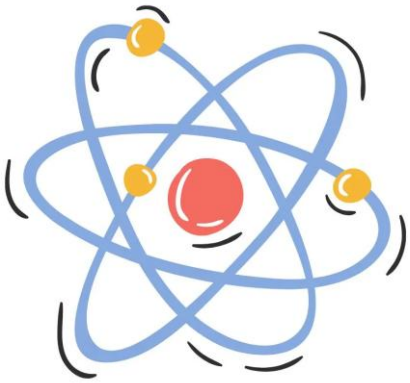

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FORMULATION AND EVALUATION OF HERBAL BUCCAL FILM OF TULSI (*Ocimum sanctum*) FOR THE MANAGEMENT OF MOUTH ULCERS: A Review

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Abstract: *Oral health is a vital component of general health, and mouth ulcers can substantially impact an individual's daily life. They sting, get all swollen, and suddenly even basic stuff like eating or talking becomes a hassle. These little sores don't just bug you for a bit they really drag down your mood and your routine. And they show up for all kinds of reasons. Maybe you bit your cheek, caught some infection, missed out on certain vitamins, got stressed, or your immune system's just acting up. Most of the usual fixes creams, gels, pills only give quick relief. They can be a pain to use, bring some annoying side effects, and let's face it, most people don't bother sticking with them for long. Lately, though, herbal remedies are getting a lot more attention. People see them as safer, they tend to help with more than one thing, and overall, folks just seem to tolerate them better. Tulsi (Ocimum sanctum) really stands out. It helps with inflammation, fights germs, acts as an antioxidant, soothes pain, and speeds up healing. That makes it a pretty strong contender for treating mouth ulcers. Now, there's something new mucoadhesive buccal films. These are thin, bendy strips you stick right on the sore. They slowly release Tulsi exactly where you need it. They're simple to use and don't taste bad, either. This study's all about making and testing those Tulsi buccal films. We used a solvent casting method, mixing different polymers and plasticizers to get the films just right strong, flexible, and sticky enough to stay put. We checked everything: strength, stickiness, how much Tulsi gets delivered, how quickly it's released, how much water the films soak up, and how well they hold up over time. The results? Pretty solid. The films are tough, deliver Tulsi steadily, stick well, and last. Tulsi buccal films really look promising. They ease pain, bring down swelling, help you heal faster, and fight off infections all while making it easier for people to actually follow through with treatment. This research proves that mixing traditional herbal medicine with new ways of delivering it can give us a safer, more effective way to treat mouth ulcers.*

Keywords: *Buccal films; Ocimum sanctum; Mouth ulcers; Herbal drug delivery system; Mucoadhesive polymers; Oral mucosa*

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Introduction

Mouth ulcers those painful ulcerative lesions in your mouth are surprisingly common. They hurt. Eating, drinking, even talking can become discomfort when you have one. Lots of things can trigger them: trauma from accidental cheek biting, maybe you're stressed out, or maybe your diet's missing something important. Sometimes it's hormones or an infection. Usually, the ulcers heal up on their own, but if they keep coming back, they can really mess with your daily life.

People usually reach for things like corticosteroid gels, antiseptic mouthwashes, or numbing creams. These can help for a bit, but honestly, the relief doesn't last. The medicine doesn't stick around in your mouth long enough, and sometimes it leads to other side effects.

That's why researchers have started paying more attention to buccal drug delivery basically, ways to get medicine to stick inside the mouth and work right where it's needed. Buccal films are especially interesting. They're thin and flexible, they stick to the inside of your cheek, and they slowly release medicine directly onto the sore. This targeted approach helps the medicine work better and makes it easier to stick to the treatment.

Lately, there's been a growing interest in herbal remedies for mouth problems, mostly because they're safer and easier to get, and they don't come with a long list of side effects. Medicinal plants can fight inflammation, kill germs, help wounds heal, and protect cells from damage. One standout is Ocimum sanctum Tulsi, or Holy Basil. In Ayurveda, Tulsi is both sacred and powerful as a medicine. It's packed with helpful stuff like eugenol, ursolic acid, rosmarinic acid, and flavonoids. These compounds are strong antioxidants and fight inflammation, too. Tulsi can even stop the growth of bacteria like Streptococcus mutans, which is a big culprit behind mouth infections and ulcers.

Oral Health Mouth Ulcer

Oral health matters a lot more than most people think. Your mouth isn't just for eating or talking it's the main gateway to the rest of your body. When something's off in there, it can mess with how you feel physically and even mentally. The World Health Organization puts it simply: good oral health means no mouth pain, no sores or infections, healthy gums, and no missing teeth. But things like bad hygiene, infections, poor diet, or other health issues can throw

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everything out of balance. Cavities, gum disease, and mouth ulcers are just a few of the problems that can show up.

Mouth ulcers doctors sometimes call them aphthous ulcers are those annoying, painful spots you find inside your mouth. They can pop up on your tongue, your cheeks, lips, or right on the floor of your mouth. Usually, they're small and round with a white or yellow center, surrounded by a red, irritated ring. Lots of things can trigger them: maybe you bit your cheek, or your dental work scratched you. Stress, shifting hormones, a lack of vitamin B, food allergies, or infections from bacteria or viruses can all cause these sores.

Doctors sort mouth ulcers into a few types. Minor aphthous ulcers are small and usually clear up in a week or so, leaving no scar. Major ones go deeper and stick around for weeks. Then there are herpetiform ulcers tiny but painful, and sometimes they join together to form a bigger sore.

Most of the time, mouth ulcers heal by themselves. But if they keep coming back or just won't go away, they can make eating, talking, and just getting through the day pretty miserable. Treatments right now include things like corticosteroid creams, antiseptic rinses, or numbing gels. The problem? They don't last long because your saliva washes them away, so you only get short-term relief. Plus, if you use these synthetic products for too long, you might end up with irritated tissues, weird tastes, or even new infections.

That's why more people are looking for safer, more natural ways to heal mouth ulcers something that really works, lasts longer, and doesn't bring a bunch of side effects. Herbal remedies and new delivery systems that stick to the inside of your mouth are getting a lot of attention.

Combining the natural healing power of Tulsi with modern buccal film technology could be a real game-changer. The idea is to create an herbal film that sticks to the sore, delivers Tulsi right where you need it, and keeps working longer than typical treatments. Plus, it skips all those side affects you get from synthetic drugs. This study is all about developing and testing a Tulsi-based buccal film to see just how well it works for treating mouth ulcers.

Advantages of Buccal Film Drug Delivery System

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1**. Skips First-Pass Metabolism**

When you use buccal films, the drug slips straight into your bloodstream through the lining of your cheek. It doesn't go through the liver first, so you get more of the drug working in your system. This boosts how effective the medicine is and helps you feel the results sooner.

2. **Stays Put for Longer**

Thanks to their mucoadhesive nature, buccal films basically stick to the inside of your mouth. This means the drug hangs around right where it's needed, which is great for treating things like mouth ulcers.

3. Works Fast

The blood vessels in your mouth are close to the surface, so the drug gets absorbed quickly. You'll notice relief faster than if you took a regular pill or capsule.

4. Easy for Everyone

Buccal films are thin, bendy, and simple to use. People who hate swallowing pills kids, older adults, anyone find these films much easier to handle.

5. Controlled, Steady Release

You can tweak the ingredients and polymers in these films to release the drug slowly and steadily. That keeps the dose consistent over time.

6. More of the Drug, Less Waste

Since the drug doesn't get chewed up by stomach acid or digestive enzymes, more of it actually makes it into your bloodstream.

7. No Needles, No Pain

These films don't involve any poking or prodding. Just stick the film in your mouth no injections or discomfort.

8. Simple to Make and Store

Manufacturing buccal films isn't complicated. Techniques like solvent-casting or hot-melt extrusion get the job done, and the films stay stable on the shelf. That makes them affordable and easy to produce in bulk.

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Pharmacological Activities Of Tulsi

1. Anti-inflammatory Activity

Tulsi packs a punch when it comes to fighting inflammation, mostly thanks to eugenol and ursolic acid. These compounds block enzymes like COX and LOX, which drive inflammation. The result? Less pain, less swelling, and a real difference for things like mouth ulcers.

2. Antimicrobial and Antifungal Activity

Tulsi isn't just about calming things down it takes the fight to bacteria and fungi too. Its extracts go after troublemakers like Streptococcus mutans, Staphylococcus aureus, E. coli, and even Candida albicans. These germs often cause oral infections or slow down ulcer healing, but Tulsi helps keep them in check.

3. Antioxidant Activity

Loaded with flavonoids and phenolic compounds, Tulsi tackles reactive oxygen species head-on, easing oxidative stress. That matters because oxidative stress is a big culprit behind tissue damage and inflammation. By fighting it off, Tulsi helps wounds in the mouth heal faster.

4. Wound-Healing Activity

Tulsi speeds up the healing process by encouraging tissue regrowth and collagen production. Its anti-inflammatory and antioxidant powers join forces to help new skin form more quickly, so wounds both in the mouth and on the skin recover faster.

5. Immunomodulatory and Adaptogenic Activity

Tulsi strengthens the immune system, making the body better at fighting infections. It's also an adaptogen, so it helps you handle physical and emotional stress more effectively.

6. Analgesic and Antipyretic Activity

Studies show Tulsi extract eases pain and bring down fever. It does this by blocking prostaglandin production and targeting pain receptors in the central nervous system.

Pharmacological Activity	Key Phytochemicals	Mechanism / Effect

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Anti inflammatory	Eugenol Ursolic acid	Inhibits COX and LOX enzymes reduces inflammation
Antimicrobial	Eugenol Linalool	Destroys oral pathogens prevents secondary infections
Antioxidant	Rosmarinic acid Apigenin	Neutralizes ROS protects tissues from oxidative stress
Wound healing	Ursolic acid Flavonoids	Stimulates collagen synthesis and epithelialization
Immunomodulatory	Flavonoids Polyphenols	Enhances immune response and stress resistance
Analgesic	Eugenol	Inhibits prostaglandin synthesis reduces pain

Formulation and Preparation of Herbal Buccal Film of Ocimum sanctum (Tulsi)

Formulation of Herbal Buccal Film

Component	Purpose	Suggested Amount (% w/w)

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Ocimum sanctum (Tulsi) extract	Active ingredient; anti-inflammatory, antimicrobial, antioxidant, wound healing	5–10
Hydroxypropyl methylcellulose (HPMC K100)	Film-forming polymer; provides structure and mucoadhesion	2–5
Sodium carboxymethylcellulose (SCMC)	Mucoadhesive polymer; improves adhesion to buccal mucosa	1–2
Polyvinyl alcohol (PVA)	Film-forming and flexible polymer; increases mechanical strength	1–2
Glycerin	Plasticizer; enhances flexibility and prevents brittleness	0.5–1.5
Propylene glycol	Plasticizer; boosts elasticity and drug release	0.5–1
Ethanol / Distilled water	Solvent; dissolves polymers and disperses extract	Q.S. to 100 mL
Sucralose / Menthol	Sweetener / Flavoring agent; enhances patient acceptability	0.1–0.3
Sodium benzoate	Preservative stops microbial growth	0.1–0.2

Preparation Method

Step 1: Make the Polymer Solution

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Start by dissolving HPMC, SCMC, and PVA in distilled water or a water-ethanol mix. Stir this mixture for a couple of hours 2 to 3 hours usually does the trick until everything is fully dissolved.

Step 2: Add the Tulsi Extract

Pour the Tulsi extract into your polymer solution. Mix it well so the extract spreads evenly through the mixture.

Step 3: Add Plasticizers and Other Ingredients

Now, mix in glycerin and propylene glycol for flexibility. Toss in your chosen sweetener (sucralose or menthol) for taste, and add sodium benzoate to keep the film fresh and free from microbes.

Step 4: Remove Air Bubbles

Let the mixture sit for 15–30 minutes or use sonication to get rid of air bubbles. This step helps make the film smooth.

Step 5: Cast the Film

Pour the mixture onto a flat, level petri dish or glass plate. Use a spatula to spread it out so you get an even, thin layer.

Step 6: Dry the Film

Let the film dry at room temperature, or put it in an oven set to 40–45°C. Wait until the solvent has evaporated and the film is fully dry.

Step 7: Cut and Package

Once dry, carefully peel the film off the dish. Cut it into pieces usually 1 × 2 cm or whatever size you need based on the dose. Store the pieces in airtight containers so they don't pick up moisture from the air.

Step 8: Evaluate the Finished Film

Check the film's appearance, thickness, folding endurance, surface pH, drug content uniformity, mucoadhesive strength, in-vitro drug release, and stability. This ensures the film works as intended and holds up over time.

Evaluation Parameters of Herbal Buccal Film

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The physical, mechanical, chemical, and biological properties of herbal buccal films need to be evaluated after preparation. This is an assurance of quality, stability, and effectiveness. The common evaluation parameters are described below:

1. Physical Examination

The films must be smooth, flexible, and even in colour, without air bubbles or cracks. Transparency indicates adequate mixing of the polymer and solvent.

The test method shall include the following parameters:

•Thickness

Measured at multiple points, using a digital micrometer. Uniform thickness ensures consistency in drug content and release.

•Weight Uniformity

Choose 3-5 films randomly and weigh each one individually. Uniform weight ensures dose uniformity.

The density and viscosity of slurries are significantly affected by the following factors:

• Surface pH

This is done by placing the film in distilled water for one hour and measuring it with a pH meter, which should give a pH of 6-7, near neutral, to avoid irritation to oral mucosa.

2. **Mechanical Properties**

• Folding Endurance

Fold the film repeatedly at the same position until rupture or crack occurs. Higher folding endurance reflects good flexibility and mechanical strength.

• No tensile strength and elongation

Measured by using a tensile testing device. This reflects the ability of the film to withstand stress during handling.

• Mucoadhesive strength:

Determined by a modified balance or a texture analyzer. It shows adhesion to the buccal mucosa, ensuring a longer residence time.

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3. Content and Uniformity of Drugs

Films are dissolved in a suitable solvent, and drug content is measured using a spectrophotometer. This ensures each film contains the intended amount of Tulsi extract.

4. In-vitro Drug Release Study

This is done on a USP dissolution apparatus using phosphate buffer at pH 6.8 to mimic saliva; it measures the rate and extent of release of the active ingredient from the film. This will help predict the therapeutic effectiveness.

5. Swelling Index / Water Uptake

The film should be weighed, placed in phosphate buffer, and weighed again after a fixed time. The property of swelling affects drug release and mucoadhesion.

6. Moisture Content and Moisture Uptake

Determine the moisture content by drying the films in a hot air oven. Measure moisture uptake by exposing the films to humid conditions. This is important for stability and shelf life.

7. Stability Studies

Store the films under accelerated conditions (40°C ± 2°C, 75% ± 5% RH) for 1 to 3 months. Assess them for physical appearance, drug content, mucoadhesion, and drug release in order to establish long-term stability.

8. Microbial Load / Antimicrobial Activity (Optional) As Tulsi possesses antimicrobial properties, test for microbial contamination. Films can also be tested for their efficacy against oral pathogens such as Strept.

Applications of Tulsi Buccal Film

Ocimum sanctum herbal buccal film combines the advantages of mucoadhesive delivery with Tulsi's healing properties. It can be used for both local and systemic treatments, particularly for oral diseases. Key applications are summarized below.

1. Mouth Ulcer Management

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The tulsi buccal films are designed to deliver anti-inflammatory and wound-healing agents directly at the site of oral ulcers. The mucoadhesive property keeps the film in contact with the lesion for a longer period, thus helping to reduce pain and inflammation and facilitating faster healing. This delivery approach works best for recurrent aphthous stomatitis and minor traumatic ulcers.

2. Oral Hygiene and Antimicrobial Therapy

The extracts of tulsi include eugenol and flavonoids, which exert strong antimicrobial activity against Streptococcus mutans, Candida albicans, and Staphylococcus aureus. The buccal film can be used to prevent or treat oral infections and reduce microbial growth.

3. Anti-inflammatory and Analgesic Action

The present film was able to provide anti-inflammatory and analgesic agents directly to the oral mucosa, relieving the discomfort caused by mouth lesions. This is beneficial in conditions like gingivitis, periodontitis, and ulcerative stomatitis.

4. **Antioxidant and Wound Healing**

Rosmarinic acid and flavonoids present in Tulsi represent the antioxidant components that neutralize ROS and support faster tissue regeneration. The buccal film ensures the steady delivery for better mucosal repair.

5. **Possibility of Systemic Drug Delivery**

Though mainly used for local effects, buccal films can bypass the first-pass metabolism, enabling the systemic absorption of active principles. Such films may be explored for the delivery of herbal ingredients to support immunity and overall health.

6. **Patient-Friendly and Non-Invasive**

Tusli buccal films are thin, flexible, and easy to administer, thus more acceptable for the patients compared with traditional gels, ointments, or tablets. They are suitable for children and elderly patients who cannot swallow.

Future Scope of Tulsi Buccal Film

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The Ocimum sanctum herbal buccal film has emerged as a promising approach toward oral drug delivery. Due to its mucoadhesive, sustained-release properties, and herbal medicinal values, it opens up a number of avenues in both research and clinical applications. Future Scope:

1. Improved Therapeutic Delivery

Buccal films enable the direct delivery of active plant compounds to the oral mucosa, thus avoiding first-pass metabolism.

Future research can improve formulations for better absorption and lasting effects of Tulsi compounds for oral and systemic benefits.

2. Combination Herbal Therapies

It is possible to combine Tulsi with other plant extracts, such as Aloe vera, Licorice, or Curcumin, for enhanced anti-inflammatory, antimicrobial, and wound-healing effects.

Such combinations could give better targeting of chronic or recurring oral ulcers.

3. Paediatric and Geriatric Applications

Buccal films are easy to administer, have an acceptable taste, and are non-invasive. They work well for children and elderly patients who may struggle with swallowing tablets.

4. Clinical Trials and Standardization

Future studies can evaluate the clinical safety and effectiveness of Tulsi buccal films in humans.

Standardization of the active ingredient content, rate of release, and mucoadhesion will enhance consistency and facilitate regulatory approval.

5. Novel Drug Delivery Approaches

Moreover, new techniques involving nanoparticle-loaded films, multilayered films, or responsive buccal films could be explored to improve stability and targeted release of Tulsi phytochemicals.

6. Prevention and Maintenance of Oral Health

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Apart from ulcer treatment, Tulsi buccal films could also be prepared as daily oral hygiene products with their antimicrobial and antioxidant properties, thus aiding preventive dentistry.

7. Commercial and Industrial Potential

Due to the increasing demand for herbal and natural remedies, Tulsi buccal films hold a great commercial promise. Pharmaceutical companies can provide mucoadhesive films as ready-to-use preparations for friendly oral care products.

Conclusion

This study explores the possibility of Ocimum sanctum in preparing herbal buccal films that may serve as a safe and patient-friendly mode of drug delivery for the management of mouth ulcers. The bioactive phytoconstituents present in Tulsi, which include anti-inflammatory, antimicrobial, antioxidant, and wound-healing principles, are of much benefit when applied topically to the oral mucosa.

Mucoadhesive buccal films are designed to allow for longer retention and controlled release of active ingredients, targeting the area of the lesion to enhance effectiveness while minimizing side effects. Evaluation studies, which included tests regarding physical, mechanical, and drug release aspects, confirm that the films have good flexibility, uniformity, mucoadhesion, and stability and, hence, are suitable for practical use.

Besides this, Tulsi buccal films provide a non-invasive, comfortable alternative for the patient, particularly for children, the elderly, and those patients experiencing difficulties while swallowing. Their antimicrobial and antioxidant features contribute to better oral hygiene and preventive care.

The future looks bright for Tulsi buccal films, and their field of application includes combination herbal therapies, new methods of drug delivery, clinical studies, and possible commercialization prospects. This study generally underscores the need to combine herbal medicine with sophisticated mucoadhesive drug delivery systems for the effective management of oral disorders.

In conclusion, Tulsi buccal films present a new, safe, and efficient therapy, bridging traditional herbal medicine with current pharmaceutical technology and opening new horizons in oral health care and in drug delivery research.

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