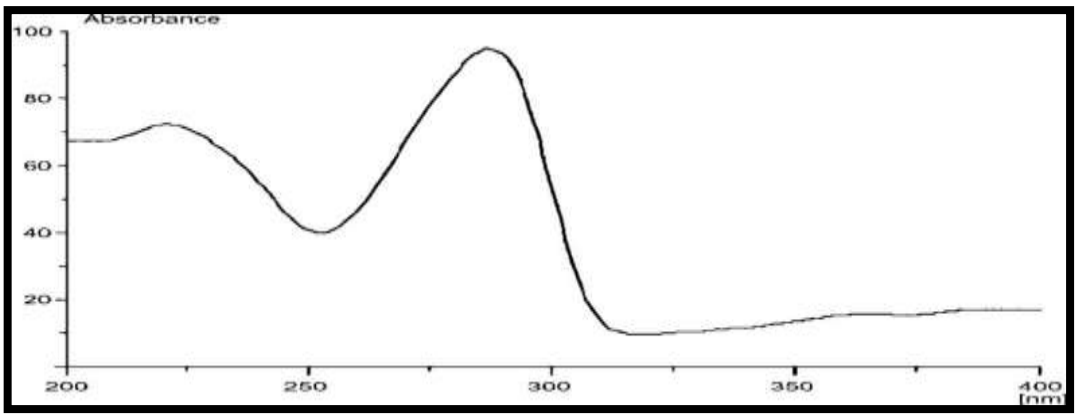

Figure 1. UV Maxima of Tadalafil in Phosphate Buffer pH 6.8 at 284.80 nm

$$\% \, Friability = \frac{W1 - W2}{W1} \times 100$$

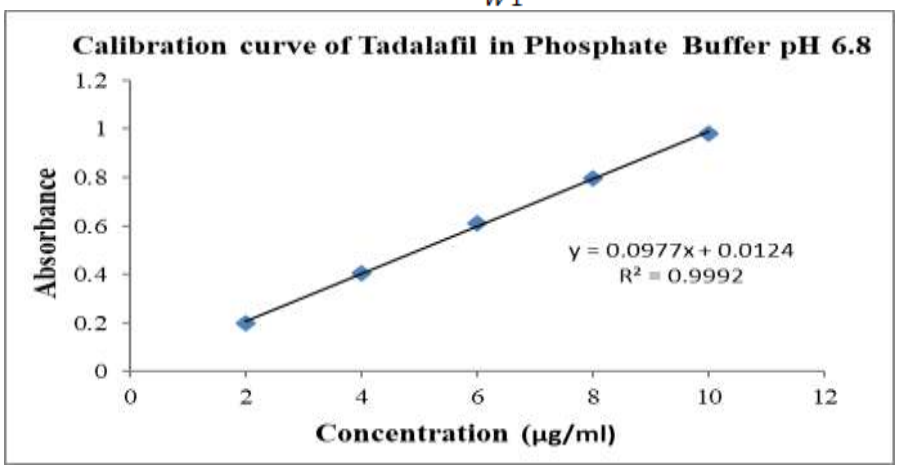

Figure 2. Calibration curve of Tadalafil in Phosphate Buffer pH 6.8

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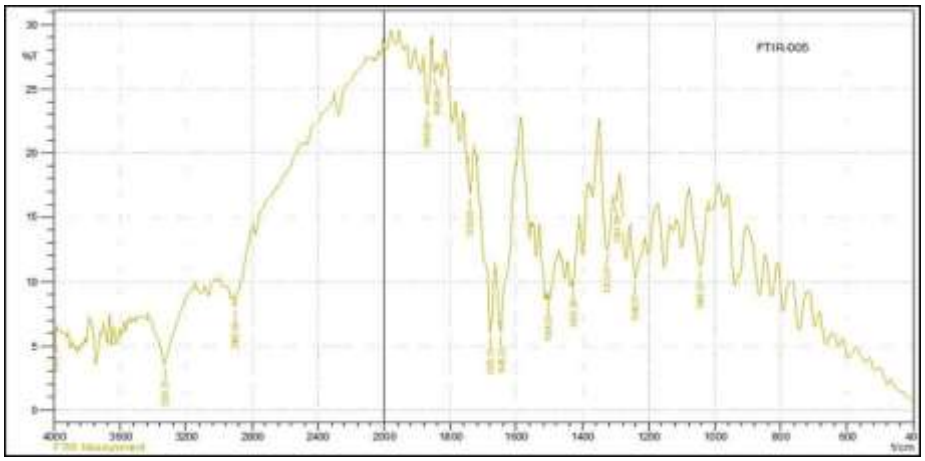
Figure 3. FTIR Spectrum of Tadalafil



Pre-compression parameter of Preliminary Batches

The powder blends (F1–F9) showed angles of repose ranging from 24.65° to 30.6°, bulk densities from 0.52 to 0.60 g/ml, tapped densities from 0.58 to 0.68 g/ml, Carr's index values between 10.25% and 16.35%, and Hausner ratios from 1.11 to 1.24. Batch F3 exhibits the best overall flow properties with the lowest Carr's index (10.25%) and Hausner ratio (1.11), indicating excellent flowability.

Post Compression Parameter of Preliminary Batches of Tablet

The tablet batches (F1–F12) showed hardness values between 3.1–3.65 kg/cm², thickness ranging from 2.61–2.83 mm, friability between 0.334–0.537%, disintegration times from 28.3–57.4 seconds, and wetting times ranging from 37.33–74.33 seconds. Batch F3 demonstrated the most favorable characteristics. It possessed a good hardness of 3.6 kg/cm², the lowest friability of 0.334%, the fastest disintegration time of 28.3 seconds, and the quickest wetting time of 37.33 seconds, with an acceptable thickness of 2.61 mm. These results indicate that Batch F3 exhibits excellent mechanical strength, minimal weight loss during handling, and rapid disintegration and wetting, making it the optimal formulation among all tested batches

OPTIMIZATION OF VARIABLES USING 3^2 FACTORIAL DESIGN

Table 1. Flow Properties of 3^2 Factorial Design Batches of Tablet

Batch	Angle of Repose(^{o})	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Carr's Index (%)	Hausner's Ratio
E1	23.43	0.399	0.4545	13	1.15
E2	**23.50**	**0.3949**	**0.4413**	**10**	**1.11**
E3	23.00	0.3897	0.4413	11	1.13
E4	28.55	0.3949	0.4690	15	1.18
E5	25.00	0.4017	0.4545	11	1.13
E6	22.50	0.3949	0.4690	15	1.18
E7	29.55	0.3949	0.4690	15	1.18
E8	23.50	0.3846	0.4545	15	1.18
E9	28.50	0.4055	0.4699	13	1.15

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Table 2. Post Compression Parameter of 3^2 Factorial Design Batches

Batch	E1	E2	E3	E4	E5	E6	E7	E8	E9
Hardness (Kg/Cm^2)	3.3	**3.1**	3.0	3.1	2.9	3.0	2.9	2.9	2.8
Friability(%)	0.44	**0.50**	0.55	0.49	0.55	0.52	0.68	0.65	0.72
Wt.Variation (%)	Pass	**Pass**	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Disintegration Time (Sec)	26	**22**	30	38	36	30	60	64	69

Table 3.In vitro dissolution study of batches with full factorial design

Time (min)	% Cumulative release								
	E1	E2	E3	E4	E5	E6	E7	E8	E9
0	0	0	0	0	0	0	0	0	0
2	39.81	58.67	48.262	41.38	47.08	41.09	44.627	50.129	41.090
4	62.55	66.30	53.121	55.10	61.75	49.50	55.930	61.00	46.75
6	72.48	82.75	66.675	73.59	72.55	60.26	69.319	71.991	56.995
8	79.76	99.57	76.84	88.35	84.54	72.42	80.492	79.360	64.40
10	82.29	_	83.76	_	_	88.92	_	85.721	76.983
12	84.85	_	98.712	_	_	_	_	_	84.691

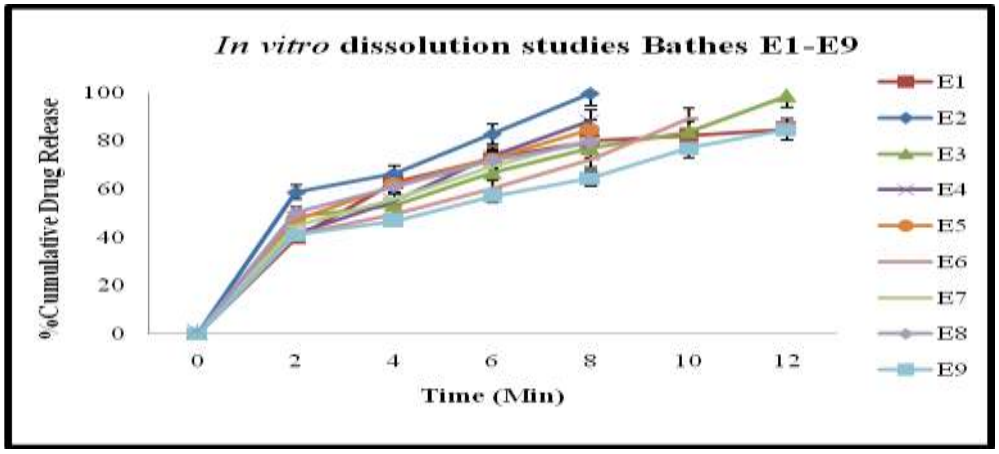

Figure 4. In vitro dissolution studies Bathes E1-E9

STASTICAL ANALYSIS OF 3^2 FACTORIAL DESIGN BATCHES

Table 4. Result of Dependent Variable

Batch	Variable level in Coded form		DT Time (Sec)	Wetting Time (Sec)	Drug Release at 8 Min (%)
	X1	X2			
E1	-1	-1	26	35	79.76
E2	**-1**	**0**	**22**	**32**	**99.57**
E3	-1	+1	30	37	76.84
E4	0	-1	38	46	88.35
E5	0	0	36	47	84.54
E6	0	+1	30	43	72.42
E7	+1	-1	60	81	80.49
E8	+1	0	64	80	79.36
E9	+1	+1	69	83	64.40

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$Y1=33.66+19.16\ (X1)+0.833\ (X2)+1.25\ (X1X2)+10.5(X11)^2+1.5(X22)^2$

The positive linear and quadratic coefficients show that increasing the concentration of either crospovidone or Kyron T-314 leads to an increase in disintegration time. The interaction term (X_1X_2) also has a mild positive effect, indicating that using both disintegrants together contributes slightly to prolonging the disintegration time. These trends are clearly represented in the response-surface plot.

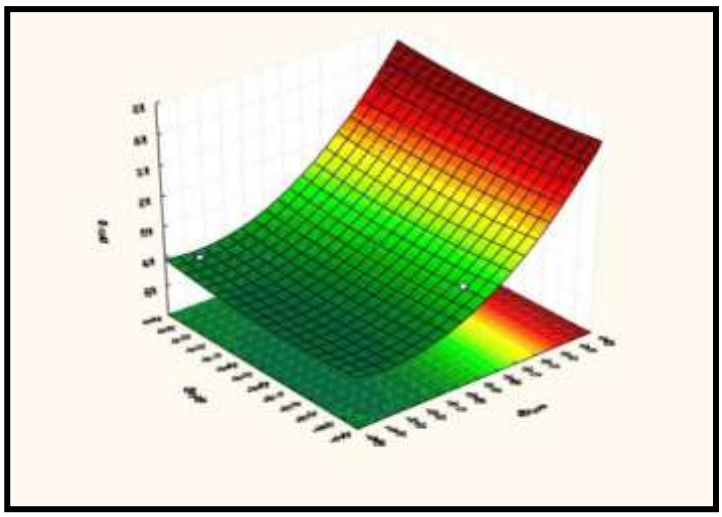
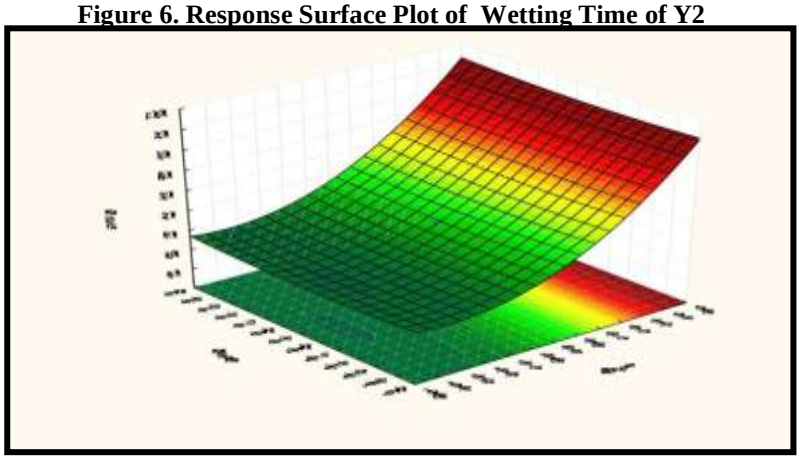


Figure 5. Response Surface Plot of Disintegration Time of Y1

$Y2= 44.56+23.34\ (X1)+0.166\ (X2)+0.16\ (X1X2)+12.66\ (X11)^2+1.16(X22)^2$

The positive coefficients indicate that increasing the levels of crospovidone and Kyron T-314 leads to an increase in wetting time. The quadratic terms also show a rising trend, confirming that higher concentrations further prolong the wetting time. The interaction term (X_1X_2) shows a slight positive effect, meaning both excipients together contribute to a gradual increase in wetting time. The response-surface plot reflects these increasing patterns clearly.

Figure 6. Response Surface Plot of Wetting Time of Y2



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$Y3= 88.95-5.32\ (X1)-5.82(X2)-1.7\ (X1X2)-10.78\ (X11)^2-3.29(X22)^2$

Both Crospovidone (X_1) and Kyron T-314 (X_2) showed negative linear, interaction, and quadratic effects, indicating that increasing either excipient especially at higher levels reduces the 8-minute drug release. Moderate levels of both ingredients give better release compared to higher concentrations.

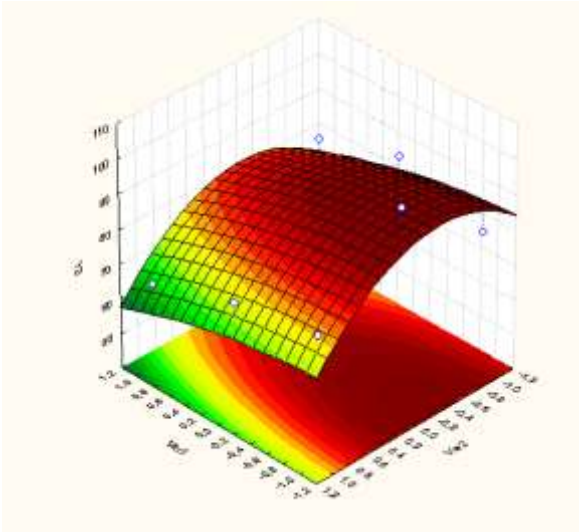

Figure 7. Response Surface Plot of Drug Release at 8 Min (%) of Y3

III. CONCLUSION

Fast-dissolving tablets, which disintegrate rapidly in the oral cavity without the need for water, have attracted considerable interest due to improved patient compliance and enhanced drug delivery. In the present study, tadalafil fast-dissolving tablets were formulated using the direct compression technique. To address the poor aqueous solubility of tadalafil, solid dispersions were prepared with PEG 40000, PEG 6000, and Poloxamer 407 using the fusion method. Among the carriers evaluated, PEG 6000 demonstrated the most pronounced solubility enhancement. The solid dispersion with a 1:1.5 drug-to-carrier ratio (SE3) was identified as optimal and selected for tablet formulation. FTIR analysis confirmed the identity of tadalafil and indicated the absence of significant drug–excipient interactions.

Twelve preliminary formulations (F1–F12) were assessed for micromeritic properties, physicochemical characteristics, and in vitro drug release. Tablets containing Kyron T-314 and Crospovidone exhibited markedly faster disintegration compared to those containing Sodium Starch Glycolate or Croscarmellose Sodium. To further investigate and optimize their combined effect, a 3^2 factorial design (E1–E9) was employed. Among the factorial batches, formulation E2—incorporating 2% Kyron T-314 and 1% Crospovidone—demonstrated superior performance, showing a disintegration time of 22 seconds and 99.57% drug release within 8 minutes, surpassing formulations containing single superdisintegrants.

Overall, the study concludes that the solid dispersion approach is highly effective in enhancing the solubility of poorly water-soluble drugs such as tadalafil. Furthermore, the 3^2 factorial design clearly demonstrated that the strategic combination of superdisintegrants significantly improves tablet disintegration behavior and accelerates drug release, thereby offering a promising platform for developing patient-friendly fast-dissolving dosage forms.

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