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Innovative Formulation and Evaluation of Sumatriptan Fast Dissolving Tablets through 3^2 Factorial Design

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Abstract

In this study, the objective aims to develop and analyse fast-dissolving tablets (FDTs) of sumatriptan using superdisintegrants primojel and crospovidone by direct compression technique. In each case tri concentrations of super disintegrant (3, 4 and 5 %) were used in the preparation of FDT's. The tablets prepared were analysed for disintegration rate, disintegration time, hardness, friability, and drug concentration. The following conclusions are derived from the obtained results. A 3-level-2-factorial experimental design is chosen to specify the percentage of the independent variables primojel crospovidone that were included in the formulation of Sumatriptan Fast Dissolving Tablets. All FDTs prepared disintegrated within 34 sec. Among the nine formulations F9 gave 100 % drug release 6 min. All of the prepared FDTs led sumatriptan to dissociate rapidly. In each instance, the levels of super disintegrant increased along with the sumatriptan's rate of disintegration.A series of equations were generated for disintegration time (DT), percent drug disintegrated in 10 minutes (PD10).Y1= 74.00 – 7.83 X1 -22.67 X2-2.75 X1X2 +1.50X12 -6X22 (DT), Y2= 96.22 + 3.17X1 +5.33 X2 -2.50 X1X2 +1.71 X12 – 4.33 X22 (PD10m). The findings indicate that a higher concentration of Superdisintegrants results in a shorter disintegration time for the dosage form, and that a suitable selection of X1 and X2 levels can alter the drug release pattern.To check the validity of equation DT was selected for 40 sec and PD10 for 98.00. The Final Formula DT Values and PD10were found to be 39 sec and 98.64 % indicating the validity of equation. Thus sumatriptan tablets could be successfully prepared using primojel and Crospovidone using 3^2 Factorial Design.

Keywords: Sumatriptan, 3^2 Factorial Designs, Fast Dissolving Tablets

Introduction

Adult migraine attacks with or without aura can be prevented by sumatriptan. Sumatriptan has been shown to be a safe and effective treatment for migraines when administered intravenously, subcutaneously, or orally. In this study, we concentrated on developing and evaluating sumatriptan FDTs by employing superdisintegrants namely primojel and crospovidone (1).

It is well acknowledged that the dosage forms administered orally is the most costeffective, convenient, and safe way to administer drugs. Tablets and hard gelatin capsules make up a large part of the available drug delivery systems. However, certain patient populations that include geriatrics, pediatrics, and individuals mentally ill, uncooperativeoften experience difficulty swallowing these dosage forms. To address these challenges, drug delivery innovations such as FDTs have been developed (2).

FDTs are a novel type of tablet that doesn't require water and dissolves, breaks down, or disperses in saliva in a couple of seconds. These systems provide the suitability of tablet dosage forms with the ease of swallowing increasing patient compliance typically associated with liquid formulations. Currently, FDTs are available

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Table 1: FDTs of Sumatriptan formulated using various superdisintegrants

Ingredient (mg/tablet)	Formulation									
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Sumatriptan	25	25	25	25	25	25	25	25	25	25
Crospovidone	3	3	3	4	4	4	5	5	5	4.07
Primojel	3	4	5	3	4	5	3	4	5	4.57
Acacia	4	4	4	4	4	4	4	4	4	4
Talc	2	2	2	2	2	2	2	2	2	2
Magnesium stearate	2	2	2	2	2	2	2	2	2	2
Microcrystalline Sodium	161	160	159	160	159	158	159	158	157	191
Total weight	200	200	200	200	200	200	200	200	200	200

for the treatment of various conditions, includingParkinson's illness, schizophrenia, migraine, dysphagia, nausea, vomiting, hypertension, and paediatric issues (3,4).

Fast dissolving tablets must meet several key requirements to ensure their effectiveness and patient acceptability. They should provide pleasing mouth feel and feature effective taste-masking properties to enhance patient compliance. Additionally, these tablets should be sufficiently hard yet friable, allowing for easy disintegration in the mouth (5). After administration, they should leave minimal or no residue, ensuring a clean and comfortable experience. The tablets must also exhibit resistance to environmental factors such as moisture and temperature, ensuring stability during storage and usage. Finally, the formulation should be compatible with conventional manufacturing processes and packaging equipment, making it feasible for mass production (6).

The main goal of the research study is to formulate and develop sumatriptan (FDT's) tablet using primojel and Crospovidone using 3^2 Factorial Design.

Materials and Methods

Materials

Sumatriptan were samples from manufactures Eisai Pharma technology Private Limited, Parawada, Visakhapatnam. All other excipients were used are of commercial grade (7,8).

Preparation of Sumatriptine FDT's

Direct compression method was used to prepare FDT's of sumatriptan combining various superdisintegrants as outlined under formulations in Table 1. The sumatriptan and excipients were thoroughly mixed in a sealed polyethylene bag, and thentrampled into 250 mg tablet using a tablet punching machine (RIMEK) with 9 mm flat punches (9,10).

Evaluation of Fast Dissolving Tablets Prepared

Uniformity of Weight: The Shimadzu balance of Model ATY 224 was used to measure the weight uniformity. Twenty tablets were sampled in order to evaluate weight control (11,12).

Tablet Hardness: The hardness of the produced tablets was measured using a monsanto hardness tester; the results were expressed in kg/cm².

Tablet Friability: A Roche friabilator was used toestimate the tablets' friability (9). The subsequent formula was used to determine the friability

Friability = [(Initial weight(IW) - Final weight(FW)) / Initial weight(IW)] × 100%

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Drug Content of Sumatriptan FDTs: Using a glass mortar and pestle, five weighted tablets were ground into fine homogenous powder. Tablet equivalent powder of 20mg of sumatriptan was transferred to 100 ml volumetric flask. Methanol was used to dissolve the powder. The solution was filtered using whatman filter paperof number 41. Using serial dilutionthe drug concentration was assessed using UV spectrophotometry at 282 nm (14,15).

Disintegration Test: Water was used as the test fluid and a single-unit disintegration test instrument (Model: Paramount), the period required for disintegration of the tablets was determined (16).

Dissolution Rate Study of Sumatriptan FDTs: The dissolution rate of the formulated sumatriptan tablets was estimated in a phosphate buffer (900 ml of pH 6.8) using LABINDIA DISSO 8000 eightstation dissolution apparatus.A temperature of 37°C ± 1°C was maintained, and the paddle speed was set at 50 rpm (17,18). Each station contained one tablet; samples of 5mlwere collected at specific time intervals, clarified, and analyzed for sumatriptan content at a wavelength of 282 nm. Fresh dissolution solution was added to replace the samples withdrawn, and corrections were applied for the drug content in the samples. This procedure was repeated three times to ensure accuracy.

Results and Discussion

Sumatriptan tablets with a rapid dissolution rate, containing 25 mg of the active ingredient, were developed using Primojel and Crospovidone as disintegrating agents, as shown in Table 1.

The independent variables are Primojel (X1) and Crospovidone (X2) and independent variables are disintegration time (DT) (Y1) and Percent drug dissolved (PD10) are selected as dependent variables (19,20).

The factorial design was used in formulation of sumatriptanl tablets in which all three levels of factor X1 (Primojel) and factor X2 (Crospovidone) are of concentration 3%, 4%, 5% (% calculated based on total Tablet weight, i.e., 200 mg)(13) were chosen as the hypothesis for the execution of the rapid dissolution of sumatriptan formulations. Overall nine fast Dissolving tablet formulations were obtained by implementing factors (X_1, X_2) as of 3^2Factorial studyand analysed to choose the best composition needed to acquire the required release of drug and to determine the relevance of the combined effects of X_1, X_2. All three levels of Crospovidone and primojel were opted and coded as -1= 3%, 0=4%, +1=5%. Nine formulations were prepared as per 3^2 Factorial Design. F10 formulation was developed to test the validity of following equations

$DT\ (Y1) = 74.00 – 7.83X1 – 22.67X2 – 2.75X1X2 + 1.50X1^2 – 6X2^2$

$PD10\ (Y2) = 96.22 + 3.17X1 + 5.33X2 – 2.50X1X2 + 1.71X1^2 – 4.33X2^2$

The tablets were produced through direct compression. Prior to tablet formation, flow characteristics were evaluated by measuring the compressibility index and angle of repose. The results demonstrated exceptional flow properties suitable for direct compression, with compressibility indices ranging from 10% to 12% across various formulations, and angle of repose measurements between 15° and 22°. Table 2 outlines the tablets physical characteristics. Tablet hardness varied between 4.0 and 6.0kg/cm², while friability testing showed weight loss under 1% for all formulations. The drug content fell within the acceptable range of 100 ± 3%. Disintegration times spanned from 15 to 30 seconds, fulfilling the official criteria for uncoated tablets (21,22).

Sumatriptan tablet dissolution rates were evaluated in pH 6.8 phosphate buffer. Figure 1 depict the dissolution results. Both zero and first-order kinetics were used to analyse the dissolution data.

The first-order model yielded higher correlation coefficient (r) values, suggesting that sumatriptan dissolution adhered to first-

order kinetics. These r values ranged from 0.918 to 0.998. The first-order dissolution rate constant (K1) was derived from the slope of the first-order linear regression. Dissolution Efficiency (DE30) values were also computed using Khan's method (23). Table 3 presents a summary of the dissolution parameters for various formulations.

A factorial design was employed to determine factors influencing the formulation process and evaluate their relative significance (24,25). This approach also helps identify interactions between chosen factors. This study utilized a 3^2 factorial experimental design to optimize sumatriptan fast dissolving tablet formulation. The selected independent variables were Primojel (X1) and Crospovidone (X2) concentrations, each tested at three levels: 3%, 4%, and 5% (based on a 250 mg

Table 2: Physical Parameters of Fast Dissolving Tablets of Sumatriptan

Formulations prepared	Hardness (Kg/cm^2)	Friability (%wt loss)	Disintegration time (min/sec)	Drug content per tablet (mg)
F1	4.7	0.68	100	24.96
F2	5	0.64	90	24.35
F3	4.5	0.54	85	25.31
F4	5.5	0.60	78	25.64
F5	4.7	0.40	75	24.32
F6	4.5	0.45	72	24.96
F7	4.0	0.34	60	24.68
F8	5.0	0.45	45	24.56
F9	5.5	0.62	34	24.65
F10	4.0	0.68	40	24.65

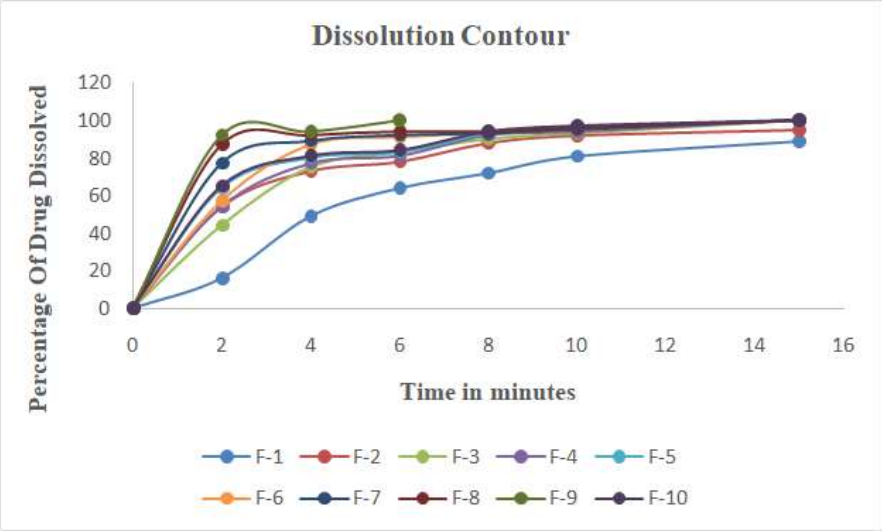

Figure 1: Dissolution Profiles of Sumatriptan Fast Dissolving Tablets

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Table 3: Dissolution Parameters of Fast Dissolving Tablets of Sumatriptan Prepared

Formulation	PD10 (min)	T50 (min)	DE15(%)	Dissolution rate K_1 (min^{-1})
F 1	81	17	59.46%	0.154
F 2	88	7.5	72.36%	0.197
F 3	93	4.5	74.36%	0.269
F 4	94	16	75.53%	0.278
F 5	96	12	77.46%	0.302
F 6	95	11	79.93%	0.297
F 7	95	5	80.5%	0.269
F 8	96	14.5	82.2%	0.267
F 9	100	29	85.33%	0.705
F10	98	11	80.75%	0.270

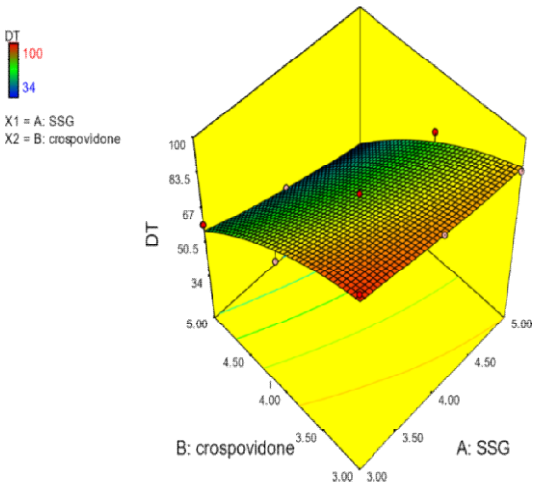

Figure 2: Response surface plots for disintegration time with X1 and X2

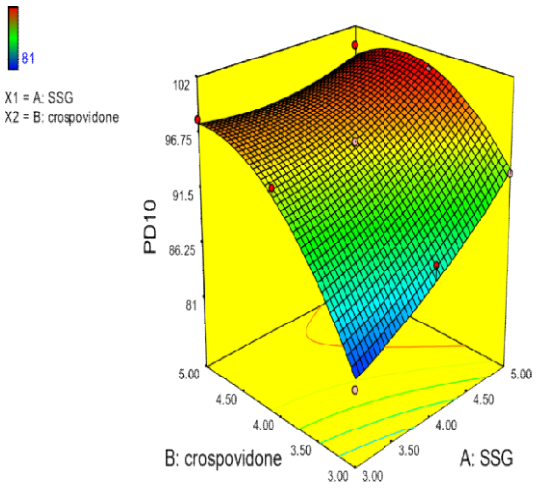

Figure 3: Response surface plots for PD10 with X1 and X2

average tablet weight). Disintegration time (DT) and percentage of drug dissolved in 10 minutes (PD10) were chosen as dependent variables.

The design was established with a 95% confidence level ($p<0.05$) for statistical significance. Design expert software was used to construct polynomial equations for DT and PD10. Figures 2 and 3 display response surface plots for disintegration time and PD10, with X1 and X2 on the x- and y-axes, respectively.

The equations for Disintegration Time (DT), percentage of drug dissolved at 6 minutes (PD6), and percentage of drug dissolved at 10 minutes (PD10) were formulated as follows (26):

$DT\ (Y1) = 74.00 - 7.83X1 - 22.67X2 - 2.75X1X2 + 1.50X1^2 - 6X2^2$

$PD10\ (Y2) = 96.22 + 3.17X1 + 5.33X2 - 2.50X1X2 + 1.71X1^2 - 4.33X2^2$

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Table 4: Dissolution parameters for predicted and observed values for check point formulation

Formulation Code	Disintegration time (DT)	Percent Drug Dissolved in 10 min.	Disintegration time (DT)	Percent Drug Dissolved in 10 min.
	Predicted values		Actual Observed Values	
F10	40 Sec	98.00%	39 sec	98.64 %

In the DT equation, the negative coefficient for X1 suggests that as Crospovidone levels decrease, disintegration time increases. This indicates that both X1 (Crospovidone) and X2 (Primojel) affect disintegration time and drug release kinetics. The findings reveal that higher concentrations of superdisintegrants result in faster disintegration, and API release from tablets can be modulated by adjusting X1 and X2 concentrations (27).

A comparison between predicted dissolution parameters from polynomial equations and experimental results is presented in Table 4. Response surface plots corroborate the derived equations for dependent variables (28). For instance, the target DT was 40 seconds, with an observed value of 39 seconds, while the PD10 goal was 98.00%, with an actual value of 98.64%, confirming the equations' reliability.

These outcomes demonstrate the successful formulation of sumatriptan tablets using Primojel and Crospovidone through a 3² Factorial Design approach (29).

Conclusion

This investigation focused on formulating and evaluating sumatriptan fast dissolving tablets (FDTs) using direct compression with superdisintegrants Primojel and Crospovidone. The FDT formulations incorporated three superdisintegrant concentrations: 3%, 4%, and 5%. Each FDT underwent assessment for various parameters, including drug content, hardness, friability, disintegration time, and dissolution rate (30).

The results led to the following conclusions:

A 3² factorial design was utilized to optimize the proportions of independent variables (Primojel and Crospovidone) in sumatriptan FDT formulation.All prepared FDTs exhibited disintegration times of approximately 34 seconds.Among the nine formulations, F9 achieved complete drug release within 6 minutes.All FDTs displayed rapid sumatriptan dissolution, with dissolution rates increasing proportionally to super disintegrant concentration. The polynomial equations for Disintegration Time (DT) and Percent Drug Dissolved in 10 Minutes (PD10) were derived as (31):

$$Y1 = 74.00 – 7.83\ X1 – 22.67\ X2 – 2.75\ X1X2 + 1.50\ X1^2 – 6\ X2^2 \text{ (DT)}$$
$$Y2 = 96.22 + 3.17\ X1 + 5.33\ X2 – 2.50\ X1X2 + 1.71\ X1^2 – 4.33\ X2^2 \text{ (PD10)}$$

The findings indicate that higher concentrations of superdisintegrants lead to faster tablet disintegration. Moreover, altering the amounts of X1 (Primojel) and X2 (Crospovidone) can influence the drug release pattern (32,33).

To confirm the accuracy of the derived equations, target disintegration time (DT) of 40 seconds and a PD10 value of 98.00% were set. The actual observed results were 39 seconds for DT and 98.64% for PD10, validating the precision and reliability of the equations (34,35).

In summary, the successful formulation of sumatriptan fast dissolving tablets can be achieved using Primojel and Crospovidone, with optimization accomplished through a 3^2 factorial design methodology.

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Conflict of interest

The authors declare that no conflict of interest.

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