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Development and Evaluation of Superdisintegrating Oral Tablets of Sumatriptan Succinate Using Direct Compression Technique

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Abstract: ***Migraine is a chronic neurological disorder characterized by recurrent attacks of moderate-to-severe headache accompanied by nausea, vomiting, photophobia, and phonophobia. Rapid onset of therapy is essential for effective management of acute migraine attacks. Conventional oral tablets of sumatriptan often exhibit delayed therapeutic action due to the time required for tablet disintegration and gastric emptying. Superdisintegrating oral tablets (SDOTs) provide rapid tablet disintegration in the oral cavity, resulting in faster drug release, improved patient compliance, and enhanced convenience, particularly for patients experiencing nausea or difficulty swallowing during migraine episodes. The present study aimed to formulate and optimize superdisintegrating oral tablets of Sumatriptan succinate using direct compression and to evaluate the influence of different superdisintegrants on tablet performance.***

Keywords: ***Sumatriptan succinate; Superdisintegrating oral tablet; Migraine; Direct compression; Crospovidone; Croscarmellose sodium; Design of Experiments; Dissolution study; Tablet optimization.***

I. INTRODUCTION

Migraine is a common and debilitating neurological disorder affecting approximately 15% of the global population and is recognized as one of the leading causes of disability among individuals below 50 years of age. It is characterized by recurrent episodes of unilateral pulsating headache accompanied by nausea, vomiting, photophobia, and phonophobia, which substantially impair the quality of life and daily activities of affected patients. Rapid relief of migraine symptoms is essential because delayed treatment often reduces therapeutic effectiveness and prolongs patient discomfort.

Sumatriptan succinate, a selective serotonin (5-hydroxytryptamine, 5-$HT_1B/_1D$) receptor agonist, is widely prescribed as the first-line therapy for acute migraine attacks. The drug exerts its therapeutic action by producing selective cranial vasoconstriction, inhibiting neurogenic inflammation, and reducing the release of vasoactive neuropeptides from trigeminal nerve endings. Although conventional oral tablets of sumatriptan are effective, their clinical utility may be limited by delayed onset of action resulting from tablet disintegration, gastric emptying, and gastrointestinal absorption. Furthermore, migraine attacks are frequently associated with nausea and vomiting, making swallowing conventional tablets difficult and reducing patient compliance. Superdisintegrating oral tablets (SDOTs), also referred to as orally disintegrating tablets, have emerged as an attractive alternative to conventional oral dosage forms. These tablets rapidly disintegrate in the oral cavity, usually within 30 seconds, without the need for water, thereby providing faster drug dissolution and improved patient convenience. Rapid tablet disintegration increases the available surface area for dissolution, which may enhance drug release and facilitate earlier therapeutic action. Such formulations are particularly beneficial for paediatric, geriatric, bedridden, and dysphagic patients as well as individuals experiencing severe migraine-associated nausea. The performance of superdisintegrating tablets is largely dependent on the type and concentration of superdisintegrants employed. Crospovidone promotes rapid water penetration through capillary action (wicking), whereas croscarmellose sodium facilitates rapid swelling after hydration. The combined use of these superdisintegrants has been reported to produce synergistic effects, resulting in rapid tablet disintegration while maintaining adequate mechanical strength. Optimization of their concentrations is therefore essential to achieve an appropriate balance between tablet hardness, friability, disintegration time, and drug release. Application of statistical optimization techniques such as Design of Experiments (DoE) has become increasingly important in pharmaceutical formulation development. Factorial experimental designs allow simultaneous evaluation of multiple formulation variables and their interactions while reducing the number of experimental trials. Response surface methodology further facilitates optimization of formulation variables to obtain products with predefined quality attributes.

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In the present investigation, superdisintegrating oral tablets of Sumatriptan succinate were formulated by the direct compression method using crospovidone, croscarmellose sodium, and Kyron T-114 as superdisintegrants. A three-level factorial Design of Experiments was employed to optimize the concentrations of crospovidone and croscarmellose sodium with respect to tablet disintegration time and hardness. The prepared formulations were systematically evaluated for physicochemical characteristics, pre- and post-compression parameters, in vitro drug release, and accelerated stability in order to identify an optimized formulation suitable for the rapid and effective management of migraine.

II. MATERIALS AND METHODS

A. Materials

Sumatriptan succinate was used as the active pharmaceutical ingredient. Crospovidone, croscarmellose sodium, and Kyron T-114 were employed as superdisintegrants. Mannitol was used as the diluent, aspartame as the sweetening agent, talc as the glidant, and magnesium stearate as the lubricant. All chemicals and reagents used in the study were of analytical grade and used without further purification.

B. Preformulation Studies

Preformulation studies were carried out to determine the physicochemical characteristics of Sumatriptan succinate prior to formulation development.

1) Organoleptic Evaluation

The drug powder was visually examined under white light for colour and appearance. Odour was assessed by gentle smelling, while texture and flow characteristics were evaluated manually by rubbing the powder between the fingers. These observations were used to assess the suitability of the drug for direct compression.

2) Solubility Study

The solubility of Sumatriptan succinate was determined in distilled water, 0.1 N hydrochloric acid, phosphate buffer (pH 6.8), and simulated saliva. An excess quantity of the drug was added separately to 10 mL of each solvent in stoppered conical flasks. The suspensions were shaken intermittently and allowed to equilibrate at room temperature for 24 h. The solutions were filtered through a 0.45 µm membrane filter, suitably diluted, and analysed using a UV–Visible spectrophotometer. Solubility was expressed in mg/mL.

3) Melting Point Determination

The melting point was determined using the capillary method. Approximately 25–50 mg of Sumatriptan succinate was filled into a sealed capillary tube and placed in a digital melting point apparatus. The temperature was increased gradually at a rate of 1–2°C/min near the expected melting range, and the temperatures corresponding to the onset and completion of melting were recorded.

4) UV Spectrophotometric Analysis

A standard stock solution of Sumatriptan succinate (100 µg/mL) was prepared by dissolving 10 mg of drug in methanol and making the volume up to 100 mL. The solution was further diluted to obtain a working solution of 10 µg/mL, which was scanned over the wavelength range of 200–400 nm to determine the maximum absorption wavelength (λmax). Standard solutions of 2–10 µg/mL were prepared from the stock solution, and absorbance was measured at 282 nm. A calibration curve was constructed by plotting absorbance against concentration to verify Beer–Lambert's law.

5) Drug–Excipient Compatibility Study

Compatibility between Sumatriptan succinate and selected excipients was evaluated using FTIR spectroscopy and Differential Scanning Calorimetry (DSC).

For FTIR analysis, the drug and physical mixtures (1:1) with individual excipients were blended with dry potassium bromide and compressed into transparent pellets. The spectra were recorded over the range of 4000–400 cm^{-1} and compared for changes in characteristic absorption peaks.

For DSC analysis, approximately 5–10 mg of the drug and physical mixtures were sealed in aluminium pans and analysed over the temperature range of 30–300°C under a nitrogen atmosphere at a heating rate of 10°C/min. The thermograms were compared to detect any thermal incompatibility.

C. Experimental Design

A three-level full factorial design was employed using Design-Expert® software (Version 13.0.5.0) to optimize the formulation variables. Crospovidone (Factor A) and croscarmellose sodium (Factor B) were selected as independent variables, while tablet disintegration time and hardness were selected as dependent responses. A total of nine formulations were generated to evaluate the individual and interaction effects of both formulation variables.

D. Preparation of Superdisintegrating Oral Tablets

Superdisintegrating oral tablets were prepared by the direct compression method. All ingredients were accurately weighed according to the formulation design and passed through a 40-mesh sieve to obtain uniform particle size. Sumatriptan succinate, crospovidone, croscarmellose sodium, Kyron T-114, mannitol, and aspartame were blended for approximately 10–15 min to obtain a homogeneous mixture. Talc was then added and mixed for 3–5 min, followed by magnesium stearate, which was blended gently for an additional 2–3 min to avoid over-lubrication. The final powder blend was compressed using a rotary tablet compression machine to obtain tablets of approximately 200 mg with adequate hardness and mechanical strength.

Ingredient (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F9 Optimized
Sumatriptan Succinate	50	50	50	50	50	50	50	50	50	50
Crospovidone	4	4	4	9	9	9	14	14	14	14
Croscarmellose Sodium	4	11	18	4	11	18	4	11	18	18
Kyron T-114	10	10	10	10	12	12	12	12	12	12
Mannitol (diluent)	120	118	116	114	112	110	108	106	104	104
Aspartame	4	4	4	4	4	4	4	4	4	4
Talc	4	4	4	4	4	4	4	4	4	4
Magnesium Stearate	4	4	4	4	4	4	4	4	4	4

E. Evaluation of Powder Blend

The prepared powder blends were evaluated for bulk density, tapped density, angle of repose, Carr's compressibility index, and Hausner's ratio according to standard pharmacopeial methods. Bulk and tapped densities were determined using a graduated cylinder method, while the angle of repose was measured by the fixed funnel method. Carr's index and Hausner's ratio were calculated from the measured density values to assess flowability and compressibility of the blends.

F. Evaluation of Tablets

The compressed tablets were evaluated for weight variation, thickness, hardness, friability, disintegration time, drug content, and in vitro drug release.

Weight variation was determined by individually weighing twenty tablets and comparing the results with pharmacopeial limits. Tablet thickness was measured using a digital Vernier caliper, while hardness was determined using a Monsanto hardness tester. Friability was evaluated using a Roche friabilator operated at 25 rpm for 4 min, and percentage weight loss was calculated. Disintegration time was determined using a USP disintegration test apparatus containing purified water maintained at 37 ± 0.5°C. Drug content was estimated by UV spectrophotometry at 282 nm after suitable dilution of powdered tablets.

G. In Vitro Dissolution Study

Dissolution studies were carried out using USP Apparatus II (paddle method). Tablets were placed in 900 mL phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C and stirred at 50 rpm. Samples (5 mL) were withdrawn at predetermined intervals, filtered through a 0.45 µm membrane filter, and analysed at 282 nm using a UV–Visible spectrophotometer. An equal volume of fresh dissolution medium was replaced after each withdrawal to maintain a constant volume. The cumulative percentage drug release was calculated and dissolution profiles were plotted.

H. Stability Study

The optimized formulation was packed in airtight containers and subjected to accelerated stability studies according to ICH Q1A(R2) guidelines at 40 ± 2°C and 75 ± 5% relative humidity for three months. Samples were withdrawn initially and after 1, 2, and 3 months for evaluation of physical appearance, hardness, friability, disintegration time, drug content, and dissolution behaviour. The stability of the formulation was assessed by comparing the results obtained at each storage interval.

III. PREFORMULATION STUDIES

A. Organoleptic Properties

The organoleptic characteristics of Sumatriptan succinate were evaluated prior to formulation to assess its suitability for direct compression. The drug was observed as a white to off-white crystalline powder possessing a fine, smooth texture without any characteristic odor. No greasiness or stickiness was observed during handling, indicating good physical characteristics for tablet manufacturing. These findings suggest that the drug possesses acceptable organoleptic properties and can be processed efficiently during formulation development.

Table 1. Organoleptic properties of Sumatriptan succinate

Parameter	Observation
Color	White to off-white crystalline powder
Odor	Odorless
Texture	Fine, smooth, non-gritty
Stickiness/Greasiness	Non-sticky, free-flowing

The observed organoleptic properties were consistent with the reported physicochemical characteristics of Sumatriptan succinate and indicated that no additional processing was required before formulation. The free-flowing nature of the drug also facilitates uniform blending with excipients during direct compression.

B. Solubility Study

Solubility is one of the critical physicochemical properties influencing drug dissolution and bioavailability. Sumatriptan succinate exhibited excellent aqueous solubility, being freely soluble in distilled water and readily soluble in phosphate buffer (pH 6.8) as well as simulated saliva. However, only slight solubility was observed in 0.1 N HCl. The high solubility of the drug in aqueous media is advantageous for orally disintegrating tablets because rapid dissolution in saliva contributes to faster drug release and an earlier onset of therapeutic action.

Table 2. Solubility profile of Sumatriptan succinate

Solvent	Nature of Solubility
Distilled water	Freely soluble
pH 6.8 phosphate buffer	Soluble
Simulated saliva	Soluble
0.1 N HCl	Slightly soluble

The observed solubility profile supports the selection of Sumatriptan succinate as a suitable candidate for superdisintegrating oral tablets intended for rapid migraine relief.

C. Melting Point Determination

The melting point of Sumatriptan succinate was determined using the capillary method to assess drug purity and thermal stability. The drug showed an onset of melting between 165°C and 167°C, with complete melting occurring between 167°C and 169°C. The average melting point was calculated as **168 ± 2°C**, which is in close agreement with reported literature values. The narrow melting range confirms the crystalline nature of the drug and indicates the absence of significant impurities.

Table 3. Melting point determination of Sumatriptan succinate

Trial	Onset (°C)	Complete (°C)
1	166	168
2	165	169
3	167	167
Mean		168

The obtained melting point demonstrates that the drug maintained its physicochemical integrity and was suitable for subsequent formulation studies.

UV Spectrophotometric Analysis

The UV spectrophotometric method was developed for quantitative estimation of Sumatriptan succinate. The maximum absorbance (λmax) was observed at 282 nm, indicating the wavelength at which the drug exhibits maximum absorption. Standard solutions in the concentration range of 2–10 µg/mL obeyed Beer–Lambert's law, demonstrating excellent linearity between absorbance and concentration.

Regression equation:

$y = 0.0583x - 0.0365$

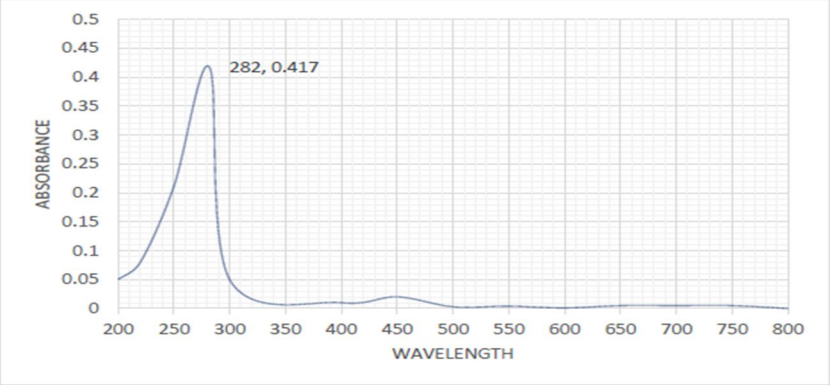

Figure 1. UV spectrum of Sumatriptan

Table 4. Calibration curve data

Concentration (µg/mL)	Absorbance
2	0.102
4	0.198
6	0.278
8	0.407
10	0.580

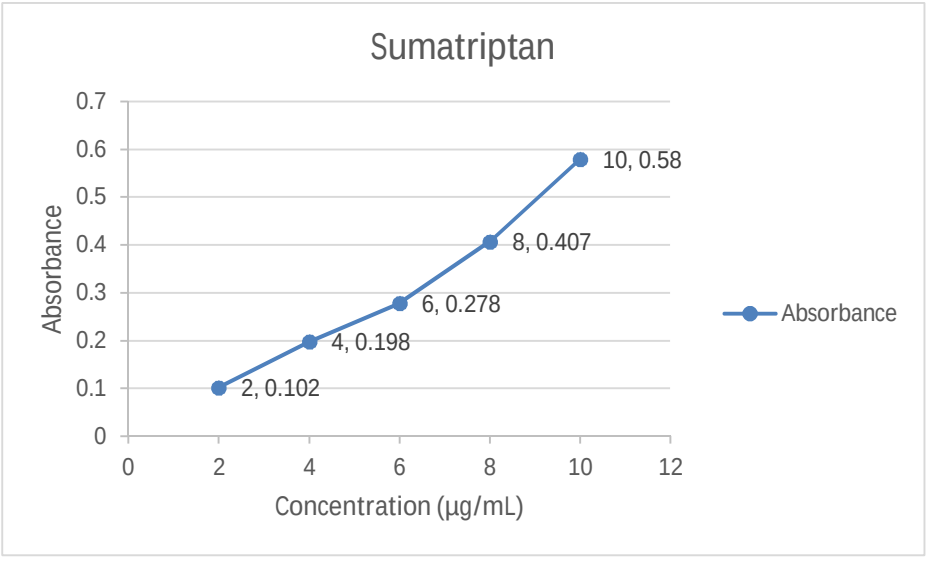

Figure 2. Calibration curve of Sumatriptan

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D. Pre-compression Evaluation of Powder Blends

The pre-compression properties of the powder blends were evaluated to determine their suitability for direct compression. Parameters including bulk density, tapped density, angle of repose, Carr's compressibility index, and Hausner's ratio were assessed, and the results are presented in Table 13. These parameters provide valuable information regarding the flowability and compressibility of the powder blends, which are critical for achieving uniform die filling and consistent tablet quality during compression.

Table. Pre-compression flow properties of Sumatriptan superdisintegrating oral tablet formulations

Formulation	Bulk Density (g/mL)	Tapped Density (g/mL)	Angle of Repose (°)	Carr's Index (%)	Hausner's Ratio
F1	0.48	0.56	30.2	14.3	1.17
F2	0.49	0.57	29.4	14.0	1.16
F3	0.50	0.58	28.8	13.8	1.16
F4	0.51	0.59	27.6	13.6	1.15
F5	0.52	0.60	26.8	13.3	1.15
F6	0.53	0.61	26.2	13.1	1.14
F7	0.54	0.62	25.4	12.9	1.14
F8	0.55	0.63	24.9	12.7	1.13
F9 Optimized	0.57	0.65	24.2	12.3	1.12

The bulk density of the prepared powder blends ranged from 0.48 to 0.57 g/mL, while the tapped density ranged from 0.56 to 0.65 g/mL. The gradual increase in both bulk and tapped density from formulation F1 to F9 indicates improved packing characteristics of the powder blends with increasing concentrations of superdisintegrants. The optimized formulation (F9) exhibited the highest bulk and tapped density values, suggesting efficient particle packing and good compressibility, which are desirable characteristics for direct compression.

The angle of repose is an important indicator of powder flowability. In the present study, the angle of repose varied between 24.2° and 30.2°. According to standard pharmaceutical classification, an angle of repose below 30° indicates good to excellent flow properties. The progressive reduction in angle of repose from F1 to F9 demonstrates improved flowability of the powder blends, which may be attributed to the improved particle arrangement and flow-promoting effect of the selected excipients. The optimized formulation (F9) exhibited the lowest angle of repose (24.2°), indicating excellent flow behaviour and ensuring uniform die filling during tablet compression.

Carr's compressibility index is commonly used to evaluate the compressibility and flow characteristics of powder blends. The values obtained ranged from 12.3% to 14.3%, which fall within the acceptable range for powders exhibiting good flowability. Lower Carr's index values indicate reduced interparticle friction and better compressibility. The optimized formulation showed the lowest Carr's index (12.3%), suggesting superior flow characteristics and minimal resistance to powder movement during compression.

Similarly, Hausner's ratio values ranged from 1.12 to 1.17, which are well below the generally accepted limit of 1.25 for freely flowing powders. The gradual decrease in Hausner's ratio across the formulations indicates an improvement in powder flow and packing efficiency. The optimized formulation (F9) exhibited the lowest Hausner's ratio (1.12), confirming excellent flowability and compressibility of the powder blend.

The pre-compression evaluation demonstrated that all powder blends possessed satisfactory flow and compressibility characteristics suitable for the direct compression method. Among the prepared formulations, F9 exhibited the most favourable pre-compression properties, including the highest bulk density and tapped density, lowest angle of repose, lowest Carr's compressibility index, and lowest Hausner's ratio. These results indicate excellent powder flow behaviour, efficient die filling, and uniform compression, which contributed to the successful preparation of high-quality superdisintegrating oral tablets of Sumatriptan. The findings are consistent with previous reports that powder blends exhibiting an angle of repose below 30°, Carr's index below 15%, and Hausner's ratio below 1.25 are considered ideal for direct compression tablet formulations.

E. Post-compression Evaluation

Table. Post-compression evaluation of Sumatriptan super disintegrating oral tablet formulations

Formulation	Weight (mg)	Thickness (mm)	Hardness (kg/cm²)	Friability (%)	Disintegration Time (sec)	Drug Content (%)
F1	200	1.21	2.2	0.82	28	90.12
F2	201	1.45	2.3	0.78	26	91.84
F3	199	1.28	2.4	0.74	25	93.25
F4	200	1.46	2.5	0.71	23	94.76
F5	201	1.49	2.6	0.68	27	95.18
F6	200	1.51	2.7	0.65	26	96.95
F7	199	1.53	2.8	0.62	24	95.42
F8	200	1.54	2.9	0.60	25	95.15
F9 (Optimized)	206	1.23	2.4	0.52	22	97.30

The post-compression evaluation of the prepared Sumatriptan superdisintegrating oral tablet formulations is summarized in **Table** . All formulations complied with the pharmacopeial requirements for physical quality attributes, indicating successful tablet manufacture by the direct compression technique. Tablet weight ranged from 199 to 206 mg, demonstrating minimal batch-to-batch variation and confirming uniform die filling during compression. The observed weight variation was well within the acceptable pharmacopoeial limits, suggesting good flow characteristics of the powder blends and excellent content uniformity.

Tablet thickness varied between 1.21 and 1.54 mm, indicating consistent compression throughout the manufacturing process. Minor differences in thickness among formulations may be attributed to variations in excipient composition and compression behavior; however, these differences were not significant enough to affect tablet quality. The optimized formulation (F9) exhibited a thickness of 1.23 mm, indicating adequate tablet compactness while maintaining rapid disintegration characteristics.

Hardness values ranged from 2.2 to 2.9 kg/cm², demonstrating adequate mechanical strength for handling, packaging, and transportation. Although hardness generally increased with formulation modifications, the optimized formulation (F9) maintained a hardness of 2.4 kg/cm², which provided an appropriate balance between mechanical integrity and rapid tablet disintegration. Excessively hard tablets may delay disintegration, whereas insufficient hardness can increase tablet breakage; therefore, the hardness obtained for F9 was considered satisfactory for orally disintegrating tablets.

Friability values for all formulations were below the pharmacopoeial acceptance limit of 1%, confirming excellent resistance to abrasion during handling and storage. The optimized formulation exhibited the lowest friability (0.52%), indicating superior mechanical durability and adequate interparticulate bonding within the tablet matrix. The reduced friability observed for F9 may be attributed to improved compression characteristics and optimized excipient composition.

Disintegration time is one of the most critical quality attributes for superdisintegrating oral tablets. The formulations disintegrated within 22–28 s, satisfying the recommended disintegration criteria for orally disintegrating tablets. The optimized formulation (F9) showed the shortest disintegration time (22 s), which can be attributed to the synergistic action of crospovidone and croscarmellose sodium. Crospovidone promotes rapid water penetration by capillary action, whereas croscarmellose sodium rapidly swells upon hydration, resulting in efficient tablet breakup and accelerated drug release.

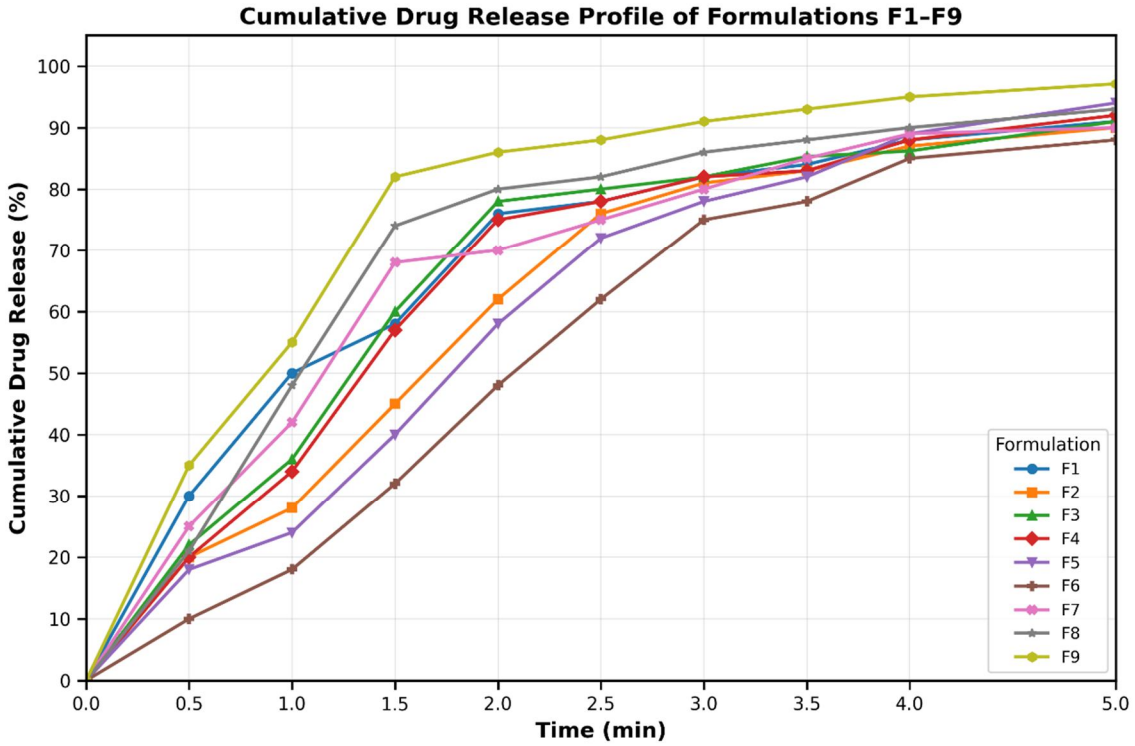

Fig 8.5.7.1: Percentage Drug Release of Sumatriptan ODT Formulations

Drug content analysis demonstrated satisfactory content uniformity among all formulations, with values ranging from 90.12% to 97.30%. The optimized formulation (F9) exhibited the highest drug content (97.30%), indicating efficient blending, uniform distribution of the active pharmaceutical ingredient, and minimal drug loss during processing. These findings confirm the suitability of the direct compression method for producing Sumatriptan superdisintegrating oral tablets with acceptable pharmaceutical quality. Overall, formulation F9 exhibited the most desirable balance of mechanical strength, rapid disintegration, low friability, and high drug content, and was therefore selected as the optimized formulation for subsequent dissolution and stability studies.

F. Accelerated Stability Study

The optimized formulation (F9) was subjected to accelerated stability testing at 40 ± 2°C and 75 ± 5% RH for a period of three months in accordance with ICH Q1A(R2) guidelines. The formulation was evaluated at predetermined intervals for physical appearance, average weight, hardness, friability, thickness, disintegration time, and drug content.

Parameter	Initial	1 Month	2 Months	3 Months
Appearance	White, intact	No change	No change	No change
Average Weight (mg)	206	206	206	205.98
Hardness (kg/cm²)	2.6	2.5	2.5	2.4
Friability (%)	0.54	0.44	0.46	0.48
Thickness (mm)	1.23	1.23	1.23	1.23
Disintegration Time (sec)	27	27	25	26
Drug Content (%)	96.30	96.30	96.10	96.00

The accelerated stability study demonstrated that the optimized formulation (F9) remained physically and chemically stable throughout the three-month storage period. No visible changes in tablet appearance, including colour, texture, or physical integrity, were observed, indicating excellent physical stability under accelerated storage conditions.

G. Optimization of Formulation by Design of Experiments (DoE)

A 3-level factorial design generated using Design-Expert® software (Version 13.0.5.0) was employed to optimize the concentrations of crospovidone (Factor A) and croscarmellose sodium (Factor B) for the development of Sumatriptan superdisintegrating oral tablets. Nine experimental formulations were prepared to evaluate the influence of these formulation variables on the critical quality attributes, namely tablet disintegration time (R1) and tablet hardness (R2). The composition of the experimental formulations and their corresponding responses are presented in Tables.

Run	F1 Crospovidone mg	F2 Sodium mg	Croscarmellose	R1 Time	Disintegration	R2 Hardness
1	4	4		18		2.1
2	4	11		28		2.8
3	4	18		18		2.1
4	9	4		18		2.1
5	9	11		32		3.2
6	9	18		45		3.5
7	14	4		16		2
8	14	11		14		1.8
9	14	18		12		2.3

H. Statistical Analysis of the Experimental Design

Analysis of variance (ANOVA) demonstrated that the developed mathematical models were statistically significant for both responses. The quadratic model generated for disintegration time exhibited a Model F-value of 147.65 ($p < 0.0001$), confirming an excellent fit of the experimental data. Both crospovidone (Factor A) and croscarmellose sodium (Factor B), together with their interaction (AB), significantly influenced tablet disintegration time. Likewise, the hardness model was also statistically significant, indicating that the concentrations of both superdisintegrants played a major role in determining tablet mechanical strength. The non-significant lack-of-fit further confirmed the adequacy and predictive capability of the developed models.

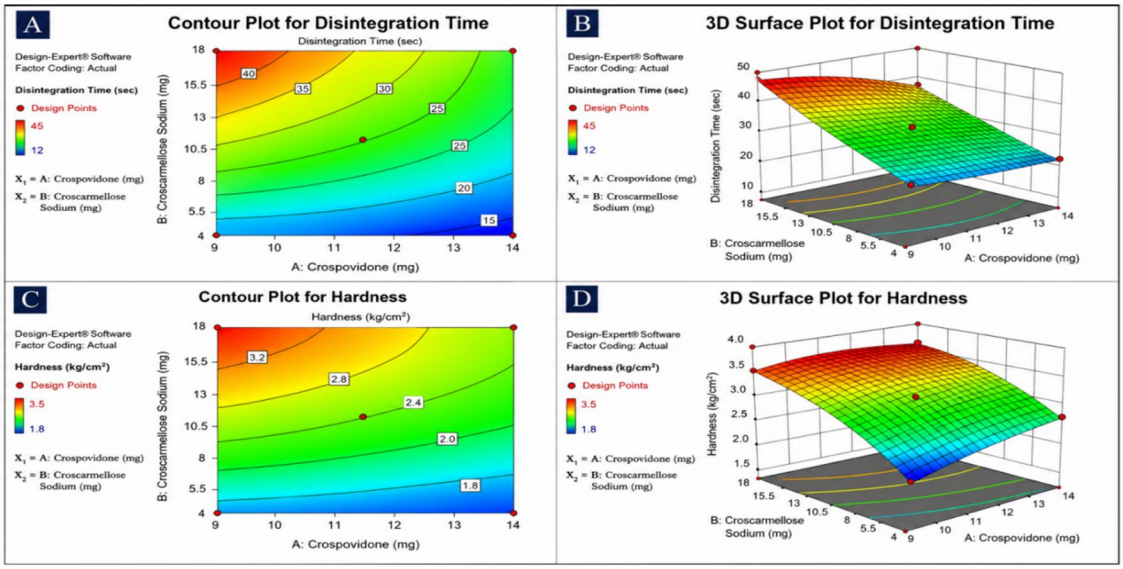

Figure 1. Response surface plots showing the effect of crospovidone and croscarmellose sodium on tablet performance:(A) Contour plot for disintegration time (B) Three-dimensional response surface plot for disintegration time (C) Contour plot for hardness (D) Three-dimensional response surface plot for hardness

I. Response Surface Analysis

The contour and three-dimensional response surface plots illustrated the combined influence of crospovidone and croscarmellose sodium on tablet disintegration time and hardness (Figure 1). Increasing the concentration of crospovidone markedly reduced tablet disintegration time because of its rapid capillary water uptake mechanism, whereas croscarmellose sodium enhanced tablet disintegration through extensive swelling upon hydration. A significant interaction between the two superdisintegrants was observed, indicating that simultaneous optimization of both variables was necessary to obtain rapid tablet disintegration without compromising tablet strength.

The response surface analysis also demonstrated that increasing both superdisintegrants beyond the optimum level produced only marginal improvements in disintegration while adversely affecting tablet hardness. Therefore, a balanced concentration of the two disintegrants was essential for achieving the desired pharmaceutical characteristics. Among the experimental formulations, F9, containing 14 mg crospovidone and 18 mg croscarmellose sodium, exhibited the most desirable response, producing the shortest disintegration time (**12 s**) while maintaining acceptable hardness (2.3 kg/cm²). The optimized formulation therefore satisfied the predefined optimization criteria and was selected for further evaluation.

J. Comparative Evaluation of the Optimized Formulation with the Marketed Product

To assess the pharmaceutical performance of the developed formulation, the optimized superdisintegrating oral tablet (F9) was compared with the marketed conventional tablet (Suminat® 50). The comparison included critical quality attributes such as hardness, friability, wetting time, disintegration time, drug content, drug release, mouthfeel, and patient compliance. The results are summarize

Table 9.1: Comparative Evaluation Table

Parameter	Optimized SDOT Formulation	Suminat 50 Tablet
Appearance	White, smooth, intact	White, intact
Hardness (kg/cm²)	2.4–2.6	4.0–5.0
Friability (%)	0.44–0.54	<1%
Wetting Time (sec)	20–38	90–120
Disintegration Time (sec)	20–22	180–300
Drug Content (%)	96–98	95–99
Drug Release in (%)	>90%	60–70%
Mouthfeel	Pleasant	Conventional
Need of Water	Not required	Required
Patient Compliance	High	Moderate

The optimized superdisintegrating oral tablet (F9) exhibited superior pharmaceutical performance compared with the marketed conventional formulation (Suminat® 50). Both formulations showed acceptable physical appearance and drug content within pharmacopeial limits, indicating satisfactory manufacturing quality. However, the optimized formulation demonstrated lower hardness (2.4–2.6 kg/cm²), which is desirable for orally disintegrating tablets as it facilitates rapid tablet breakup while maintaining sufficient mechanical integrity. Despite the lower hardness, friability remained below 1%, confirming adequate resistance to mechanical stress during handling and transportation.

A remarkable improvement was observed in the wetting and disintegration characteristics of the optimized formulation. The wetting time was reduced to 20–38 s, whereas the marketed tablet required 90–120 s. Likewise, the optimized formulation disintegrated within 20–22 s, compared with 180–300 s for the conventional marketed tablet. The rapid disintegration can be attributed to the synergistic action of crospovidone and croscarmellose sodium, which promote rapid water uptake by capillary action and swelling, respectively, resulting in faster tablet disintegration.

IV. CONCLUSION

The present study successfully developed and optimized superdisintegrating oral tablets (SDOTs) of Sumatriptan succinate using the direct compression technique with a systematic Design of Experiments (DoE) approach. Preformulation studies confirmed the suitability of the drug for formulation development by demonstrating acceptable physicochemical properties, good aqueous

solubility, and compatibility with the selected excipients as evidenced by FTIR and DSC analyses. The factorial experimental design effectively optimized the concentrations of crospovidone and croscarmellose sodium, which significantly influenced tablet disintegration time and mechanical strength.

All prepared formulations exhibited satisfactory pre-compression flow properties and complied with pharmacopeial requirements for post-compression quality attributes. Among the investigated formulations, F9, containing 14 mg of crospovidone and 18 mg of croscarmellose sodium, was identified as the optimized formulation. It demonstrated excellent powder flow characteristics, acceptable hardness, low friability, rapid wetting and disintegration, uniform drug content, and a superior dissolution profile, releasing more than 90% of the drug within 5 minutes. Accelerated stability studies performed according to ICH guidelines confirmed that the optimized formulation remained physically and chemically stable throughout the three-month storage period without significant changes in tablet quality or drug content.

Comparison with the marketed conventional tablet (Suminat® 50) further demonstrated the superiority of the developed superdisintegrating formulation. The optimized tablet exhibited markedly shorter wetting and disintegration times, faster drug release, improved mouthfeel, and eliminated the need for water during administration, thereby offering enhanced patient convenience and compliance, particularly for patients experiencing acute migraine attacks accompanied by nausea or dysphagia.

The developed Sumatriptan succinate superdisintegrating oral tablet represents a promising patient-friendly dosage form capable of providing rapid drug release and improved therapeutic performance. The optimized formulation has the potential to improve the clinical management of acute migraine and may serve as a suitable alternative to conventional oral tablets. Further pharmacokinetic, bioavailability, and in vivo clinical studies are recommended to establish an in vitro–in vivo correlation and confirm its therapeutic advantages for future commercialization.

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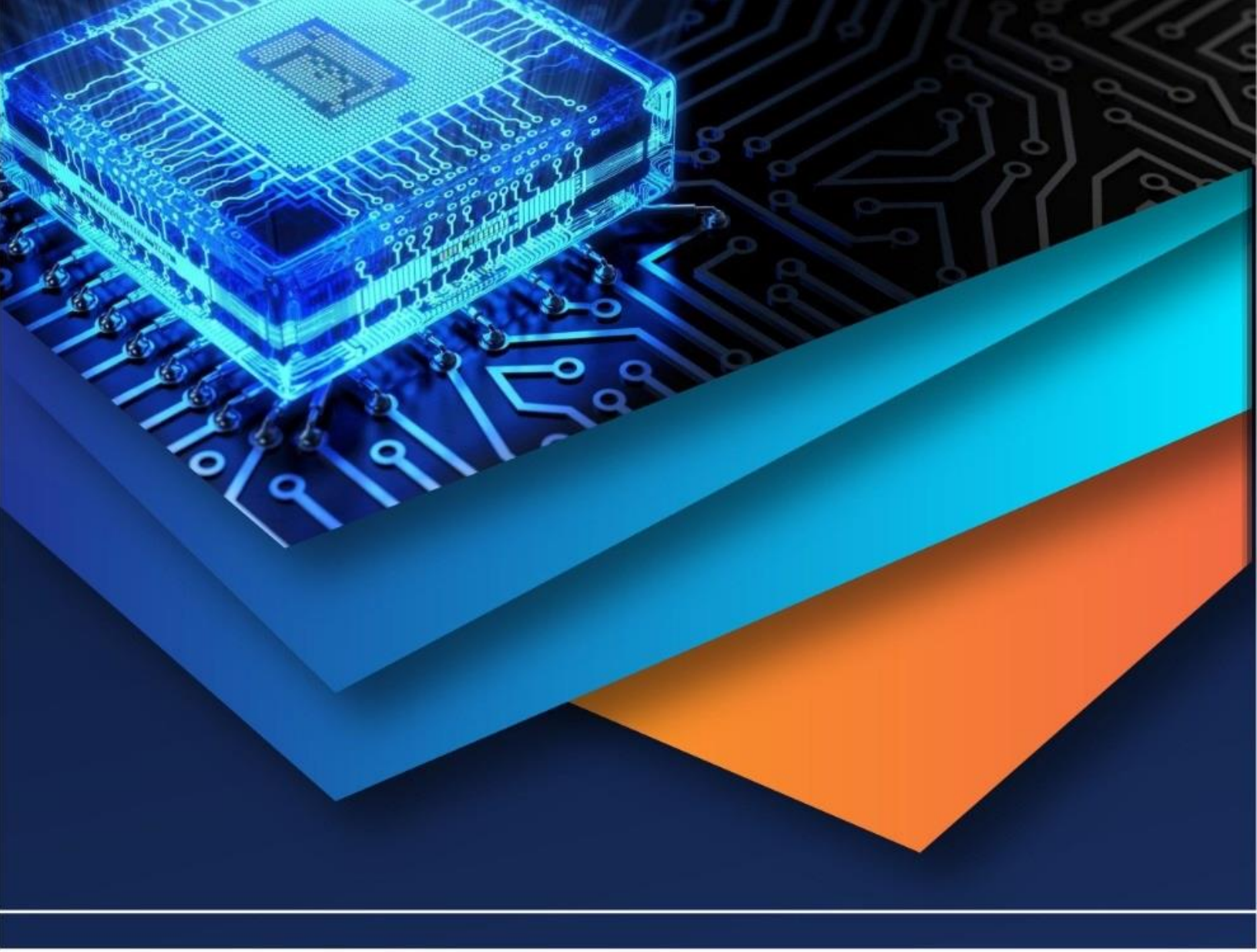

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