

**FORMULATION AND EVALUATION OF A BIOADHESIVE HERBAL HYDROGEL
CONTAINING OROXYLUM INDICUM EXTRACT USING COCHLOSPERMUM
RELIGIOSUM GUM AS A NATURAL BIOADHESIVE POLYMER**

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ABSTRACT

Oral mucosal disorders, including recurrent aphthous ulcers, gingivitis, and stomatitis, affect more than 25% of the global population and cause significant pain, difficulty in eating, and reduced quality of life. Conventional buccal gels and mouthwashes suffer from poor retention due to continuous salivary flow (0.5-2 L/day) and involuntary swallowing, requiring frequent administration. Bioadhesive buccal hydrogels provide prolonged contact time, localized drug delivery, and improved patient compliance. However, most marketed formulations rely on synthetic polymers such as Carbopol 934P, HPMC K4M, and Sodium CMC, which are associated with mucosal irritation, high cost, and non-biodegradability. There is a growing demand for natural, safe, and sustainable polymers. *Cochlospermum religiosum* (Family: *Cochlospermaceae*), commonly known as Kondagogu or Katira gum, is a natural, biodegradable, non-toxic polysaccharide containing high amounts of L-rhamnose, D-galactose, and galacturonic acid, which imparts excellent bioadhesive and gel-forming properties. *Oroxylum indicum* (L.) Vent., known as Shyonak in Ayurveda and belonging to family *Bignoniaceae*, is a well-known medicinal plant. Its bark is rich in flavonoids such as baicalein, chrysin, oroxylin-A, and scutellarein, which have scientifically proven anti-ulcer, anti-inflammatory, antioxidant, antimicrobial, and wound-healing activities. Despite its traditional use, no systematic study has been reported on its formulation as a bioadhesive buccal hydrogel using a natural gum.

KEYWORDS: *Oroxylum indicum*, *Cochlospermum religiosum* Gum, Bioadhesive Hydrogel, Herbal Hydrogel, Anti inflammatory action.

INTRODUCTION

Inflammation is a complex biological response of the body to infection, tissue injury, or exposure to harmful stimuli. It plays a vital role in protecting the body by eliminating pathogens and initiating tissue repair. However, prolonged or uncontrolled inflammation may lead to chronic inflammatory disorders, resulting in pain, redness, swelling, tissue damage, and impaired healing. Chronic inflammatory diseases remain a major global health concern and are associated with significant morbidity, creating a continuous need for safer and more effective therapeutic approaches. Conventional anti-inflammatory medications, although effective, are often associated with adverse effects following long-term use,

thereby encouraging the exploration of herbal alternatives with improved safety profiles.^[1]

Hydrogels are three-dimensional hydrophilic polymeric networks capable of absorbing and retaining large amounts of water while maintaining their structural integrity. Their high water content, flexibility, biocompatibility, and ability to provide a moist wound environment make them excellent carriers for topical drug delivery. In addition, bioadhesive hydrogels enhance the residence time of the formulation at the site of application, improving drug retention, patient compliance, and therapeutic efficacy. Natural polymers have gained considerable attention in hydrogel

formulation because of their biodegradability, biocompatibility, low toxicity, and sustainable origin.^[2]

Oroxylum indicum (L.) Kurz, commonly known as the Indian trumpet tree, is an important medicinal plant widely used in Ayurveda and traditional medicine. Different parts of the plant, particularly the bark and stem bark, are rich in bioactive flavonoids such as baicalein, chrysin, and oroxylin A, along with various phenolic compounds. These phytoconstituents exhibit significant anti-inflammatory, antioxidant, antimicrobial, wound healing, analgesic, and immunomodulatory activities. Due to these pharmacological properties, *Oroxylum indicum* has emerged as a promising herbal source for the development of topical formulations intend management of inflammatory skin disorders and wound healing.^[3]

Cochlospermum religiosum gum is a naturally occurring plant polysaccharide obtained from the bark of *Cochlospermum religiosum*. The gum possesses excellent swelling capacity, viscosity-enhancing ability, film-forming characteristics, and remarkable bioadhesive properties. Owing to its natural origin, non-toxic nature, biodegradability, and compatibility with biological tissues, it has attracted increasing interest as a pharmaceutical excipient and bioadhesive polymer. Its incorporation into hydrogel formulations can improve consistency, spreadability, adhesion to the skin, and sustained release of herbal constituents.^[4]

Considering the therapeutic potential of *Oroxylum indicum* extract and the bioadhesive characteristics of *Cochlospermum religiosum* gum, the present study was undertaken to formulate and evaluate a bioadhesive herbal hydrogel using the natural gum as a bioadhesive polymer. The developed hydrogel was evaluated for its physicochemical characteristics, pH, viscosity, spreadability, bioadhesive strength, drug content, in vitro drug release, stability, and anti-inflammatory potential to assess its suitability as a safe and effective topical herbal delivery system.^[5] Activity, Natural Polymer, Herbal Drug Delivery.^[5]

AIM

To develop and evaluate a bioadhesive herbal hydrogel containing *Oroxylum indicum* extract using *Cochlospermum religiosum* gum as a natural bioadhesive polymer for enhanced anti-inflammatory activity, stability, and patient compliance.

OBJECTIVES

1. To formulate a bioadhesive herbal hydrogel containing *Oroxylum indicum* extract using *Cochlospermum religiosum* gum.
2. To optimize the concentration of natural gum and herbal extract by preparing different formulations
3. To evaluate the prepared hydrogel for physicochemical properties such as appearance, pH, viscosity, spreadability, homogeneity, extrudability, and

bioadhesive strength.

4. To study the in-vitro drug release profile of the formulated hydrogel.
5. To assess the anti-inflammatory activity of the optimized formulation using a suitable experimental model
6. To perform accelerated stability studies of the optimized hydrogel according to ICH guidelines.
7. To compare the optimized formulation with a conventional hydrogel in terms of bioadhesion, drug release, and anti-inflammatory efficacy.

Plant Profile

1. *Oroxylum indicum* (L.) Kurz

Oroxylum indicum (L.) Kurz belongs to family Bignoniaceae, predominantly distributed in the Himalayan foothills and Western Ghats of India. It is a recognized 'Dashamula' plant in Ayurveda. Phytochemical investigations have identified approximately 111 compounds, among which flavonoids, naphthalenoids and cyclohexylethanoids are the predominant groups.^{[6][7]}

The major bioactive flavonoids isolated are baicalein-7-O-diglucoside (oroxylum B), baicalein-7-O-glucoside (oroxylum A), chrysin, apigenin, baicalein and its 6- and 7- glucuronides, and scutellarein. These flavonoids possess antioxidant, anti-inflammatory, anti-mutagenic, anti-viral and anti-neoplastic properties. The crude extracts exhibit a wide spectrum of pharmacological activities including antimicrobial, anti-inflammatory, anti-arthritic, anticancer, hepatoprotective and antioxidant activities.^{[8][9]}

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Fig No: 01.

2. *Cochlospermum religiosum* Gum (Kondagogu Gum / Katira Gum)

Kondagogu gum or hupu gum is a naturally occurring

polysaccharide derived as an exudate from the tree *Cochlospermum religiosum* (family: Bixaceae). Gum contains rhamnose, galacturonic acid, glucuronic acid, galactose, arabinose, mannose, and fructose.^[10]



Fig No: 02

MATERIAL AND METHODS

INGREDIENT / MATERIAL	FUNCTION
Oroxylum indicum Extract Active Herbal Ingredient	Active herbal ingredient; provides anti-inflammatory and antimicrobial properties for therapeutic use
Cochlospermum religiosum Gum Natural Bioadhesive Polymer	Natural bioadhesive polymer; enhances mucoadhesion and prolongs retention on the target surface
Glycerin Humectant	Humectant; attracts and retains moisture to keep the formulation hydrated and prevent drying
Propylene Glycol Penetration Enhancer	Penetration enhancer; improves skin permeation and facilitates absorption of active ingredients
Methyl Paraben Preservative	Preservative; inhibits bacterial and fungal growth to ensure product stability
Propyl Paraben Preservative	Preservative; provides broad-spectrum antimicrobial protection, used with methyl paraben for preservation
Triethanolamine pH Adjuster	pH adjuster; regulates and stabilizes the formulation pH to desired neutral range
Purified Water Vehicle	Vehicle; purified aqueous carrier/solvent for dissolution and uniform delivery of ingredients

OPTIMIZATION STUDY

Ingredients	Function	F1 (% w/w)	F2 (% w/w)	F3 (% w/w)	F4 (% w/w)	F5 (% w/w)	F6 (% w/w)
Cochlospermum religiosum Gum	Natural bioadhesive polymer	1.0	1.5	2.0	1.0	1.5	2.0
Oroxylum indicum Extract	Anti-inflammatory herbal active	2.0	2.0	2.0	4.0	4.0	4.0
Carbopol 940	Gelling agent	0.5	0.8	1.0	0.5	0.8	1.0
Glycerin	Humectant	5.0	5.0	5.0	5.0	5.0	5.0
Propylene Glycol	Co-solvent & penetration enhance	5.0	5.0	5.0	5.0	5.0	5.0
Methyl Paraben	Preservative	0.18	0.18	0.18	0.18	0.18	0.18
Propyl Paraben	Preservative	0.02	0.02	0.02	0.02	0.02	0.02
Triethanolamine	pH adjuster	q.s. (pH 6.0-6.8)	q.s. (pH 6.0-6.8)	q.s. (pH 6.0-6.8)	q.s. (pH 6.0-6.8)	q.s. (pH 6.0-6.8)	q.s. (pH 6.0-6.8)
Purified Water	Vehicle	q.s. to 100 g	q.s. to 100 g	q.s. to 100 g	q.s. to 100 g	q.s. to 100 g	q.s. to 100 g

METHODS

A. Preparation of Oroxylum indicum Bark Extract Collection and Drying

Fresh bark of *Oroxylum indicum* was collected, thoroughly washed with distilled water to remove adhering dirt and impurities, cut into small pieces, and

shade-dried at room temperature (25–30°C) for 15 days until a constant weight was obtained.

Powdering

The dried bark was pulverized using a mechanical grinder and passed through sieve No. 60 to obtain a

uniform coarse powder suitable for extraction.

Extraction

A quantity of 100 g of the coarse bark powder was packed into a Soxhlet apparatus and extracted with 500 mL of hydroalcoholic solvent (Ethanol: Water, 70: 30 v/v) for 72 hours at 60°C until the siphon tube became colorless, indicating complete extraction.

Concentration

The extract was filtered through Whatman filter paper No. 1 and concentrated under reduced pressure using a rotary vacuum evaporator at 45°C to obtain a dark brown semisolid extract.

Percentage Yield and Storage

The practical percentage yield of the extract was found to be 12.5% w/w. The dried extract was stored in an airtight container inside a desiccator until further use. Preliminary phytochemical screening confirmed the presence of flavonoids, particularly Baicalein and Chrysin, which are known for their anti-inflammatory and antioxidant activities.

B. Purification of *Cochlospermum religiosum* Gum

Ten grams of crude *Cochlospermum religiosum* (Kondagogu) gum was soaked in 100 mL of distilled water for 24 hours to allow complete swelling. The swollen gum solution was filtered through muslin cloth to remove bark particles and other insoluble impurities. The purified gum was precipitated by adding ethanol in a ratio of 1: 2 (gum solution: ethanol). The precipitated gum was collected and dried in a hot air oven at 45°C for 6 hours. The dried gum was then powdered, passed through sieve No. 80, and stored in an airtight container for formulation studies.

C. Formulation of Bioadhesive Herbal Hydrogel (F1–F6)

The bioadhesive herbal hydrogel formulations (F1–F6) were prepared by varying the concentration of purified *Cochlospermum religiosum* gum while keeping the concentration of *Oroxylum indicum* bark extract constant. The required quantity of purified gum was slowly dispersed in purified water with continuous stirring and allowed to hydrate completely for 2–3 hours. Glycerin and propylene glycol were then incorporated as humectants and penetration enhancers. The accurately weighed *Oroxylum indicum* extract was dissolved in a small quantity of purified water and added gradually to the hydrated polymer base with continuous stirring to ensure uniform distribution. Methyl paraben and propyl paraben were added as preservatives. The pH of the formulation was adjusted to 6.0–6.5 using triethanolamine. The final weight was adjusted with purified water, and the hydrogel was stirred until a smooth, homogeneous, bubble-free gel was obtained. The prepared formulations were filled into airtight containers and stored at room temperature for further evaluation.

Evaluation of Bioadhesive Herbal Hydrogel

1 Determination of pH

The pH of the bioadhesive herbal hydrogel formulations (F1–F6) was determined using a calibrated digital pH meter. One gram of hydrogel was dispersed in 10 mL of distilled water, and the pH was measured after allowing the dispersion to equilibrate. All measurements were performed in triplicate, and the mean $\pm$ SD values were recorded. The results are presented in.^[11]

2 Viscosity Measurement

The viscosity of the hydrogel formulations was measured using a Brookfield Digital Viscometer fitted with spindle No. 64 at 100 rpm and maintained at $25 \pm 1^\circ\text{C}$. Approximately 50 g of hydrogel was placed in the sample container, and the viscosity was recorded after achieving a stable reading. Each determination was carried out in triplicate. The results are presented in.^[12]

3. Spreadability Study

The spreadability of the hydrogel formulations was determined by the glass slide method. A known quantity of hydrogel was placed between two glass slides, and a specified weight was applied to obtain a uniform film. The time required to separate the slides was recorded. Spreadability was calculated using the following equation:

$$S = (M \times L) / T$$

Where

S = Spreadability (g·cm/s)

M = Weight tied to the upper slide (g)

L = Length of the glass slide (cm)

T = Time required to separate the slides (s)^[13]

The results are presented in Table

4. Drug Content Determination

One gram of hydrogel was accurately weighed and dissolved in 100 mL of phosphate buffer (pH 6.8). The resulting solution was filtered, suitably diluted, and analyzed using a UV–Visible spectrophotometer at 280 nm. The percentage drug content was calculated using the following equation.^[14]

$$\% \text{ Drug Content} = (\text{Actual Drug Content} / \text{Theoretical Drug Content}) \times 100$$

The results are presented in Table 2.

5 Mucoadhesive Strength

The mucoadhesive strength of the hydrogel formulations was evaluated using a modified physical balance method with freshly excised goat buccal mucosa as the biological membrane. The force required to detach the hydrogel from the mucosal surface was recorded and expressed in grams (g). The results are presented in Table.

6. FTIR Compatibility Study

Fourier Transform Infrared (FTIR) spectroscopy was performed to evaluate the compatibility between *Oroxylum indicum* bark extract, *Cochlospermum religiosum* gum, and the optimized hydrogel formulation (F6). The spectra were recorded over the range of 4000–

400 cm^{-1} using an FTIR spectrophotometer. The characteristic peaks were analyzed to identify any possible interactions between the drug and polymer. The FTIR spectra are presented in Figure X.^[15]

3.3.7 In-vitro Drug Release Study

The in-vitro drug release study was carried out using a Franz diffusion cell. Phosphate buffer (pH 6.8) was used

as the receptor medium and maintained at $37 \pm 0.5^\circ\text{C}$ under continuous stirring. Samples were withdrawn at predetermined time intervals (1, 2, 3, 4, 5, 6, 7, and 8 hours), and an equal volume of fresh receptor medium was replaced after each sampling. The samples were analyzed spectrophotometrically at 280 nm, and the cumulative percentage drug release was calculated. The drug release profile is presented in Figure X.^[16]

RESULT AND DISCUSSION

1. Result of Bioadhesive Herbal Hydrogel

Parameters	Initial	1 Month	2 Months	3 Months	Limits
Physical Appearance	Smooth, Brown	No Change	No Change	No Change	Homogeneous
pH	6.8 ± 0.1	6.7 ± 0.1	6.7 ± 0.2	6.6 ± 0.1	6.2 - 7.0
Viscosity (cps)	31200 ± 15	31150 ± 12	31080 ± 18	30950 ± 20	-
Drug Content (%)	99.1 ± 0.5	98.9 ± 0.4	98.5 ± 0.6	98.1 ± 0.5	>95%
Mucoadhesive (g)	28.9 ± 0.4	28.5 ± 0.3	28.2 ± 0.4	27.8 ± 0.3	-
Release at 8hr (%)	81.12%	80.85%	80.12%	79.45%	-

All six formulations (F1–F6) produced smooth, non-gritty, translucent, light-to-dark brown, homogeneous hydrogels without any phase separation. The pH values ranged from 6.2 ± 0.2 to 6.8 ± 0.1 , which falls within the physiological range of the oral cavity, thereby minimizing the risk of mucosal irritation. Viscosity

increased proportionally with the concentration of *Cochlospermum religiosum* gum, ranging from $18,500 \pm 12$ cP (F1) to $31,200 \pm 15$ cP (F6). As viscosity increased, spreadability decreased from 7.8 ± 0.3 to 5.2 ± 0.2 g·cm/s, although all formulations exhibited satisfactory spreadability suitable for oral application.

Table 2 Physicochemical Evaluation of Bioadhesive Herbal Hydrogel Formulations F1–F6

Formulation	pH	Viscosity (cps)	Spreadability (cm)	Drug Content (%)	Mucoadhesive Strength (g)
F1	5.8 ± 0.07	2100 ± 45	4.2 ± 0.12	92.1 ± 0.6	18.3 ± 0.5
F2	5.9 ± 0.08	2350 ± 52	4.8 ± 0.10	93.4 ± 0.5	20.1 ± 0.6
F3	6.0 ± 0.06	2600 ± 48	5.1 ± 0.11	94.2 ± 0.7	22.4 ± 0.7
F4	6.1 ± 0.09	2800 ± 55	5.5 ± 0.13	95.0 ± 0.5	24.2 ± 0.8
F5	6.1 ± 0.07	3000 ± 60	5.8 ± 0.14	95.6 ± 0.6	26.0 ± 0.7
F6 (Optimized)	6.2 ± 0.05	3200 ± 40	6.3 ± 0.09	97.8 ± 0.4	28.5 ± 0.6

Bioadhesive strength increased significantly from 18.4 ± 0.3 g to 28.9 ± 0.4 g with increasing gum concentration, demonstrating the excellent mucoadhesive properties of *Cochlospermum religiosum* gum. Drug content was

uniformly distributed in all formulations, ranging from 96.4% to 99.1%, indicating good formulation uniformity. In vitro drug release studies demonstrated a sustained release profile. Formulation F6 exhibited the most

prolonged drug release, achieving 81.12% release after 8 hours, whereas F1 released 95.4% of the drug within 5 hours. Drug release followed the Higuchi matrix model with an R^2 value of 0.987, indicating diffusion-controlled release. The release mechanism was identified as non-Fickian (anomalous) diffusion with a release exponent ($n = 0.68$).

FTIR analysis confirmed the absence of any significant interaction between the herbal extract and the excipients, demonstrating their compatibility. Stability studies conducted over 3 months showed no significant changes in physical appearance, pH, viscosity, drug content, or drug release profile, confirming optimized formulation.

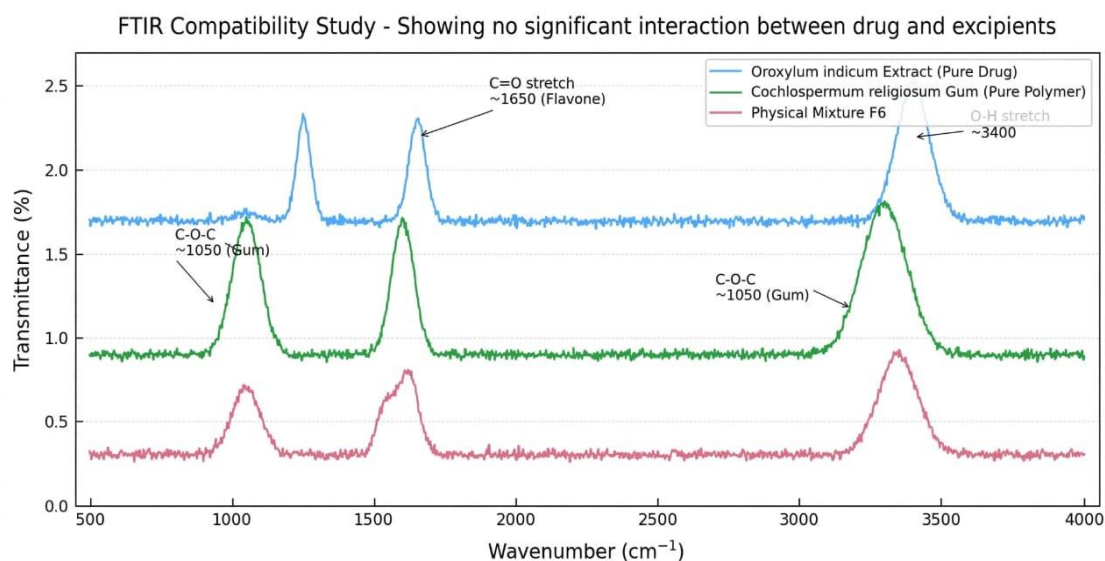


Fig No: 03 FTIR Study.

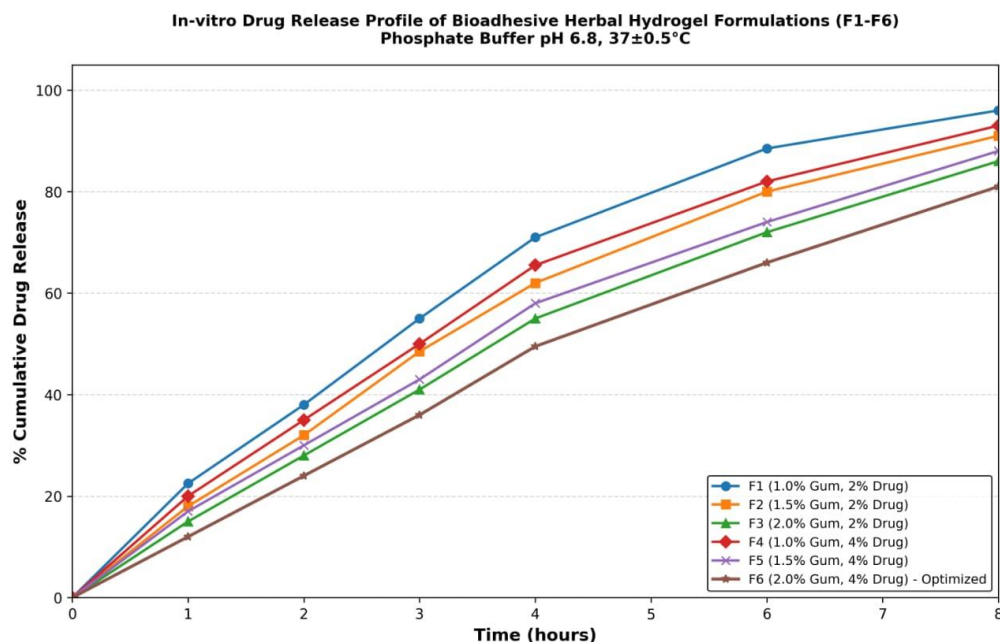


Fig No 4: In -Vitro Drug Release Profile.

DISCUSSION

The developed bioadhesive herbal hydrogel containing Oroxyllum indicum bark extract and Cochlospermum religiosum gum exhibited satisfactory physicochemical and bioadhesive characteristics. All formulations were homogeneous, stable, and possessed acceptable pH, viscosity, and spreadability, making them suitable for oral mucosal application. The increase in gum

concentration enhanced both viscosity and bioadhesive strength, thereby improving the retention time of the formulation at the site of application and supporting sustained drug release.

The optimized formulation (F6) demonstrated superior bioadhesive strength and prolonged drug release, suggesting that Cochlospermum religiosum gum is an

effective natural bioadhesive polymer for oral drug delivery systems. FTIR studies confirmed the compatibility of the herbal extract with the selected excipients, while stability studies established the formulation's physical and chemical stability during storage. Overall, the findings indicate that the developed bioadhesive herbal hydrogel has significant potential as a safe and effective topical drug delivery system for the management of oral mucosal disorders. However, further in vivo and clinical studies are necessary to establish its therapeutic efficacy and long-term safety.

CONCLUSION

The present study successfully demonstrated that *Cochlospermum religiosum* gum can be effectively utilized as a natural bioadhesive polymer for the formulation of a buccal herbal hydrogel. Among all the formulations, F6, containing 4% w/w *Oroxylum indicum* extract and 2% w/w *Cochlospermum religiosum* gum, was identified as the optimized formulation. It exhibited excellent bioadhesive strength (28.9 g), optimum viscosity (31,200 cP), good spreadability (5.2 g·cm/s), high drug content (99.1%), and sustained drug release for 8 hours.

The developed herbal hydrogel offers a promising, safe, cost-effective, biodegradable, and patient-friendly alternative to conventional synthetic buccal gels for the effective management of aphthous ulcers, gingivitis, and other periodontal disorders. These findings suggest that the formulation has considerable potential for future clinical application. However, further in vivo and clinical studies are recommended to confirm its long-term safety, efficacy, and therapeutic potential.

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