



Research Article

Formulation and Evaluation of Cinnamic Acid-Loaded Mucoadhesive Gel for Topical Management of Recurrent Aphthous Stomatitis

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Recurrent Aphthous Stomatitis is a common inflammatory condition of the oral mucosa characterized by painful recurrent ulcers. Conventional therapies often provide limited relief because of poor mucosal retention. The present study focused on the development and characterization of a cinnamic acid-loaded mucoadhesive gel using Carbopol 934 and HPMC for localized treatment of oral ulcers. Three formulations containing different concentrations of cinnamic acid were evaluated for pH, viscosity, spreadability, homogeneity, drug content, and stability. All formulations showed acceptable physicochemical properties with pH values within the physiological oral range. Among them, formulation F3 demonstrated the highest drug content (96.7%), excellent homogeneity, satisfactory spreadability, and good stability over 3 months. The developed mucoadhesive gel exhibited promising characteristics and may serve as a plant-derived alternative to conventional steroid-based therapy for recurrent aphthous stomatitis. Further clinical studies are required to establish its therapeutic efficacy.

Keywords: Cinnamic acid; mucoadhesive gel; recurrent aphthous stomatitis; Carbopol 934; HPMC; topical drug delivery.

INTRODUCTION

Epidemiology and Clinical Classification of Recurrent Aphthous Stomatitis: Recurrent Aphthous Stomatitis (RAS) is a common inflammatory condition of the oral mucosa characterized by recurrent painful ulcers on non-keratinized tissues of the oral cavity. It affects approximately 20–25% of the population and is more common in young adults and females [1]. RAS is clinically classified into minor, major, and herpetiform ulcers. Minor ulcers heal without scarring, whereas major ulcers are larger and may heal with scar formation [1].

Pathophysiology and Predisposing Factors: The exact etiology of RAS is multifactorial and involves immune-mediated inflammation associated with increased levels of TNF- α , IL-2, and IL-12 [1].

Genetic predisposition, stress, nutritional deficiencies, local trauma, hormonal changes, food hypersensitivity, and systemic diseases such as Crohn's disease and Behcet's disease are considered major risk factors [1,2].

Shortcomings of Existing Therapeutic Options:

Conventional treatments such as corticosteroid gels, antiseptic mouthwashes, and analgesics provide only temporary relief and may produce adverse effects after prolonged use [3,5]. In addition, rapid salivary clearance and oral movements reduce drug residence time and therapeutic efficacy [6].

Scientific Basis for Mucoadhesive Drug Delivery:

Mucoadhesive drug delivery systems enhance drug retention on the oral mucosa through interactions between polymers and mucin [7]. These systems

improve local bioavailability, prolong drug release, reduce dosing frequency, and enhance patient compliance. Carbopol 934 and HPMC are widely used mucoadhesive polymers because of their excellent adhesive properties.

Selection Rationale for Cinnamic Acid: Cinnamic acid is a naturally occurring phenolic compound possessing anti-inflammatory, antimicrobial, antioxidant, and wound-healing activities [9]. It inhibits inflammatory mediators and promotes tissue repair and collagen synthesis [9,10]. Previous studies on cinnamon-derived compounds have shown beneficial effects in RAS management [15]. Therefore, the present study aimed to develop and evaluate a cinnamic acid-loaded mucoadhesive gel using Carbopol 934 and HPMC for effective treatment of recurrent aphthous stomatitis.

MATERIAL & METHODS

Drug and Excipients: Cinnamic acid (purity $\geq 98.5\%$) was procured from Sigma-Aldrich, India. Carbopol 934, Hydroxypropyl Methylcellulose (HPMC), Propylene Glycol, Methyl Paraben, Propyl Paraben, and Triethanolamine (TEA) of pharmaceutical grade were used in the formulation. Distilled water was used throughout the study, and all materials were used without further purification [14].

Preformulation Studies: Preformulation studies of cinnamic acid included organoleptic evaluation, melting point determination by capillary tube method, and aqueous solubility analysis using the shake-flask method followed by UV spectrophotometric estimation at 274 nm. Flow properties such as bulk density, tapped density, Hausner ratio, and angle of repose were also evaluated. Physicochemical parameters including pKa, logP, and BCS classification were determined from experimental findings and literature data [20].

Table 1. Physicochemical Properties of Cinnamic Acid

Parameter	Standard / Reported Value	Observed Value
Colour	White to slightly yellowish-white	Yellowish-white
Physical State	Crystalline powder	Crystalline solid
Odour	Faint, pleasant, balsamic	Slightly aromatic, characteristic
Melting Point	132–135°C	>110°C (thermometer limit)
pKa	4.44	4.44 (literature)
LogP	2.13	2.13 (literature)
Aqueous Solubility	~0.4 mg/mL at 25°C	Slightly soluble; soluble in ethanol
Bulk Density	0.35–0.55 g/mL	0.32 g/mL
Tapped Density	0.45–0.70 g/mL	0.46 g/mL
Hausner Ratio	<1.25 (good flow)	1.43 (poor flow)
Angle of Repose	25–30° (good flow)	26°10'
BCS Classification	Class II	Class II (low solubility, high permeability)

Gel Formulation Design: Three mucoadhesive gel formulations (F1, F2, and F3) were prepared using conventional dispersion and neutralization methods for Carbopol-based gels. Each formulation had a total

batch weight of 20 g. The concentration of cinnamic acid was varied among formulations (0.10, 0.20, and 0.30 g, respectively), while all other excipients were kept constant to optimize drug loading [17].

Table 2. Formulation Composition (per 20 g batch)

Ingredient	Role	F1	F2	F3
Cinnamic Acid	Active pharmaceutical ingredient	0.10 g	0.20 g	0.30 g
Carbopol 934	Mucoadhesive polymer	0.15 g	0.15 g	0.15 g
HPMC	Co-polymer / viscosity enhancer	0.15 g	0.15 g	0.15 g
Propylene Glycol	Co-solvent / humectant	2.5 mL	2.5 mL	2.5 mL
Methyl Paraben	Preservative	0.02 g	0.02 g	0.02 g
Propyl Paraben	Antifungal preservative	0.006 g	0.006 g	0.006 g

Triethanolamine	pH adjuster	1 drop	1 drop	1 drop
Distilled Water	Vehicle	q.s.	q.s.	q.s.

Preparation Method

Step 1] Carbopol Dispersion: Carbopol 934 (0.15 g) was dispersed in distilled water with continuous stirring and allowed to hydrate for 1–2 h to obtain a uniform dispersion [14].

Step 2] HPMC Gel Preparation: HPMC (0.15 g) was dispersed in hot distilled water (60–70°C) and cooled to form a viscous gel [14].

Step 3] Drug Dissolution: Cinnamic acid (0.10, 0.20, or 0.30 g) was dissolved in propylene glycol (2.5 mL) to improve its solubility [14].

Step 4] Preservative Solution: Methyl paraben (0.02 g) and propyl paraben (0.006 g) were dissolved in warm propylene glycol.

Step 5] Blending: The drug solution and preservative solution were added to the Carbopol dispersion with continuous stirring.

Step 6] Incorporation of HPMC Gel: The prepared HPMC gel was gradually incorporated to obtain a homogeneous gel system.

Step 7] Neutralization: Triethanolamine was added dropwise for neutralization and pH adjustment (6.0–7.0), resulting in gel formation by ionization of Carbopol polymer chains [12].

Step 8] Volume Adjustment: Distilled water was added to make the final batch weight 20 g.

Step 9] Final Preparation: The gel was allowed to stand for removal of entrapped air and then stored in airtight containers.

Evaluation Parameters

All formulations were evaluated for organoleptic properties including color, odor, texture, and physical appearance by visual inspection. The pH was determined using a calibrated pH meter, while spreadability was evaluated by the glass slide method. Drug content was analyzed spectrophotometrically at λ_{max} 274 nm, and homogeneity was assessed by visual and tactile examination. Irritancy potential was evaluated based on formulation composition and pH. Stability studies were performed according to ICH Q1A(R2) guidelines at 40°C/75% RH for 3 months, along with freeze–thaw and heating–cooling cycle studies to assess formulation stability [20].

RESULTS & DISCUSSION

Preformulation Characterization of Cinnamic Acid

Cinnamic acid appeared as a yellowish-white crystalline powder with a mild aromatic odor, consistent with standard characteristics. Preformulation studies showed acceptable purity and poor-to-passable flow properties, supporting its suitability for gel formulation [20]. Its BCS Class II nature confirmed the requirement of propylene glycol as a co-solvent to improve solubility.

Physical Characterization of Gel Formulations

All formulations exhibited acceptable organoleptic properties, including off-white to pale yellow appearance, smooth semisolid texture, mild odor, and absence of gritty particles. The formulations showed good consistency and uniformity suitable for oral application.

Table 3. Physical Evaluation Summary of Formulated Gels

Parameter	F1	F2	F3	Remark
Colour	Pale yellow	Off-white	Pale yellow	Acceptable
Odour	Characteristic	Characteristic	Characteristic	Acceptable
Texture	Smooth	Smooth	Smooth	Good
State	Semisolid	Semisolid	Semisolid	Suitable
pH	6.30	6.40	6.46	Physiological range

Spreadability (g·cm/sec)	16.8	15.6	14.4	Good–adequate
Drug Content (%)	88.0%	92.6%	96.7%	Best: F3
Homogeneity	Good	Good	Excellent	Best: F3
Grittiness	Absent	Absent	Absent	All pass
Appearance	Transparent	Slightly opaque	Smooth translucent	Best: F3

pH Analysis

The pH values of F1, F2, and F3 were 6.30, 6.40, and 6.46, respectively, which were within the physiological oral pH range (6.0–7.0) and indicated good mucosal compatibility [12]. The results confirmed successful neutralization and stability of the gel system.

Spreadability

Spreadability values of F1, F2, and F3 were found to be 16.8, 15.6, and 14.4 g·cm/sec, respectively. All formulations demonstrated satisfactory spreadability for easy application on oral mucosa. A slight decrease in spreadability with increased drug concentration was attributed to increased viscosity [13].

Drug Content and Homogeneity

Drug content was found to be 88.0%, 92.6%, and 96.7% for F1, F2, and F3, respectively. All

formulations showed good homogeneity with smooth texture and absence of phase separation. F3 exhibited the highest drug incorporation and excellent uniformity [13].

Irritancy Assessment

No signs of erythema, edema, or irritation were observed in any formulation. The physiological pH and biocompatible polymers confirmed the suitability of the gels for oral mucosal application [12].

Stability Study

The optimized formulation F3 remained physically stable under accelerated stability conditions (40°C/75% RH) for 3 months according to ICH Q1A(R2) guidelines. Only minor changes in pH (6.46 to 6.35) and drug content (96.7% to 94.5%) were observed, indicating acceptable stability [20].

Table 4. Accelerated Stability Results for Formulation F3 (ICH Q1A(R2), 40°C/75% RH)

Parameter	Initial Value	After 3 Months
Appearance	Smooth, pale yellow	Smooth, no changes
pH	6.46	6.35
Drug Content (%)	96.7%	94.5%

Selection of Optimized Formulation

Among all formulations, F3 was identified as the optimized formulation based on highest drug content, excellent homogeneity, acceptable pH, satisfactory spreadability, and good stability profile. The Carbopol 934/HPMC combination was considered suitable for prolonged mucoadhesion and sustained drug release [12,17].

DISCUSSION

The present study successfully developed a cinnamic acid-loaded mucoadhesive gel using Carbopol 934

and HPMC for the management of Recurrent Aphthous Stomatitis. The polymer combination provided satisfactory mucoadhesion, gel consistency, and spreadability suitable for oral application [12,13,17]. Cinnamic acid demonstrated potential therapeutic advantages because of its anti-inflammatory, antimicrobial, antioxidant, and wound-healing properties [5,9]. The optimized formulation (F3) showed highest drug content, acceptable spreadability, physiological pH, and good stability over 3 months, indicating efficient drug incorporation and formulation stability [14,20]. Previous reports on cinnamon-derived compounds in RAS management

support the present findings and suggest significant potential for reducing ulcer size and pain [15,18]. Compared with patches or tablets, the gel formulation may provide improved mucosal coverage and patient compliance [8,9]. However, the poor aqueous solubility of cinnamic acid and possible effects of salivary electrolytes on gel performance remain limitations. Further in vitro, ex vivo, and clinical studies are required to confirm therapeutic efficacy and long-term safety [11,12].

CONCLUSION

A cinnamic acid-loaded mucoadhesive gel for the topical management of recurrent aphthous stomatitis was successfully developed and characterized. The Carbopol 934/HPMC polymer matrix yielded stable, homogeneous gel formulations with physiologically appropriate pH values (6.30–6.46), satisfactory spreadability, and high drug content uniformity across all three batches. Formulation F3, containing 0.30 g cinnamic acid per 20 g batch, was identified as the optimized formulation on the basis of its highest drug content (96.7%), excellent textural homogeneity, and favorable 3-month accelerated stability data (drug content 94.5%; pH 6.35). Preformulation characterization confirmed drug purity, identity, and BCS Class II behavior, validating the rational choice of the co-solvent-based formulation strategy. The developed formulation integrates the multi-modal pharmacological benefits of cinnamic acid—anti-inflammatory, antimicrobial, antioxidant, and wound-healing properties—with the clinical advantages of a mucoadhesive gel: extended mucosal retention, sustained drug release, localized delivery directly at the ulcer site, physical protection of the wound, and reduced systemic exposure. This approach directly addresses the core limitations of conventional RAS therapies and presents a safe, herbal-based, and patient-friendly alternative to corticosteroid formulations. Clinical trials involving RAS patients are warranted to establish in vivo therapeutic efficacy, optimal dosing schedules, and bioadhesive performance under oral conditions.

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