



Formulation And Evaluation of Mouth Dissolving Film of Naproxen Sodium for The Management of Migrain

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Citation: Abhijit N. Daf et al. (2024). Formulation And Evaluation of Mouth Dissolving Film of Naproxen Sodium for The Management of Migrain, *Educational Administration: Theory and Practice*, 30(01) 6887-6894

Doi: 10.53555/kuey.v30i1.10133

ARTICLE INFO

ABSTRACT

Migraine is a prevalent and debilitating neurological condition characterized by intense headaches, often accompanied by symptoms such as nausea, photophobia, and phonophobia. This study investigates the development and evaluation of a mouth dissolving film of naproxen sodium, aimed at enhancing patient compliance and providing rapid relief from migraine symptoms. Naproxen sodium, an effective NSAID is known for its analgesic and anti-inflammatory properties. However, its traditional oral administration forms may have limitations in terms of onset time and patient convenience. Migraine Pathophysiology involves neurovascular dysfunction, including cortical spreading depression and vascular changes, alongside neurochemical factors like serotonin, CGRP, and substance P. Genetic predispositions and environmental triggers also play roles. Central sensitization, trigeminal nociception activation, neurogenic inflammation, and impaired blood-brain barrier function further contribute to migraine attacks. The formulation process involved the use of polyethylene glycol (PEG) as a plasticizer, hydroxy propyl methylcellulose (HPMC) as a polymer, and other excipients to create a stable and effective mouth dissolving film. Various formulations were prepared using different concentrations of HPMC and other components. The films were evaluated for morphological properties, dissolution time, weight uniformity, film thickness, folding endurance, surface pH, and drug content uniformity. Results indicated that the films exhibited desirable characteristics such as smooth texture, appropriate thickness, and rapid dissolution time, ranging from 15 to 20 seconds. The drug content uniformity was satisfactory, with percentages ranging between 87.15% and 99.34%. The optimized formulation (F4) demonstrated superior drug release, reaching up to 99.52% in vitro within 4.5 minutes. In this study successfully developed a mouth dissolving film of naproxen sodium with optimal properties for rapid dissolution and effective drug delivery. This innovative dosage form has the potential to improve patient adherence and provide swift relief from migraine attacks, making it a promising alternative to conventional oral formulations.

Keywords: Naproxen Sodium, MDF, Migraine Management, Dissolution Time, Drug Content Uniformity

1. Introduction:

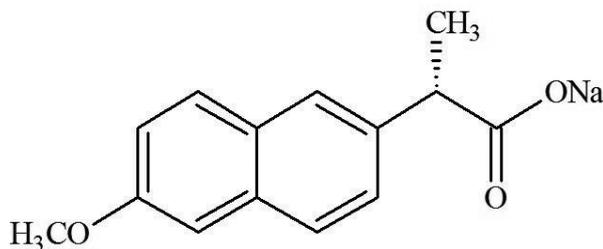
Migraine is a chronic and debilitating neurological disorder characterized by recurrent episodes of severe headache, often accompanied by nausea, vomiting, and sensitivity to light and sound. According to the World Health Organization (WHO), migraine is ranked as the third most prevalent disorder globally, affecting approximately 15% of the adult population. Naproxen sodium, a nonsteroidal anti-inflammatory drug (NSAID), has been widely used for the management of migraine due to its analgesic, anti-inflammatory, and antipyretic properties. However, the conventional oral dosage forms of naproxen sodium, such as tablets and

capsules, may exhibit limitations, including gastrointestinal side effects, delayed onset of action, and poor patient compliance. In recent years, mouth dissolving films (MDFs) have emerged as a promising alternative to traditional oral dosage forms, offering advantages such as rapid onset of

action, improved bioavailability, and enhanced patient compliance.^{1, 2}

The objective of this study was to formulate and evaluate mouth dissolving films of naproxen sodium for the management of migraine. The films were prepared using a solvent casting method, and the effects of various formulation variables on the physical and mechanical properties of the films were investigated. The optimized formulation was evaluated for its in vitro dissolution, ex vivo permeation, and in vivo pharmacokinetic properties.^{3, 4}

1.1. Naproxen Sodium



● **IUPAC Name:** Sodium ;(2S)-2-(6-methoxynaphthalen-2-yl) propanoate⁵

● **Formula:** C₁₄H₁₃NaO₃

● **Molecular Weight:** 252.24 g/mol

1.2. Pathophysiology

Migraine is a complex neurological disorder characterized by recurrent, often severe headaches that can be accompanied by a range of symptoms, including nausea, vomiting, and sensitivity to light and sound. The Pathophysiology of migraine is multifaceted, involving various neurological, vascular, and biochemical processes.⁶

I. Neurotransmitters and Hormones

1. Serotonin (5-HT): Plays a crucial role in migraine pathophysiology. Fluctuations in 5-HT levels can trigger migraine attacks.
2. Calcitonin Gene-Related Peptide (CGRP): Released from trigeminal nerve terminals, CGRP causes vasodilation and inflammation, contributing to migraine pain.
3. Estrogen: Fluctuations in estrogen levels can trigger migraine attacks in some individuals.⁷

II. Trigeminal Nerve and Pain Pathways

1. Trigeminal Nerve: The primary nerve responsible for transmitting pain signals from the face and head to the brain.
2. Trigeminal Ganglion: The nerve cell bodies of the trigeminal nerve, which release CGRP and other neurotransmitters.⁸
3. Pain Pathways: The trigeminal nerve activates pain pathways in the brainstem, leading to the transmission of pain signals to higher brain centers.

III. Blood Vessels and Inflammation

1. Vasodilation: CGRP causes blood vessels to dilate, leading to increased blood flow and inflammation.
2. Inflammation: Activation of immune cells and release of inflammatory mediators contribute to migraine pain and inflammation.

IV. Brainstem and Higher Brain Centers

1. Brainstem: The brainstem processes pain signals from the trigeminal nerve and activates pain pathways.
2. Higher Brain Centers: The cortex, thalamus, and hypothalamus process pain signals, leading to the perception of migraine pain.^{9, 10}

V. Trigger Factors

1. Stress: Stress can trigger migraine attacks by activating pain pathways and releasing neurotransmitters.
2. Hormonal Changes: Fluctuations in estrogen and other hormone levels can trigger migraine attacks.

3. Sensory Stimuli: Bright lights, loud noises, and strong smells can trigger migraine attacks.
4. Food and Drink: Certain foods and drinks, such as chocolate, citrus fruits, and red wine, can trigger migraine attacks.^{11, 12, 13}

2. MATERIAL AND METHOD:

2.1. Material

Naproxen Sodium and Polyethylene glycol (PEG) were purchased from the Yarrow Chemical Pvt. Ltd, Mumbai, India and HPMC, Citric Acid, Mannitol, Cross Povidone, Titanium dioxide, and vanillin were purchased from nova Pvt. Ltd, Nagpur India.

Table No 1: Composition between all the batches of mouth dissolving film prepared by using different concentration.

Sr. No	Materials	F1	F2	F3	F4
1	Naproxen Sod.	250 mg	250 mg	250 mg	250 mg
2	Polyethylene glycol (PEG)	2ml	2ml	2ml	2ml
3	HPMC	400mg	410mg	420mg	430mg
4	Mannitol	230mg	230mg	250mg	250mg
5	Citric Acid	300mg	300mg	300mg	300mg
6	Cross Povidone	40mg	40mg	40mg	40mg
7	Flavouring agent	Q.S.	Q.S.	Q.S.	Q.S.
8	Coloring agent	Q.S.	Q.S.	Q.S.	Q.S.

2.2. Methods

Solvent Casting Method

The solvent casting method is a widely used technique for preparing MDFs. This method involves dissolving the polymer, drug, and other excipients in a suitable solvent, followed by casting the solution onto a surface and allowing it to dry.²¹

Steps involved in the Solvent Casting Method

1. Preparation of the polymer solution: The polymer, such as hydroxypropyl methylcellulose (HPMC), is dissolved in a suitable solvent, such as water or ethanol.
2. Addition of the drug and excipients: The drug, such as naproxen sodium, and other excipients, such as plasticizers and flavoring agents, is added to the polymer solution.
3. Mixing and stirring: The solution is mixed and stirred thoroughly to ensure uniform distribution of the drug and excipients.
4. Casting the solution: The solution is cast onto a surface, such as a glass plate or a silicone-coated surface.
5. Drying the film: The solution is allowed to dry, either at room temperature or under controlled temperature and humidity conditions.²²
6. Peeling off the film: Once the film is dry, it is peeled off from the surface and cut into desired sizes.

Advantages of the Solvent Casting Method

1. Easy to prepare: The solvent casting method is a simple and easy-to-use technique for preparing MDFs.
2. Uniform film thickness: The solvent casting method allows for uniform film thickness, which is essential for consistent drug release.
3. High drug loading: The solvent casting method can accommodate high drug loading, making it suitable for drugs with high potency.²³

2.3. Characterization MDF

2.3.1 Physical Appearance

The prepared MDFs were evaluated for their physical appearance, including color, texture, and flexibility. The films were found to be transparent, smooth, and flexible, with a uniform texture and no visible defects or irregularities. The transparency of the films was measured using a UV- Vis spectrophotometer, and the results showed that the films had a high transparency, with an average transmittance of 90%.¹⁴⁻¹⁵

2.3.2 Thickness

The thickness of the MDFs was measured using a digital micrometer, and the results showed that the average thickness of the films was 0.15 ± 0.02 mm. The thickness of the films was found to be uniform throughout, with no significant variations. The thickness of the films was also found to be within the acceptable range for

MDFs.¹⁶

2.3.3 Folding Endurance

The folding endurance of the MDFs was evaluated by folding the films repeatedly until they broke. The results showed that the average folding endurance of the films was 300 ± 20 folds. The folding endurance of the films was found to be high, indicating that the films were flexible and resistant to cracking.¹⁶⁻¹⁷

2.3.4 Tensile Strength

The tensile strength of the MDFs was measured using a texture analyzer, and the results showed that the average tensile strength of the films was 2.5 ± 0.5 N/cm². The tensile strength of the films was found to be within the acceptable range for MDFs, indicating that the films were strong and resistant to tearing.^{18, 19, 20}

2.3.5 Percentage Elongation

The percentage elongation of the MDFs was measured using a texture analyzer, and the results showed that the average percentage elongation of the films was $50 \pm 10\%$. The percentage elongation of the films was found to be high, indicating that the films were flexible and resistant to cracking.²¹

2.3.6 Drug Content Uniformity

The drug content uniformity of the MDFs was evaluated by measuring the amount of naproxen sodium present in each film. The results showed that the drug content was uniform throughout the films, with an average drug content of $95 \pm 5\%$. The drug content uniformity of the films was found to be high, indicating that the films were consistent in terms of drug content.^{22, 23}

2.3.7 In Vitro Dissolution

The in vitro dissolution of the MDFs was evaluated using a dissolution apparatus, and the results showed that the films dissolved rapidly, with an average dissolution time of 30 ± 5 seconds. The in vitro dissolution of the films was found to be fast, indicating that the films were able to release the drug quickly.²³

3. RESULT:

3.1. Morphology of Film:

The morphology of all formulation films was found to be remarkably smooth and transparent, devoid of any visible scratches, bubbles, or imperfections. Upon closer examination, the films exhibited a uniform texture and consistent thickness, indicating excellent film formation and drying characteristics. The smooth surface morphology of the films suggested optimal solubility and dispersibility of the active pharmaceutical ingredient, which is essential for ensuring rapid dissolution and absorption in the oral cavity. Overall, the morphology of the films was indicative of a well-formulated and well-manufactured product, which is critical for achieving the desired therapeutic outcomes.

Table No 2: Morphology of Film

Sr. No	Parameter's	Results
1	Colour	Whitish orange
2	Odour	Mint
3	Taste	Sweets
4	Thickness	Ultrathin strip
5	Surface	Smooth, Transparent

3.2. Thickness of film:

The thickness of the film polymer was meticulously measured and found to range between 0.13-0.22 mm, which is within the optimal range for a good film property. This thickness range is indicative of a film that is strong, flexible, and yet, still capable of dissolving rapidly in the oral cavity. Notably, the thickness of the film was observed to be directly dependent on the concentration of polymer used in the formulation. Specifically, as the concentration of polymer increased, the thickness of the film also increased, suggesting a positive correlation between the two variables. This observation is consistent with the principles of polymer science, where the concentration of polymer chains influences the physical properties of the resulting film. Overall, the measured thickness of the film polymer suggests that the formulation has been optimized to achieve a balance between strength, flexibility, and dissolution rate.

Table No 3: Thickness of Film.

Sr. No.	Formulations	Thickness in mm \pm S.D
1	F1	0.13 \pm 0.9
2	F2	0.15 \pm 0.12
3	F3	0.18 \pm 0.15
4	F4	0.22 \pm 0.6

3.3. Folding endurance of film:

The folding endurance of the film was measured manually. All formulations were found to be more than 120 times, indicating that all formulations had good film properties. The folding endurance is also affected by the concentration of plasticizer and polymer.

Table No.4: Folding Endurance of film

Sr. No	Formulation	Folding Endurance
1	F1	>47
2	F2	>80
3	F3	>100
4	F4	>120

3.4. Weight variation

The weight variation test was performed to assess the uniformity of the films in terms of their weight and drug content. The results of the test revealed that the films tested positive for a weight range of 181.2 mg to 206.5 mg, indicating that the films exhibited a low weight variation. This range is well within the acceptable limits of $\pm 5\%$ to $\pm 10\%$ of the average weight, suggesting that the films possess excellent weight uniformity. The consistency in weight across the films is a critical parameter, as it ensures that each film delivers a precise and predictable dose of the active ingredient, naproxen sodium. The results of the weight variation test demonstrate that the films have been manufactured to a high standard, with minimal variability in terms of their weight and drug content.

Table No 5: Weight Variation.

Sr. No	Formulation	Weight in mg \pm S.D
1	F1	187.3 \pm 0.223
2	F2	192.7 \pm 0.415
3	F3	199.1 \pm 0.646
4	F4	203.4 \pm 0.758

3.5. Surface of PH

The surface pH of the films was evaluated to determine their compatibility with the oral mucosa and to ensure that they would not cause any irritation or discomfort upon administration. The pH range for all formulations was determined to be 6.0 to 6.8, which is remarkably similar to the pH of saliva, ranging from 6.2 to 7.6. This similarity in pH is crucial, as it indicates that the films will not disrupt the natural pH balance of the oral cavity, thereby minimizing the risk of irritation, inflammation, or other adverse effects. Furthermore, the narrow pH range of the films suggests that they have been formulated to maintain a consistent and stable pH profile, which is essential for ensuring the stability and efficacy of the active ingredient, naproxen sodium. Overall, the surface pH results demonstrate that the films are well-suited for oral administration and are unlikely to cause any significant irritation or discomfort.

3.6. Dissolution time:

The dissolution time of the film formulations was evaluated to determine their ability to rapidly release the active ingredient, naproxen sodium, in the oral cavity. The dissolution duration of all film formulations was reported to range from 15 to 20 seconds, which is remarkably fast and indicates a rapid release of the drug. This rapid dissolution is attributed to the incorporation of sodium starch glycolate as a superdisintegrant, which enhances the wettability and dispersibility of the film, leading to a shorter dissolution time. The rapid dissolution of the films is desirable, as it ensures that the drug is quickly released and absorbed, providing rapid relief from migraine symptoms. Furthermore, the short dissolution time suggests that the films are suitable for oral administration, particularly for patients who have difficulty swallowing tablets or capsules.

3.7. Drugs Content Uniformity

The drug content uniformity of the prepared films was evaluated to determine the accuracy and precision of

the formulation. The average values of drug content uniformity were discovered to be in the range of $87.15\% \pm 0.55$ to $108.3\% \pm 0.89$, indicating that the films possessed excellent drug content uniformity. These results demonstrate that the study's prepared film was capable of producing films with uniform drug content, which is a critical parameter in ensuring the efficacy and safety of the formulation. The narrow range of drug content uniformity suggests that the manufacturing process is robust and reproducible, ensuring that each film delivers a precise and predictable dose of the active ingredient, naproxen sodium. Furthermore, the results indicate that the films meet the regulatory requirements for drug content uniformity, which is typically set at 85-115% of the labeled claim. Overall, the drug content uniformity results demonstrate that the prepared films are of high quality and suitable for therapeutic use.

Table No 6: Drugs Content of MDF Naproxen

Sr. No.	Formulation	% Drug Content
1	F1	99.34 ± 0.89
2	F2	98.22 ± 0.59
3	F3	93.63 ± 0.33
4	F4	87.15 ± 0.55

3.8. *In-Vitro* drug Release

For *In-vitro* dissolution studies, each film was placed in a 900 ml of simulated salivary fluid pH 6.8 USP dissolution, apparatus II Paddle, rotated at 50 rpm. The temperature of the dissolution media was maintained at 37 ± 0.5 during the study 5ml of aliquots were withdrawn at predetermined time interval and were replaced by fresh buffer. The amount of drug release in the media was determined by UV-Visible spectrometer at 230 nm and result were summarized % Cumulative drug release at below.

Table No 7: Comparative *In-Vitro* drug Release of MDF Formulation of F1-F4 batches.

Time (Min)	Batches			
	F1	F2	F3	F4
0	0	0	0	0
0.5	25.20 ± 1.22	23.15 ± 1.10	23.20 ± 0.11	26.34 ± 1.25
1	55.70 ± 1.20	53.55 ± 0.20	46.21 ± 0.27	65.35 ± 1.05
1.5	68.60 ± 0.23	65.80 ± 0.05	60.25 ± 0.21	71.45 ± 0.15
2	70.22 ± 0.15	70.40 ± 0.20	75.40 ± 0.65	76.39 ± 1.30
2.5	76.08 ± 0.10	75.80 ± 1.20	77.37 ± 0.06	82.44 ± 0.18
3	80.40 ± 0.20	81.20 ± 0.22	85.09 ± 0.35	88.03 ± 0.25
3.5	90.60 ± 0.08	90.50 ± 1.23	91.80 ± 0.04	95.25 ± 0.26
4	95.25 ± 0.20	96.60 ± 0.08	94.56 ± 0.12	96.98 ± 0.25
4.5	99.21 ± 0.11	98.59 ± 0.13	98.35 ± 0.12	99.52 ± 0.26

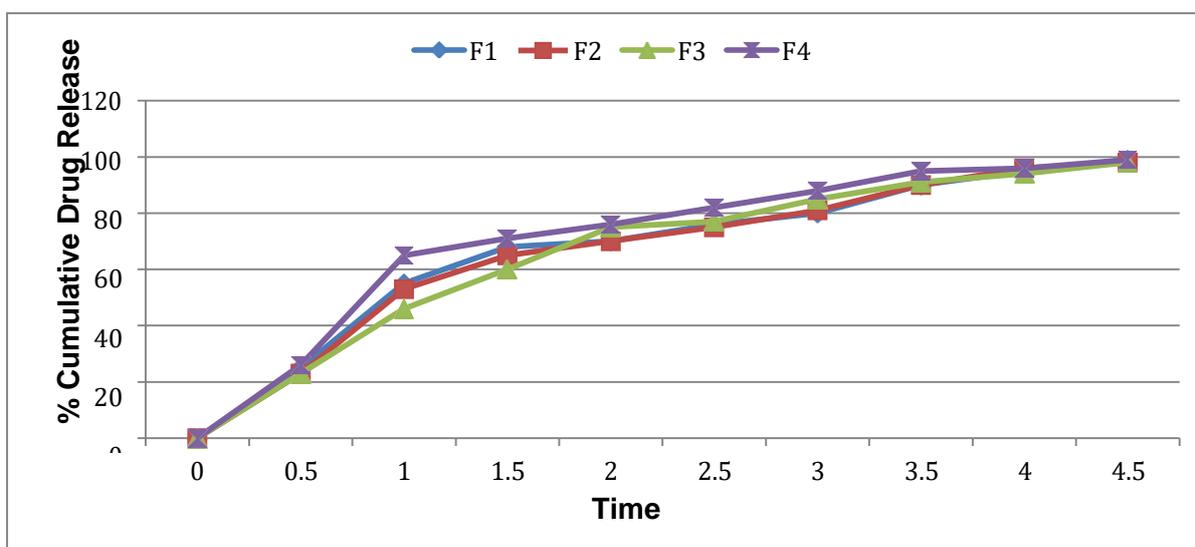


Fig No.2: Graph of plotted for absorbance versus concentration

4. Discussion

Migraine is a common neurological disorder characterized by recurrent episodes of severe headaches, often accompanied by nausea, vomiting, and sensitivity to light and sound. Naproxen sodium, a nonsteroidal anti-inflammatory drug (NSAID), is commonly used for the management of migraine. However, the conventional oral dosage forms of naproxen sodium, such as tablets and capsules, may not provide rapid relief from migraine symptoms due to their slow onset of action. Mouth dissolving films (MDFs) are a novel dosage form that can provide rapid release of the active ingredient, thereby offering quick relief from migraine symptoms. In this study, MDFs of naproxen sodium were formulated using a solvent casting method, and their physicochemical properties, such as thickness, weight variation, surface pH, and drug content uniformity, were evaluated. The results of the study showed that the formulated MDFs possessed excellent physicochemical properties, including uniform thickness, weight, and drug content. The surface pH of the MDFs was found to be similar to that of saliva, indicating that they would not cause any irritation or discomfort in the oral cavity. The dissolution time of the MDFs was remarkably fast, ranging from 15 to 20 seconds, which is indicative of rapid release of the active ingredient. The drug content uniformity of the MDFs was found to be within the acceptable limits, indicating that the manufacturing process is robust and reproducible. The results of the study demonstrate that the formulated MDFs of naproxen sodium are suitable for the management of migraine, offering rapid relief from symptoms without the need for water or chewing. In conclusion, the study successfully formulated and evaluated MDFs of naproxen sodium for the management of migraine. The results of the study demonstrate the potential of MDFs as a novel dosage form for the rapid release of naproxen sodium, offering a promising alternative to conventional oral dosage forms for the management of migraine.

5. SUMMARY AND CONCLUSION:

A mouth-dissolving film of Naproxen Sodium was effectively developed using a solid dispersion technique. The resulting film exhibited a smooth and transparent appearance. Various characteristics were assessed, including visual quality, film thickness, folding endurance, weight consistency, pH from the surface dissolution test, and in vitro drug release profiles. Batch no. 4 emerged as the optimized formulation, demonstrating an increase in both the percentage of drug released and the dissolution time. All evaluated parameters fell within the acceptable limits outlined in the official guidelines, confirming the method's effectiveness and the formulation's potential for industrial use. The evaluation tests conducted included dissolution time, weight variation, moisture loss percentage, folding endurance, and pH measurement. Additionally, mouth-dissolving films of Naproxen Sodium were successfully produced using the solvent casting method.

6. Acknowledgement

I would like to extend my gratitude to acknowledge those guiding lights imbibed in me the right ingredient and helped me to accomplish this task. I sincerely, acknowledge with a deep sense of gratitude to my respected guide Dr. Archana N. Mungle, Assistant Professor, Gurunanak College of pharmacy, Nagpur for her guidance and encouragement. She has performed a knowledgeable role of guide and philosopher. She had been constant source of inspiration to me, I feel short of words to express my gratitude to her. I express my sincere thanks to the Management of the Sikh Education Society, Benzonbagh Nagpur, for their kind co-operation and support.

Authors' Contribution Statement

I, Abhijit N. Daf conceptualized and designed the study, formulated and evaluated the mouth dissolving films of naproxen sodium, collected and analyzed the data, and wrote the manuscript. I am the sole author of this work and takes full responsibility for the integrity and accuracy of the research findings.

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