

Formulation and Evaluation of Herbal Oral Strip for Migraine Relief

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Abstract: *Migraine is a common neurological disorder characterized by severe headache, nausea, vomiting, and sensitivity to light and sound, which significantly affects the quality of life and daily activities of patients. Conventional therapies used for migraine management may produce adverse effects and are often difficult to administer during migraine attacks due to nausea and swallowing difficulties. Therefore, the present study aimed to formulate and evaluate a herbal fast dissolving oral film containing ginger (Zingiber officinale) and tulsi (Ocimum sanctum) extracts for migraine relief.*

The herbal oral film was prepared by the solvent casting method using Hydroxypropyl Methylcellulose (HPMC) as the film-forming polymer and glycerin as a plasticizer. Ginger and tulsi were selected due to their anti-inflammatory, antioxidant, analgesic, antiemetic, adaptogenic, and neuroprotective properties which may help in reducing migraine symptoms. The prepared films were evaluated for various physicochemical parameters including physical appearance, thickness, weight variation, surface pH, folding endurance, disintegration time, dryness, and tackiness.

The formulated oral film showed smooth appearance, good flexibility, uniform thickness, satisfactory mechanical strength, and acceptable surface pH suitable for oral administration. The average thickness and weight of the film were found to be 0.18 mm and 24 mg respectively. The folding endurance value was 120 folds, indicating good flexibility. The film showed rapid disintegration within 35 seconds, demonstrating its suitability for fast drug delivery and rapid onset of action. The prepared films were also found to be non-tacky, easy to handle, and free from cracks.

The study concluded that the developed ginger and tulsi-based herbal oral film possesses satisfactory pharmaceutical properties and may serve as a promising, patient-friendly, and effective alternative dosage form for migraine management. Further pharmacological and clinical studies are recommended to confirm its therapeutic efficacy and long-term safety.

Keywords: Ginger extract (Zingiber officinale), Tulsi extract (Ocimum sanctum), HPMC, Fast Dissolving Oral Film

I. INTRODUCTION

Migraine is a chronic neurological disorder characterized by recurrent episodes of severe headache commonly associated with nausea, vomiting, photophobia. The headache is usually unilateral and pulsating in nature and may last from a few hours to several days.⁽¹⁾⁽²⁾ Migraine is considered one of the most common neurological disorders affecting millions of people worldwide, especially women. It significantly affects the quality of life of patients and interferes with normal daily activities, social interaction, concentration, and work productivity.⁽³⁾ Migraine attacks may occur occasionally or frequently depending on the severity and triggering factors associated with the condition.

Migraine is not simply a normal headache but a complex neurovascular disorder involving both neurological and vascular mechanisms. The exact pathophysiology of migraine is not completely understood; however, activation of the trigeminovascular system is considered a major factor responsible for migraine pain.⁽¹⁾ During migraine attacks, stimulation of trigeminal nerves leads to the release of inflammatory neuropeptides such as calcitonin gene-related peptide (CGRP) and neurokinin. These mediators produce vasodilation of cerebral blood vessels and neurogenic



inflammation resulting in throbbing headache and associated symptoms. ⁽⁴⁾ In some patients, cortical spreading depression also contributes to migraine aura and pain generation. ⁽⁵⁾

Several triggering factors are responsible for initiating migraine attacks. Common triggers include emotional stress, anxiety, sleep deprivation, hormonal imbalance, dehydration, fasting, bright light, loud sound, fatigue, weather changes, and certain food items such as chocolate, cheese, and caffeinated beverages. ⁽⁶⁾⁽⁷⁾ Due to variation in triggering factors and symptoms among patients, migraine management remains a challenging condition in clinical practice.

Migraine generally progresses through different phases including prodrome, aura, headache phase, and postdrome. During the prodromal phase, patients may experience mood changes, food cravings, neck stiffness, and irritability. Aura occurs in some patients and includes visual disturbances such as flashing lights, blurred vision, zig-zag lines, and temporary loss of vision. The headache phase is characterized by moderate to severe throbbing pain accompanied by nausea, vomiting, and sensitivity to light and sound. After the headache subsides, patients may experience weakness, confusion, fatigue, and difficulty concentrating during the postdrome phase. ⁽⁸⁾⁽²⁾

Conventional therapy for migraine includes the use of analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), ergot derivatives, antiemetics, and triptans. Although these medications are effective in reducing migraine symptoms, prolonged use may produce various adverse effects such as gastric irritation, dizziness, drowsiness, medication overuse headache, and dependency. In addition, oral tablets may become difficult to administer during migraine attacks due to nausea and vomiting. ⁽⁹⁾⁽¹⁾ Therefore, the development of alternative drug delivery systems with improved patient compliance and rapid onset of action has become an important area of pharmaceutical research.

Herbal medicines have gained considerable attention in recent years due to their natural origin, safety, lower incidence of side effects, and therapeutic effectiveness. Medicinal plants have been widely used in traditional systems of medicine for the treatment of neurological disorders, stress, pain, inflammation, and gastrointestinal disturbances. Herbal formulations are considered beneficial for long-term use because they provide symptomatic relief with comparatively fewer adverse effects than synthetic drugs. ⁽¹⁰⁾

In the present study, Ginger and Tulsi were selected as herbal active ingredients for the development of a fast dissolving oral film intended for migraine relief.

Ginger (*Zingiber officinale*) is a well-known medicinal plant widely used for its anti-inflammatory, antioxidant, analgesic, and antiemetic properties. The major bioactive constituents present in ginger include gingerol, shogaol, and zingerone. Ginger has been reported to reduce nausea, vomiting, inflammation, and headache intensity associated with migraine attacks. It also improves blood circulation and exhibits neuroprotective activity. ⁽¹¹⁾⁽¹²⁾ Due to its rapid antiemetic effect, ginger is considered highly beneficial during the early stages of migraine where nausea and vomiting are prominent symptoms.



Fig no 1. Ginger



Tulsi (Ocimum sanctum), commonly known as holy basil, is one of the most important medicinal herbs used in Ayurveda. Tulsi possesses adaptogenic, anti-stress, antioxidant, anti-inflammatory, and immunomodulatory properties.



Fig no 2. Tulsi

Stress and anxiety are considered major triggering factors for migraine attacks, and tulsi helps in calming the nervous system and reducing stress-induced symptoms. The presence of active phytoconstituents such as eugenol, ursolic acid, and flavonoids contributes to its therapeutic activity.^{(13) (14)} Tulsi also exhibits mild analgesic and neuroprotective effects which may help in improving migraine-associated discomfort.

The combination of ginger and tulsi may provide synergistic benefits in the management of migraine symptoms. Ginger mainly helps in reducing nausea, inflammation, and headache intensity, whereas tulsi helps in stress reduction and calming of the nervous system. Therefore, the use of these herbal ingredients in a novel oral dosage form may improve therapeutic effectiveness and patient acceptability.

Fast dissolving oral films are thin polymeric films designed to disintegrate rapidly when placed on the tongue without the need for water. These films offer several advantages such as rapid onset of action, ease of administration, improved bioavailability, accurate dosing, portability, and enhanced patient compliance. Oral films are particularly beneficial for pediatric, geriatric, and migraine patients who may experience difficulty in swallowing conventional tablets during episodes of nausea and vomiting.^{(15) (16)}

The formulation of oral films generally involves the use of film forming polymers, plasticizers, sweetening agents, flavoring agents, and active ingredients. Hydroxypropyl methylcellulose was selected as a film polymer in the present study due to its excellent film forming ability, non-toxicity, flexibility, transparency, and rapid hydration properties. Glycerin was used as a plasticizer to improve flexibility and prevent brittleness of the film. Sweetening and flavoring agents were added to improve palatability and patient acceptability.⁽¹⁷⁾

The solvent casting method is one of the most commonly used techniques for the preparation of oral films because it produces smooth, uniform, and flexible films with good mechanical properties. In this method, polymer and other ingredients are dissolved in suitable solvent systems, casted on a flat surface, and dried to obtain thin films. The prepared films are further evaluated for thickness, folding endurance, surface pH, disintegration time, appearance, and other quality control parameters.^{(18) (19)}

The present research work focuses on the formulation and evaluation of herbal fast dissolving oral film containing ginger and tulsi extract for migraine relief. The developed formulation is expected to provide rapid symptomatic relief, improved convenience, enhanced patient compliance, and better therapeutic effectiveness. This study may also contribute towards the development of safer and patient-friendly herbal drug delivery systems for neurological disorders.



II. MECHANISM OF ACTION

The drug delivery system can use the tongue or any other mucosal tissue in the mouth. The film is quickly moistened by saliva and then breaks down, releasing the drug for oral mucosal absorption. This is due to the use of hydrophilic polymer and other excipients.

IDEAL FEATURES OF ORAL THIN FILMS

The drug should be good taste. The drug should dissolve easily in saliva and be highly moisture-resistant. The drug should have the right amount of tension resistance. The drug should be ionized in the pH of the oral cavity. The drug should be able to permeate the oral mucosa and medications¹¹ should be able to act quickly.⁽²⁰⁾

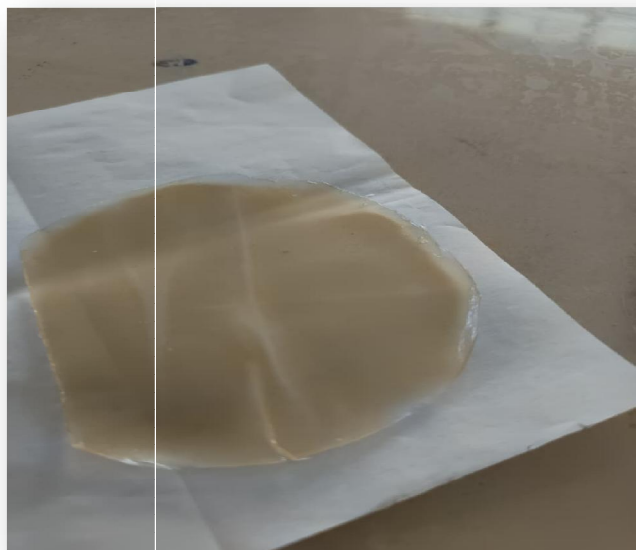


Fig no 3. Physical Appearance of Prepared Herbal Oral Thin Film

III. LITERATURE SURVEY

Sr. No.	Author & Reference	Formulation	Outcomes
1	Kathpalia H, Garg A. Fast Dissolving Films: A Novel Approach for Drug Delivery System. International Journal of Pharmaceutical Sciences Review and Research. 2014;25(2):31-40. ⁽²¹⁾	Oral dissolving films prepared using HPMC, PVA and Pullulan polymers by solvent casting method with plasticizers such as PEG-400 and Propylene glycol.	Showed rapid dissolution without water, improved patient compliance, rapid drug absorption and avoidance of first-pass metabolism.
2	Maghbooli M, Golipour F, Moghimi Esfandabadi A, Yousefi M. Comparison between efficacy of ginger and sumatriptan in the ablative treatment of common migraine. Phytother Res. 2014;28(3):412-415. ⁽¹²⁾	Ginger preparation containing active constituents gingerols, shogaols and zingerone used for migraine management.	Reduced headache severity, nausea and photophobia; demonstrated anti-emetic effect and a favorable safety profile.



3	Cohen MM. Tulsi – Ocimum sanctum: A herb for all reasons. <i>Journal of Ayurveda and Integrative Medicine</i> . 2014;5(4):251–259. ⁽¹⁴⁾	Tulsi extract rich in eugenol, rosmarinic acid, ursolic acid and flavonoids showing anti-inflammatory and neuroprotective activity.	Demonstrated antioxidant, anti-inflammatory and stress-reducing effects, supporting its potential role in migraine therapy.
4	Maghbooli M, Golipour F, Moghimi Esfandabadi A, Yousefi M. Comparison between efficacy of ginger and sumatriptan in the ablative treatment of common migraine. <i>Phytother Res</i> . 2014;28(3):412-415. ⁽¹²⁾	Polyherbal formulations combining ginger and other herbal extracts through oral/mucosal delivery systems.	Reduced migraine pain score and attack duration; synergistic action improved therapeutic efficacy and rapid relief.

Table no. 1 Literature Survey

NEED FOR STUDY

Sr. No.	Need for Study	Short Description
1	High Prevalence of Migraine	Migraine is a common neurological disorder affecting quality of life, productivity, and daily activities. Better treatment options are needed.
2	Limitations of Conventional Dosage Forms	Tablets and capsules are difficult to use during migraine attacks due to nausea, vomiting, and swallowing problems.
3	Advantages of Oral Films	Oral films dissolve quickly in the mouth, require no water, improve patient compliance, and provide rapid drug release.
4	Role of Ginger in Migraine	Ginger possesses anti-inflammatory, analgesic, and antiemetic properties that may help reduce migraine symptoms.
5	Role of Tulsi in Migraine	Tulsi shows anti-inflammatory, antioxidant, and neuroprotective effects useful in migraine management.
6	Synergistic Herbal Approach	Combination of ginger and tulsi may provide enhanced therapeutic effect through multiple mechanisms of action.
7	Demand for Herbal Medicines	Growing interest in natural therapies due to concerns about side effects of synthetic medicines.
8	Lack of Herbal Oral Film Products	No widely available herbal oral film specifically developed for migraine treatment exists.
9	Need for Scientific Formulation Study	Herbal oral films require evaluation for compatibility, stability, strength, and drug release properties.
10	Research Contribution	The study supports development of novel herbal drug delivery systems and scientific validation of traditional medicine.

Table no. 2 Need of Study

IV. AIM AND OBJECTIVES

Aim

To formulate, optimise, and evaluate oral dissolving films incorporating standardised extracts of *Zingiber officinale* (ginger) and *Ocimum tenuiflorum* (tulsi) for the rapid management of migraine headache, with the goal of developing a safe, effective, patient-compliant, and commercially viable herbal dosage form.

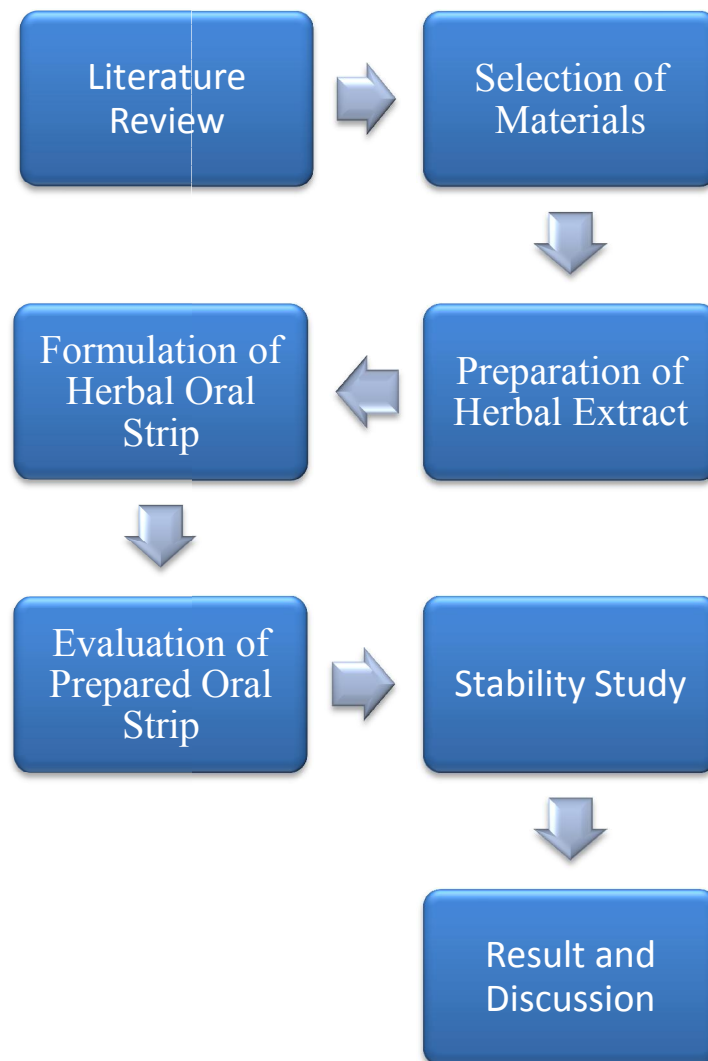


Objectives

To formulate a herbal oral dissolving film containing natural extracts such as ginger and tulsi for migraine management.

1. To evaluate the effectiveness of herbal extracts in providing relief from migraine symptoms.
2. To develop a fast-dissolving oral film that disintegrates rapidly in the oral cavity for easy drug administration.
3. To improve patient compliance by preparing a convenient, portable, and non-invasive dosage form.
4. To study the physicochemical properties of the prepared oral film such as thickness, pH, folding endurance, weight variation, and drug content uniformity.
5. To assess the disintegration and dissolution behavior of the formulated herbal oral film.
6. To investigate the stability and quality of the developed herbal oral dissolving film formulation.
7. To provide a safe, herbal-based alternative approach for migraine treatment with minimal side effects.

Plan of work



- 1. Literature Review**
 - Study of migraine, causes, symptoms, and treatment.
 - Study of herbal drugs used for migraine relief.
 - Review of oral strip drug delivery system and its advantages.
- 2. Selection of Materials**
 - Selection of herbal extract for anti-migraine activity.
 - Selection of polymer (HPMC).
 - Selection of plasticizer (Glycerin/PEG).
 - Selection of solvents, sweeteners, and other excipients.
- 3. Preparation of Herbal Extract**
 - Collection and drying of herbal material.
 - Powder preparation.
 - Extraction by maceration method.
 - Filtration and concentration of extract.
- 4. Formulation of Herbal Oral Strip**
 - Preparation of polymer solution.
 - Addition of herbal extract and plasticizer.
 - Proper mixing to obtain uniform solution.
 - Casting of solution in petri plate.
 - Drying of strip in hot air oven.
 - Cutting and storage of oral strips.
- 5. Evaluation of Prepared Oral Strip**
 - Evaluation tests performed:
 - Physical appearance
 - Thickness test
 - Weight variation test
 - Folding endurance
 - Surface pH
 - Disintegration time
 - Drug content uniformity
 - Dissolution study using artificial saliva.
- 6. Stability Study**
 - Storage of formulation under suitable conditions.
 - Observation of physical appearance, pH, and performance.
- 7. Result and Discussion**
 - Discussion of formulation characteristics.
 - Analysis of evaluation parameters and drug release behavior.

V. MATERIAL AND EQUIPMENT

Sr. No.	Name of Material	Category	Role in Formulation
1	Ginger Extract	Herbal Active Ingredient	Ginger possesses anti-inflammatory, antioxidant, analgesic, and antiemetic properties. It may help in reducing migraine-associated headache, nausea, and inflammation. Active constituents such as



			gingerol and shogaol contribute to its therapeutic activity.
2	Tulsi Extract	Herbal Active Ingredient	Tulsi exhibits anti-stress, adaptogenic, antioxidant, and neuroprotective properties. It helps in calming the nervous system and reducing stress-induced migraine symptoms.
3	Hydroxypropyl methylcellulose (HPMC)	Film Forming Polymer	Used for preparation of thin, smooth, flexible, and fast dissolving oral film. It provides structural integrity and rapid hydration characteristics.
4	Glycerin	Plasticizer	Used to improve flexibility and prevent brittleness of prepared oral film.
5	Methyl Paraben	Preservative	Used to prevent microbial growth and improve stability of formulation.
6	Ethanol	Extraction Solvent	Used in hydroalcoholic extraction process during maceration of herbal materials.
7	Distilled Water	Solvent	Used for preparation of polymeric solution and extraction procedure.
8	Saccharin Sodium	Sweetening Agent	Used to improve taste and palatability of oral film
9	Peppermint flavour	Flavoring Agent	Used to provide pleasant taste and mouthfeel.

Table no. 3 Material used for formulation

Sr. no	Name of Equipment	Use
1	Weighing Balance	Used for accurate weighing and measurement of individual herbal ingredients and excipients to ensure correct formulation composition.
2	Mortar and Pestle / Electric Grinder	Used to grind dried herbal materials into fine and uniform powder.
3	Sieves / Mesh	Used to remove coarse particles and obtain uniformly sized herbal powders
4	Glass Beakers	Used for holding and mixing herbal powders and polymeric solutions during formulation process.
5	Spatulas	Used for thorough mixing and transfer of materials without contamination.
6	Measuring Cylinder	Used for accurate measurement of liquids such as ethanol, distilled water, glycerin, and extracts.
7	Magnetic Stirrer / Glass Rod	Used for continuous stirring and preparation of homogeneous polymeric solution.
8	Filter Paper and Funnel	Used for filtration of herbal extract after maceration process.
9	Water Bath	Used for controlled heating and concentration of herbal extract.
10	Petri Dish	Used for casting and drying of oral film solution.
11	Drying Trays	Used for spreading and drying herbal materials before grinding and extraction.
12	Hot Air Oven	Used for controlled drying of herbal materials and prepared oral films when required.
13	Micrometer Screw Gauge /	Used for determination of thickness of oral film.



	Vernier Caliper	
14	pH Paper / pH Meter	Used for determination of surface pH of prepared oral film.
15	Stopwatch	Used for measurement of disintegration time of oral film.

Table no. 4 Equipment used

VI. EXPERIMENTAL WORK

1. Selection of Herbal Ingredients

Ginger and Tulsi were selected as herbal active constituents because of their beneficial effects in the management of migraine and associated symptoms.

Ginger

- Possesses significant anti-inflammatory activity
- Helps in reducing migraine-associated nausea and vomiting
- Exhibits antioxidant and mild analgesic properties
- Contains active phytoconstituents such as gingerol and shogaol

Tulsi

- Shows adaptogenic and anti-stress activity
- Helps in calming the nervous system
- Possesses antioxidant and neuroprotective properties
- Useful in reducing stress-related migraine symptoms

2. Collection and Preparation of Herbal Materials

- Ginger and tulsi were obtained from a suitable commercial source.
- The collected materials were cleaned thoroughly to remove dirt and other impurities.
- The materials were dried under appropriate conditions until complete drying was achieved.
- Dried herbal materials were powdered using a grinder.
- The powder was passed through a sieve to obtain uniform particle size.

3. Preparation of Herbal Extract

Step 1: Preparation of Solvent

A hydroalcoholic solvent system containing ethanol and distilled water was prepared in suitable proportion.

Step 2: Maceration Process

Accurately weighed ginger and tulsi powders were soaked in the prepared solvent for 24 hours with intermittent stirring.

Step 3: Filtration

The macerated mixture was filtered using filter paper and funnel to separate the extract from the marc.

Step 4: Concentration

The filtrate obtained was concentrated on a water bath at controlled temperature to obtain concentrated herbal extract.

Step 5: Storage

The concentrated extracts were collected and stored properly for further formulation studies.



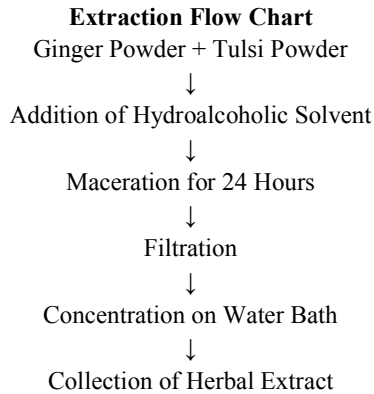


Fig no 4. Preparation of Herbal Extracts (Ginger and Tulsi)

4) Formulation of Fast Dissolving Oral Film

Solvent Casting Method

Ingredient	Quantity
HPMC	800mg
Ginger Extract	2ml
Tulsi Extract	2ml
Glycerin	2ml
Methyl Paraben	0.5ml
Sodium Saccharin	0.5ml
Distilled Water	20ml

Table no. 5 Composition of Formulation

Formulation Procedure

Step 1: Preparation of Polymeric Solution

- Required quantity of Hydroxypropyl Methylcellulose (HPMC) was weighed accurately.
- Distilled water was taken in a clean beaker.



- HPMC was added slowly with continuous stirring to avoid lump formation.
- The solution was allowed to hydrate completely to obtain a viscous polymeric solution.

Step 2: Incorporation of Herbal Extract

- Ginger extract was added into the polymeric solution with continuous stirring.
- Tulsi extract was then incorporated and mixed uniformly.

Step 3: Addition of Excipients

- Glycerin was added as a plasticizer to improve film flexibility.
- Methyl paraben was added as preservative.
- Suitable sweetening and flavoring agents were incorporated to enhance palatability.

Step 4: Removal of Entrapped Air

- The prepared solution was kept undisturbed for a few minutes to remove entrapped air bubbles.

Step 5: Casting of Film

- The bubble-free solution was poured carefully into a clean petri dish and spread uniformly to obtain uniform thickness.

Step 6: Drying

- The casted film was dried at room temperature for approximately 24 hours.

Step 7: Peeling and Cutting

- The dried film was carefully peeled from the petri dish.
- The film was cut into suitable dimensions to obtain oral strips.

5) Evaluation of Prepared Oral Film

Evaluation Test	Purpose
Physical Appearance	To observe color, transparency, and surface smoothness
Thickness Test	To determine uniformity in film thickness
Folding Endurance	To evaluate flexibility and mechanical strength
Surface pH	To determine compatibility with oral mucosa
Disintegration Time	To measure time required for film disintegration

Table no. 6 Evaluation test

VII. EVALUATION PARAMETER

1) Appearance

The formulated films should be checked for their appearance. Film should be checked visually for their appearance.

2) Thickness of films:

The thickness of the film was measured by micrometer screw gauge at three different places and average of three values was calculated. This is essential to ascertain uniformity in the thickness of the film which is directly related to the accuracy of dose in the film.



3) Weight of films / weight variation:

Oral fast dissolving films were weighed on analytical balance and average weight can be determined for each film. It is desirable that films should have nearly constant weight. It is useful to ensure that a film contains the proper amount of excipients and API.

4) pH value:

World Journal of Pharmaceutical Research The pH value was determined by dissolving one oral film in 10 ml distilled water and measuring the pH of the obtained solution. All determinations were performed in triplicate. It is necessary that strip should have nearly uniform pH value.

5) Folding endurance:

Folding endurance of the film is essential to study the elasticity of the film during storage and handling. The folding endurance of the film films was determined by repeatedly folding one film at the same place till it broke. This is considered to reveal good film properties. A film (2 X 2 cm) was cut evenly and repeatedly folded at the same place till it breaks. The number of times the film could be folded at the same place without breaking gave the exact value of folding endurance. All determination were performed in triplicate.

6) Disintegration time:

It was determined visually in a glass beaker filled with 25 ml distilled water with swirling every 10seconds. The time at which film started to break or disintegrate was recorded as the in-vitro disintegration time. It was performed in triplicate.



Fig no 5. Evaluation of Disintegration Time of Prepared Herbal Fast Dissolving Oral Film.



7) Dryness / Tack test:

Tack is the tenacity with which strip adheres to an accessory or a piece of paper that has been pressed into contact with the strip.

VIII. RESULT

1) Physical Appearance of Herbal Oral Film

The prepared herbal oral dissolution film containing ginger and tulsi extracts was visually evaluated for color, texture, flexibility, and surface smoothness.

Parameter	Observation
Colour	Light green / pale brown
Appearance	Smooth and transparent / semi-transparent
Texture	Soft and flexible
Surface	Uniform, non-sticky
Odour	Characteristic herbal odour

Table no. 7 Physical Appearance

The formulated oral film showed a smooth surface, acceptable appearance, and good flexibility without cracks.

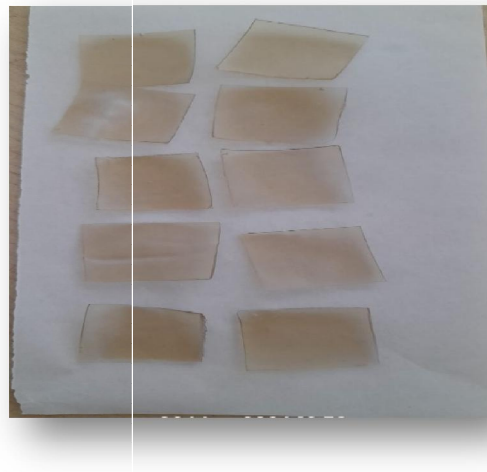


Fig no 6. Prepared Herbal Fast Dissolving Oral Film Strips

2) Thickness Test

Thickness of oral film was measured using a micrometer screw gauge/vernier caliper at different points.

Trial	Thickness (mm)
1	0.18
2	0.19
3	0.17

Table no. 8 Thickness test

Average Thickness = 0.18 mm

The film showed uniform thickness indicating proper casting and homogeneous distribution of ingredients.

3) Weight Variation Test

Different oral strips were weighed individually using a digital balance.



Strip Number	Weight (mg)
1	25
2	23
3	24

Table no. 9 Weight variation

Average Weight = 24 mg

Minimal weight variation confirmed uniform drug distribution in the formulation.

4) Surface pH Test

Surface pH of the film was measured to ensure compatibility with oral mucosa.

pH = 6.7

The pH was found near neutral range, indicating suitability for oral administration without irritation.

5) Folding Endurance Test

Film was repeatedly folded at the same position until it broke.

Folding Count = 120 folds

High folding endurance indicated good flexibility and mechanical strength.

6) Disintegration Time

Disintegration study was performed using artificial saliva.

Disintegration Time = 35 sec

The herbal oral film disintegrated rapidly, showing suitability for fast oral drug delivery.

7) Dryness

Parameter	Observation
Dryness	Completely dried
Surface	Smooth and uniform
Moisture	No residual moisture observed
Cracks	Absent

Table no. 10 Dryness test

The prepared oral strip showed complete and uniform drying without cracks or excess moisture. The film possessed a smooth surface and satisfactory physical appearance, indicating proper drying during formulation.

8) Tack test

Parameter	Observation
Tackiness	Non-tacky / slightly tacky
Handling property	Easy to handle
Stickiness	Not observed

Table no. 11 Tack test

The formulated oral strip was found to be non-tacky and easy to handle. No excessive stickiness was observed, indicating suitable concentration of polymer and plasticizer in the formulation.



IX. DISCUSSION

The present study focused on the formulation and evaluation of a **herbal fast dissolving oral film containing ginger and tulsi extracts for migraine relief**. The aim was to develop an oral strip that provides rapid disintegration, easy administration, and improved patient compliance.

Ginger and tulsi were selected due to their beneficial properties in migraine management. Ginger possesses anti-inflammatory, antioxidant, analgesic, and antiemetic activities that help reduce migraine pain, nausea, and vomiting. Tulsi shows adaptogenic, antioxidant, and anti-stress properties which may help in reducing stress-related migraine symptoms.

The herbal extracts were prepared by the **hydroalcoholic maceration method**, which is effective for extracting active phytoconstituents from herbal materials. The oral film was prepared by the **solvent casting method** using **HPMC** as the film-forming polymer, **glycerin** as plasticizer, and **methyl paraben** as preservative.

The prepared films showed acceptable physical appearance, smooth texture, and uniform film formation. Thickness evaluation indicated proper casting and uniformity of the films. Folding endurance results demonstrated good flexibility and mechanical strength. Surface pH was found suitable for oral administration, indicating compatibility with the oral cavity.

The films exhibited **rapid disintegration**, which is an important characteristic of fast dissolving oral films and may contribute to quicker onset of action. Transparency and homogeneity studies confirmed uniform distribution of ingredients within the formulation.

Overall, the developed ginger, tulsi oral film showed satisfactory evaluation results and may be considered a promising herbal formulation for migraine management. However, further studies such as **drug content analysis, dissolution testing, stability studies, and clinical evaluation** are required to confirm its efficacy and safety.

X. CONCLUSION

The present study was successfully carried out to formulate and evaluate a herbal oral dissolution film for anti-migraine therapy using ginger (*Zingiber officinale*) and tulsi (*Ocimum sanctum*) extracts. The herbal extracts were selected due to their reported anti-inflammatory, analgesic, antioxidant, and therapeutic properties, which may help in the management of migraine symptoms. The oral film was prepared by the solvent casting method using suitable film-forming polymers, plasticizers, and other excipients.

The prepared formulation was evaluated for various parameters including physical appearance, thickness, weight variation, surface pH, folding endurance, disintegration time, drug content uniformity, and mechanical properties. The obtained results demonstrated that the formulated film possessed good flexibility, smooth appearance, acceptable surface pH, uniform thickness, and satisfactory mechanical strength.

The oral film exhibited rapid disintegration characteristics, which indicates its suitability for fast drug delivery through the oral cavity. Uniform distribution of herbal extracts within the film confirmed the effectiveness of the formulation method. The formulation also showed desirable handling properties and patient-friendly characteristics.

The developed herbal oral dissolution film provides several advantages such as:

Easy administration

Fast disintegration and rapid onset of action

Improved patient compliance

No requirement of water for administration

Convenient dosage form for patients suffering from migraine attacks

From the overall evaluation studies, it can be concluded that the developed ginger and tulsi-based herbal oral film has good pharmaceutical properties and shows potential as an effective alternative dosage form for migraine management.

However, further studies such as stability studies, detailed pharmacological evaluation, and clinical investigations are recommended to confirm its long-term safety, efficacy, and therapeutic performance. Therefore, this research suggests



that herbal oral dissolution films may serve as a promising, patient-friendly, and effective approach for anti-migraine treatment.

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