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Formulation and *In-vitro* Evaluation of Orodispersible Sumatriptan Tablets: Implications for Rapid Therapeutic Delivery and Drug Safety

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ABSTRACT

The demand for Orodispersible Tablets (ODTs) has increased notably in recent years, particularly for pediatric and geriatric populations with swallowing difficulties. Sumatriptan, a selective serotonin 5-HT1B/1D receptor agonist, is widely used in the treatment of acute migraine; however, its oral bioavailability is limited (~15%) due to extensive first-pass metabolism. The present study aimed to formulate and evaluate orodispersible tablets of sumatriptan using the wet granulation method to enhance dissolution and improve therapeutic performance. The prepared formulations were evaluated for pre- and post-compression parameters, all of which were within pharmacopeial limits. Among the formulations, batch F5 demonstrated optimal performance, achieving 98% drug release within 15 minutes. FTIR and DSC analyses confirmed the absence of significant drug–excipient interactions, indicating formulation stability. The enhanced dissolution profile suggests the potential for faster onset of action, which is critical in acute migraine management. Such rapid-release formulations may improve therapeutic outcomes, enhance patient compliance, and potentially reduce the need for repeated dosing, thereby minimizing dose-related adverse effects and supporting safer, patient-centered therapy.

Keywords: Orodispersible tablet; sumatriptan; sodium starch glycolate; anti-migraine.

1. INTRODUCTION

Oral drug delivery remains the most used route of administration because of its convenience, patient compliance, cost-effectiveness, and ease of manufacturing. Tablets represent one of the most widely utilized solid dosage forms due to their accurate dosing, stability, and portability. However, conventional tablets may present swallowing difficulties for certain patient populations, including pediatric, geriatric, and mentally ill patients, as well as individuals suffering from dysphagia or nausea. These limitations have led to the development of novel oral drug delivery systems such as orodispersible tablets (ODTs).[1,2]

Orodispersible tablets are designed to disintegrate rapidly in the oral cavity without the need for water, usually within seconds, resulting in improved patient convenience and compliance. The rapid disintegration and dissolution of these tablets may also enhance drug absorption and provide a faster onset of therapeutic action. ODTs are particularly beneficial for patients who have limited access to water, such as travelers or emergency patients, and for those who have trouble swallowing conventional dosage forms.[3,4]

Migraine is a common neurological disorder characterized by recurrent episodes of severe headaches often accompanied by nausea, vomiting, and sensitivity to light and sound. Rapid onset of drug action is essential for effective management of acute migraine attacks. Sumatriptan is a selective serotonin 5-HT1B/1D receptor agonist used in the treatment of acute migraine. It works by vasoconstriction of cranial blood vessels and inhibiting the release of inflammatory neuropeptides associated with migraine pathophysiology. However, sumatriptan exhibits relatively low oral bioavailability due to extensive first-pass

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metabolism and incomplete absorption following oral administration.[5]

Therefore, the development of an orodispersible tablet formulation of sumatriptan may enhance the dissolution rate and facilitate a faster onset of therapeutic action. The use of superdisintegrants can significantly accelerate tablet disintegration and drug release, while wet granulation serves as an effective manufacturing technique to improve granule flow properties, compressibility, and uniformity of drug distribution. Beyond formulation characteristics, orodispersible tablets may also have important implications in therapeutic optimization and drug safety. Rapid drug release and absorption may influence pharmacokinetic profiles, potentially reducing variability in drug response and minimizing dose-related adverse effects. Furthermore, improved patient compliance associated with such formulations may contribute to safer and more effective migraine management, highlighting the relevance of advanced formulation strategies within the broader framework of drug vigilance and patient-centered therapy.

The present study aims to formulate and evaluate orodispersible tablets of sumatriptan using the wet granulation method. The prepared formulations were evaluated for pre-compression and post-compression parameters as well as *in-vitro* drug release to determine their suitability as a fast-acting oral dosage form for migraine therapy.

2. MATERIALS & METHODS

2.1 Chemicals and Reagents

Various chemicals and reagents used in the present study are represented in Table 1.

2.2 Instruments and Equipment

Various instruments and reagents used in the present study are presented in Table 2.

2.3 Pre-formulation Studies

2.3.1 Preparation of Standard Calibration of Sumatriptan

A primary stock solution of sumatriptan (1000 µg/mL) was prepared by accurately weighing 100 mg of the drug and dissolving it in a small volume of phosphate buffer (pH 6.8) in a 100 mL volumetric flask, followed by making up the volume to 100 mL with the same buffer. The solution was scanned in the range of 200–400 nm using a UV–Visible spectrophotometer to determine the absorption maximum (λ_{max}), which was found to be 282 nm. A secondary stock solution (10 µg/mL) was prepared by diluting 1 mL of the primary stock solution to 100 mL with phosphate buffer (pH 6.8). From this solution, further dilutions were made to obtain concentrations of 1, 2, 3, 4, and 5 µg/mL. The absorbance of these solutions was measured at 282 nm against phosphate buffer (pH 6.8) as blank. A calibration curve was constructed by plotting absorbance versus concentration, and the linear regression equation obtained was used to determine the drug concentration in the sample solutions.

2.3.2 Fourier Transforms-Infrared Spectroscopy (FT-IR) Studies

FTIR spectroscopy was performed to discover possible interactions between sumatriptan and the excipients used in the formulation. The FTIR spectra of the pure drug and the physical mixture of drug with selected excipients were recorded using an FTIR spectrophotometer. The samples were prepared using the potassium bromide (KBr) pellet method and scanned over a wavelength range of 4000–400 cm^{-1}. The characteristic peaks obtained in the spectra were analyzed to identify any drug–excipient interactions.[7]

2.3.3 Differential Scanning Calorimetry (DSC) Studies

DSC analysis was performed to evaluate the thermal behavior of sumatriptan and to investigate possible interactions between the drug and excipients. DSC thermograms of the pure drug and the physical mixture of drug with selected excipients were recorded using a differential scanning calorimeter. A small quantity of the sample was accurately weighed, sealed in an aluminum pan, and heated at a controlled rate under a nitrogen atmosphere. The samples were scanned over a suitable temperature range to detect endothermic and exothermic transitions. The obtained thermograms were analyzed to identify any potential drug–excipient interactions.[7]

2.4 Pre-Compression Characterization of Powder Blend

2.4.1 Bulk Density and Tapped Density

Bulk density and tapped density were determined by measuring the initial volume and tapped volume of the powder blend using a graduated cylinder method.[8] About 2 g of powder blend was transferred into a measuring cylinder, and the initial volume was recorded. The cylinder was tapped repeatedly until a constant volume was obtained.

Table 1: Chemicals and reagents

S. No	Chemical	Manufacturer
1	Sumatriptan	Dr. Reddy's Laboratories Pvt. Ltd. (Gift sample), India
2	Microcrystalline cellulose (MCC)	Otto Manufacturers, USA
3	Polyvinyl pyrrolidone (PVP K-30)	Essel Fine Chemicals, Mumbai, India
4	Mannitol	S.D. Fine Chemicals, Mumbai, india
5	Sodium starch glycolate	Dr. Reddy's Laboratories Pvt. Ltd. (Gift sample), India
6	Crospovidone	Dr. Reddy's Laboratories Pvt. Ltd. (Gift sample), India
7	Saccharine	Essel Fine Chemicals, Mumbai, India
8	Magnesium stearate	S.D. Fine Chemicals, Boisar, India
9	Talc	S.D. Fine Chemicals, Boisar, India

Table 2: Instruments and equipment

S. No	Instrument	Manufacturer
1	Electronic balance (CTG-302)	Citizen Scales Pvt. Ltd., India
2	Hardness Tester (Monsanto Hardness Tester)	Campbell Electronics, India
3	Friability tester (Roche)	Roche friabilator, USA
4	Rotary tablet punching machine	Saimach Pharmatech Pvt. Ltd., India
5	Vernier caliper	Seiko, China
6	Dissolution testing apparatus (DS-8000)	Lab India, India
7	Density tap tester	ElectroLab, India
8	UV-Visible spectrophotometer (Spectro 2080)	Analytical Technologies Ltd., China
9	FTIR spectrophotometer	Shimadzu, China
10	Hot air oven	Tempo Instruments Pvt. Ltd., India
11	Differential scanning calorimeter	Agilent Technologies, USA

2.4.2 Compressibility Index and Hausner's Ratio

Carr's index and Hausner's ratio were calculated using the values of bulk density and tapped density. These parameters provide data about flow properties and compressibility of the powder blend.[7]

2.4.3 Angle of Repose

Angle of repose was determined using the fixed funnel method. The powder blend was allowed to flow through a funnel placed at a fixed height above a flat surface. The height and radius of the powder cone formed were measured and the angle of repose was calculated using the following equation:[9]

$$\theta = \tan^{-1} (h / r)$$

where, h = height; r = radius of powder cone

2.5 Formulation of Sumatriptan Orodispersible Tablets

Orodispersible tablets of sumatriptan were prepared by the wet granulation method (Table 3). All ingredients were accurately weighed and passed through sieve No. 80 prior to use. The required quantities of sumatriptan, microcrystalline cellulose (MCC), sodium starch glycolate (SSG), crospovidone, and polyvinyl pyrrolidone (PVP) were blended uniformly and passed through sieve No. 20. PVP was used as a binder during granulation. The wet mass obtained after binder addition was passed through sieve No. 20 to form granules and subsequently dried at 40 °C. The mass was then passed through sieve No. 20 to obtain granules.

The prepared granules were dried at 40°C for approximately 20 minutes to reduce the moisture content to about 2–5%. Magnesium stearate and talc were added as lubricants and mixed with the dried granules for 2–3 minutes. The lubricated granules were evaluated for flow properties and compressed into tablets using a 10-station rotary machine with 8 mm concave punches, each containing 10 mg of sumatriptan. The same procedure was followed for all formulations, ensuring therapeutic efficiency while maintaining drug safety and stability.

2.6 Evaluation of Post-Compression Parameters

The prepared sumatriptan orodispersible tablets were evaluated for various post-compression parameters. Tablet thickness was measured using a vernier caliper to ensure uniform tablet dimensions. Weight variation was determined by weighing twenty tablets individually and calculating the percentage deviation from the average weight. Hardness was measured using a Monsanto hardness tester, while friability was evaluated using a Roche friabilator operated at 25 rpm for 4 minutes to assess tablet mechanical strength. Wetting time was determined by placing a tablet on folded tissue paper in a Petri dish containing distilled water and recording the time required for complete wetting of the tablet surface.

Table 3: Different formulation of sumatriptan orodispersible tablets

F. No.	Sumatriptan (mg)	MCC (mg)	Mannitol (mg)	SSG (mg)	PVP (mg)	Saccharine (mg)	Mg. Stearate (mg)	Talc (mg)	Total wt. (mg)
F_1	10	102.5	15	1.5	15	1	3	2	150
F_2	10	101.0	15	3	15	1	3	2	150
F_3	10	99.5	15	4.5	15	1	3	2	150
F_4	10	98	15	6	15	1	3	2	150
F_5	10	96.5	15	7.5	15	1	3	2	150
F_6	10	95	15	9	15	1	3	2	150

Note: MCC = microcrystalline cellulose; SSG = sodium starch glycolate; PVP = Polyvinylpyrrolidone
The variation in superdisintegrant concentration was intended to evaluate its impact on drug release behavior and potential therapeutic performance.

For content uniformity, a quantity of powdered tablets equivalent to 100 mg of sumatriptan was dissolved in 100 mL of phosphate buffer (pH 6.8), was passed through a Whatmann No. 1 filter paper and analyzed spectrophotometrically at 282 nm after sufficient dilution with phosphate buffer P H 6.8.[7-11]

2.7 Disintegration Test

The disintegration time of tablets was determined using a standard USP disintegration test apparatus consisting of a basket rack assembly that moves vertically at 28–32 cycles per minute in a beaker containing the specified medium. One tablet was placed in each tube with a disc, and the apparatus was operated for the required time. Tablets were considered to pass the test if all six tablets disintegrated completely within the specified time limit; if one or two tablets failed, the test was repeated with additional tablets, and at least 16 out of 18 tablets were required to disintegrate.[8]

2.8 *In-vitro* Dissolution Studies

In-vitro dissolution studies were carried out using a USP dissolution apparatus (basket method). A single tablet was placed in a wire mesh basket attached to a rotating shaft and immersed in the dissolution medium contained in a 1000 mL cylindrical flask with a hemispherical bottom, maintained at 37 ± 0.5 °C. The basket was rotated at the specified speed and samples of the dissolution medium were withdrawn at predetermined time intervals. The amount of drug released in the samples was determined spectrophotometrically using the calibration curve.

2.9 *In-vitro* Drug Release Kinetic Studies

The dissolution data obtained for all formulations were analyzed using different kinetic models including zero-order, first-order, Higuchi, Hixson–Crowell, and Korsmeyer–Peppas models to evaluate the mechanism and rate of drug release. The Korsmeyer–Peppas equation was specifically applied to interpret the release mechanism of the drug from the prepared formulations.[12]

3. RESULTS

3.1 Standard Calibration Curve of Sumatriptan

Standard calibration curve of sumatriptan was drawn by plotting absorbance *vs* concentration at 282 nm. Standard calibration curve of sumatriptan is linear in the range between 0-30µg/ml and is shown in Fig. 1. Linear regression analysis was performed on the absorbance data obtained from the calibration curve. The analysis showed a slope (m) of 0.096, an intercept (c) of 0.006, and a correlation coefficient (R^2 = 0.998), indicating good linearity of the method. The relationship between absorbance and concentration followed the linear equation y = mx + c, which was used to calculate the drug concentration in the samples. The derived regression equation was,

Absorbance (y) = 0.096x + 0.006

where *x* represents drug concentration and *y* represents the absorbance.

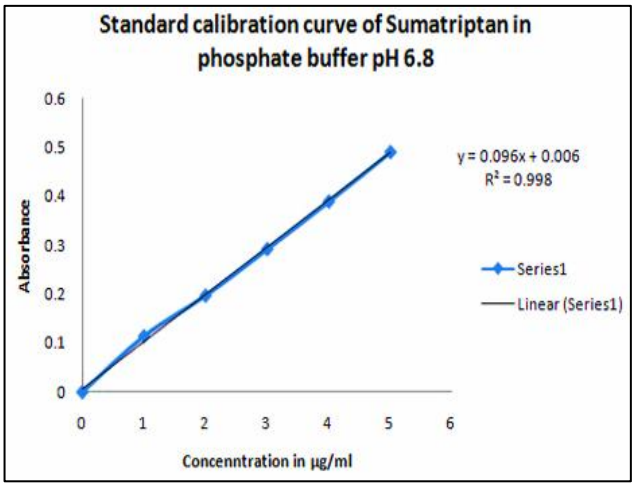


Fig. 1: Calibration curve of Sumatriptan

3.2 FTIR Studies of Sumatriptan

The physicochemical compatibility of the pure drug (Sumatriptan) and the polymers used in the formulations were established through FTIR studies (Fig. 2a and 2b). Sumatriptan exhibits characteristics peaks at respective wave numbers i.e. S=O stretching (1079 cm^{-1}), tertiary amine (3094 cm^{-1}), C–N stretching (1296 cm^{-1}, 1233 cm^{-1}), C-S stretching (634 cm^{-1}), and N–H stretching (3376 cm^{-1}). Thus, it was evident that all the characteristic peaks that were present in the spectra of pure drug were observed in the same region in the spectra of optimized formulations of sumatriptan tablet (F6) indicating that there was no significant interaction between the drugs and the polymers. However, other peaks were absorbed in optimized formulation which could be due to the presence of polymers.

3.3 DSC Studies of Sumatriptan

DSC studies were conducted on the pure drug and for optimized formulation (F6). DSC thermogram of pure sumatriptan showed sharp endothermic peak at 172.3°C. Similar endothermic peaks were obtained at 159.1°C for the optimized formulation. The endothermic peak that appears at 247.2°C for sumatriptan also appears at 217.2°C in optimized formulation without any shifts. The presence of typical peaks indicates that the drug is compatible with the selected excipients with sumatriptan succinate and there is no thermal (physical) incompatibility between the selected ingredients. DSC thermogram of optimized formulation, drug and polymers are shown in Fig. 3a and 3b.

3.4 Pre-Compression Parameters of Sumatriptan

The bulk densities of prepared granules of all formulations were found to be in the range of 0.400 to 0.547 g/cm^3 and the tapped densities were found to be between 0.430 to 0.58 g/cm^3 . This indicates good packing capacity for granules. Carr's index values below 15 indicate good flow properties. Carr's indexes of all the formulations were found between 5.6 to 13 that indicate excellent to passable flow properties.

In all formulations, the Hausner's ratio ranged between 1.06 and 1.15, indicating good flow properties, whereas formulations with a Hausner's ratio greater than 1.25 typically require the addition of a glidant to improve flowability. Angle of repose is suitable for particles greater than 150 µm, with values ≤25 indicating free-flowing material and values ≥40 suggesting poor flow. The angle of repose for all formulations was within the range of 13.7 to 23.7, confirming good flow characteristics of the granules. These findings collectively indicate that the powder blends possessed adequate flowability and compressibility, making them suitable for efficient tablet compression. The evaluation results of all pre-compression parameters for formulations F1 to F6 are shown in Table 4.

3.5 Post-Compression Parameters of Sumatriptan

All the physical parameters evaluated after compression of sumatriptan orodispersible tablets were found to be satisfactory. Typical tablet defects, such as capping, chipping and picking, were not observed. The physicochemical characterizations of different batches of sumatriptan orodispersible tablets are given in Table 5. The average thickness of the tablets ranged between 3.32 to 3.39 mm and all the formulations were within acceptable limits. All the batches showed uniform thickness. Weight variations for different formulations were found to be 148 to 152 mg. The average percentage deviation of all tablet formulations was found within the limit, and hence all formulations passed the test for uniformity of weight as per official requirement. The hardness of all the sumatriptan orodispersible tablets formulations ranged from 2.4 to 3.8 kg/cm^2 that were according to the specification. The percentage friability of all the formulations ranged from 0.47% to 0.61% and was found within the prescribed limits. The percentages of drug content of the entire formulations of sumatriptan tablet (F1 to F6) were found between 98.22 to 102.60 which were within the acceptable limits. Comparing wetting time of formulation F3 and F5, it was concluded that the formulation F3 prepared by wet granulation method showed lesser wetting time as compared to other formulation (Fig. 4).

3.6 *In-vitro* Dissolution Studies

The *in-vitro* dissolution study was carried out to evaluate the drug release behavior of the prepared sumatriptan orodispersible tablets (Table 6). The results showed that all formulations exhibited rapid drug release in phosphate buffer (pH 6.8). Among the formulations, F5 and F6 showed faster drug release due to the higher concentration of the superdisintegrant SSG, which enhanced tablet disintegration and dissolution.

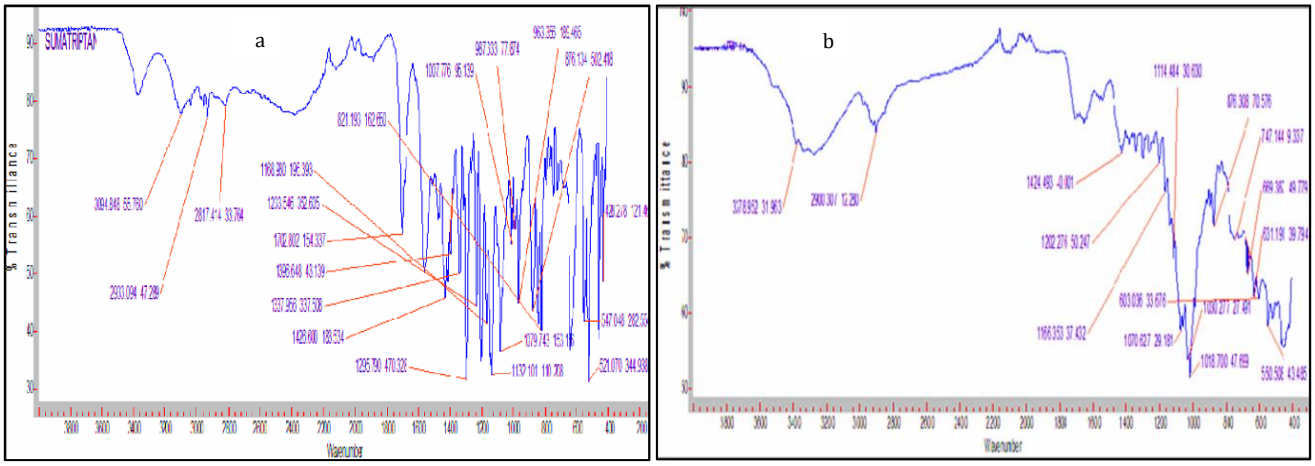


Fig 2: FT-IR spectra of sumatriptan (a) pure drug; (b)optimized formulation

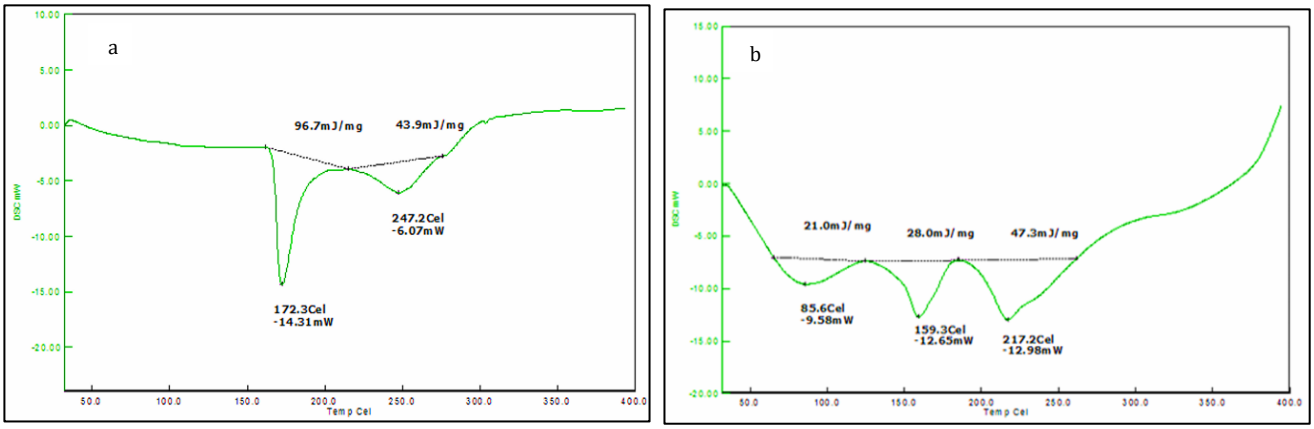


Fig. 3: DSC thermogram of sumatriptan (a) pure drug; (b)optimized formulation

Table 4: Pre-compression evaluation of the prepared Sumatriptan orodispersible granules

Formulation Batch	Bulk Density (g/mL)	Tapped Density (g/mL)	Compressibility Index (%)	Hausner's Ratio	Angle of Repose (θ)
F1	0.547	0.584	6.3	1.06	16.95
F2	0.408	0.433	6.9	1.06	20.75
F3	0.460	0.520	11.5	1.13	17.70
F4	0.500	0.530	5.6	1.06	13.70
F5	0.440	0.480	8.3	1.09	23.70
F6	0.400	0.460	13	1.15	20.30

Table 5: Post-compression evaluation of the prepared sumatriptan orodispersible tablets

Formulation Batch	Weight Variation (mg)	Hardness (kg/cm²)	Friability (%)	Wetting Time (sec)	Disintegration Time (sec)	Drug Content (%)
F1	152	3.8	0.58	38	68	102.23
F2	151	3.5	0.47	35	58	99.51
F3	150	3.3	0.61	35	50	101.39
F4	150	2.9	0.49	32	45	98.62
F5	149	2.5	0.55	29	36	101.46
F6	148	2.3	0.59	30	35	98.58

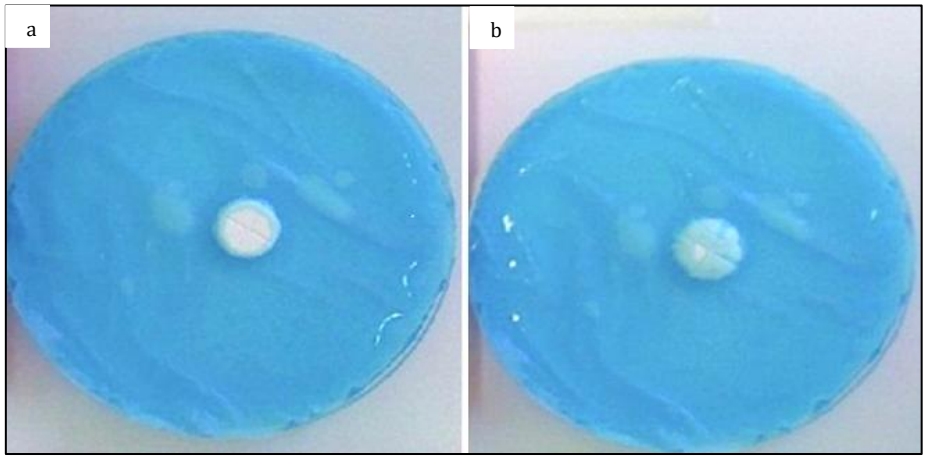


Fig. 4: Wetting time of sumatriptan orodispersible tablet of (a) formulation F5 after 29 seconds (b) formulation F3 after 20 seconds

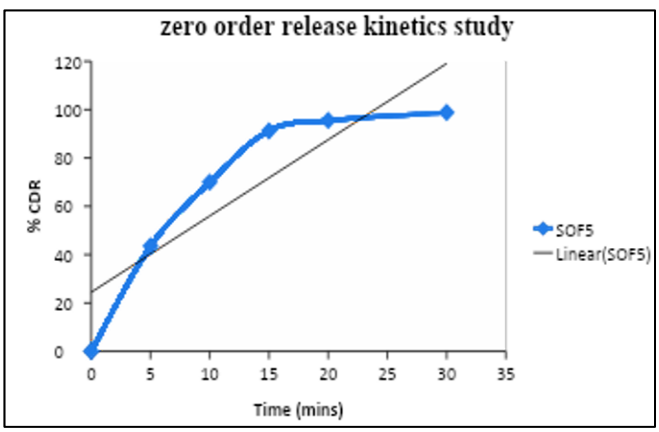
The optimized formulation demonstrated nearly complete drug release within a short period of time, indicating good dissolution characteristics suitable for orodispersible drug delivery. These results confirm that the prepared tablets provide rapid drug release and may lead to faster onset of therapeutic action. Rapid drug release observed in optimized formulations suggest the potential for a faster onset of action, which is critical in the effective management of acute migraine attacks. Such rapid-release formulations may reduce the need for additional dosing, thereby potentially minimizing cumulative drug exposure and associated adverse effects, while also improving patient compliance and overall therapeutic outcomes.

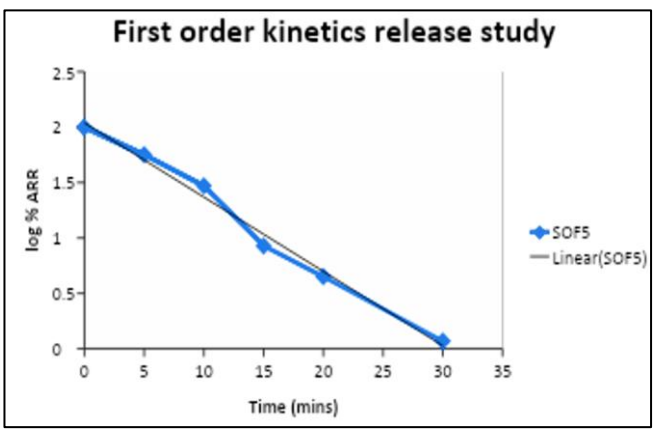
Table 6: *In-vitro* release studies of sumatriptan orodispersible tablets

Time (min)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
5	12.1	29.5	30.9	36.2	46.2	43.5
10	39.7	32.4	39.6	40.5	55.8	69.9
15	66.6	63.3	46.3	53.3	72.7	91.3
20	72.4	65.6	69.5	73.2	86.4	95.5
30	80.5	74.2	80.6	82.5	99.9	98.8

3.7 *In-vitro* Drug Release Kinetic Studies

The *in-vitro* dissolution data of the optimized formulation F5 were fitted to different kinetic models including zero-order, first-order, Higuchi, and Korsmeyer–Peppas models, and the corresponding plots were constructed (Fig. 5). The correlation coefficient (R^2) values obtained for the models were 0.77 for zero-order, 0.989 for first-order, 0.953 for the Higuchi model, and 0.873 for the Korsmeyer–Peppas model. The first-order model showed the highest R^2 value (0.989), indicating that the drug release from the optimized formulation follows first-order release kinetics. The release exponent (n) obtained from the Korsmeyer–Peppas model was 1.37, suggesting that the drug release follows Super Case II transport mechanism.





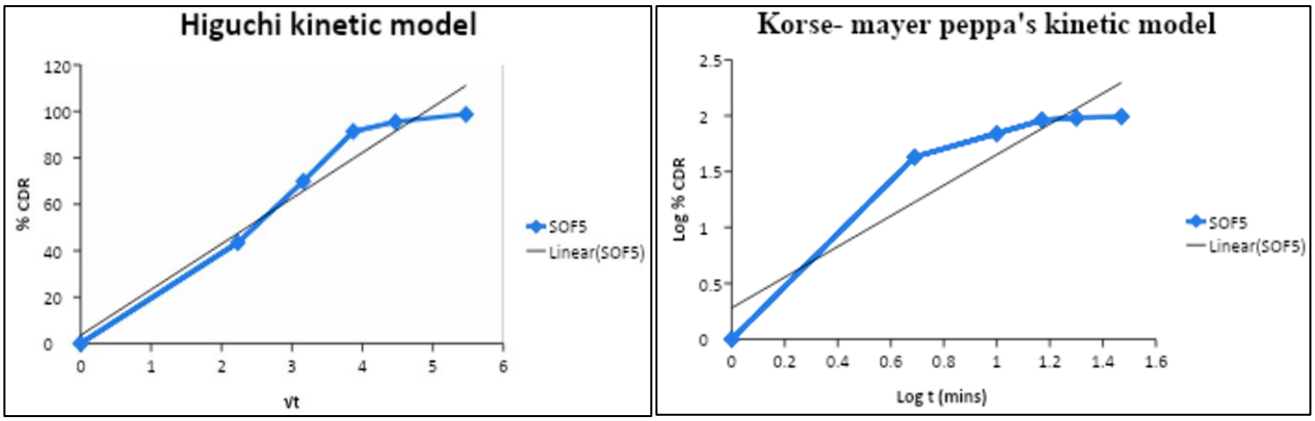


Fig 5: *In-vitro* drug release kinetic studies of sumatriptan orodispersible tablet

4. DISCUSSION

The present study focused on the formulation and evaluation of orodispersible tablets of sumatriptan using the wet granulation method. Pre-compression parameters, including bulk density, tapped density, compressibility index, Hausner's ratio, and angle of repose, were within acceptable limits, indicating satisfactory flowability and compressibility of the powder blends and their suitability for tablet compression. These findings are consistent with established pharmaceutics principles that highlight the importance of optimal flow and compressibility in ensuring uniformity and quality of solid dosage forms.[1]

The optimized formulations demonstrated rapid disintegration and enhanced dissolution, which may have important therapeutic implications in the management of acute migraine. Accelerated drug release may facilitate a faster onset of action, a critical factor in reducing the intensity and duration of migraine attacks. Sumatriptan is known for its relatively low oral bioavailability due to extensive first-pass metabolism; therefore, improving dissolution characteristics may enhance drug absorption and therapeutic performance.[6]

From a drug safety perspective, improved bioavailability and rapid onset may reduce the need for repeated dosing, thereby potentially lowering the risk of dose-related adverse effects associated with sumatriptan therapy. Furthermore, optimized drug delivery systems may contribute to more predictable pharmacokinetic profiles, minimizing inter-individual variability in drug response and supporting safer pharmacotherapy.[13]

Post-compression evaluation confirmed that all formulations complied with pharmacopeial standards, exhibiting uniform weight, adequate mechanical strength, and friability below 1%. A decrease in wetting and disintegration times with increasing concentrations of superdisintegrants further supports the efficiency of the formulation strategy. Superdisintegrants such as sodium starch glycolate and crospovidone are known to enhance water uptake and swelling, thereby facilitating rapid tablet disintegration and drug release.[4] Drug content uniformity across all batches was within acceptable limits, indicating consistent drug distribution and reliability of the manufacturing process.

FTIR and DSC analyses confirmed the absence of significant drug–excipient interactions, demonstrating the chemical and thermal stability of sumatriptan within the formulation matrix. Such compatibility is essential for maintaining drug efficacy and ensuring long-term stability of the dosage form.[2] *In-vitro* dissolution studies revealed rapid and near-complete drug release, particularly in formulations F5 and F6, which outperformed other batches and the marketed product. This enhanced dissolution behavior is likely attributable to improved disintegration, increased surface area, and efficient wetting of the tablet matrix.[9]

Collectively, these findings indicate that the optimized formulation offers improved pharmaceutical performance and is suitable for rapid drug delivery via the orodispersible route. In a broader therapeutic context, such formulations may enhance clinical outcomes by improving onset of action and patient compliance while potentially reducing adverse effects. Integration of optimized drug delivery systems with supportive approaches such as lifestyle modification, dietary regulation, and stress management techniques, may further contribute to a comprehensive and patient-centered strategy for migraine management.[14]

5. CONCLUSION

Sumatriptan succinate orodispersible tablets were successfully formulated using sodium starch glycolate, demonstrating satisfactory physicochemical properties and good drug–excipient compatibility as confirmed by FTIR and DSC analyses. Among the formulations, batch F5 exhibited optimal performance with rapid drug release and acceptable tablet characteristics. The enhanced dissolution profile suggests potential for faster onset of action in acute migraine management, which may improve therapeutic outcomes and patient compliance while potentially reducing the need for repeated dosing and associated adverse effects. Overall, the developed formulation represents a promising strategy for improved drug delivery and effective migraine therapy.

Conflict of Interest: The authors declare that there is no conflict of interest regarding the publication of this study.

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