



## FORMULATION AND EVALUATION OF NAPROXEN MOUTH DISSOLVING FILM FOR THE MANAGEMENT OF SEVERAL MENSTRUAL PAIN

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### ABSTARCT

Menstrual pain (dysmenorrhea) significantly impacts women's quality of life, with non-steroidal anti-inflammatory drugs (NSAIDs) like naproxen as first-line therapy. Conventional naproxen tablets face challenges including delayed onset (30-60 minutes), gastrointestinal irritation, and swallowing difficulties during nausea episodes. This college project conducts a comparative study of naproxen-loaded mouth dissolving films (MDFs) versus standard tablets for rapid management of moderate-to-severe menstrual pain. MDFs were formulated using solvent casting technique with hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA), glycerol as plasticizer, and super disintegrants like croscarmellose sodium. Films (2x3 cm, 200 mg naproxen) were optimized for <60 seconds disintegration, >90% drug release in 5-30 minutes, uniform thickness (0.1-0.2 mm), and folding endurance (>300 folds). Physicochemical evaluations included weight variation, pH (5.8-6.8), drug content (95-102%) and in vitro dissolution in simulated saliva (pH 6.8). Comparative assessment simulated clinical use: MDFs achieved faster disintegration and dissolution than tablets, enhancing bioavailability by avoiding first-pass metabolism. Results demonstrate MDFs superior rapid onset (15-30 min relief onset vs. 45-60 min for tablets), improved patient compliance, and reduced side effects, positioning them as innovative orodispersible delivery for dysmenorrhea. This formulation addresses unmet needs in women's health, with scalability for commercial production. The study highlights solvent casting's simplicity for academic settings, providing a practical model for pharmacy students exploring novel drug delivery systems. **Objective:** To prepare mouth dissolving films containing naproxen using suitable film-forming polymers and excipients for Menstrual pain for rapid onset of action. Compare different formulations of naproxen mouth dissolving films for physical and pharmaceutical properties. **Result:** Formulate & evaluate films for thickness, weight uniformity, folding endurance, surface pH, drug content, disintegration time, and in vitro drug release & to assess the suitability of the optimized film for rapid onset of action in menstrual pain relief determine the patient compliance potential of the developed formulation for use in dysmenorrhea.

**KEYWORDS:** Naproxen, Mouth Dissolving Film, Dysmenorrhea, Solvent casting & Menstrual pain.

## 1. INTRODUCTION

### 1.1. MENSTRUAL CYCLE

The female reproductive system, unlike the male, undergoes regular cyclic changes known as the menstrual cycle, which serves as the body's periodic preparation for ovulation and potential pregnancy. The most noticeable aspect of the female reproductive system is menstruation, or cyclic vaginal bleeding, which occurs alongside a

series of coordinated hormonal shifts. Menstruation, also known as menarche when it first begins, typically starts around puberty with a median age of 12. Menstrual cycles cease at menopause, which has an average onset around age 51.<sup>[1]</sup> Human reproduction is regulated by hormones, guiding processes from the onset of menstrual cycles during puberty to the complexity of ovulation, implantation, and gestation. At the cycle's outset,

declining estrogen and progesterone levels result in the elimination of the endometrial lining. They regulate follicle maturation and ovulation, while estrogen and progesterone, produced by the follicles and corpus luteum, prime the endometrial for optimized conditions for a fertilized egg.<sup>[2]</sup>

The menstrual cycle, which typically lasts 28 days in eumenorrheic women, is regulated by interactions among hypothalamic, pituitary, and ovarian hormones. These creation of P4, follicle-stimulating hormone (FSH), luteinizing hormone (LH), and E2 occurs in distinct phases, resulting in hormonal fluctuations that influence physical performance and metabolic requirements.<sup>[3]</sup> The hypothalamic–pituitary–gonadal (HPG) axis, commonly referred to as the hypothalamic–pituitary ovarian (HPO) axis in women, underlies these cyclical hormonal changes by coordinating the production of E2 and P4 across the menstrual cycle.<sup>[4]</sup>

During the menstrual cycle, from the first day of menstruation to the day preceding the next menstrual period, various changes occur in a woman's body caused by major hormonal fluctuations. Therefore, menstrual-related symptoms are one of the most common problems faced by women.<sup>[5]</sup> The psychological effects of the menstrual cycle have received increasing interest particularly due to their clinical relevance in premenstrual disorders such as PMS and PMDD. Premenstrual psychological changes can include emotional changes, such as irritability, mood liability, or depressed mood, as well as cognitive symptoms such as difficulties concentrating.<sup>[6]</sup>

## 1.2. PHASES OF MENSTRUAL CYCLE

A typical MC lasts around 28 days and consists of a follicular phase (i.e., characterized by 12–14 days' duration, high levels of estrogen and low progesterone), ovulation phase (i.e., 1–3 days' duration and preceded by a second increase in estrogen), and a luteal phase (i.e., 12–14 days' duration, with high levels of progesterone and medium levels of estrogen).<sup>[7]</sup>

- Phase I (Menstrual Phase): In this research, this phase was considered from the first day of bleeding two day. The assessment of phase I was conducted as soon as possible from the first day of bleeding, with the cut-off for this first assessment being day 5 of the menstrual cycle.<sup>[8]</sup>
- Phase II (Follicular Phase): The follicular phase was defined as the first day after a user stopped reporting bleeding to the date of the peak LH level. The development of the ovarian follicle characterizes the follicular phase and culminates in ovulation.<sup>[9]</sup>
- Phase III (Ovulation Phase): A peak in serum Estradiol, or its urine metabolite estrone-3-glucuronide (E1G), marks the presence of a growing follicle and the opening of the fertile window. It triggers a luteinizing hormone (LH) surge that marks the time of peak fertility. However, an LH surge may not always result in the release of a mature egg.<sup>[10]</sup>
- Phase IV (Luteal Phase): In the luteal phase, the corpus luteum secretes primary progesterone. After a short drop oestrogen, both estrogen and progesterone increase and reach a peak around the mid-luteal phase, after which they rapidly decline in the LL phase to contribute to menstruation.<sup>[11]</sup>

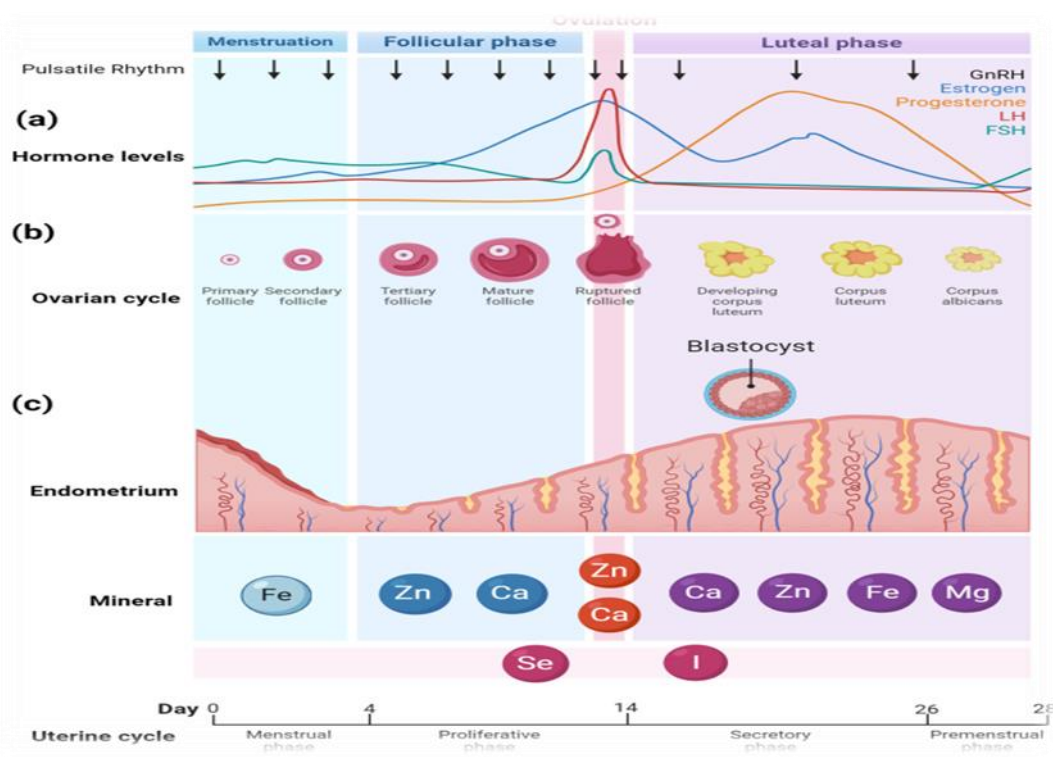


Fig no. 01: Phases of Menstrual Cycle.

### 1.3. DYSMENORRHEA

Dysmenorrhea is defined as pain that starts just before menstruation and lasts during this period. The pain is most severe on the first and second days. Menstrual pain caused by an excessive secretion of prostaglandins, vasopressin and Leucotrienes due to uterine contractions.<sup>[12]</sup> Dysmenorrhea or menstrual pain constitutes the main gynaecological complaint for many young women. Previous studies estimate that 60–90% of young university women worldwide suffer from dysmenorrhea. The literature distinguishes between two types of dysmenorrhea: primary dysmenorrhea, which is not, related to any anatomical physiological alteration, and secondary dysmenorrhea, which is associated with a gynaecological problem, not endometriosis.<sup>[13]</sup>

The development of an optimal diet for patients with dysmenorrhea constitutes a major challenge. Diets with low nutrient density, low in vitamins and minerals, and abundant in processed foods, may exert a negative impact on women's overall health and well-being, and increase the risk of diet-related diseases which, under certain circumstances, can lead to menstrual disorders and menstrual distress symptoms.<sup>[14]</sup> Some women experience symptoms during menstruation that may condition their quality of life, especially among younger women. These include menstrual pain, nausea, vomiting, diarrhoea, dizziness, irritability, depressive symptoms and headache. Menstrual pain or dysmenorrhea is a chronic, recurrent type of pain that manifests as menstrual cramps or painful periods, usually in the form of pelvic or lower abdominal pain, although it can also be experienced as low back pain and may be accompanied by other menstrual symptoms.<sup>[15]</sup>

### 1.4. TREATMENT OF MENSTRUAL PAIN

Pain severity and its consequences force women to use pharmacological and non-pharmacological treatments such as herbs, yoga, acupuncture, and aromatherapy. Drugs mainly used are the non-steroidal anti-inflammatory drugs (NSAIDs) (first-line treatment), mefenamic acid, or oral contraception. Their effectiveness is attributed to their action on prostaglandin as NSAIDs inhibit prostaglandin synthesis whereas oral contraceptives reduce endometrial thickness which is followed by a reduction of prostaglandin release.<sup>[16]</sup>

- Strips of an elastic kinesio tape (K-Active®) or sham tape (Sport Tape®), 5 cm wide and multi-coloured, were cut from a roll. Two strips were placed on the skin on the underbelly area, over the pubic joint.<sup>[17]</sup>
- Piroxicam is an anti-inflammatory agent that has analgesic and antipyretic effects. It works by making cyclooxygenase enzymes reverse their inhibition functions, including inhibition of prostaglandin prostanoïd synthesis.<sup>[18]</sup>
- Herbal roll-on formulations offer several advantages, particularly in managing localized conditions like menstrual cramps. Roll-ons are

portable, easy to apply, and hygienic, making them highly user-friendly during menstruation.<sup>[19]</sup>

### 1.5. COMPARISON OF NAPROXEN FILM WITH OTHER DRUG

Orally disintegrating/soluble thin films oral strips are defined as “drug delivery systems containing a water-soluble polymer that, when placed on the tongue or in the oral cavity, quickly disperses with saliva, dissolves or adheres to the mucous membrane, and releasing the drug within a few seconds.<sup>[20]</sup> The oral route of drug administration is the most acceptable to patients; however, some oral forms may cause inconveniences, especially in patients with swallowing difficulties. To avoid the risk of choking, the active substance can be administered in the form of a film quickly disintegrating in the oral cavity.<sup>[21]</sup> The thin film is usually prepared using water-soluble polymers that can dissolve in the oral cavity, however, the patient adherence is often challenged in such dosage forms, where the patient may swallow the entire or partial film. Therefore, the formulations are usually designed where the active pharmaceutical ingredients (APIs) are administered in the mouth or small intestines.<sup>[22]</sup> They are placed in the oral cavity, where they should disintegrate in approximately 30 s and release the active substance. After the oral membrane breaks down, the released API is swallowed by the patient, and then the substance is absorbed into the bloodstream. Taking the drug in this form does not require chewing or drinking water.<sup>[23]</sup>

### 1.6. ADVANTAGES

- Excellent dose flexibility.
- Water is not required.
- Swallowing is avoided.
- Bioavailability may be improved by buccal absorption.

### 1.7. DISADVANTAGES

- Controlled-release is challenging.
- Taste masking is challenging.
- Retention time in mouth may alter bioavailability.
- Uniformity of dose may be challenging.<sup>[24]</sup>

## 2. DRUG PROFILE

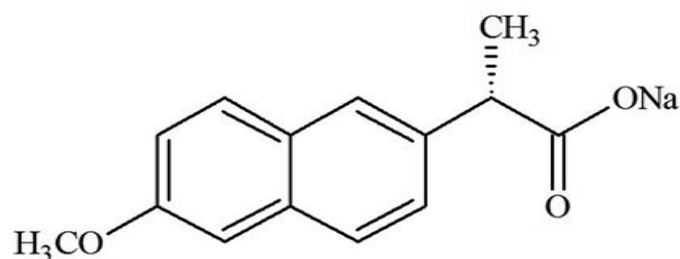


Fig no. 02: Structure of Naproxen.

**IUPAC Name:** - Sodium ; (2S)-2-(6-Methoxynaphthalen-2-yl) Propanoate.

**Formula:** - C<sub>14</sub>H<sub>13</sub>NaO<sub>3</sub>

**Molecular Weight:** - 252.24 g/mol

### 2.1. ABOUT NAPROXEN

Naproxen was initially approved in 1976 for prescription use and remained a prescription drug until it received approval as an over-the-counter (OTC) medication in 1994. Naproxen has been FDA-approved to treat acute gout, ankylosing spondylitis, bursitis, polyarticular juvenile idiopathic arthritis, osteoarthritis, tendonitis, rheumatoid arthritis, pain, and primary dysmenorrhea. It is considered the first-line treatment for acute gouty arthritis, osteoarthritis, musculoskeletal pain, inflammation, and dysmenorrhea. While Naproxen and other NSAIDs have FDA approval for the treatment of inflammatory arthropathies, such as rheumatoid arthritis and ankylosing spondylitis, they do not alter the course of the disease, nor do they prevent joint and soft tissue destruction that are common sequelae of these diseases. In these cases, disease-modifying anti-rheumatic drugs (DMARDs) have become the first-line treatment for inflammatory arthropathies, and NSAIDs such as naproxen are used as adjunctive therapy.<sup>[25]</sup>

### 2.2. MECHANISM OF ACTION

NSAIDs (non-steroidal anti-inflammatory drugs) are the class of most widely used drugs for their proved efficacy against pain and inflammation. NSAIDs constitute 5 to 10% of all medication prescribed every year. Naproxen, an acid derivative of propionic acid, a non-selective COX inhibitor, is a well-known member of NSAIDs. It used anti-inflammatory drug in the treatment of arthritis, gout, ankylosing spondylitis, and tendinitis. Furthermore, naproxen also shows antipyretic and analgesic activity and is effective in the treatment of

dysmenorrhea, rheumatoid arthritis, and post-operative pain.<sup>[26]</sup>

The biochemical mechanism of inflammation is a very simplified means of interleukin (IL)-1 $\beta$  production via cells as the response to the bacterial or viral presence in the intracellular environment. (IL)-1 $\beta$  is a “starter” for inflammation mediator production as COX-2 (COX—cyclooxygenase). COX-2 with COX-1 induces arachidonic acid production, where this acid is transformed into prostaglandin endoperoxide H<sub>2</sub> (PGH<sub>2</sub>), which starts inflammation in the human body. NSAIDs (non-steroidal anti-inflammatory drugs), such as naproxen, work as reverse inhibitors for COX-1 and COX-2. The result of described inhibition is blocking prostaglandin production in human cells.<sup>[27]</sup>

### 2.3. ADMINISTRATION

Nonsteroidal anti-inflammatory drugs (NSAIDs), which have been shown to be superior to both placebo and acetaminophen, are a first-line therapy for primary dysmenorrhea. NSAIDs act by reducing prostaglandin production. NSAIDs should be initiated one to two days before the onset of menses and continued in regular dosing intervals through the first two to three days of bleeding, correlating with the highest levels of prostaglandins. There is no difference between individual NSAIDs, including cyclooxygenase-2 inhibitors, for pain relief or safety. Commonly prescribed NSAIDs include ibuprofen (800 mg initially, followed by 400 to 800 mg every eight hours) and naproxen (500 mg initially, followed by 250 to 500 mg every 12 hours); both medications can be purchased over the counter, often for less than \$10 per month. NSAIDs can also have a secondary benefit of reducing heavy menstrual bleeding.<sup>[28]</sup>

## 3. EXPERIMENTAL WORK

Table No.1: List of Oral Dissolving Film of Naproxen.

Sr. No.	Content	F1	F2	F3	F4
1.	Naproxen	500mg	500mg	500mg	500mg
2.	HPMC E5	1gm	1gm	1.2gm	1.3gm
3.	PEG 400	0.1gm	0.2gm	0.1gm	0.1gm
4.	Polyvinyl pyrrolidone K30	0.004gm	0.004gm	0.004gm	0.004gm
5.	Citric Acid	0.01gm	0.01gm	0.01gm	0.02gm
6.	Na Benzoate	0.01gm	0.01gm	0.01gm	0.01gm

7.	Glycerol	0.5ml	0.6ml	0.8ml	0.5ml
8.	Vanillin	0.02gm	0.02gm	0.02gm	0.02gm
9.	Ethanol	5ml	6ml	5ml	8ml
10.	Water	QS	QS	QS	QS

### 3.1. Methods of Preparation of ODFs

1. Fast dissolving films of naproxen were prepared by the solvent casting method.
2. The required amount of polymer, HPMC, was dissolved in a suitable quantity of water with continuous stirring for 1 hour.
3. The optimized amount of polyethylene glycol (PEG), polyvinyl pyrrolidone K30, citric acid, sodium benzoate, glycerol, and vanillin were dissolved in ethanol and then added to the polymeric solution.
4. The required amount of naproxen was dissolved in water and Sonicator to ensure proper dispersion.
5. This drug solution was then added to the polymeric solution and stirred for 30 minutes using a magnetic stirrer.
6. The resulting solution was kept undisturbed to remove entrapped air bubbles.
7. The solution was then cast into a plastic Petri dish of appropriate surface area and dried at controlled room temperature or in a microwave oven at elevated temperature.
8. After drying, the films were carefully removed from the Petri dish, cut into the required size for testing, and stored in airtight plastic bags until further use.<sup>[29]</sup>

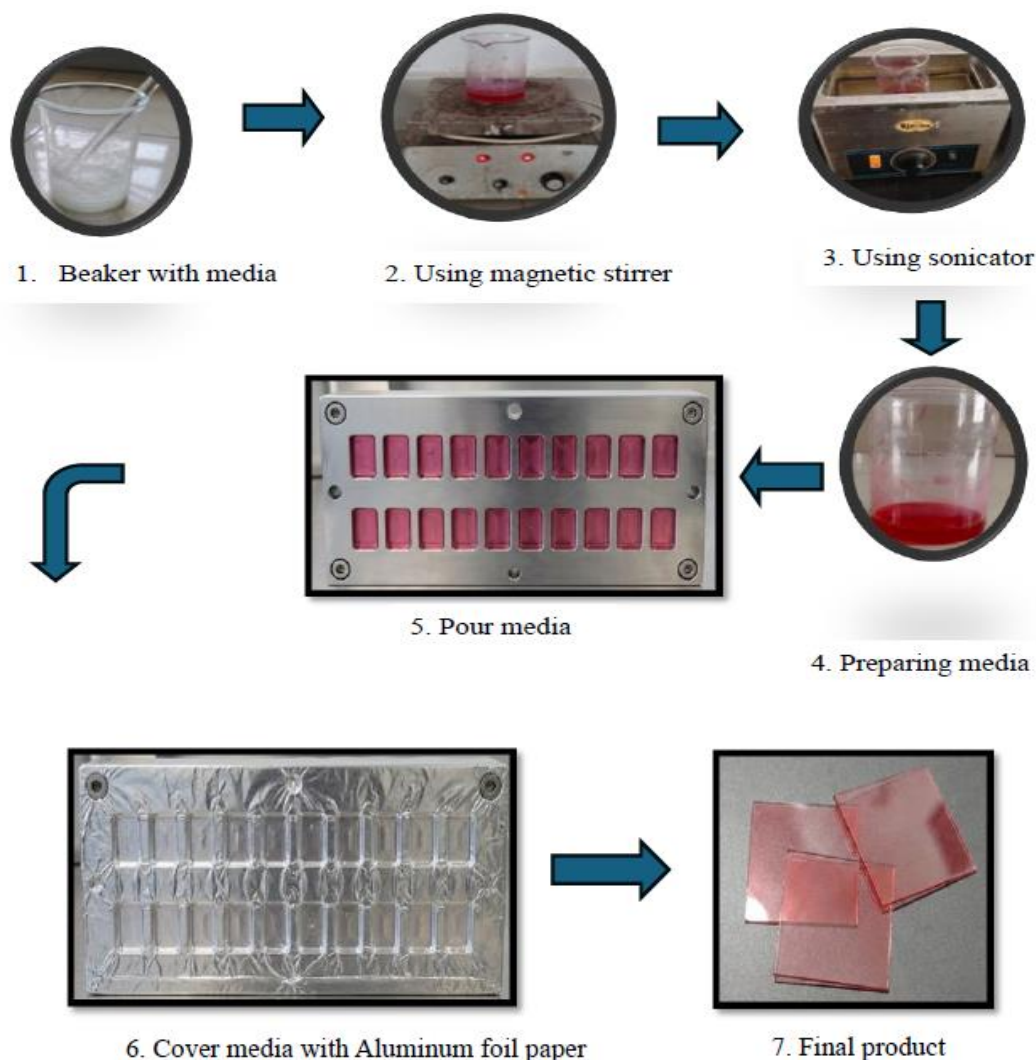


Fig N o. 03: Preparation of Oral Dissolving Film of Naproxen.

### 4. EVALUATION PARAMETER

**1. Visual Appearance:** The visual appearance of a pharmaceutical film is an important quality parameter that affects patient acceptability and product elegance.

An ideal film should be smooth, uniform, flexible, and free from defects such as cracks, bubbles, or stickiness. Factors like color, transparency, surface texture, and thickness uniformity influence the appearance of the

film. Proper formulation and drying produce a clear and attractive film, indicating good quality and stability.

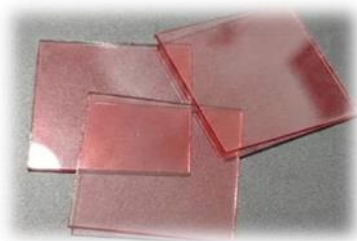


Fig no. 04: Visual appearance.

**2. Determination of Disintegration Time:** The disintegration time test was conducted manually by placing the film into a 10 mL simulated saliva solution (Phosphate buffer pH 6.8) in a beaker glass and stirred continuously every 10 Sec. The time required for the film to dissolve completely is considered as disintegration time.



Fig no. 05: Disintegration test.

**3. Weight Uniformity:** The weight uniformity test was carried out by weighing 20 units of ODF at a size of 2×2

cm. The weight of ODF was tabulated and the results were expressed as the average weight  $\pm$  SD.



Fig no. 06: Weight Uniformity Test.

**4. Surface pH:** Surface pH was determined to evaluate the acceptability of the ODF administration in the oral cavity. ODF was placed in a petri dish, and then wetted by using 0.5 mL purified water for 60 Sec. The surface pH of ODF should be within the normal range of salivary pH 6.8–7.4.<sup>[30]</sup>



Fig no. 07: pH Test.

## 5. RESULT AND DISCUSSION

Table no. 02: Evaluation Parameter of Oral Dissolving Film of Naproxen.

Sr No.	Parameter	F1	F2	F3	F4
1.	Colour	No colour	Pink colour	Pink colour	Pink colour
2.	Odour	Pleasant	Pleasant	Pleasant	Pleasant
3.	Appearance	Smooth	Smooth	Rough (air bubbles)	Smooth
4.	Flexibility	Low flexible	Moderate flexible	Not flexible	High flexible
5.	Disintegration time	36 sec	30 sec	35 sec	46 sec
6.	Weight uniformity	0.065gm	0.072gm	0.075gm	0.079gm
7.	Surface pH	6.2	6.5	7.3	7.5

## 6. CONCLUSION

This comparative study shows that naproxen mouth dissolving film is a promising and effective dosage form for the management of menstrual pain. Compared with conventional tablets, the film offers faster disintegration, quicker drug release, and easier administration without the need for water, which makes it highly convenient for patients during painful menstrual episodes. The rapid onset of action is especially useful in dysmenorrhea, where timely relief is important. Studies on naproxen fast-dissolving formulations report improved dissolution and better patient acceptability, supporting the potential of this delivery system for pain management.

In addition, the mouth dissolving film may improve patient compliance by reducing swallowing difficulty and minimizing gastric discomfort often associated with oral NSAIDs. Its thin, flexible nature and rapid oral absorption make it a practical alternative to traditional tablets or capsules. From a formulation point of view, the use of suitable polymers and super disintegrants can produce films with good mechanical strength, uniform drug content, and efficient release characteristics.

In conclusion, naproxen mouth dissolving film can be considered a novel, patient-friendly, and efficient option for managing menstrual pain. It has the potential to

provide faster relief, better convenience, and improved compliance, making it a valuable dosage form for future pharmaceutical development and clinical use.

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