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Original Article

Formulation and Evaluation of Mouth Dissolving Films of Sumatriptan Succinate Using Super Disintegrating Agent

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ABSTRACT

Background: The purpose of this study was to formulate and evaluate Mouth-Dissolving Films (MDF) of Sumatriptan Succinate with super disintegrating agent Polacrilin Potassium, aimed at providing a fast and efficient delivery system for migraine relief. The patient can consume the formulation without water because the films are made to dissolve in few seconds when they come into touch with a wet surface, such the tongue. It results in increased patient compliance. **Objectives:** The present study aimed to formulate mouth dissolving film of Sumatriptan Succinate which is a widely used medication for acute migraine attacks but the bioavailability is very less in oral administration due to first pass metabolism and the mouth-dissolving film formulation provides the advantage of rapid onset of action. **Materials and Methods:** MDFs of Sumatriptan Succinate were prepared by the solvent casting method employing various film-forming polymers like HPMCE15, Glycerine as a plasticizer, and super disintegrating agents Polyacrylic Potassium, and the films are evaluated for their physical, mechanical, and drug release properties. The solvent casting method is most commonly used for preparing Mouth Dissolving Films (MDFs) that involves dissolving the Active Pharmaceutical Ingredient (API), film-forming polymers, plasticizer, and other additives in a suitable solvent to form a uniform solution, which is then cast into a film and dried. The results indicated that the films containing Polacrilin Potassium in optimum concentration and HPMC E15 in optimum concentration exhibited acceptable disintegration time, good folding endurance, drug release profiles, and mechanical properties. Formulation F9 containing HPMC E15 300 mg and Polacrilin Potassium 25 mg was the best formulation, having disintegration time lies between 9-17 sec, a higher dissolution rate and drug release was 100%. **Conclusion:** Mouth dissolving films formulated in this study can be used as an alternative for conventional dosage form effectively with rapid onset of action and with better patient compliance. The mouth dissolving film of Sumatriptan Succinate holds high translational potential due to its ability to be used with high efficacy, patient comfort, and rapid migraine pain relief. It is non-invasive, fast-acting, and user-friendly drug delivery systems. With continued research into in vivo performance, taste masking, and formulation optimization, this delivery platform could become a standard treatment modality for acute migraine attacks.

Keywords: Drug Delivery, Film Formulation, Migraine Relief, Mouth Dissolving Films, Polymers, Rapid, Release, Sumatriptan.

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INTRODUCTION

Oral formulations, including tablets and capsules, are commonly used for its easy administration, but they can have slow onset of action and not convenient for pediatric and geriatric patients.[1] MDFs dissolve in the oral cavity without the need for water, making them convenient and ideal for patients who have difficulty swallowing or who are in situations where water is not available.[2] Mouth-Dissolving Films (MDFs) represent a novel dosage form offering the advantages of rapid disintegration. The selection of mouth dissolving film of Sumatriptan Succinate is justified by its ability to offer rapid relief, enhanced bioavailability, and patient-friendly non-invasive administration, all of which are critically important in the acute management of migraine. Its combination of clinical efficacy, convenience, and patient compliance makes it a promising and innovative drug delivery system in the Novel Drug Delivery System.

Sumatriptan Succinate is a targeted agonist of the 5-HT1 receptor, mainly utilized for the immediate treatment of migraine attacks. Mouth dissolving films of Sumatriptan succinate was chosen because of its rapid onset, necessity for treating acute migraine attacks, and the challenges posed by traditional oral dosage

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forms due to migraine-related nausea and vomiting. These films provide a quick-dissolving, user-friendly method which is perfect for those suffering from migraines, allowing for quick drug absorption by avoiding the hepatic first-pass metabolism. HPMC E15 was selected as the polymer for film formation because of its film-forming capabilities, safety, and pleasant mouth feel.

This study aims to develop and evaluate mouth-dissolving films of Sumatriptan Succinate with the help of Super Disintegrating Agents (SDIs), focusing on the formulation, optimization, and *in vitro* evaluation of their physical, mechanical, and drug release properties. Super disintegrating agents are a class of compounds which primarily aid in the rapid disintegration of orally disintegrating tablets and films.[3] SDIs promote dissolution of poorly water-soluble drugs.[4] Polacrilin potassium (KYRON T-314) is used as super disintegrating agent.[5] It is a crosslinked polymer of methacrylic acid and divinyl benzene supplied as a potassium salt. Polacrilin potassium is a weakly acidic cationic exchange resin. The disintegrating property is due to its extremely large swelling capacity in aqueous solutions.[6]

Sumatriptan Succinate is the succinate salt form of sumatriptan as shown in Figure 1, which belongs to the triptan class of chemicals, is called sumatriptan succinate. Because of its poor permeability and high solubility, it is categorized as a BCS Class III medication. It is applied to migraine treatment. By specifically binding to and activating serotonin 5-HT1 receptors, it stimulates the 5-HT1B receptors, which causes the meningeal, dural, cerebral, or pial blood vessels to contract.[7] This action reduces vascular pulsation, potentially providing relief from migraine headaches. The half-life of the drug is 2.5 to 3 hr only. Oral bioavailability of the drug is approx. 17 to 25% so to increase the disintegration, it is formulated in mouth mouth-dissolving film.[8]

HPMC E15 is used for film forming property, Glycerine is used for excellent plasticizer property, Polacrilin potassium is used as super disintegrating agent, and Citric acid monohydrate is used saliva-stimulating agent and helps in better disintegration.[9,10]

MATERIALS AND METHODS

Sumatriptan Succinate, Methocel E-15 LV Premium (HPMC E-15), Glycerine, Sucralose, Sodium benzoate agents, and Polacrilin Potassium were gifted by Intas Pharma, Dehradun. All other excipients used in the study were procured from local suppliers.

Determination of Absorption Maxima of Sumatriptan Succinate

The solution of the drug in phosphate buffer pH 6.8 was scanned using UV-visible double beam spectrophotometer in the range of 200 to 400 nm to fix the maximum wavelength, and the UV spectrum was obtained.[11]

Preparation of Calibration Curve

10 mg of Sumatriptan was dissolved in 100 mL of phosphate buffer of pH 6.8. Dilutions of the above solution were made at a concentration. 10 µg/mL, 20 µg/mL, 30 µg/mL, 40 µg/mL, and 50 µg/mL. Absorbance was measured at each concentration at lambda max. Standard curve between concentration and absorbance.[12] was prepared. Absorbance obtained for various concentrations of Sumatriptan succinate in phosphate buffer pH 6.8 are determined.

Drug Excipient Compatibility Studies

A Fourier transform infrared spectrophotometer was used to record FTIR spectra for physical mixtures, and pure drugs. The analysis was carried out in Shimadzu- Spectrophotometer.[13,14]

Preparation of Mouth Dissolving Films of Sumatriptan Succinate

The most common method for preparing Mouth Dissolving Films (MDF) involves the solvent casting technique.[15] In this process a total of nine formulations (F1 to F9) of Sumatriptan succinate, each containing an 8 mg dose, were prepared using varying compositions of film-forming agents, sweeteners, plasticizers, stabilizers, disintegrating agents, preservatives, and other excipients as shown in Table 1.

Manufacturing Process of Formulation of Mouth Dissolving Films

First, half of the total water (heated to 45-50) was used to dissolve the Active Pharmaceutical Ingredient (API) by manual stirring until it was completely dissolved. The remaining excipients (plasticizer, polymers and super disintegrating agent Polacrilin Potassium) were dissolved separately in the other half quantity of the water. Both solutions were then mixed together with manual stirring and then sonicated. After sonication solution was filtered using a muslin cloth, and the filtered solution was poured into petri plates (90 mm) and dried for 24 hr at 50°C. The dried solution petri plates were then kept in the refrigerator for 45 min. After refrigeration, the resulting strips were cut into the desired length as per the calculation.

Strip size calculation

Size of Petri plate taken for film formation: 90 mm (9 cm). Area of Petri plate: $\pi r^2 = \pi \times (4.5)^2 = 63.5\ cm^2$.

Size of strip required for 8 mg Sumatriptan

Total area of Petri plate x Drug content required in each strip = $63.5 \times 8 = 4\ cm^2 = (2 \times 2)\ cm^2$ Total quantity of drug taken in petri plate: 125.

During the preparation of mouth dissolving films of Sumatriptan Succinate, several uniformity measures were implemented to ensure consistency in drug content, film thickness, weight, and

mechanical properties. The drug was uniformly dispersed in the polymeric solution using continuous stirring by sonication to prevent lump formation. Drying conditions were carefully controlled to avoid non uniform distribution of drug or uneven solvent evaporation. After drying, the films were cut into uniform sizes to assess weight variation, which was kept within pharmacopeia limits. Thickness was measured at multiple points to ensure even distribution, while drug content uniformity was evaluated by films and analysing them by UV spectroscopy Visual inspection was also conducted to check for surface smoothness and defects such as air bubbles or cracks. These measures collectively ensured the reproducibility and reliability of the formulation, meeting both clinical standards and commercial production requirements.

Evaluation of Mouth Dissolving Films

The physical characterization of Mouth Dissolving Films (MDFs) can be performed through visual inspection, evaluating attributes such as colour, thickness, brittleness, surface smoothness, and the film's ability to form properly.[16] Prepared films were further subjected to *in vitro* evaluation, assessing parameters such as uniformity of weight, film thickness, pH, water content, folding endurance, disintegration time, and percentage drug content and the dissolution studies/rate.[17-20]

Description

Films were taken in a Petri dish or on white paper and observed for transparency and smoothness.

Uniformity of weight

The weight of individual films (2 x 2 cm^2) was taken and marked on the strips, which had a variation to the maximum and minimum from the average weight, and calculated the % of deviation.

Thickness

The thickness of the films was calculated using a screw gauge at multiple points in the corners and in the centre.

Surface pH

Surface pH of strips of all formulations has been checked, and results were recorded in Table 2 for all formulations.

Folding endurance

Folding endurance test was performed to verify the brittleness of the strips. Folding endurance of the films were determined by repeatedly folding the film of size (2x2 cm^2) at the same time till it breaks. Folding endurance of all formulations was recorded in Table 2.

Water content

Water content of films of all formulations has been checked by KF apparatus.[21]

Disintegration time

Disintegration time of all strips was checked in petri dish. 2-4 mL of water was taken in each petri dish and added one strip in each petridish on the surface of water and rotated the dish horizontally until the sliced film is dissolved.[22]

Percentage drug content

Percent drug content (assay) of drug in a mouth dissolving film was determined using high-performance liquid chromatographic analysis. A C18 column with dimensions of 250 × 4.6 mm and a particle size of 5 µm was used for separation. The mobile phase was pumped through the system at a flow rate of 1.5 mL per minute, and a sample volume of 10 µL was injected each time. The detection of the drug was carried out at a wavelength of 226 nm. Throughout the analysis, the column temperature was maintained at 25°C to ensure consistent and reliable results.

Mobile phase: (Buffer-1: Acetonitrile -75:25)

Buffer 1

Dissolved 0.97 g dibutyl amine, 0.735 g phosphoric acid and 2.93 g sodium dihydrogen phosphate in 750 mL of water, pH of this solution is adjusted to 6.5 with sodium hydroxide solution. After pH adjustment solution was diluted to 1000 mL with water.

Diluent: (Buffer-2: Acetonitrile-75:25).

Buffer 2

Dissolved 2.925 g of sodium dihydrogen phosphate in 600 mL of water, pH of this solution adjusted to 6.5 with sodium hydroxide solution. After pH adjustment this solution diluted to 750 mL with water. Then 250 mL of Acetonitrile was added to this solution.

Blank: Diluent.

- **Standard solution:** 15 mg of Sumatriptan Succinate standard was dissolved in 100 mL volumetric flask with diluent and diluted to 100 mL with diluent.
- **Test preparation:** Test sample equivalent to 15 mg of Sumatriptan was dissolved in 100 mL volumetric flask with diluent. After sonication for about 10 min, solution was diluted to 100 mL volumetric flask.
- **System Suitability:** % RSD of Standard achieved as 0.60% (Acceptance Criteria: NMT 2.0%).

In vitro drug release study

Dissolution was performed on USP Type-1 apparatus (basket).[23] Oral mouth dissolving films of size 2 x 2 cm^2 were taken in the dissolution basket containing 900 mL of pH 6.8 Phosphate buffer (maintained at 37±0.5°C) and RPM set as 100. Sample for dissolution analysis was taken after every 2 min and same amount was replaced with fresh dissolution medium (pH 6.8 Phosphate buffer). Withdrawn samples were filtered and analysed on UV

spectrophotometer at 226 nm wavelength (λ_{max} of Sumatriptan Succinate).

Stability Studies

- **Storage conditions:** Stability testing was carried out under accelerated conditions to ensure the films maintain the physical and chemical characteristics of drug.[24]
- **Shelf life:** The stability of the drug and the film's physical properties like dissolution, physical appearance, and mechanical strength over time are monitored.[25]

RESULTS AND DISCUSSION

Determination of absorbance maxima of sumatriptan succinate

The absorbance of drug in the pH 6.8 phosphate buffer was observed at λ_{max} of 226 nm against the blank on UV-visible spectrophotometer.

Preparation of Calibration Curve

The graph of absorbance vs concentration for Sumatriptan was found to be linear in the concentration range of 10 - 50 µg/mL. The graph of absorbance vs concentration for Sumatriptan was found to be linear in the concentration range of 10 - 50 µg/mL in the pH 6.8 phosphate buffer. The drug obeys Beer-Lambert's law in the range of 10 - 50 µg/mL.

FTIR Studies

As shown in Figure 2, it was evident that the IR characteristic peaks of Sumatriptan Succinate at 2962.54, 3211.79, 3733.6 cm^{-1} were prominent, indicating the authenticity of the molecule.

The FTIR analysis of drug and excipients indicates that there are no significant interactions because the characteristic absorption band of Sumatriptan succinate remains unchanged. The characteristic peaks show the presence of secondary amine, aromatic and aliphatic groups, and sulphonide group.

Evaluation of Mouth Dissolving Films

In the initial stage of development, various formulations (without the active pharmaceutical ingredient, API) were tested to assess preliminary criteria for Mouth Dissolving Films (MDFs), including physical appearance, surface roughness, and colour uniformity. Based on these trials, a total of 9 formulations (F1-F9) were selected for further evaluation with the API. All of these formulations were evaluated for their physicochemical

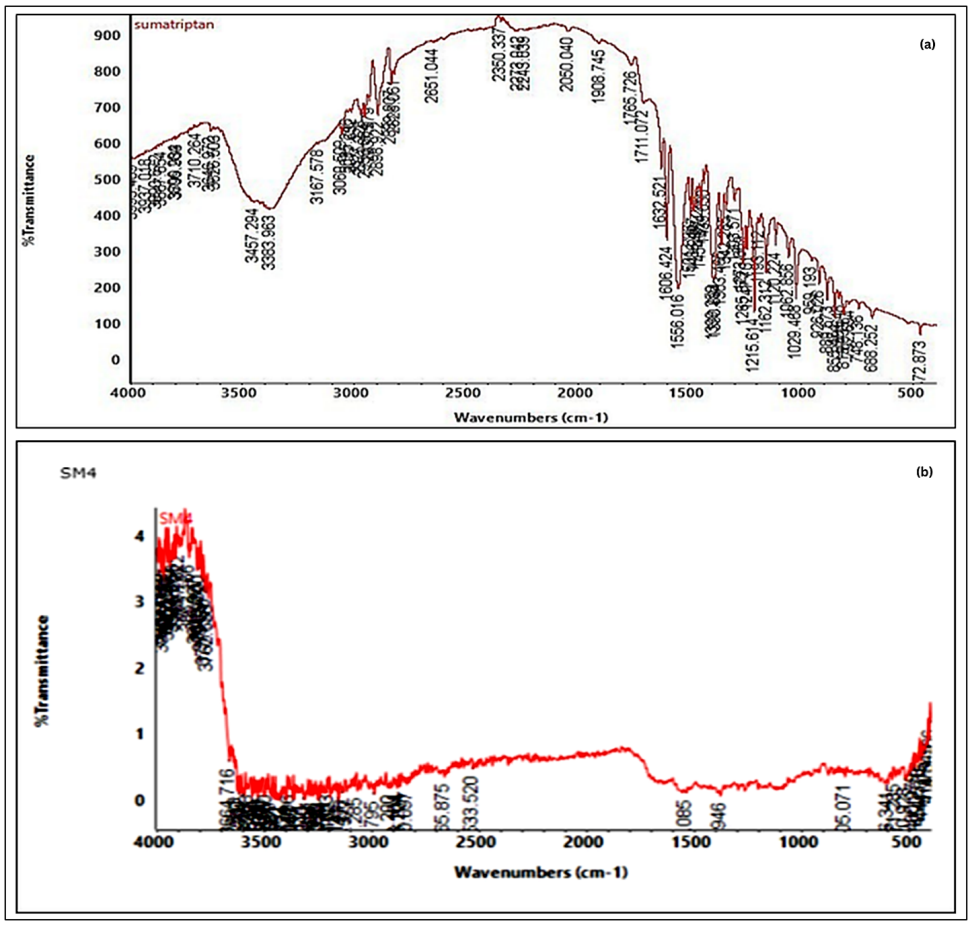

Figure 1: Shows FTIR of (a) Sumatriptan succinate and (b) Sumatriptan succinate with excipients.

Table 1: Compositions of mouth dissolving film formulations of sumatriptan succinate.

Ingredients (mg)	F-1	F-2	F-3	F-4	F-5	F-6	F-7	F-8	F-9
Sumatriptan (mg)	125	125	125	125	125	125	125	125	125
Methocel E-15 LV Premium (mg)	200	250	300	300	300	300	300	300	300
Glycerin (mL)	1	1	1	1	1	1	1	1	1
Sucralose (mg)	10	10	10	10	10	10	10	10	10
Polacrilin Potassium (mg)	--	--	--	12.5	15	17.5	20	22.5	25
Sodium Benzoate (mg)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Dry Flavor Strawberry (mg)	2	2	2	2	2	2	2	2	2
Water (mL)	25	25	25	2	2	25	25	25	25
Citric Acid Monohydrate (mg)	15.6	15.6	15.6	15.6	15.6	15.6	15.6	15.6	15.6

Table 2: Observation table of physical parameters of formulated mouth dissolving films.

Test Name	F1	F2	F3	F4	F5	F6	F7	F8	F9
Uniformity of weight (%)	Min.: 6.24%, Max.: 4.69%	Min.: 4.17%, Max.: 5.62%	Min.: 5.34%, Max.: 5.12%	Min.: 4.76%, Max.: 5.47%	Min.: 7.44%, Max.: 5.38%	Min.: 6.22%, Max.: 6.13%	Min.: 5.96%, Max.: 4.55%	Min.: 1.95%, Max.: 2.13%	Min.: 1.23%, Max.: 1.17%
Film thickness (mm)	0.062±0.008	0.067±0.009	0.071±0.007	0.063±0.006	0.068±0.008	0.070±0.006	0.064±0.007	0.063±0.004	0.064±0.003
Surface pH	6.1±0.02	6.2±0.02	6.2±0.03	6.1±0.02	6.1±0.05	6.3±0.02	6.5±0.02	6.6±0.02	6.6±0.03
Folding endurance (no.)	103±2	104±2	104±1	103±1	107±1	106±2	109±1	111±0	111±1
Water content (wt.%)	13.6	13.5	13.5	13.1	13.4	13.1	12.8	12.6	12.7
Disintegration time (seconds)	36-50	32-48	30-36	36-46	28-46	26-34	24-36	12-21	9-17

properties, as they met the initial criteria for MDFs, such as smooth appearance, even surfaces, good film-forming ability, and ease of handling, making them suitable for further testing.

- **Description:** All films of formulations F1 to F9 were found to have even colour and size.
- **Uniformity of weight:** The result obtained for uniformity of weight is recorded in below, mentioned Table 2.
- **Thickness:** The Thickness of strips of all four formulations was found satisfactory and recorded in Table 2.
- **Surface pH:** Surface pH of strips of all formulations has been measured and results are recorded in below Table 2 for all formulations.
- **Folding endurance:** The Folding endurance of all four formulations was found satisfactory and recorded in Table 2.

Water content (by Karl Fischer titration)

The water content of films of all formulations has been checked by Karl Fischer apparatus and found satisfactory, and the water content values were recorded in Table 2.

Disintegration time Disintegration times of all formulations were found satisfactory and mentioned in Table 2.

Percentage drug content (assay) and *in vitro* drug dissolution studies

The percentage drug content (assay) was conducted for all the formulations (F1 to F9) shown in Figure 2.

Based on the chromatograms, formulations F8 and F9 exhibited the highest percentage of drug content (assay) and uniformity as compared to formulations F1 to F7.

In vitro drug release study

Results of *in vitro* drug release compiled in Figure 3 below:

Drug release kinetics analysis

To determine the best-fitting model and release mechanism, kinetic models were applied to the release model. Using DD solver®, a Microsoft® Excel-based add-in application, the release data of all the formulations was assessed for Higuchi, zero order, first order, Hixon Crowell, as shown in Table 3.

Whereas:

- k_0/ k1/ kH/ Kkp/ kHC are the rate constants of the respective models.
- R^2 tells you how well the kinetics models fit your data.
- MSE measures how far your predicted values are from the actual ones.

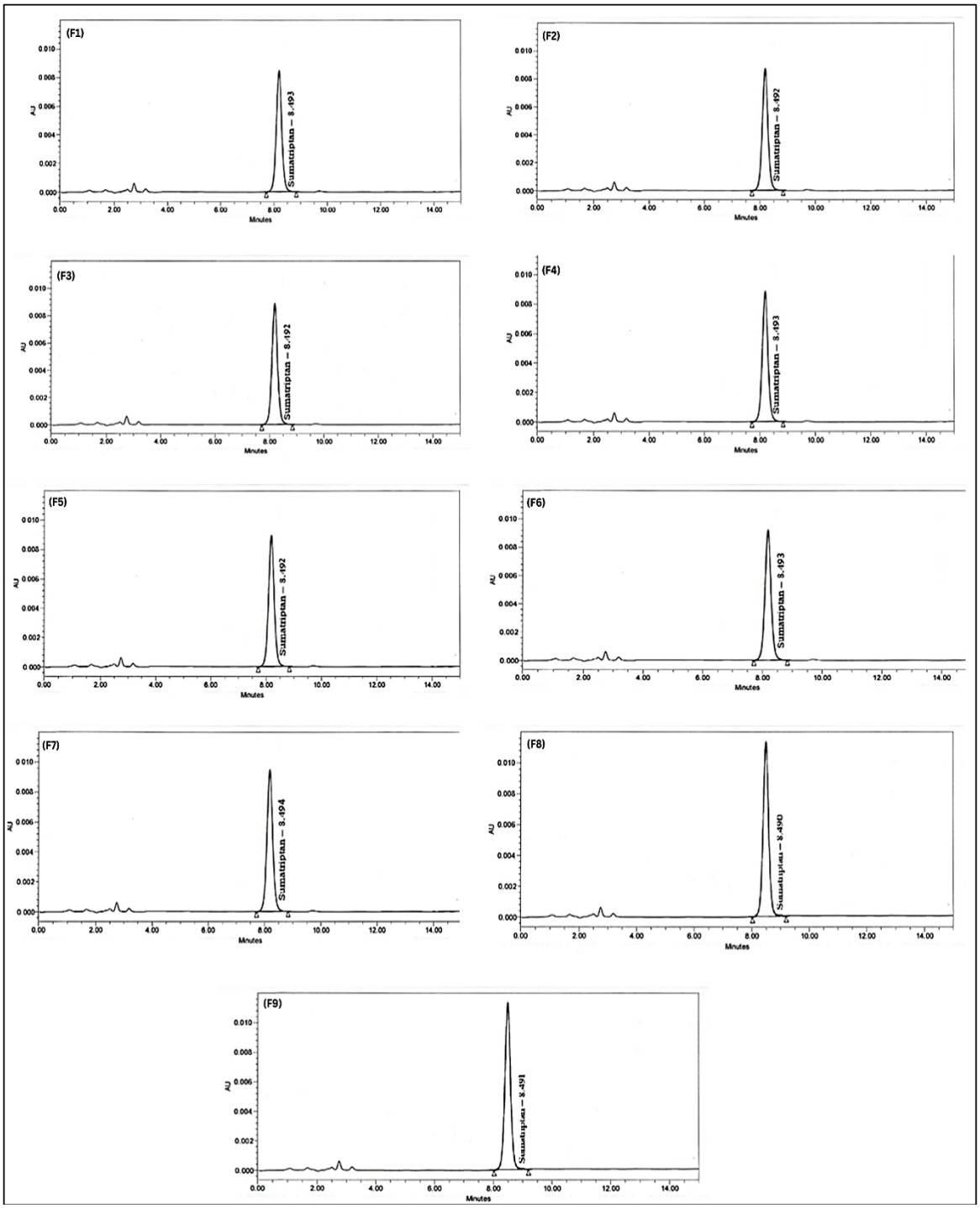

Figure 2: Chromatogram of MDF formulations of sumatriptan succinate (F1-F9). The assay results for formulations F1 to F7 were found to be on the lower side, ranging from 75.5% to 90.7%. Whereas the assay results for formulations F8 and F9 demonstrated nearly uniform drug content 4 i.e. approx. 100.9% and 101.8% respectively.

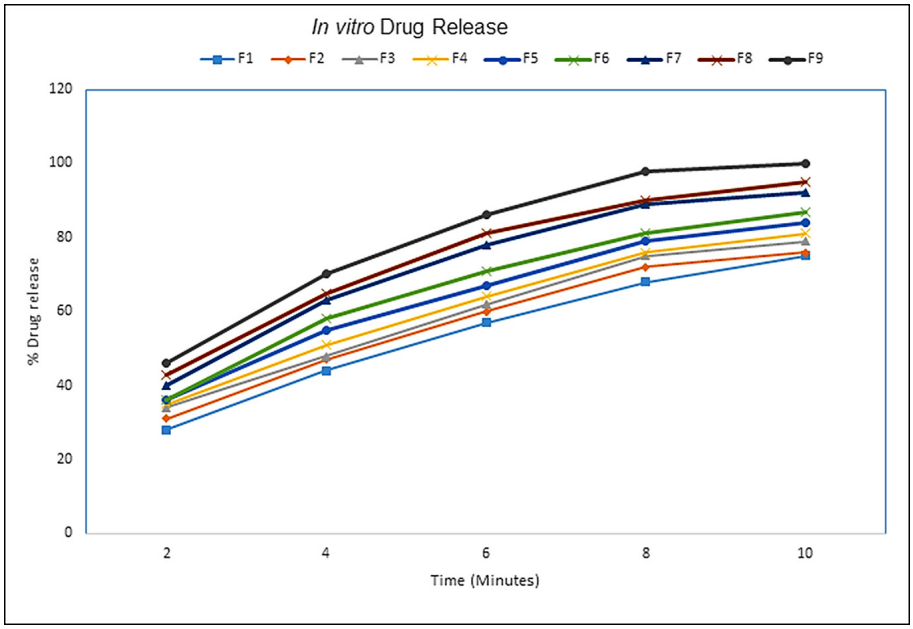

Figure 3: In vitro drug release of sumatriptan succinate MDF formulations (F1-F9).

- WSS can give a weighted sum of squared deviations, sometimes more sensitive to data variation.
- AIC helps select the best-fitting model by balancing goodness-of-fit and model complexity.

The coefficient of correlation (R^2) in zero order for each formulation had lower values, as shown by the results in Table 3. These values were less than those of every other model, including the Higuchi, Korsmeyer-Peppas, Hixson-Crowell, and first-order models. Thus, there was no time dependence in the medication release. However, R^2 values of all formulations had first-order kinetics greater than 0.9, which suggests concentration-dependent release.

In all formulations, the Higuchi model's data plots showed high R^2 values of greater than 0.9. Therefore, it can be said that the drug release diffusion mechanism was followed almost. Data fitting for the Hixon-Crowell model similarly produced regression and correlation coefficient R^2 values for each formulation that were greater than 0.9, suggesting a time-dependent change in the formulations' surface area.

Stability studies

Because of its high cumulative percentage of drug release and it's *in vitro* disintegration time results, the F9 formulation was chosen for stability testing. In accordance with ICH recommendations, stability studies were carried out under various circumstances. Based on these findings, it was determined that formulation F9 is stable and has mostly maintained its original characteristics.

The accelerated stability study of the optimized formulation (F9) showed that the formulation remained stable over time. Its appearance stayed clear and transparent throughout the study, indicating no visible changes. The disintegration time was 15 sec in the first week and slightly increased to 16 sec in the following weeks, after which it remained constant up to 45 days. The drug content was found to be 101% in the first week and then stabilized at 100% from the second week onwards. Overall, these results suggest that the formulation maintained its quality and performance under accelerated stability conditions.

The formulated Sumatriptan Succinate mouth dissolving film meets standard Pharmacopoeial requirements and compares favourably with other reported formulations in terms of drug release, mechanical integrity, and patient compliance factors. These findings support the film's potential for both clinical use in acute migraine therapy and commercial development as a novel, patient-centric drug delivery system. Although Sumatriptan MDFs are not yet widely available in commercial markets, the current formulation has demonstrated comparable or superior performance to existing fast-dissolving tablets in terms of disintegration and onset of action potential. This suggests that MDFs may offer a competitive edge in terms of patient convenience and therapeutic efficacy. Fast-disintegrating formulations of sumatriptan (50/100 mg) showed more rapid efficacy and lower headache recurrence than conventional tablets and placebo. Mouth-dissolving thin films of sumatriptan succinate show much faster dissolution/disintegration, earlier t_{max} (~15 min), and higher bioavailability vs conventional tablets. Marketed fast-release tablets provide improved speed over conventional formats but still fall short of sublingual film performance. Although direct head-to-head clinical trials of films vs marketed tablets are limited, evidence strongly suggests films could offer superior onset and patient experience. Sumatriptan core physical parameters and dissolution behaviour have been well evaluated. Nonetheless, a comparative *in vitro* release study with a marketed

Table 3: Kinetics modelling of dissolution data of formulated mouth dissolving films.

Kinetic Models		F1	F2	F3	F4	F5	F6	F7	F8	F9
Zero Order	k0	8.491	8.845	9.191	9.436	9.845	10.218	11.055	11.373	12.145
	R^2	0.7488	0.6230	0.5842	0.5252	0.4784	0.4795	0.3695	0.2686	0.2245
	MSE	89.2455	129.186	146.495	167.277	195.436	215.132	288.336	326.359	390.836
	WSS	356.982	516.745	585.982	669.110	781.745	860.527	1153.35	1305.43	1563.34
	AIC	31.3884	33.2378	33.8664	34.5297	35.3076	35.7877	37.2521	37.8715	38.7729
First Order	k1	0.143	0.156	0.168	0.178	0.195	0.212	0.255	0.276	0.325
	R^2	0.9920	0.9796	0.9718	0.9768	0.9857	0.9969	0.9972	0.9964	0.9726
	MSE	2.8576	6.9879	9.9267	8.1744	5.3558	1.2790	1.2626	1.6254	13.8275
	WSS	11.4305	27.9517	39.7069	32.6977	21.4232	5.1160	5.0503	6.5017	55.3101
	AIC	14.1814	18.6524	20.4076	19.4365	17.3224	10.1618	10.0973	11.3603	22.0648
Higuchi Model	kH	23.224	24.293	25.263	25.979	27.137	28.168	30.543	31.473	33.637
	R^2	0.9738	0.9814	0.9839	0.9917	0.9901	0.9833	0.9716	0.9758	0.9645
	MSE	9.3116	6.3778	5.6845	2.9397	3.6979	6.8908	12.9646	10.8035	17.9136
	WSS	37.2463	25.5113	22.7380	11.7587	14.7918	27.5632	51.8583	43.2141	71.6543
	AIC	20.0878	18.1956	17.6202	14.3230	15.4704	18.5824	21.7426	20.8308	23.3593
Korsmeyer -Peppas Model	Kkp	19.068	21.893	23.335	24.828	26.509	27.448	31.125	33.319	36.079
	R^2	0.9964	0.9888	0.9884	0.9932	0.9906	0.9839	0.9720	0.9789	0.9693
	MSE	1.6906	5.1109	5.4478	3.1723	4.7105	8.8912	17.0977	12.5599	20.6598
	WSS	5.0719	15.3328	16.3434	9.5168	14.1314	26.6736	51.2932	37.6798	61.9795
	AIC	12.1186	17.6500	17.9691	15.2653	17.2420	20.4184	23.6878	22.1456	24.6340
Hixson-Crowell Model	kHC	0.041	0.044	0.047	0.049	0.053	0.057	0.068	0.073	0.085
	R^2	0.9603	0.9289	0.9215	0.9184	0.9281	0.9510	0.9733	0.9738	0.9909
	MSE	14.1222	24.3502	27.6510	28.7591	26.9306	20.2593	12.2281	11.6871	4.6015
	WSS	56.4886	97.4008	110.604	115.037	107.726	81.0374	48.9124	46.7486	18.4060
	AIC	22.1702	24.8942	25.5298	25.7262	25.3978	23.9746	21.4502	21.2239	16.5634

or conventional sumatriptan formulation would strengthen the formulation's performance assessment. Acceptability is generally high, especially for patients needing rapid relief without water or swallowing difficulties.

CONCLUSION

During this study, systemic approach was used to prepared the Mouth Dissolving film of Sumatriptan Succinate by using solvent casting method with varying composition of different polymers like HPMC E15 (film forming agent), Glycerine (plasticizer), and super disintegrating agent like Polacrilin Potassium are used as super disintegrating agent. All the nine formulations have good and smooth appearance but formulation F9 was considered as best formulation due to high drug content of 101.8%, a disintegration time between 9-17 sec, folding endurance of 111 and 100% drug release. In all formulations, the Higuchi model's data plots showed high R^2 values of greater than 0.9. Therefore, it can be said that the drug release diffusion mechanism was followed almost.

Mouth dissolving films are used as an alternative route for those drugs which shows poor bioavailability in oral conventional route. Total Nine formulations have been prepared by solvent casting technique, All the formulations showed good physical characteristics and good release. Formulation F9 was observed as optimized formulation for Sumatriptan Succinate in comparison to other formulations due to better mechanical properties and highest percentage of drug content (assay). The formulation F9 shows disintegration time of 9-17 sec and the drug content was 100%. The present study concludes that Sumatriptan succinate can be given in form of mouth dissolving films using super disintegrating agent with better and faster release with better patient compliance.

The formulation and evaluation of a Mouth Dissolving Film (MDF) of Sumatriptan Succinate showed promising results in terms of rapid disintegration time, uniform drug content, mechanical strength, and improved drug release profile. These characteristics indicate that the MDF is well-suited for the acute management of migraine, where fast onset of action is critical. Clinically, this

formulation offers a significant advantage for migraine patients who often experience vomiting, making it difficult to swallow conventional tablets. The MDF bypasses the need for water and allows for pre-gastric absorption, potentially reducing the onset time. From a commercial perspective, Sumatriptan Succinate mouth-dissolving films present a valuable opportunity to meet the unmet needs of migraine sufferers and improve patient compliance. The formulation process is cost-effective and scalable, making it viable for large-scale production.

ABBREVIATIONS

API: Active Pharmaceutical Ingredient; **AIC:** Akaike Information Criterion; **BCS:** Biopharmaceutics Classification System; **FTIR:** Fourier Transform Infrared Spectroscopy; **HPMC:** Hydroxypropyl Methylcellulose; **HPMC E15:** Hydroxypropyl Methylcellulose E15 Grade; **ICH:** International Council for Harmonisation; **IR:** Infrared; **KF:** Karl Fischer; **MDF:** Mouth Dissolving Film; **MSE:** Mean Squared Error; **ODF:** Oral Dissolving Film; **pH:** Potential of Hydrogen; **R^2:** Coefficient of Determination; **RSD:** Relative Standard Deviation; **SDI:** Super Disintegrating Agent; **USP:** United States Pharmacopeia; **UV:** Ultraviolet; **WSS:** Weighted Sum of Squares.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

SUMMARY

This study was designed to create and test Mouth-Dissolving Films (MDFs) of Sumatriptan Succinate, aimed at providing faster relief for migraine sufferers. Since traditional oral tablets of Sumatriptan Succinate have poor bioavailability (due to the first-pass metabolism), developing a film that dissolves quickly in the mouth could offer quicker absorption and improved patient comfort, especially for those who have difficulty swallowing or fast action is required without the need for water. Nine different formulations were prepared using HPMC E15 as the film-forming polymer, Glycerine as a plasticizer, and Polacrilin Potassium as a super disintegrant. After evaluating all the formulations, Formulation F9 was found to be the best formulation because

Of excellent drug content of 101.8%, fast disintegration time of (9-17 sec), and complete drug release of 100% (10 min). Additionally, drug release studies showed that the films followed first-order kinetics, meaning the release rate depended on how much drug was still available. The stability testing confirmed that F9 remained physically stable and effective over time.

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