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Formulation Of Herbal Oral Mouth Ulcer Gel

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ABSTRACT

The present study aimed to develop a herbal tooth gel utilizing *Acmella oleracea* extract, a traditionally used medicinal plant known for its therapeutic properties. Spilanthol, the major bioactive constituent of *Acmella oleracea*, is recognized for its anti-inflammatory effects, making it a suitable candidate for oral care applications. The formulated gel was evaluated through various physical parameters and demonstrated a homogeneous appearance, smooth texture, a neutral pH of 7.5, translucent clarity, and good extrudability. Stability tests indicated that the formulation retained its physical integrity over time. Anti-inflammatory activity was confirmed by turbidity analysis, indicating protein denaturation—a marker for anti-inflammatory potential.

After comparing the marketed preparations with the developed herbal tooth gel, the research's findings indicate that the herbal tooth gel is as attractive as the marketed treatment .These findings support the formulation's effectiveness and its potential application in maintaining oral hygiene and managing mouth ulcers. The study underscores the viability of incorporating herbal extracts into modern dental care products and suggests further exploration into natural formulations for enhanced public dental health outcomes.

Keywords: *Acmella oleracea*, spilanthol, mouth ulcer, mouth ulcer gel, anti-inflammatory activity, evaluation tests, formulation, herbal extract.

INTRODUCTION

Mouth ulcers, sometimes referred to as oral ulcers or aphthous ulcers, are tiny, excruciating lesions that appear in the soft tissues of the mouth, such as the gums, tongue, inner cheeks, lips, and floor of the mouth. They can impact persons of all ages and are among the most prevalent disorders affecting the oral mucosa.These ulcers are usually circular or oval in shape, with a red, inflammatory border encircling a yellow or white center. Mouth ulcers are generally not dangerous, although they can be quite uncomfortable, particularly when speaking, eating, drinking, or brushing. Approximately 4% of people worldwide suffer with oral ulcers at any given time, making them a prevalent condition.

In particular, up to 25% of people worldwide may develop aphathous ulcers.[1]A breakdown in the mucosal barrier, which causes localized inflammation and ulceration, is frequently the cause of mouth ulcers. Direct harm, immune system responses, or underlying systemic diseases may be the cause of this. For example, ulceration occurs when the body's immune reaction unintentionally targets the mucous membranes in autoimmune illnesses. Either directly or through the body's inflammatory reaction, infections can cause tissue damage. The body's capacity to maintain healthy mucosal tissues is hampered by nutritional deficits, which increases the risk of ulceration.[2] Acmella oleracea, which contains spilanthol, exhibits analgesic and anti-inflammatory qualities when a mouth ulcer is discovered.[3]

Through a number of natural processes, Acmella oleracea aids in the treatment of mouth ulcers. When administered, one of its main ingredients, spilanthol, produces a tingling and numbing feeling that rapidly reduces ulcer pain. Because of this, it can be helpful in offering instant comfort. The plant's anti-inflammatory qualities, in addition to its pain-relieving effects, aid in lowering the ulcer's surrounding swelling and redness. It promotes quicker healing and keeps the ulcer from growing worse by reducing inflammation. Additionally, because of its antibacterial properties, Acmella oleracea can combat oral pathogens such as Lactobacillus species and Streptococcus mutans. Controlling these bacteria helps avoid infections that could impede the healing of ulcers since they are frequently implicated in gum disease and tooth decay.[4]

The most effective formulation was created by combining five different formulations with different amounts of extracts. Following formulation, the gel's physiochemical characteristics, including pH, color, odor, solubility, viscosity, texture, consistency, spreadability, irritancy, tube extrudability, and anti-inflammatory action, were evaluated. Stability experiments were also conducted. The many types of fungal infections, their causes, diagnosis, and treatment are the main topics of this article. Additionally, the use of herbs in mouth ulcer formulations to treat different kinds of mouth ulcers is covered.[5]

INTRODUCTION TO MOUTH ULCER

A mouth ulcer, also known as an aphthous ulcer or canker sore, is characterized by small, painful ulcers that develop on the mucous membranes within the mouth. These ulcers are often round or oval in shape, with a white or yellowish core surrounded by a crimson halo. They are most commonly found in the non-keratinized mucosa, which includes the inner cheeks, lips, soft palate, and tongue. Many variables are believed to contribute to the formation of mouth ulcers, even if the exact etiology of these conditions is yet unknown. These include hormonal changes, stress, local trauma (such biting the inside of the cheek), genetic predisposition, dietary deficiencies (particularly in iron, folic acid, and vitamin B12), and some systemic conditions including celiac disease and inflammatory bowel diseases.

Most mouth ulcers heal on their own without leaving any scars in 10 to 14 days. A doctor may need to examine recurring or persistent ulcers in order to rule out underlying medical issues. In order to minimize pain and promote healing, care typically focuses on avoiding known triggers, maintaining good tooth hygiene, and applying topical medications.[6]

Types of mouth ulcer

The types of mouth ulcers are as follows:

1. Aphthous Stomatitis (Canker Sores): Usually spherical, tiny, painful ulcers with a red border and a white or yellow center.

2. Herpetic Stomatitis (Cold Sores): Usually blisters packed with fluid that burst and leave painful sores, this condition is brought on by the herpes simplex virus.

3. Traumatic Ulcers: Caused by mechanical trauma or discomfort, such as dental work or cheek biting.

4. Chemically Induced Ulcers: These are brought on by irritation by chemical substances like as mouthwash, acidic meals, or pharmaceuticals.

5. Infectious Ulcers: Resulting from viral, bacterial, or fungal diseases (e.g., syphilis, candidiasis).

6. Ulcers Associated with Systemic Disease: Linked to systemic diseases such as HIV/AIDS, lupus, or Crohn's disease.[7]

Overview of mouth ulcer

A. causes

1. Dental work or ill-fitting dentures are to blame.

2. Some people may develop mouth ulcers as a result of hormonal fluctuations, such as those that occur during menstruation or pregnancy.

3. Inadequate intake of vitamins, including iron, folate, and B12.

4. In rare instances, bacterial infections might also result in ulcers.

B. sign and symptoms

1. Talking, eating, and drinking—especially hot or spicy foods—usually make pain worse.

2. The area surrounding the ulcer may enlarge slightly.

3. Tiny, round or oval ulcers with a red border and a white, yellow, or gray core.

4. Depending on their size and location, ulcers can make swallowing, speaking, and eating challenging.[8]

C. Diagnosis

1. Clinical Diagnosis: Aphthous ulcers are characterized by round or oval ulcers, white or yellowish cores, and a red border.The underside of the tongue, cheeks, and inside of the lips are typical sites.

2. Patient History: It is essential to have a thorough history of ulcer recurrence, its duration, and its causes, such as stress, particular foods, trauma, or drugs.The diagnosis may also be aided by a family history of recurring ulcers.

3. Exclusion of Other Conditions: Behçet's disease, celiac disease, or Crohn's disease should be taken into consideration if the ulcers are recurrent and accompanied by systemic symptoms. Diagnosis entails ruling out other causes of oral lesions, such as herpes simplex, oral cancer, leukoplakia, and lupus.

4. Laboratory Examinations (if required):

• When a systemic cause is suspected, blood tests may be conducted to check for autoimmune indicators (such as antinuclear antibodies), vitamin deficiencies, and iron deficiency.

• In certain situations, a biopsy or culture may be advised in order to rule out infections or cancer.[9]

D. Current treatment

Treatment category	**Examples**	**Mechanism of action**
1.Topical corticosteroid	Triamcinolone acetonide, Fluocinolone acetonide, Clobetasol propionate	Reduce inflammation, promote healing
2. Topical Analgesics	Lidocaine (1–2%), Amlexanox (5%)	Provide pain relief, reduce inflammation
3.Topical Antiseptics	Chlorhexidine (0.2%), Triclosan	Chlorhexidine (0.2%), Triclosan
4.Topical Hyaluronic Acid	Hyaluronic acid (0.2%) gel	Promote tissue repair and healing
5. Topical Antibiotics	Doxycycline (0.1%), Tetracycline, Minocycline	Inhibit metalloproteinases, reduce inflammation
6. Laser Therapy	Low-level laser therapy (LLLT)	Promote healing, reduce pain
7. Nutritional Supplements	Vitamin B12, Iron, Zinc	Address deficiencies, reduce ulcer frequency and severity
8. Natural Remedies	Honey, Coconut oil, Aloe vera, Turmeric, Vitamin E	Anti-inflammatory, antimicrobial, promote healing

[10]

5.3 Physiology of mouth ulcer

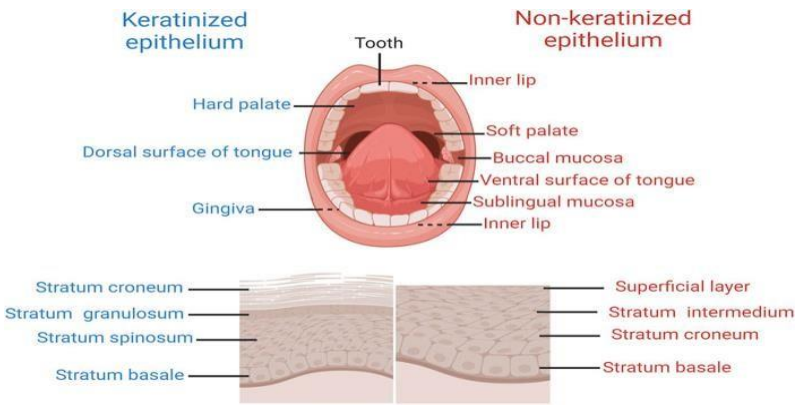

Fig.1. Physiology of mouth ulcer

• Epithelium keratinized

Keratinized epithelium cells develop and collect lipids as they enlarge during migration. The stratum spinosum contains tiny organelles known as membrane-coating granules or lamellar granules that transport certain lipids.

• The non-keratinized epithelium

In contrast, polar molecules such as cholesterol, cholesterol esters, and glycosphingolipids make up the majority of the lipids in non-keratinized epithelium. Additionally, keratinized epithelium has more membrane-coated granules in its stratum spinosum than non-keratinized epithelium.[11]

5.4 Invasion of mouth ulcer

The most important herb used to treat mouth ulcers is Acmella oleracea, which contains spilanthol. Because of its antiviral, antibacterial, antiseptic, diuretic, anti-inflammatory, and wound-healing qualities, it has long been used in traditional medicine to treat ailments like toothaches, stomatitis, and throat infections. The systematic review covers in vivo investigations on mice in which plethysmometry was used to measure the reduction of edema and inflammation was generated by injecting carrageenan into the paw. Additionally, murine macrophages were used in in vitro investigations. These studies verified that Spilanthol has significant pain-relieving and anti- inflammatory properties. However, additional studies using other animals and clinical trials are required to confirm these results and clarify the exact mechanisms and active ingredients causing its therapeutic effects. Spilanthol's biological potential should be recognized despite the paucity of research on its anti-inflammatory qualities.The capacity of spilanthol to lower nitric oxide production, which is frequently increased during inflammation. Higher spilanthol concentrations resulted in larger drops in nitric oxide levels because the substance acted in a dose-dependent way. For instance, spilanthol decreased the generation of nitric oxide by 60% at a concentration of 90 micromolar and by 20% at a value of 360 micromolar.Furthermore, it was discovered that spilanthol inhibited the activation of NF-κB, a protein that is essential for activating genes linked to inflammation. Spilanthol assisted in reducing the total inflammatory response in the cell model by blocking this route. hese findings imply that spilanthol exhibits encouraging anti-inflammatory properties in lab settings; however, further investigation is required to completely comprehend its therapeutic potential, particularly in living creatures.[12]

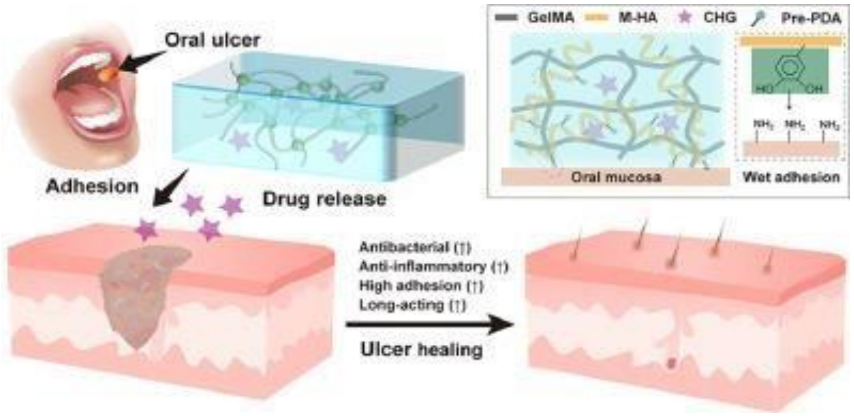

Fig. 2 Hydrogel-Based Drug Delivery System for Oral Ulcer Treatment

HERBAL MOUTH ULCER GEL

An all-natural and efficient way to treat mouth ulcers is with herbal mouth ulcer gels. These gels reduce pain and inflammation while hastening the healing process by utilizing the medicinal qualities of plants.[13]

6.1 Benefits

1. Herbal formulations typically have fewer negative effects than synthetic drugs.
2. Because the gel form enables direct administration to the afflicted area, the active herbal elements are guaranteed to reach the exact location that is required.
3. Herbal gels are often simple to apply and stable at room temperature.
4. Practical for frequent use.
5. result in quicker healing and more efficient alleviation.[14]
6. They are affordable and environmentally friendly.
7. They are commonly available and safe to purchase.

6.2 Drawbacks

Because the production of herbal medicines is not standardized, herbal mouth ulcer gels frequently have variable concentrations of active components and inconsistent quality. Reduced efficacy and inconsistent outcomes across various items or batches may arise from this.[13]

6.3 Herb profile

Herb	synonym	Biological source	Active constituent	Uses	Figure (fig.3 Plant of *Acmella Oleracea*)
Acmella olracea	Spilanthes acmella	the entire plant encompassing its leaves, steams, flowers, and roots.	spilanthol	1. Toothache relief 2. use in herbal toothpastes 3. anti inflammation activity.	

6.4 Spilanthol's Mode of Action

1. Anti-inflammatory Properties
Important biological mechanisms that cause inflammation are modulated byspilanthol:

• Transcription Factor Inhibition:
Spilanthol inhibits the activity of a number of transcription factors that control genes linked to inflammation:

TNF-α, IL-1β, and IL-6 transcription is inhibited by NF-κB.

AP-1, ATF4, FOXO1, IRF1, and ETS1: These elements play a role in immunological signaling and stress reactions.

• Downregulation of iNOS (inducible Nitric Oxide Synthase):
Spilanthol lowers the generation of nitric oxide (NO), which is frequently increased in inflammatory tissues, by blocking iNOS.

• Inhibition of COX Enzymes:
Specifically COX-2, which lowers the production of prostaglandins, lipid mediators that increase temperature, pain, and inflammation.

2. Antioxidant Activity: By scavenging reactive oxygen species (ROS),spilanthol reduces oxidative stress, which in turn lessens inflammation and cellular damage.

3. Pain-Relieving (Analgesic) Effect: Spilanthol causes sensory neurons' TRPV1 (Transient Receptor Potential Vanilloid 1) channels to open.
This contributes to the local anesthetic and pain-relieving actions and produces a tingling or numbing sensation.

4. Antimicrobial Properties: Spilanthol helps prevent infection and inflammation by rupturing bacterial cell membranes, reducing microbial enzyme activity, and altering quorum sensing in some bacteria.[15]

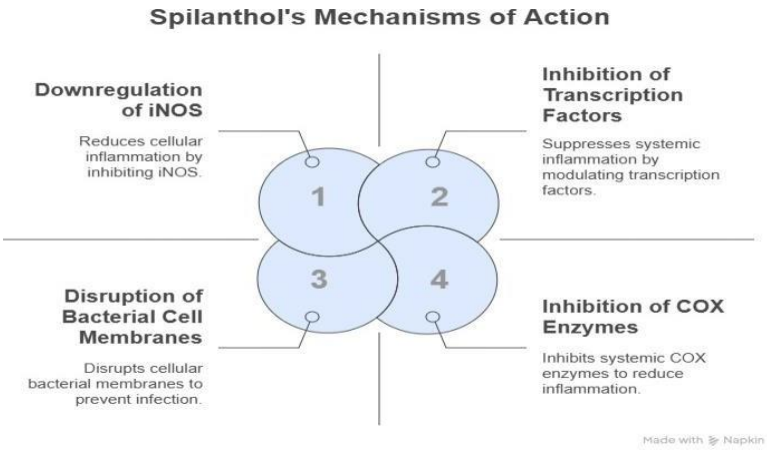

Fig. 4 MOA of Spinanthol

METHODOLOGY

8.1. Resources:

Chemicals:
Triethanolamine (Loba Chemicals), Sodium Benzoate (Loba Chemicals), Sodium Saccharine (Loba Chemicals), Polyethylene Glycol-4000 (RJSPM store), Sodium Carboxy Methyl Cellulose (S.D. Fine-Chem. Ltd.), and peppermint water [16].

Extract: Acmella oleracea dried flower

A. Plant collecting
Acmella oleracea powder and flowering tops were purchased at the neighborhood market.

8.2 : Extraction Methods

A popular method for separating bioactive substances like spilanthol from plant materials like Acmella oleracea is soxhlet extraction. With this technique, chemicals are continuously extracted using a solvent, usually in a reflux environment. Because of its polarity and effectiveness in extracting a wide variety of phytochemicals, methanol is frequently selected.

Plant Material Preparation:

• Dry Acmella oleracea at room temperature or in an oven set to low heat (less than 40°C).
• To enhance surface area, grind into a fine powder.

Configure the Soxhlet Device:

• Fill a cellulose thimble with the plant material that has been powdered.
The thimble should be loaded into the Soxhlet extractor.

Extraction:

• Pour the selected solvent, methanol:water (4:1, v/v), into the round-bottom flask.
• Gently warm the apparatus to cause the solvent to boil and condense.
• For six to twelve hours, depending on the solvent and quantity of plant material, the solvent constantly syphons through the plant material to extract spilanthol.

Evaporation:-

Evaporate in a Petri plate in the sun for approximately three, four, or five hours.

Fig. 5 Extraction of spinanthol

8.3 Identification test:

1. Iodine Test:
Iodine reacts with alkenes and alkynes' carbon-carbon double bonds (C=C). Spilanthol's aliphatic chain has conjugated double bonds.

• Use ethanol or chloroform to dissolve a tiny quantity of your extract that contains spilanthol.
• Include a few drops of chloroform or diluted iodine solution (I_2 in KI).

2. Phenolic/OH Groups Test with Ferric Chloride :
Phenols and ferric chloride ($FeCl_3$) combine to generate colorful complexes, which are typically blue, green, or purple. Although spilanthol lacks a phenol group, the presence of impurities or oxidized products may cause a modest reaction because of the amide or weak enol-like activity.

• Add a few drops of 1% neutral ferric chloride solution after dissolving the sample in ethanol.[17]

Fig. 6 Identification of spinanthol

8.4 Optimization:-

Sr. No	Ingredients	Role	F1	F2	F3	**F4**
1	Extract	Anti-inflammatory agent	-	-	-	**1g**
2	Carbopol-940	Gelling properties	1.5 g	-	-	-
3	Xanthan gum	Gelling properties,	-	(1.5 g)	-	-
		thickening agent				
4	Methyl cellulose	Gelling properties	-	-	(1.5g)	-
5	Sodium CMC	Stabilizer, Texture modifier	1 g	1g	1g	1g
6	Sodium Saccharin	Sweetening agent	0.5	0.5	0.5	0.5
7	SLS	Surfactant	2g	-	-	-
8	Polyethylene Glycol-4000 (2 g)	Humectant	2 g	2 g	2 g	2 g
9	Sodium Benzoate	Preservative	0.5	0.5	0.5	0.5
10	Tri- ethanolamine (q.s)	pH adjuster ,emulsifier	q.s	q.s	q.s	q.s
11	Distilled Water (q.s)	Solvent	20ml	20ml	20ml	20ml
12	Peppermint water	Solvent, Flavoring Agent	-	-	-	q.s

8.5 Formulation for gel:-

1. Use enough filtered water to dissolve 0.5 g of sodium benzoate. Stir until dissolved completely.
2. Add 2.5 mL of spilanthol extract that has been dissolved in peppermint water to the solution above.
Next, include 2 grams of PEG (polyethylene glycol). To guarantee even mixing and prevent air entrapment, stir slowly and constantly.
3. To create a stable gel basis, gradually add 1 g of sodium carboxymethyl cellulose (NaCMC) while stirring constantly.
4. Gradually add triethanolamine while stirring constantly to create a uniform gel. This aids in emulsion stabilization and pH adjustment.
5. To enhance the formulation's flavor, add 0.5 g of sodium saccharin.
6. To guarantee total dissolution and consistent consistency, move the formulation to a mechanical stirrer and mix well.
7. Fill dry, clean collapsible tubes with the prepared gel. Keep at room temperature in a dry, cool location. [16]

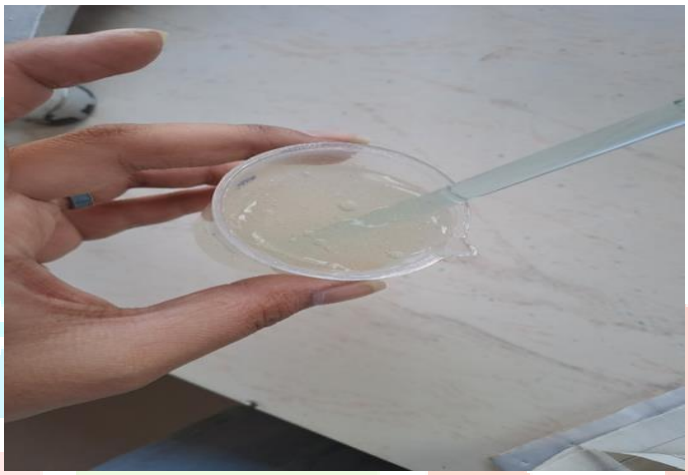

Fig. 7 Gel formulation

EVALUATION TEST

Sr. no	Parameter s		F1	F2	F3	F4
1	Physical Examinatio n	Colour	White	slight yellowish	Pale yellow	Translucent whitish
		Odour	Odourless	Very mild	Neutral	herbaceous
		Smoothn ess	granulated	Sticky	non- smooth texture	Uniform
2	Transparen cy		Opaque	Opaque	Opaque	Translucent
3	Homogenei ty		Non homogeno us	Homogen ous	Non homogen ous	Homogenous
4	pH		5	6	7	7
5	Particles		granulated	Slightly granulated	granulate d	Uniform
6	Stability Study		Discolorat ion	Sticky	Precipitat ion form	Stable
7	Spread ability		Granular	Sticky	Non -uniformit y	uniform
8	Anti- inflammato ry activity		-	-	-	Anti-inflammatory activity present

1. Physical Inspection (Smoothness, Color, Odor):
The color of the prepared gel was assessed. The dark brown color was examined visually.
By sniffing the product (herbaceous), the odor was discovered.
By rubbing the gel formulation between the fingertips, the smoothness was evaluated.

2. Transparency: Transparency About 5 milliliters of the prepared gel were placed in a 10- milliliter test tube, and the transparency of the gel was visually examined.

Fig. 8 Gel transparency test

3. pH: Using pH paper, the formed gel's pH was ascertained. Using this technique, we transfer a tiny quantity of the liquid under test into a sterile container. Dip a single strip of pH paper into the solution for a brief period of time—one to two seconds is sufficient.The pH value is then ascertained by removing the strip, waiting for the color to change (typically within a few seconds), and comparing the strip's color to the pH color chart that came with the paper. The pH was then discovered to be 6-7.

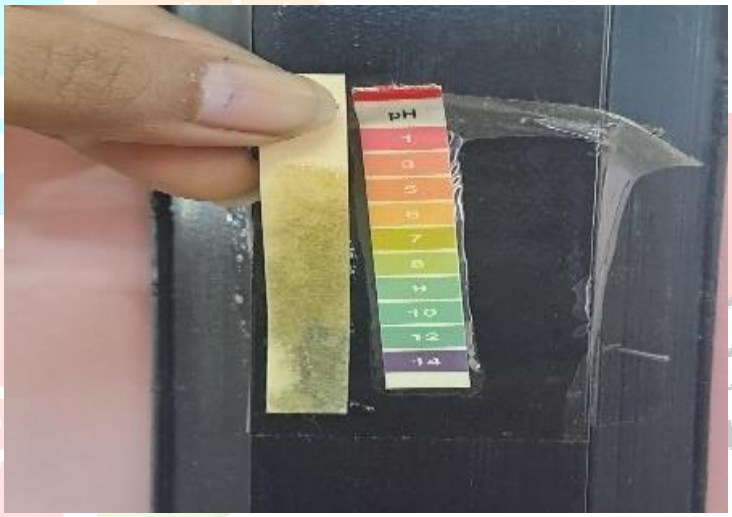

Fig. 9 pH of gel

4. Homogeneity: Using standard force, the gel will extrude a uniform bulk from the transparent collapsible tube or any suitable container. Additionally, the majority of the contents must protrude from the container's crimp before being gently rolled.

5. Determination of sharp and edge abrasive particles: To identify sharp and edge abrasive particles, extrude the material on the butter paper until it is 15 to 20 cm long. Do this again for a minimum of five collapsible tubes. Check for the presence of hard-edged, sharp abrasive particles by pressing the contents of the entire length with the tip of your finger. Such particles must not be present in gel.

6. Stability Study: The prepared gel was put into detachable tubes and kept for a month at room temperature and humidity levels. Its appearance, pH, and spreadability were examined.

7. Spreadability:-In this method, slip and drag characteristic of gel involve. Formulated gel (2g) placed on the ground slide under study. The formulated gel placed (Sandwich like) between this slide and another glass slides for 5 min to expel air and to provide a uniform film of the gel between slides. Excess of the gel was scrapped off from the edges. The top plate was then subjected to pull of 80 g with the help of string attached to the hook and the time (Sec) required by the top slide to cover a distance of 7.5 cm was noted. A short

interval indicated better spreadability. [18]

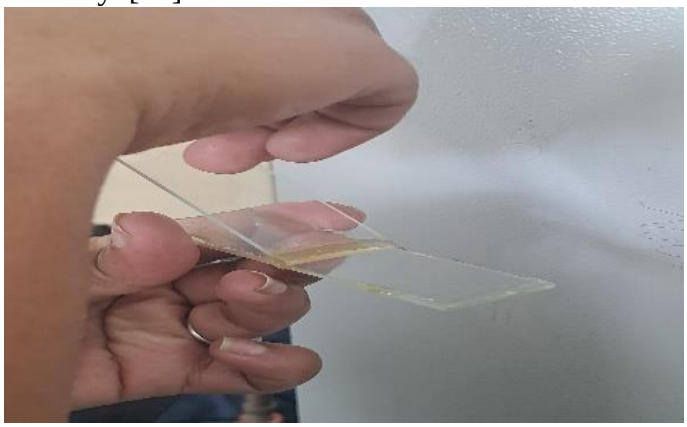

Fig. 10 Spreadability test

8. In-Vitro Anti-inflammatory activity (Inhibition of Albumin): The extract was screened for anti-inflammatory activity by using inhibition of albumin denaturation technique. Test solutions containing different concentration of extract was mixed with 0.2 ml of egg albumin and 2.8ml of phosphate buffered saline (PBSpH6.4).

Detection of anti-inflammatory activity by Protein denaturation

Colorimetric techniques that use dyes like Congo Red or Thioflavin T, which bind to denatured or aggregated protein structures preferentially, can be used to quantitatively measure protein denaturation. These colors mostly interact with areas rich in β-sheets that are revealed when proteins unfold or aggregate. The dyes show distinctive spectrum changes upon binding, such as increased fluorescence for Thioflavin T or a red shift in absorbance for Congo Red. The degree of protein denaturation directly correlates with the strength of the resultant color or fluorescence signal. Greater unfolding and aggregation of proteins are indicated by higher color intensity, whereas less denaturation or retention of the natural protein structure is shown by lower intensity. Greater unfolding and aggregation of proteins are indicated by higher color intensity, whereas less denaturation or retention of the natural protein structure is shown by lower intensity. This technique offers a sensitive and trustworthy way to track structural alterations in proteins under different physiological or stressful circumstances. [20][21]

The degree of protein denaturation: higher denaturation levels are shown by higher color intensity, whereas more stable, natural protein conformations are reflected by lower color intensity. Because stable proteins are less likely to cause inflammatory reactions when misfolded or aggregated, a decrease in color intensity can be read as a reduced degree of protein denaturation, which is frequently linked to greater anti-inflammatory activity.[22][23][24]

Study comparison: Colorimetric Detection Applying the Congo Red

Principle: Denatured or aggregated proteins, particularly those with β-sheet-rich structures— which are frequently seen in misfolded or aggregated proteins—are selectively bound by the dye Congo Red.These dyes modify their optical characteristics when they bind.The absorbance shifts red in Congo Red.

How it operates:

1. Congo Red is combined with protein samples.
2. The exposed hydrophobic areas or β-sheet aggregates created after denaturation are where the dyes attach.
3. A color change (Congo Red) is brought about by the binding.
4. Greater intensity results in increased protein aggregation and denaturation.--- no ability to reduce inflammation
5. reduced intensity results in reduced denaturation, or preservation of the natural protein structure.Reduced anti-inflammatory properties

OBSERVATIONS

Sr. no	Components	Dye Readings	Interpretation
	Blank	1.13	There aggregation of proteins → very less anti-inflammatory
1	Extract	0.85	Medium dye binding → minor denaturation so less anti-inflammatory
2	Ibuprofen	0.45	Very Low dye binding → more anti-inflammatory
3	Marketed gel	0.80	Small increase → minimal denaturation, good protein stability
4	(batch F4)	0.91	Significant increase → normal protein denaturation/aggregation

Batch F4 has a dye reading of 0.91, indicating a moderate degree of protein denaturation and aggregation, according to the results of the dye-binding experiment. This figure indicates that batch F4 maintains a very stable protein environment because it is still much lower than the extract and the blank, even if it is somewhat higher than the marketed gel's reading of 0.80. With a reading of 0.80, the commercially available gel exhibits low levels of protein denaturation, indicating powerful anti-inflammatory properties.
The marketed formulation performs better than batch F4, although the difference is little, suggesting that batch F4's anti-inflammatory efficacy is almost equal. Its performance indicates that it supports moderate anti-inflammatory capabilities and good protein stability, making it a prospective option that is comparable in effectiveness to the commercial formulation.

RESULT AND DISCUSSION

1. Extract Test

Test Type	Test Name	Result / Observation	Inference
Identification	Iodine Test	Decolourization observed indicates unsaturation (yellow to colourless)	Spilantol confirmed
Identification	Ferric Chloride Test	No colour change – suggests no phenolic group	Spilantol confirmed

2. Formulation Test

Sr.No	Parameters	Interpretation
1	Physical Appearance	Greenish gel, smooth, mild odour
2	Transparency	Translucent
3	pH	7.5
4	Homogeneity	Smooth and uniform
5	Sharp Particles Check	No sharp or abrasive particles found
6	Stability Study	Stable at all test conditions
7	Spreadability	Good – spreads easily in short time
8	In Vitro Anti-inflammatory Test	Good activity – less protein denaturation

DISCUSSION

As a possible substitute for commercially available tooth gels, the herbal tooth gel made using Acmella Oleracea extract has encouraging qualities. The Soxhlet technique of extraction made sure that the bioactive components, particularly spilanthol, which has analgesic and anti- inflammatory qualities, were recovered efficiently. The extract's favorable qualities for inclusion into a gel basis were confirmed by preformulation investigations.

The ideal consistency, spreadability, and homogeneity were attained with the aid of a gelling system based on carbopol and xanthan gum and suitable excipients such as sodium CMC and polyethylene glycol. To ensure that the formulation would not irritate the oral mucosa, triethanolamine was successfully utilized to bring the pH down to 7.
Physical assessments revealed that the gel had the perfect physical characteristics (easy extrudability and spreadability) and a nice appearance (smooth texture, transparent nature), both of which are essential for user happiness and patient compliance. Crucially, the gel was safe for everyday usage since it included no sharp edges.

Significant anti-inflammatory action is shown by this formulation, which is almost as effective as the commercial product. According to the findings, it promotes a stable protein environment with no denaturation or aggregation, which suggests that it may have anti-inflammatory properties.
Despite having a slightly lower potency than the commercially available gel, the difference is negligible, making Batch F4 a viable substitute with strong protein stability and mild anti- inflammatory qualities.

According to stability testing, even when exposed to varying temperatures and humidity levels, the formulation maintained its physical and chemical stability for a month without experiencing any appreciable changes in color, pH, or spreadability. This implies that the product may be economically successful and has a decent shelf life.

The study emphasized a number of advantages when comparing the herbal formulation to commercially available gels, including its natural origin, reduced risk of adverse effects, environmental friendliness, and

equivalent (or superior) performance. As a safer substitute for artificial oral gels, the discovered Acmella Oleracea gel has great promise for further research and clinical use.

SUMMARY AND CONCLUSION

Summary

The goal of the study was to create and assess a herbal oral gel utilizing extract from Acmella oleracea, a plant that has strong anti-inflammatory, antioxidant, and analgesic effects because of its bioactive ingredient, spilanthol. Using a methanol-water solvent mixture and the Soxhlet extraction technique, the extract was effectively made. Sodium CMC, polyethylene glycol, triethanolamine, sodium benzoate, sodium saccharin, and peppermint water were combined to create a stable gel formulation after extensive preformulation research.

Numerous physical characteristics, including color, look, texture, pH, transparency, spreadability, extrudability, and stability, were assessed for the F4 formulation. In every way, it produced outstanding outcomes that were on par with or better than those of marketed goods.
Interestingly, the in vitro anti-inflammatory tests revealed that the gel's anti-inflammatory efficacy was higher than that of commercial preparations because it had less protein denaturation.

Conclusion

With its favorable physicochemical characteristics and notable biological activity, the Acmella Oleracea herbal gel was shown to be stable, efficient, and patient-friendly. Its creation provides a possible herbal substitute for dental gels made with chemicals, meeting the growing demand from consumers for safe and natural healthcare solutions. With few adverse effects, the formulation has the potential for more clinical research and commercial manufacturing with the goal of advancing public oral health. In order to confirm the herbal gel's effectiveness and safety profile in actual circumstances, further research may entail in vivo clinical trials, extensive microbiological testing, and production scaling up.

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