

# Novel Drug Delivery Based Fast Dissolving Oral Film of Syzygium Aromaticum

Atharva Ajit Kolbe<sup>1</sup>, Satyam Narayan Kumbhar<sup>2</sup>, Saniya Amin Jamadar<sup>3</sup>, Silvie Gonsalvis<sup>4</sup>

Rahul A. Pawar<sup>5</sup>, Dr. Manoj Kadam<sup>6</sup>

<sup>1,2,3,4,5</sup>Shree Saraswati Institute of Pharmacy, Tondavali-41660

<sup>6</sup>Professor, Shree Saraswati Institute of Pharmacy, Tondavali-416602

**Abstract**—This research focused on the formulation of fast dissolving oral film containing extract of Syzygium aromaticum to treat pain in teeth. The extract of Syzygium aromaticum was formulated as film by solvent casting method using various polymer like pectin. Polyethylene glycol as plasticiser. Vanillin as flavouring agent & mannitol is a sweetener. This idea of quick dissolving dosage form has gained popularity as a new delivery method. By reducing dosing frequency. This approach will give better bioavailability optimal stability. It will also avoid first fast metabolism of medicine. From the above result it is evident that the developed formulation can be an innovative dosage form to improve the drug delivery, onset of action, additionally it will increase patient compliance. Oro dispersible is the term referred to dosage form which disperse into mouth i.e. oral cavity. The time required to disintegrate should be no more than 3 minutes. Dosage forms in which they are available are tablets & mouth dissolving films which when placed in oral cavity release drug instantaneously with rapid onset of action.

**Index Terms**—Syzygium Aromaticum, Spice, Volatile, Analgesic, Laung, Oral Film

## I. INTRODUCTION

Oral films are an advanced technology used in the development of oral disintegrating dosage forms. These are thin, elegant strips made from edible and water-soluble polymers, available in various shapes and sizes such as squares, rectangles, and discs. The films may be transparent or opaque, as well as flexible or brittle. They are designed to dissolve rapidly on the tongue without requiring water. Fast dissolving films (FDFs) possess a large surface area, which promotes rapid disintegration. They reduce the risk and fear of choking, are simple to administer and handle, and

allow convenient packaging and manufacturing, thereby overcoming many limitations associated with orally fast disintegrating tablets. However, these dosage forms have certain disadvantages, including low drug-loading capacity and restricted taste-masking ability. [1]

A fast-dissolving film is generally a thin strip with a thickness of about 1–10 mm and an area ranging from 1–20 cm<sup>2</sup>, irrespective of its shape. Drugs can usually be incorporated up to a single dose of nearly 30 mg. Rapid dissolution in saliva occurs because of a specially designed matrix containing water-soluble polymers. The film exhibits low tackiness for easy handling and application, but upon wetting, it develops wet tack and mucoadhesive properties that help it remain attached to the site of application. The films are formulated with suitable flexibility and mechanical strength to support manufacturing operations such as rewinding, die-cutting, and packaging. [2]

When placed on the patient's tongue, the fast-dissolving film immediately encounters saliva and hydrates rapidly on the mucosal surface. It adheres to the application site, quickly disintegrates, and dissolves, releasing the drug either for absorption through the oral mucosa or through the gastrointestinal tract after swallowing.[3]

## History And Background:

Oral film technology was first developed in the late 1970s to overcome the swallowing challenges commonly associated with conventional tablets and capsules, especially among paediatric and geriatric populations. Over the years, these films have become increasingly popular in the pharmaceutical sector due to their lower susceptibility to breakage, precise dose

delivery, rapid drug release, and user-friendly administration. They are also known by terms such as oral strips, buccal films, and buccal strips.

Several bio adhesive mucosal drug delivery systems have been formulated, including adhesive tablets, gels, ointments, and patches. Among these, polymer-based films intended for buccal administration are often referred to as mouth-dissolving films. Typically, oral films have a shelf life of approximately 2–3 years, depending on the active pharmaceutical ingredient (API), although they remain highly vulnerable to moisture exposure. An ideal oral film should possess attributes such as stability, ease of transport, simple handling and administration, no need for water during use, and an acceptable taste.[4]

Because of these benefits, oral films are particularly advantageous for children, elderly individuals, bedridden patients, and those experiencing conditions such as dysphagia, Parkinson's disease, mucositis, or persistent vomiting. Initially, oral films were marketed as breath-freshening and personal care products, including dental strips and soap strips. Subsequently, they were introduced into the pharmaceutical markets of the United States and Europe for therapeutic purposes. The first commercially available oral strip was launched by Pfizer under the brand name Listerine PocketPaks, primarily as a breath-freshening product.[5]



Fig. 1 Oral Film [6]

## II. OBJECTIVES

1. To enhance patient adherence and acceptability of the dosage form.
2. To ensure a quick onset of pharmacological effect through rapid drug release.
3. To improve the drug's bioavailability by facilitating efficient absorption.

4. To develop a portable and user-friendly dosage form that offers ease of handling and administration.
5. To formulate a fast-dissolving oral film that can be administered without the need for water.
6. To provide a convenient dosage option for paediatric, geriatric, and dysphagic patients who have trouble swallowing conventional tablets and capsules.
7. To achieve uniform drug distribution within the film for accurate and consistent dosing. [7]

### Advantages

1. Eliminates the need for water during administration, making it more convenient for patients.
2. Minimizes the risk of choking or swallowing difficulties associated with conventional dosage forms.
3. Offers simple, convenient, and patient-friendly administration.
4. Utilizes taste-masking techniques to effectively reduce the unpleasant bitterness of drugs.
5. Provides a satisfactory sensory experience with a pleasant taste, texture, and mouthfeel.
6. Rapidly dissolves or disintegrates in the oral cavity within seconds, resulting in a faster therapeutic effect.
7. Enhances patient compliance, particularly among paediatric, geriatric, and bedridden patients.
8. Facilitates quicker drug absorption and may improve bioavailability by bypassing first-pass metabolism in some cases.[8]

### Disadvantages

1. Drugs that are unstable in the buccal environment or at the pH of the oral cavity cannot be effectively delivered through this route.
2. Medications that have the potential to irritate the oral mucosal tissues are not suitable for incorporation into oral films.
3. This dosage form is generally appropriate only for drugs that are effective at relatively low doses.
4. Oral films possess a restricted drug-loading capacity, limiting the amount of active ingredient that can be incorporated.
5. Drugs that exhibit instability or cause irritation under oral cavity pH conditions are unsuitable for administration via oral films.

6. The films are highly sensitive to moisture and therefore require careful packaging and storage conditions.[9]

### III. APPLICATIONS

1. Fast-dissolving oral films are widely used in the treatment of localized pain, allergic conditions, sleep-related disorders, and diseases involving the central nervous system (CNS).
2. Water-soluble films can be employed for topical applications, serving as analgesic or antimicrobial agents in wound management.
3. Oral disintegrating films have the potential to improve the bioavailability of drugs that exhibit poor absorption when administered through conventional dosage forms.
4. Dissolving films are also useful in topical therapy for wound treatment due to their pain-relieving and antibacterial properties.
5. Taste-masking techniques incorporated into these films help conceal the unpleasant or bitter taste of medications, thereby improving patient acceptability.
6. These films provide a convenient drug delivery system for paediatric, geriatric, and dysphagic patients who have difficulty swallowing tablets or capsules.
7. They can be used to achieve rapid drug release and a faster onset of therapeutic action.[10]

### IV. METHODS AND MATERIAL OF PREPARATION OF ORAL FILM

- A. Solvent Casting Method
- B. Hot - Melt Method
- C. Semi – Solid Casting Method
- D. Solid - Dispersion Method
- E. Rolling Method

#### A. SOLVENT CASTING METHOD

The solvent casting technique is among the most used methods for the preparation of oral dissolving films (ODFs). In this process, water-soluble polymers and other excipients are dissolved in a suitable solvent to form a clear, homogeneous, and viscous solution. The active pharmaceutical ingredient (API), along with necessary additives, is dissolved separately in a smaller volume of solvent and then mixed thoroughly

with the polymeric solution. The resulting mixture is added to the aqueous viscous solution to obtain a uniform casting solution.

To ensure the production of films with consistent thickness and quality, any entrapped air is eliminated through vacuum deaeration. The prepared solution is then spread onto a suitable surface, dried under controlled conditions, and cut into films of the desired size and shape. The selection of an appropriate solvent largely depends on the properties of the API. Factors such as drug–excipient compatibility, solubility in the chosen solvent, polymorphic characteristics, and sensitivity to temperature must be carefully considered during formulation development. Additionally, strict control of environmental conditions is essential during the manufacturing and packaging processes. Since oral dissolving films are highly susceptible to moisture, precautions must be taken to prevent moisture uptake, which can adversely affect their stability and mechanical properties. Temperature control is equally important, as it helps maintain the desired viscosity of the casting solution and prevents degradation of heat-sensitive drug substances.[11]

### V. COMPONENTS OF AN ORAL FILM

- A) Drug / API
- B) Polymer
- C) Solvent
- D) Plasticizer
- E) Saliva Stimulating Agent.
- F) Flavoring Agent.
- G) Sweetener

#### A) Drug/Active Pharmaceutical Ingredient (API):

The active pharmaceutical ingredient (API) generally represents around 30–40% of the total composition of the film. Drugs with high potency, significant first-pass metabolism, and those intended for patients with poor compliance are considered ideal candidates for oral fast dissolving buccal films. The incorporation of an API can positively influence the film's texture while enhancing its dissolution characteristics and content uniformity.

However, the bitter or unpleasant taste of certain APIs, particularly in paediatric formulations, may negatively affect patient acceptance. Therefore, taste-masking

techniques are commonly employed before incorporating the API into the film matrix. Several methods are available to improve palatability, with one of the most frequently used approaches involving the combination of bitter drugs with flavouring excipients that provide a pleasant taste. This strategy is commonly referred to as taste masking or taste obscuration.

The choice of API is primarily determined by its potency and suitability for buccal delivery. APIs typically constitute 30–40% of the film formulation and are selected for drugs that exhibit high potency, undergo extensive first-pass metabolism, and are intended for patients who may have difficulty adhering to conventional dosage forms. Additionally, APIs contribute to improving the film's texture, dissolution performance, and drug distribution uniformity. Despite these advantages, taste remains a significant concern, especially in formulations designed for children.

#### Ideal Characteristics of the Selected Drug:

- Drugs with low to moderate molecular weight are preferred, with an optimum dose generally not exceeding 40 mg.
- The drug should be stable and readily soluble in both water and saliva while remaining partially unionized at the pH of the oral cavity.
- It should possess adequate permeability to effectively cross the oral mucosal membrane.[12]

#### B) Film-Forming Polymer:

Film-forming polymers are the primary components of oral fast dissolving films and play a crucial role in determining their physical and mechanical properties. The nature and concentration of the polymer significantly affect the strength, flexibility, and integrity of the film. Therefore, the finished film should possess adequate mechanical resistance to withstand handling, packaging, storage, and transportation without tearing or breaking.

Typically, polymers constitute nearly 45% of the total dry weight of the film formulation. Hydrophilic polymers are widely employed in oral film preparations because they readily absorb saliva and dissolve quickly in the oral cavity. Depending on the

desired characteristics of the final product, either a single polymer or a blend of multiple polymers may be incorporated into the formulation. Among the available options, pullulan is a naturally occurring polymer obtained from non-animal sources and can be utilized without the need for chemical modification.

#### a. Natural Polymers:

Examples include cellulose derivatives, pectin, zein, gelatine, shellac, waxes, gums, natural rubber, and chitosan.

#### b. Synthetic Polymers:

Examples include polybutadiene, hydri rubber, silicone rubber, polyisobutylene, acrylonitrile, neoprene, and butyl rubber.

#### c. Semi-Synthetic Polymers:

Examples include polyvinyl alcohol, polyvinyl chloride, polyethylene, and polypropylene.[13]

#### C) Plasticizer

Plasticizers are important excipients in oral fast dissolving film formulations and are generally incorporated at concentrations of 0–20% w/w of the dried polymer weight. Their primary function is to enhance the flexibility of the film while minimizing brittleness. The inclusion of plasticizers improves the mechanical characteristics of the film, such as tensile strength and percentage elongation. In addition, they facilitate film formation by lowering the polymer's glass transition temperature. The choice of an appropriate plasticizer depends largely on its compatibility with the selected polymer and the solvent system employed during film preparation.

Nevertheless, the use of unsuitable or excessive amounts of plasticizer may result in defects such as cracking, peeling, or splitting of the film. Certain plasticizers may also affect the drug release and absorption profile.[14]

#### D) Saliva-Stimulating Agents

Saliva-stimulating agents are incorporated into oral thin films to promote saliva secretion, thereby accelerating film disintegration and dissolution within the oral cavity. Salivary flow can be enhanced with organic acids such as citric acid, malic acid, tartaric acid, and ascorbic acid. These agents may be employed individually or in combination, typically at concentrations ranging from 2–6% w/w of the total strip weight.[15]

#### E) Flavouring Agents

Flavouring agents are included in oral film formulations to improve palatability and conceal any unpleasant or bitter taste associated with the active ingredient. Any flavour approved by the USFDA may be utilized for this purpose. Flavouring substances may be obtained from synthetic flavour oils, oleoresins, or natural plant-derived extracts sourced from fruits, flowers, and leaves. The amount of flavour incorporated depends on the specific flavouring material used. Common examples include essential oils such as menthol; mint varieties including peppermint, spearmint, sweet mint, and wintergreen; spice flavours like cinnamon and clove; citrus flavours such as lemon and orange; and sweet flavours including chocolate and vanillin.[16]

#### F) Sweeteners

Sweeteners are widely used in pharmaceutical and nutraceutical products intended for dissolution in the oral cavity, as they enhance taste and patient acceptability. Conventional sweetening agents commonly used include sucrose, glucose, dextrose, fructose, liquid glucose, and isomaltose. Among these, fructose is often preferred because of its higher sweetening capacity compared to sorbitol and mannitol. Polyhydric alcohols such as sorbitol, mannitol, and isomaltose may also be incorporated alone or in combination, as they provide a pleasant mouthfeel and a cooling sensation. These polyols are particularly advantageous in oral formulations because they exhibit low cytotoxicity and do not leave an undesirable aftertaste.[17]

#### Drug/Active Pharmaceutical Excipient- Clove

Clove (*Syzygium aromaticum*), also known by its synonym *Eugenia Caryophyllus*, is a member of the Myrtaceae family. It is obtained from the dried flower buds of the clove tree and has been extensively utilized in traditional healthcare systems, food industries, and pharmaceutical formulations. The primary chemical constituents present in clove are eugenol (50–87%), eugenol acetate (5–15%),  $\beta$ -caryophyllene, and Gallotannic acid, with eugenol serving as the main active compound responsible for its numerous medicinal benefits. Clove possesses a wide range of biological activities, including antibacterial, anti-inflammatory, antioxidant, analgesic, and carminative properties. Furthermore, due to its distinctive aroma

and pleasant flavour, it is commonly incorporated as a flavouring agent in various food and pharmaceutical products.[18]



Fig. No 2 The dried flower buds of *Eugenia Caryophyllus* [19]

#### Polymer Used – Pectin

In recent decades, natural materials have gained significant attention due to their easy availability, affordability, non-toxic nature, and excellent biocompatibility, making them promising carriers for drug delivery applications. Plant-based materials and their derivatives offer numerous advantages to the pharmaceutical industry, serving as sources of many therapeutically active compounds and pharmaceutical excipients. Pectin is a naturally occurring polysaccharide that is commonly extracted under acidic conditions from various plant sources, including oranges, other citrus fruits, and apple pomace. Owing to its outstanding biodegradability and biocompatibility, pectin has found a wide range of applications in both the pharmaceutical and food industries. This review aims to provide a brief overview of the sources, classification, chemical characteristics, and pharmaceutical applications of pectin.

#### Properties of Pectin Polymer in Oral Films

- High biocompatibility with living tissues.
- Natural biodegradability.
- Strong gelation potential.
- Favourable water solubility.
- Superior film-forming ability for the development of oral thin. [20]

**Plasticizer – Polyethylene Glycol 400**

Plasticizers improve the flexibility of polymer films by lowering their glass transition temperature (T<sub>g</sub>), which in turn reduces film brittleness and friability. They can also enhance the tensile strength of the prepared films. It is essential that plasticizers are compatible with the drug, solvent system, and polymer used in the formulation. [21]

**Saliva Stimulating Agent - Lactic Acid**

Lactic acid functions as a salivary stimulant by creating a slightly acidic condition in the oral cavity, which enhances saliva production and facilitates the quick breakdown of fast-dissolving oral films. [22]

**Flavouring Agent – Vanillin**

Vanillin, which is the main constituent of vanilla bean extract, is frequently incorporated as a flavouring agent in oral film formulations. It serves multiple functions, including masking unpleasant taste, improving overall flavour profile, providing a pleasant aroma, and offering broad versatility in pharmaceutical formulations.

The major roles and benefits of vanillin are:

1. Effective taste-masking properties.
2. Enhancement of the overall flavour profile.
3. Contribution of a characteristic pleasant aroma.
4. Wide applicability across different pharmaceutical. [23]

**Sweetener – Mannitol**

Mannitol, a type of polyol or sugar alcohol, is commonly incorporated into oral film formulations due to its numerous functional benefits. It serves as an effective sweetening agent, provides a pleasant cooling effect in the mouth, acts as a bulking agent to improve formulation characteristics, and exhibits non-hygroscopic properties, which help maintain the stability and quality of the oral films.

The major roles and benefits of Mannitol

1. Effective taste-masking properties.
2. Enhancement of the overall flavour profile.
3. Contribution of a characteristic pleasant aroma.
4. Wide applicability across different pharmaceutical formulations and products. [24]

**VI. FORMULATION OF AN ORAL FILM****Method Used for Preparation – Solvent Casting Method**

Procedure:

1. Take a clean beaker with 10ml of distilled water as a solvent.
2. By dissolving the necessary amount of selected polymer pectin 500 mg in sufficient quantity of distilled water.
3. With constant stirring with the help of magnetic stirrer, for 1hr./ 2hr. by completing polymer dissolve.
4. Then add plasticizer polyethylene glycol 400 mg and saliva stimulating agent lactic acid 15mg with continuous stirring.
5. Add specific amount of flavoring agent vanillin in it and sweetener as a mannitol.
6. After the complete dissolving of material poured the sample in selected Petri plates.
7. Then cast in Petri plate and passed through drying equipment like oven at 40 to 50 c for over a night. Then this film is cut into strips and packed in sealed atmospheric resistance pouched.

**VII. MASTER FORMULA**

| Sr No | Ingredients                | F1     | F2     | F3     | F4     | F5     |
|-------|----------------------------|--------|--------|--------|--------|--------|
| 1.    | Clove (mg)                 | 1 ml   | 1ml    | 1ml    | 1ml    | 1ml    |
| 2.    | Polyethylene Glycol 40(mg) | 0.25   | 0.25   | 0.25   | 0.25   | 0.25   |
| 3.    | Lactic Acid (ml)           | 1.5    | 1.5    | 1.5    | 1.5    | 1.5    |
| 4.    | Vanillin                   | 0.15   | 0.15   | 0.15   | 0.15   | 0.15   |
| 5.    | Mannitol                   | 0.15   | 0.15   | 0.15   | 0.15   | 0.15   |
| 6.    | Water                      | Q.S.   | Q.S.   | Q.S.   | Q.S.   | Q.S.   |
| 7.    | Pectin                     | 0.4 gm | 0.45gm | 0.5 gm | 0.5 gm | 0.6 gm |

Table No.1 Master Formula

## VIII. INGREDIENT AND THEIR ROLES:

| Sr No | Ingredients                   | Roles                    |
|-------|-------------------------------|--------------------------|
| 1     | Clove Oil                     | Analgesic                |
| 2     | Polyethylene Glycol 400 (PEG) | Plasticizer              |
| 3     | Lactic Acid                   | Saliva Stimulating Agent |
| 4     | Vanillin                      | Flouring Agent           |
| 5     | Mannitol                      | Sweetener                |
| 6     | Water (H <sub>2</sub> O)      | Solvent                  |
| 7     | Pectin                        | Polymer                  |

Table No. 2 Role of Ingredient

## IX. EVALUATION TEST FOR AN ORAL FILM

- ❖ Thickness of the Film
- ❖ pH Value
- ❖ Folding Endurance
- ❖ Percent Elongation
- ❖ Drug Content Uniformity
- ❖ In Vitro Dissolution Study
- ❖ Dryness / Tack Test
- ❖ Transparency
- ❖ Disintegration Time (Petri Dish Method)
- ❖ Percentage Moisture Loss

Evaluation Parameters for an Oral Film:

Morphological Properties:

The oral films were evaluated for various physical characteristics, including homogeneity, colour, transparency, and odor. All formulations were stored under room-temperature conditions. For protection and storage, the films were sealed in aluminium pouches.

The Thickness of the Film:

Film thickness was measured using a micrometre screw gauge (0–10 mm range, 0.001 mm precision). The instrument was first adjusted to ensure a zero reading, after which the film was positioned between the anvils for measurement. Each sample was analysed in triplicate, and the mean value was calculated and reported.



Fig. No. 3 Micrometer

Measurement of thickness (F)

1. F1

$$= \text{Main Scale} + \text{Circular Scale} \times \text{Least Factor}$$

$$= 0.1 + 0.18 \times 0.01$$

$$= 0.1018$$

2. F2

$$= \text{Main Scale} + \text{Circular Scale} \times \text{Least Factor}$$

$$= 0.1 + 0.2 \times 0.01$$

$$= 0.102$$

3. F3

$$= \text{Main Scale} + \text{Circular Scale} \times \text{Least Factor}$$

$$= 0.1 + 0.23 \times 0.01$$

$$= 0.1023$$

4. F4

$$= \text{Main Scale} + \text{Circular Scale} \times \text{Least Factor}$$

$$= 0.1 + 0.28 \times 0.01$$

$$= 0.1028$$

5. F5

$$= \text{Main Scale} + \text{Circular Scale} \times \text{Least Factor}$$

$$= 0.1 + 3.1 \times 0.01$$

$$= 0.131$$

pH Value:

To determine the pH, the film sample was dissolved in 10 ml of distilled water. The pH meter electrode was then placed in contact with the solution, and the reading was taken after a 1-minute equilibration period. All measurements were performed three times, and the average value was reported. A consistent and nearly uniform pH across all film samples was considered desirable.



Fig. No. 4 Digital pH Meter

#### Folding Endurance:

Folding endurance was evaluated to assess the flexibility and mechanical strength of the film during storage and handling. The test was performed by repeatedly folding a film sample at the same location until it fractured. A uniformly cut film strip (2 cm) was used for the evaluation, and the number of folds required to cause breakage was recorded. All measurements were conducted in triplicate. Higher folding endurance values indicated better film quality and durability.



Fig. No. 5 Folding Endurance.

|              |     |
|--------------|-----|
| Excellent    | 222 |
| Good         | 232 |
| Satisfactory | 220 |
| Poor         | 214 |
| Very Poor    | 208 |

Table No. 3 Folding Endurance Result

#### Drug Content Uniformity:

Drug content was determined by dissolving a 2 cm × 2 cm film sample in 100 mL of distilled water to obtain a solution with a concentration of 20 µg/mL. A 2 mL

aliquot of this solution was then withdrawn and diluted to 10 mL with distilled water. The resulting solution was filtered through Whatman filter paper and analysed using a UV-Visible spectrophotometer at the drug's maximum absorption wavelength ( $\lambda_{max}$ ). Content uniformity for each film batch was evaluated in triplicate to ensure consistency and accuracy.

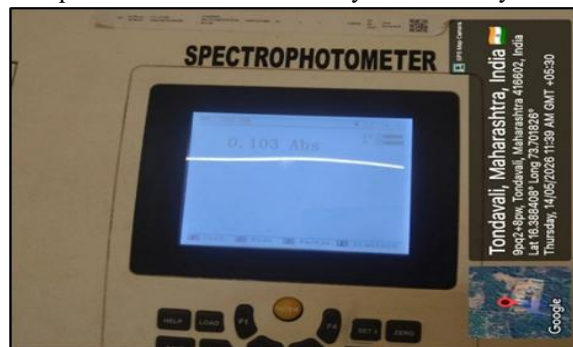


Fig. No. 6 (F1)



Fig. No. 7 (F2)

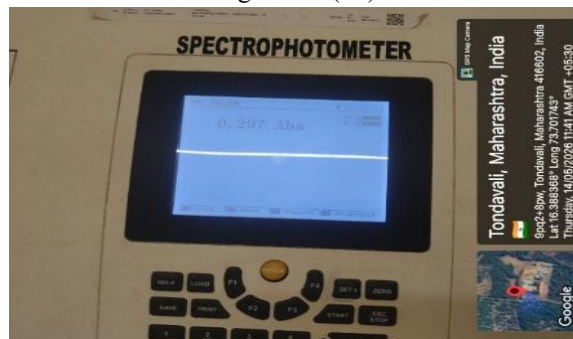


Fig. No. 8 (F3)

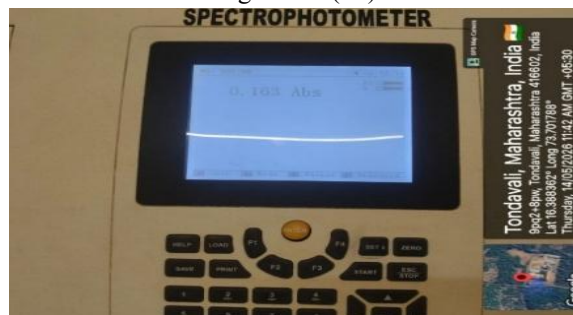


Fig. No. 9 (F4)

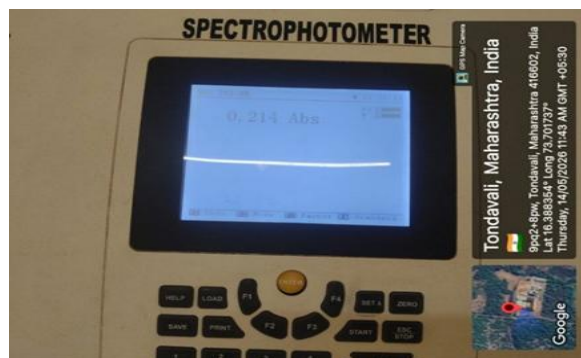


Fig. No. 21 (F5)

Dryness / Tack test:

Tack refers to the adhesive property of a film strip, indicating its ability to stick to another surface, such as an accessory or a piece of paper, when brought into contact under slight pressure.

Transparency:

The transparency of the films can be evaluated using a UV spectrophotometer. A rectangular piece of the film is cut and placed in the spectrophotometer cell, and its transparency is measured at 600 nm. The transparency value is then calculated using the following equation:

$$\text{Transparency} = (\log T_{600}) / b = -\epsilon \text{TVC}$$

Whereas  $T_{600}$  = transmittance at 600nm  $b$  = film thickness (mm)

$C$  = concentration  $f$ )

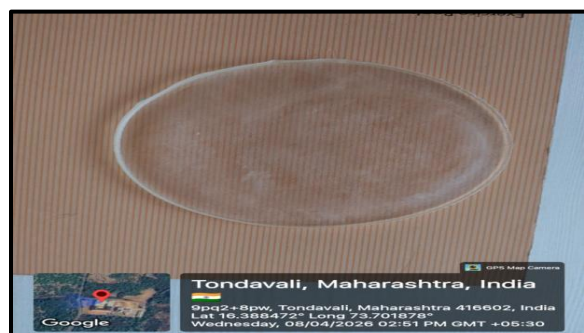
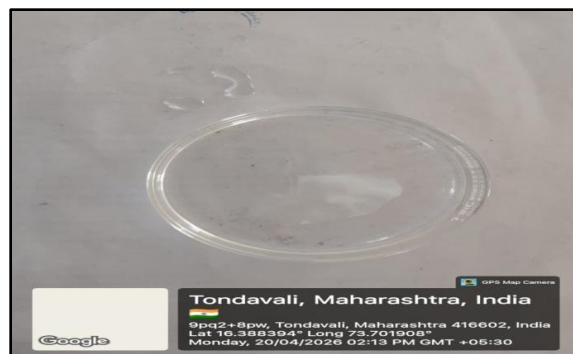


Fig No. 11 Transparency

Disintegration Time (Petri Dish Method):

This method was performed using a Petri plate, where the oral thin film was placed at the centre of a dish containing 10 mL of distilled water. The time required for the film to completely disintegrate was recorded. The experiment was repeated three times to ensure reliability.

Disintegration Time = 51 Sec

Fig No. 11 Disintegration by  
(Petri Dish Method)Fig. No. 12 Disintegration by  
(Disintegration Apparatus)

Percentage Moisture Loss:

The percent moisture loss test was performed to evaluate the physical stability and integrity of the film. A  $2 \times 2$  cm film sample was cut and weighed initially. It was then stored in a desiccator containing fused anhydrous calcium chloride for three days. After this period, the film was removed and reweighed. The percentage moisture loss was calculated using the following formula:

$$\text{Percentage Moisture Loss} = (\text{Initial Weight} - \text{Final Weight}) / \text{Initial Weight} \times 100$$



Fig No. 13

## Anhydrous Calcium Chloride

1. Moisture Loss of f1 (%) =  $\frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100$   
 $= \frac{0.7 - 0.59}{0.7} \times 100$   
 $= 11 \%$
2. Moisture Loss of f2 (%) =  $\frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100$   
 $= \frac{0.8 - 0.7}{0.8} \times 100$   
 $= 10 \%$
3. Moisture Loss of f3 (%) =  $\frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100$   
 $= \frac{0.7 - 0.65}{0.7} \times 100$   
 $= 5 \%$
4. Moisture Loss (%) =  $\frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100$   
 $= \frac{0.8 - 0.53}{0.8} \times 100$   
 $= 27 \%$
5. Moisture Loss (%) =  $\frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100$   
 $= \frac{0.8 - 0.69}{0.8} \times 100$   
 $= 11 \%$

## Result of Evaluation Test

| Sr No | Evaluation Test     |        |        | Results |        |        |
|-------|---------------------|--------|--------|---------|--------|--------|
|       |                     | F1     | F2     | F3      | F4     | F5     |
| 1.    | Thickness of Film   | 0.10   | 0.102  | 0.1023  | 0.1028 | 0.131  |
| 2.    | pH                  | 6.64   | 6.88   | 6.51    | 6.60   | 6.75   |
| 3.    | Folding Endurance   | 232    | 222    | 220     | 214    | 208    |
| 4.    | Disintegration Time | 47 Sec | 51 Sec | 53 Sec  | 56 Sec | 58 Sec |
| 5.    | Percentage Loss     | 11 %   | 10 %   | 5 %     | 27 %   | 11 %   |

Table No. 4 Result of Evaluation Test

## X. CONCLUSION

Based on the evaluation results, batch F2 was identified as the most suitable formulation for the development of the oral film. In conclusion, clove-based fast-dissolving oral films represent an innovative and convenient approach for delivering the therapeutic benefits of clove. These films facilitate rapid disintegration and absorption, thereby providing quick onset of action and improved effectiveness. Their ease of administration, portability, and

acceptable taste make them a practical option for users seeking natural wellness alternatives. Overall, this formulation integrates the traditional medicinal value of clove with modern drug delivery technology, resulting in an effective and user-friendly oral film that supports health and well-being, especially for on-the-go use.

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