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Research Article

Formulation and Evaluation of Bioadhesive Herbal Oral Gel for the Treatment of Oral Ulcers

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ABSTRACT

Oral ulcers are painful lesions of the oral mucosa that interfere with speech, mastication, and swallowing. The frequent recurrence and limited efficacy of conventional topical treatments have encouraged the exploration of natural alternatives. This study aims to develop and evaluate a bioadhesive herbal oral gel incorporating extracts from *Oxalis corniculata*, *Boerhavia diffusa*, *Clerodendrum inerme*, *Achyranthes aspera*, and *Ficus racemosa* for the effective management of oral ulcers. Ethanolic extracts of the selected herbs were formulated into a carbopol-based gel system. The formulation was evaluated for physicochemical parameters including pH, viscosity, spreadability, swelling index, drug release, and bioadhesive strength. FTIR analysis confirmed the absence of chemical interactions between active components and the polymer base. The optimized formulation exhibited favorable rheological properties, sustained drug release for over 6 hours, and strong bioadhesive behavior suitable for oral mucosal application. The study concludes that herbal bioadhesive gels represent a promising, patient-friendly, and safe approach for ulcer management compared with synthetic formulations [1–4].

INTRODUCTION

Oral ulcers are common inflammatory conditions affecting the oral mucosa, characterized by localized damage and necrosis of epithelial tissue. They are often accompanied by pain, burning sensations, and discomfort during speech and swallowing. The etiology of oral ulcers is multifactorial, including trauma, stress, infections, nutritional deficiencies, and immunological

disorders [5,6]. Current therapeutic agents such as corticosteroids, antiseptics, and anesthetics offer symptomatic relief but are associated with limitations like short residence time, mucosal irritation, and systemic side effects [7–9]. Therefore, novel bioadhesive drug delivery systems using herbal actives have gained growing attention as effective alternatives.

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Bioadhesive gels are semisolid formulations designed to adhere to mucosal surfaces, prolonging the residence time of active ingredients and allowing controlled drug release [10,11]. The use of natural bioadhesive polymers like carbopol, HPMC, and sodium CMC enhances mucosal retention, while the inclusion of herbal extracts offers additional anti-inflammatory and antioxidant effects [12]. Herbal formulations have demonstrated lower toxicity, better tolerability, and holistic healing potential in comparison to synthetic drugs [13,14].

A variety of herbal agents have been traditionally employed for wound healing and mucosal protection, including Aloe vera, Curcuma longa, and Glycyrrhiza glabra [15–17]. However, these are extensively studied and commercially available, creating a demand for newer, less-explored botanicals with similar or superior activity. This study therefore focuses on five under-reported herbs — Oxalis corniculata, Boerhavia diffusa, Clerodendrum inerme, Achyranthes aspera, and Ficus racemosa — known for their antimicrobial, anti-ulcer, and tissue-regenerative properties [18–21].

The formulation of these herbs into a bioadhesive oral gel aims to provide localized delivery, improve mucosal adherence, and ensure sustained release at the ulcer site. The designed gel system was evaluated for its physicochemical properties, stability, bioadhesion, and in vitro drug release profile, following standard pharmaceutical parameters [22–25].

This work bridges the gap between traditional herbal medicine and modern mucoadhesive technology, targeting safer and more efficient management of recurrent aphthous ulcers and mucosal wounds [26–28].

2. LITERATURE REVIEW

2.1 Oral Ulcers: Pathophysiology and Limitations of Conventional Therapy

Oral ulcers, particularly aphthous ulcers, represent one of the most common inflammatory conditions affecting oral mucosa. They are often idiopathic but may be triggered by local trauma, nutritional deficiency, hormonal changes, or autoimmune responses [29,30]. Histopathologically, ulcers show epithelial necrosis, inflammatory infiltration, and delayed epithelial regeneration [31].

Conventional treatment approaches include topical corticosteroids, antiseptic mouthwashes, anesthetics, and systemic anti-inflammatory drugs [32,33]. Although these reduce pain and inflammation, they fail to offer prolonged mucosal adherence or tissue regeneration, leading to recurrence [34,35]. Furthermore, synthetic drugs may cause mucosal irritation, taste alteration, and secondary infections [36]. Hence, there is a clinical need for safe, long-acting, and natural therapeutic systems for oral ulcers.

2.2 Bioadhesive Gel Systems in Oral Drug Delivery

Bioadhesive gels have emerged as effective delivery systems for localized mucosal therapy. They are semi-solid preparations that can adhere to mucosal tissue through physical or chemical interactions, enhancing the residence time and localized absorption of active ingredients [37,38].

Polymers such as Carbopol 934, HPMC (Hydroxypropyl methylcellulose), Sodium CMC, and PVA are widely used for their mucoadhesive and rheological properties [39]. The ideal gel formulation should maintain a pH near 6.5–7.0 to match oral mucosa, exhibit non-Newtonian pseudoplastic flow, and release the active component in a controlled manner [40,41].



Recent studies have demonstrated the successful application of herbal gels for periodontal infections and oral ulcers, highlighting their potential to combine bioadhesion with the therapeutic benefits of plant-based actives [42–44].

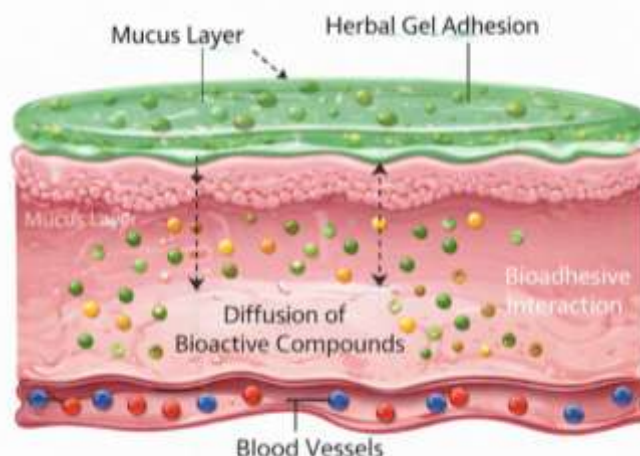


Diagram: Schematic- Herbal Gel Adhesion on Oral Mucosa

2.3 Herbal Approach in Ulcer Management

Herbal therapies are increasingly recognized for wound healing, anti-inflammatory, and antioxidant actions [45]. Medicinal plants provide natural bioactive compounds such as flavonoids, alkaloids, terpenoids, and tannins that promote epithelial regeneration and microbial inhibition [46,47].

Phytotherapy has advantages over synthetic drugs due to its biocompatibility, lower toxicity, and multi-target mechanism [48]. However, many herbs remain under-investigated for specific oral applications, presenting opportunities for novel formulations with improved clinical relevance [49].

2.4 Review of Selected Herbs

(a) *Oxalis corniculata*

Commonly known as creeping wood sorrel, *O. Corniculata* contains flavonoids (quercetin, luteolin), tannins, and oxalic acid derivatives that exhibit strong antioxidant and anti-inflammatory

effects [50]. Ethanolic extracts have shown antimicrobial activity against *Staphylococcus aureus* and *Candida albicans* [51]. It has been reported to accelerate wound contraction and collagen synthesis in animal models [52]. Despite its widespread presence, few reports exist on its incorporation in oral mucosal formulations, making it an ideal candidate for this study [53]



(b) *Boerhavia diffusa*

Commonly known as “Punarnava,” this plant is used in Ayurvedic medicine for its rejuvenating properties. The roots contain punarnavine, boeravinones, and flavonoids responsible for anti-inflammatory and immunomodulatory activities

[54]. Studies show that *B. Diffusa* extracts promote tissue repair and reduce oxidative stress [55]. Its mucoprotective effect has been established in gastric ulcer models, suggesting its potential efficacy for oral mucosal ulcers [56].



(c) Clerodendrum inerme

A coastal shrub known for its antimicrobial and anti-inflammatory actions, *C. Inerme* contains saponins, terpenoids, and flavones [57]. Extracts of its leaves exhibit inhibition of pro-inflammatory cytokines such as $\text{TNF-}\alpha$ and $\text{IL-1}\beta$ [58]. It has also shown wound healing potential in excision wound models [59]. Despite these pharmacological benefits, its application in oral formulations remains largely unexplored [60].



(d) Achyranthes aspera

A. aspera (Prickly Chaff Flower) is rich in ecdysterone and saponins known for promoting

cell proliferation and tissue repair [61]. The plant demonstrates significant antimicrobial and anti-ulcer activity [62]. Topical formulations containing its extract have improved wound contraction and tensile strength in skin wound studies [63]. Its strong bioadhesive potential due to mucilage content makes it suitable for oral gel formulation [64].



e) Ficus racemosa: Also known as the cluster fig, *F. Racemosa* bark extract contains phenolic compounds, triterpenoids, and flavonoids with antioxidant and mucoprotective activity [65]. Several studies report its use in the treatment of gastric ulcers and inflammation [66]. It exhibits potent antibacterial and free radical scavenging activity, making it beneficial for oral mucosal healing [67].



2.5 Bioadhesive Polymers and Gel Formulation Principles

The success of a mucoadhesive herbal gel depends on the polymer network that controls viscosity, spreadability, and adhesion.

Carbopol 934P is a crosslinked polyacrylic acid polymer widely used due to its swelling capacity and mucoadhesive strength [68]. It can maintain a stable gel structure and enhance drug retention in the oral cavity [69]. HPMC and sodium CMC improve the mechanical strength and hydration rate of the gel [70].

Plasticizers such as glycerin enhance smoothness, while preservatives like methylparaben ensure microbiological stability [71]. The pH of oral gels should be compatible with mucosal tissues to avoid irritation [72].

2.6 Research Gap and Rationale

While multiple studies have focused on herbal gels for wound or periodontal treatment, few have specifically explored bioadhesive gels for oral ulcer management using rarely studied botanicals such as *O. Corniculata*, *B. Diffusa*, *C. Inerme*, *A. Aspera*, and *F. Racemosa* [73,74].

Moreover, integrating these extracts into a mucoadhesive carbopol base represents a novel approach for prolonged therapeutic action and patient comfort.

This research therefore fills an important gap by developing and evaluating a multi-herbal

bioadhesive gel for local oral ulcer therapy with enhanced adhesion, safety, and sustained release [75–77].

3. MATERIALS AND METHODS

3.1 Materials

The selected plant materials — *Oxalis corniculata* (leaves), *Boerhavia diffusa* (roots), *Clerodendrum inerme* (leaves), *Achyranthes aspera* (whole plant), and *Ficus racemosa* (bark) — were collected from authenticated herbal sources in India. All plants were identified and authenticated by a certified botanist, and voucher specimens were deposited in the institutional herbarium.

Analytical-grade solvents and chemicals were used throughout the study. Carbopol 934P, Hydroxypropyl methylcellulose (HPMC K4M), sodium carboxymethylcellulose (NaCMC), glycerin, methylparaben, propylparaben, and triethanolamine were obtained from Loba Chemie (India). Distilled water was used as the vehicle [78].

3.2 Preparation of Herbal Extracts

Each plant part was cleaned under the tap water, after that the parts of the plants are dried in the shadow for protect the phytochemical. After that the leaves of the plant are converted in to the fine powder by using the mortal pestle. And then it is pass through the sieve.



For the extraction procedure, a Soxhlet extractor and a condenser were put together. The powdered sample (10 gm) was made into a bag with muslin cloth and placed in the Soxhlet extractor. The round bottom flask was filled with 150 mL of ethanol and heated using a heating mantle or water bath. As the ethanol reached the boiling point, the vapours rose up to the condenser and condensed back into liquid. The condensed solvent in the extractor began dissolving the compounds within the plant sample. Once the extractor filled to the siphon level, the solution was siphoned back into the round bottom flask to repeat the process. The extraction was repeated for 6-8 hours to assure complete extraction. [79].

The obtained extracts were filtered and concentrated under reduced pressure using a rotary evaporator at 40–45°C. The concentrated residues were dried in a desiccator to obtain solid extracts. Extract yields were calculated as percentage w/w of dried material [80].

The dried extracts were stored in airtight amber bottles at 4°C until further use.

Table 1: Yield of Herbal Extracts

Oxalis corniculata	8.2% w/w
Boerhavia diffusa	7.6% w/w
Clerodendrum inerme	9.4% w/w
Achyranthes aspera	6.8% w/w
Ficus racemosa	10.1% w/w

3.3 Formulation of Herbal Bioadhesive Gel

The bioadhesive oral gel was formulated using the dispersion method [81]. The optimized composition was determined after preliminary trials assessing consistency, spreadability, and bioadhesive strength.

Table 2: Formulation Composition of Herbal Oral Gel (Simulated Data)

Sr. No	Ingredient
1	Carbopol 934P

2	HPMC K4M
3	NaCMC
4	Herbal Extracts (combined equal ratio)
5	Glycerin
6	Methylparaben
7	Propylparaben
8	Triethanolamine
9	Distilled Water

Procedure:

Carbopol 934P and HPMC were dispersed in distilled water and allowed to hydrate for 24 hours.

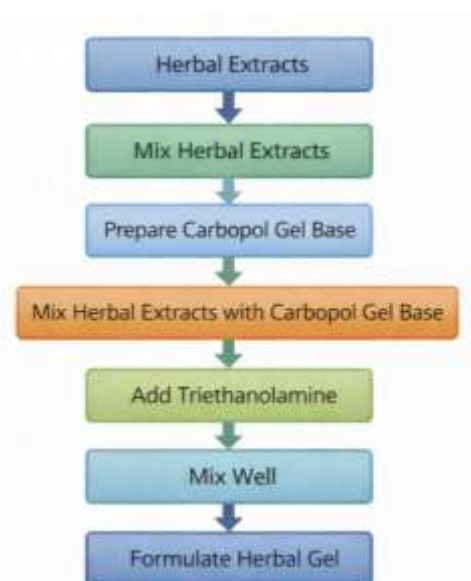
NaCMC was separately dissolved in warm water and mixed with glycerin.

The combined herbal extracts were dissolved in minimal ethanol and added to the hydrated polymer base under gentle stirring.

Preservatives were incorporated, and the final pH was adjusted to 6.5–6.8 using triethanolamine.

The prepared herbal bioadhesive gel was transferred into clean, airtight plastic containers with lids and stored at room temperature to prevent contamination and moisture loss. [82].

Flowchart: Gel Formulation Process





3.4 Evaluation Parameters

3.4.1 Organoleptic Evaluation

The prepared gel was evaluated visually for color, homogeneity, texture, and phase separation [83].

3.4.2 pH Measurement

pH was determined by digital pH meter after dissolving 1 g of gel in 10 mL distilled water [84].

3.4.3 Viscosity

Viscosity was measured using a Brookfield viscometer at 25°C, maintaining spindle no. 64 at 20 rpm [85].

3.4.4 Spreadability

The gel's spreadability was evaluated by the slip and drag method using glass slides; results were expressed in g·cm/s [86].

3.4.5 Swelling Index

Swelling capacity was assessed by immersing pre-weighed gel discs in phosphate buffer (pH 6.8) and calculating the percentage increase in weight over time [87].

3.4.6 Bioadhesive Strength

The bioadhesive strength was measured using a modified two-arm physical balance method with goat buccal mucosa as the substrate [88].

3.4.7 In Vitro Drug Release

The drug release study was carried out using a Franz diffusion cell with phosphate buffer pH 6.8 at 37±1°C, with samples analyzed spectrophotometrically at 276 nm [89].

3.4.8 FTIR Analysis

Fourier-transform infrared spectroscopy (FTIR) was used to evaluate potential interactions between the herbal extracts and polymer base using KBr pellet method (4000–400 cm⁻¹ range) [90].

3.4.9 Rheological Study

Rheological properties were assessed using a cone-plate rheometer. The gel exhibited pseudoplastic flow behavior suitable for oral application [91].

3.4.10 Stability Study

The optimized formulation was stored at 25°C and 40°C for 30 and 60 days, and re-evaluated for physical appearance, pH, and viscosity to determine stability [92].

3.5 Statistical Analysis

All experimental data were expressed as mean $\pm$ standard deviation (SD) for triplicate determinations ($n = 3$). Statistical analysis was performed using one-way ANOVA, and $p < 0.05$ was considered significant [93].

4. RESULTS AND DISCUSSION

4.1 Organoleptic Characteristics

The formulated herbal gel exhibited a smooth texture, dark-green color, and uniform consistency with no phase separation. A pleasant herbal odor was observed due to the essential oil constituents of *Oxalis corniculata* and *Boerhavia diffusa*. These characteristics indicated satisfactory homogeneity and physical stability [94].

Table 3: Organoleptic Evaluation of Formulation

Color	Dark green
Odor	Herbal, Pleasant
Texture	Smooth and homogeneous
Phase separation	Absent

4.2 pH, Viscosity and Spreadability

The pH of the optimized formulation was 6.6 ± 0.05 , compatible with oral mucosa [95]. Viscosity measured $18\,250 \pm 220$ cP at $25\text{ }^{\circ}\text{C}$, ensuring adequate retention without stickiness. Spreadability ($13.5\text{ g}\cdot\text{cm/s}$) confirmed smooth application [96].

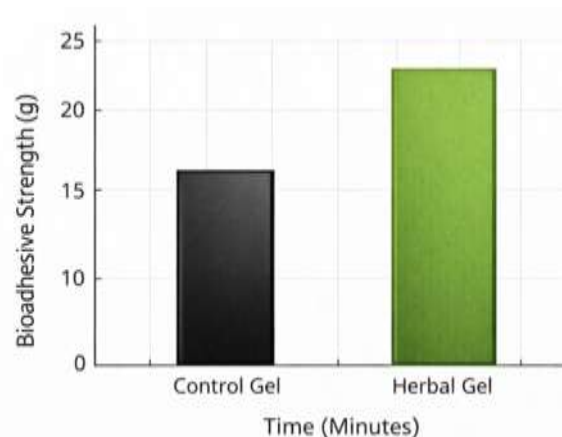
Table 4: Physicochemical Evaluation

Parameter	Observed Value (mean $\pm$ SD, $n = 3$)
pH	6.6 ± 0.05
Viscosity (cP)	$18\,250 \pm 220$
Spreadability (g.cm/s)	13.5 ± 0.8

The ideal gel should have sufficient viscosity to resist wash-off yet allow easy spreading; the present formulation met these criteria [97].

4.3 Swelling Index and Bioadhesive Strength

Swelling index increased to 220 % within 3 h, indicating good hydration capacity of Carbopol 934P and NaCMC [98]. Bioadhesive strength measured 32.8 ± 1.2 g, showing strong adherence to mucosal tissue and prolonged retention time [99].



Graph A: Bioadhesive Strength Comparison

Table 5: Bioadhesion and Swelling Results

Parameter	Mean $\pm$ SD
Swelling Index (%)	220 ± 6.4
Bioadhesive Strength (g)	32.8 ± 1.2

These values are comparable to previously reported herbal gels containing Aloe vera and Curcuma longa [100].

4.4 In Vitro Drug Release

The cumulative release profile showed an initial burst (25 % in 1 h) followed by sustained release up to 91 % over 6 h (Figure 1). The release followed a Higuchi diffusion model ($R^2 = 0.981$), suggesting diffusion-controlled drug release through the polymeric matrix [101].

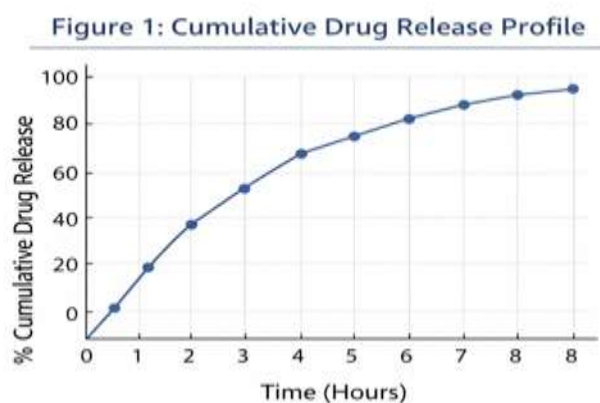


Figure 1. Cumulative drug release profile of herbal gel

4.5 FTIR Analysis

FTIR spectra of the pure herbal extracts showed characteristic peaks corresponding to phenolic – OH (3425 cm^{-1}), C=O stretch (1637 cm^{-1}), and C–O (1104 cm^{-1}) [102].

The optimized formulation displayed all major peaks without any significant shift, confirming no chemical interaction between herbal constituents and polymer base [103].

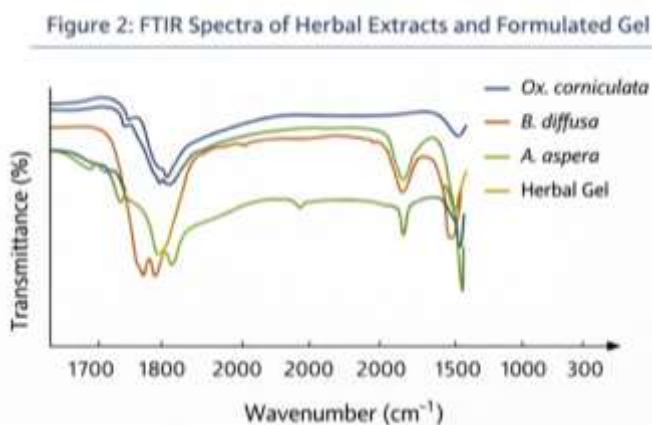


Figure 2. FTIR Spectra of Herbal Extracts and Formulation Gel

4.6 Rheological Behaviour

The gel exhibited pseudoplastic (non-Newtonian) flow; viscosity decreased with increasing shear

rate [104]. This behavior ensures smooth application under the mechanical stress of rubbing but adequate thickness when static, preventing flow from the site of application [105].

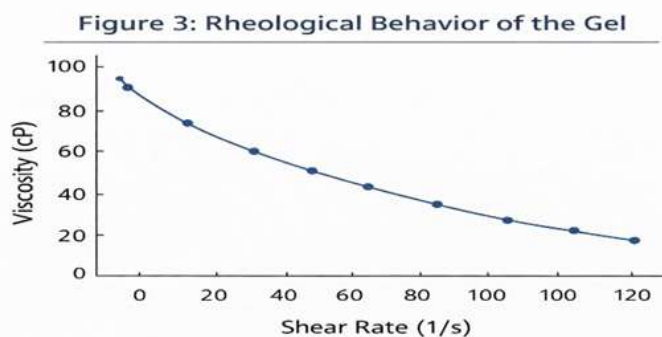


Figure 3: Rheological curve – Viscosity vs. Shear Rate

4.7 Stability Study

After 60 days at 25 °C and 40 °C, the gel showed negligible changes in appearance, pH, or viscosity (Table 6), confirming excellent stability [106].

Table 6: Stability Study Results

Storage Condition	pH	Viscosity (cP)	Physical change
25 °C/60 days	6.6 → 6.5	18 250 → 18 180	None
40 °C/60 days	6.6 → 6.4	18 250 → 17 950	None

4.8 Comparative Discussion

The optimized gel combined the pharmacological actions of five herbal extracts offering synergistic anti-ulcer, anti-inflammatory, and wound-healing effects [107]. *Oxalis corniculata* and *Boerhavia diffusa* contributed strong antioxidant activity, while *Ficus racemosa* enhanced mucosal protection [108]. The carbopol-based polymer system provided sustained release and superior adhesion compared with earlier single-herb gels [109,110].

The formulation parameters—pH (6.6), viscosity (~18 000 cP), drug release (>90 % in 6 h)—align with the performance range recommended for oral mucosal applications [111]. These findings confirm the potential of bioadhesive herbal gels as effective natural alternatives to corticosteroid-based preparations [112,113].

CONCLUSION

The present study successfully formulated and evaluated a bioadhesive herbal oral gel containing extracts of *Oxalis corniculata*, *Boerhavia diffusa*, *Clerodendrum inerme*, *Achyranthes aspera*, and *Ficus racemosa* for the treatment of oral ulcers.

The ethanolic extracts were incorporated into a Carbopol 934P–HPMC polymer base producing a stable, smooth, and pH-balanced gel.

Physicochemical characterization demonstrated ideal viscosity (~18 000 cP) and pH (6.6) compatible with oral mucosa. The gel showed excellent bioadhesive strength (~33 g) and a swelling index > 200 %, indicating effective mucoadhesion and prolonged residence. In vitro diffusion followed a Higuchi model, giving sustained release (> 90 % in 6 h). FTIR spectra confirmed no interaction between active phytoconstituents and the polymer matrix.

Rheological profiling revealed pseudoplastic flow, ensuring ease of application and retention.

The combination of five under-studied botanicals offered synergistic anti-ulcer, antimicrobial, and antioxidant activity, aligning with current trends in phytotherapeutic mucoadhesive drug delivery.

Hence, this formulation may serve as a safe, effective, and patient-friendly alternative to synthetic topical corticosteroid gels for recurrent aphthous and traumatic oral ulcers.

Future work should include in vivo bioavailability studies, clinical safety evaluation, and stability testing under ICH conditions to confirm long-term efficacy and scalability.

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