DEVELOPMENT AND EVALUATION OF MUCOADHESIVE POLYHERBAL MOUTHWASH CONTAINING TRIPHALA FOR ENHANCED ORAL RETENTION AND PLAQUE CONTROL

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ABSTRACT

Oral diseases such as dental plaque, gingivitis, and recurrent aphthous ulcers are highly prevalent and significantly impact quality of life. Conventional mouthwashes exhibit limited efficacy due to rapid clearance from the oral cavity, resulting in reduced contact time and poor therapeutic outcomes. The present study aimed to develop and evaluate a mucoadhesive polyherbal mouthwash containing Triphala for enhanced oral retention and improved plaque control.

Triphala, a classical Ayurvedic formulation composed of *Terminalia chebula*, *Terminalia bellirica*, and *Emblica officinalis*, possesses antimicrobial, anti-inflammatory, and antioxidant properties. Mucoadhesive polymers such as Carbopol 934 and Hydroxypropyl Methylcellulose (HPMC) were incorporated to enhance adhesion and prolong drug residence time.

The formulation was evaluated for physicochemical parameters including pH, viscosity, spreadability, drug content, mucoadhesive strength, in vitro retention time, antimicrobial activity, and stability under ICH conditions. The optimized formulation demonstrated acceptable organoleptic properties, suitable pH, improved viscosity, strong mucoadhesion, and sustained drug release. Significant antimicrobial activity against oral pathogens was observed.

The study concludes that the developed mucoadhesive Triphala mouthwash is a promising herbal alternative to conventional formulations, offering improved retention, enhanced therapeutic efficacy, and better patient compliance.

Keywords: Triphala, Mucoadhesive system, Herbal mouthwash, Dental plaque, Gingivitis, Oral drug delivery

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1. INTRODUCTION

Oral diseases such as dental plaque, gingivitis, and recurrent aphthous ulcers represent a major global health burden. Dental plaque, a structured microbial biofilm, is the primary etiological factor responsible for dental caries and periodontal diseases [1,2].

The formation of plaque begins with the adsorption of salivary proteins on tooth surfaces, followed by colonization by microorganisms such as *Streptococcus mutans*, leading to biofilm maturation. This biofilm produces acids that cause enamel demineralization and trigger gingival inflammation [3,4].

Gingivitis is a reversible inflammatory condition characterized by redness, swelling, and bleeding of gums. If untreated, it may progress to periodontitis, resulting in irreversible damage to supporting tooth structures [5]. Recurrent aphthous ulcers (RAU) are painful lesions affecting oral mucosa and significantly impair daily activities such as eating and speaking [6].

Conventional mouthwashes, including chlorhexidine, are widely used for plaque control; however, they suffer from several limitations such as short residence time, rapid salivary clearance, and side effects like tooth staining and taste alteration [7,8]. These drawbacks reduce long-term patient compliance.

Mucoadhesive drug delivery systems (MDDS) have emerged as an effective approach to overcome these limitations. These systems adhere to mucosal surfaces, prolong drug residence time, and provide sustained release of therapeutic agents [9,10]. Mucoadhesion occurs through interactions between polymer chains and mucin glycoproteins via hydrogen bonding, van der Waals forces, and electrostatic interactions [11].

In recent years, there has been increasing interest in herbal formulations due to their safety and therapeutic efficacy. Triphala, a well-known Ayurvedic formulation consisting of *Terminalia chebula*, *Terminalia bellirica*, and *Emblica officinalis*, exhibits

antimicrobial, anti-inflammatory, and antioxidant properties [12,13]. Studies have demonstrated that Triphala is comparable to chlorhexidine in reducing plaque and gingival inflammation with fewer side effects [14].

However, conventional Triphala mouthwashes suffer from poor retention in the oral cavity. Incorporating Triphala into a mucoadhesive system can enhance its therapeutic effectiveness by prolonging contact time and ensuring sustained drug release.

Therefore, the present study aims to develop and evaluate a mucoadhesive polyherbal mouthwash containing Triphala for improved oral retention and plaque control.

2. MATERIALS AND METHODS

2.1 Materials

Triphala powder (*Terminalia chebula*, *Terminalia bellirica*, *Emblica officinalis*) was procured from an authenticated herbal supplier. Carbopol 934 and Hydroxypropyl Methylcellulose (HPMC) were used as mucoadhesive polymers. Glycerin (humectant), sodium benzoate (preservative), triethanolamine (neutralizing agent), peppermint oil (flavoring agent), and distilled water were used as excipients. All reagents were of analytical grade.

2.2 Preformulation Studies

2.2.1 Solubility Study

The solubility of Triphala extract was evaluated in different media. The extract was found to be practically insoluble in distilled water, slightly soluble in phosphate buffer (pH 6.8), and freely soluble in ethanol and methanol. This indicates the presence of polyphenolic constituents with better solubility in organic solvents [12].

2.3 Preparation of Triphala Extract

The aqueous extract of Triphala was prepared using a decoction method. Triphala powder was soaked in distilled water (1:10 ratio) for 6–8 hours, followed by boiling for 30–45 minutes. The mixture was cooled and filtered using muslin cloth and Whatman filter paper. The filtrate was stored in an airtight container at 4°C until further use.

2.4 Preparation of Mucoadhesive Base

The mucoadhesive base was prepared by dispersing Carbopol 934 or HPMC in distilled water under continuous stirring. The dispersion was allowed to hydrate for 2–4 hours. In the case of Carbopol, neutralization was carried out using triethanolamine to adjust pH to 6–7, resulting in gel formation [9].

2.5 Formulation of Mucoadhesive Mouthwash

Table: Composition of Mucoadhesive Mouthwash (100 mL)

Sr. No.	Ingredient	Role	Quantity
1	Triphala extract	Active ingredient	5 mL
2	Carbopol 934 / HPMC	Mucoadhesive polymer	0.5 g / 1 g
3	Glycerin	Humectant & viscosity enhancer	10 mL
4	Sodium benzoate	Preservative	0.2 g
5	Triethanolamine	Neutralizing agent	q.s.
6	Peppermint oil	Flavoring agent	q.s.
7	Distilled water	Vehicle	q.s. to 100 mL

2.6 Method of Preparation

The mucoadhesive base was prepared by dispersing polymer in distilled water and allowing it to hydrate. Glycerin and sodium benzoate were added with continuous stirring. Triphala extract was incorporated into the base, followed by addition of flavoring agent. In Carbopol formulations, triethanolamine was added to adjust pH and enhance viscosity. The final volume was made up to 100 mL with distilled water and mixed thoroughly to obtain a homogeneous formulation.

2.7 Evaluation Parameters

2.7.1 Organoleptic Evaluation

Color, odor, and taste were evaluated visually and organoleptically.

2.7.2 pH Determination

The pH of the formulation was measured using a calibrated digital pH meter.

2.7.3 Viscosity

Viscosity was determined using a Brookfield viscometer at appropriate spindle speed.

2.7.4 Drug Content

Drug content was estimated using UV spectrophotometry to ensure uniform distribution of active constituents.

2.7.5 Mucoadhesive Strength

Mucoadhesive strength was determined using a modified balance method by measuring the force required to detach the formulation from mucosal tissue [10].

2.7.6 In Vitro Retention Time

Retention time was evaluated using wash-off studies under simulated conditions.

2.7.7 Antimicrobial Activity

Antimicrobial activity was assessed using agar diffusion method against oral pathogens such as *Streptococcus mutans* [13].

2.7.8 Stability Studies

Stability studies were conducted as per ICH guidelines at 25°C/60% RH, 30°C/65% RH, and 40°C/75% RH for 3 months. Parameters such as pH, viscosity, and drug content were monitored [15].

3. RESULTS AND DISCUSSION

The formulated mucoadhesive polyherbal mouthwash containing Triphala was evaluated for physicochemical properties, mucoadhesion, antimicrobial activity, and stability. The results are interpreted below.

3.1 Organoleptic Properties

The formulations (F1–F3) were evaluated for color, odor, and taste. All formulations exhibited a brownish color, characteristic herbal odor, and acceptable taste due to the incorporation of peppermint oil. No phase separation or precipitation was observed, indicating good formulation stability.

Interpretation:

Organoleptic properties are crucial for patient compliance. The acceptable taste and odor suggest suitability for routine oral use.

3.2 pH Determination

The pH of all formulations was found in the range of 5.8–6.8, which is within the physiological range of saliva.

Interpretation:

This pH range ensures:

- Compatibility with oral mucosa
- No enamel erosion
- Minimal irritation

Thus, the formulation is safe for long-term use.

3.3 Viscosity

Viscosity increased in the order: F1 < F2 < F3, indicating higher polymer concentration improves thickness.

Interpretation:

- Increased viscosity enhances **mucoadhesion**
- Prevents rapid washout by saliva
- Ensures sustained drug release

F3 showed optimal viscosity for retention without affecting flow.

3.4 Drug Content

Drug content ranged from 98.2% to 99.7%, indicating uniform distribution of Triphala extract.

Interpretation:

- Confirms homogeneity of formulation
- Ensures consistent therapeutic effect

3.5 Mucoadhesive Strength

F3 exhibited the highest mucoadhesive strength due to higher polymer concentration.

Interpretation:

- Strong adhesion ensures prolonged retention
- Enhances contact time with oral mucosa
- Improves therapeutic efficacy

3.6 In-vitro Retention Time

Retention time followed the order: **F3 > F2 > F1**

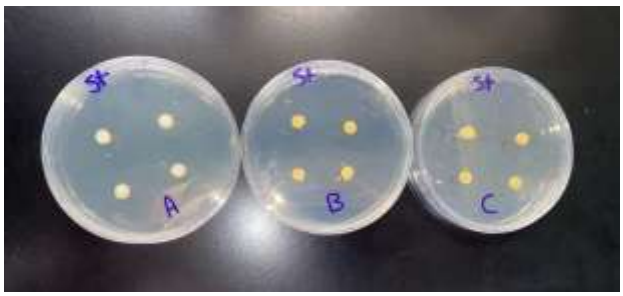
Interpretation:

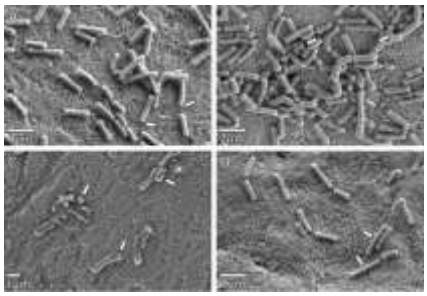
Mucoadhesive polymers (Carbopol/HPMC) interact with mucin, forming strong bonds via:

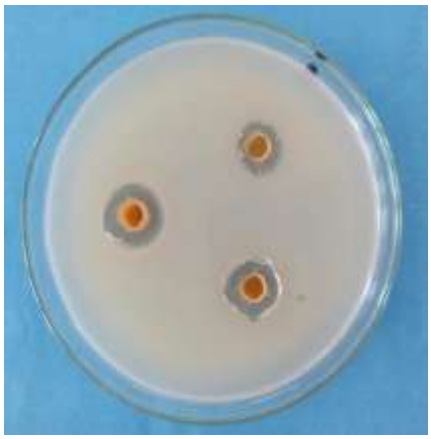
- Hydrogen bonding
- Electrostatic interactions

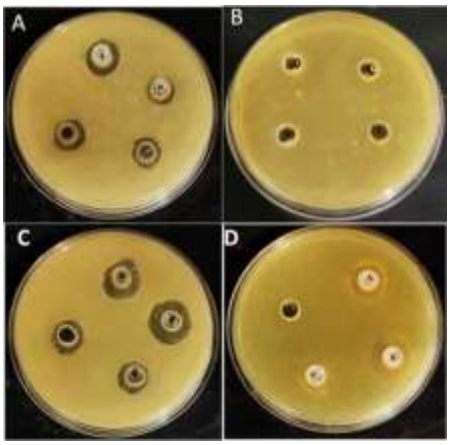
This leads to **prolonged drug residence time**, overcoming the limitation of conventional mouthwashes.

3.7 Antimicrobial Activity









The antimicrobial study showed significant zones of inhibition against *Streptococcus mutans*.

Interpretation:

- Triphala exhibits strong antimicrobial activity due to tannins and polyphenols
- Mechanism includes:
    - Disruption of bacterial cell wall
    - Inhibition of enzyme activity
    - Prevention of biofilm formation

F3 showed the highest antimicrobial activity due to better retention and sustained release.

3.8 Stability Studies (ICH Conditions)

The formulations were stable under:

- 25°C / 60% RH
- 30°C / 65% RH
- 40°C / 75% RH

Observations:

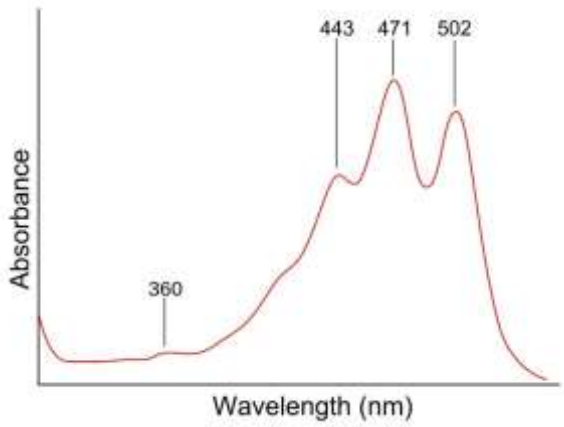
- Slight decrease in hardness
- Minor increase in friability
- Drug content remained above 98%
- No significant change in floating behavior

Interpretation:

- Formulation remained physically and chemically stable
- No significant degradation observed
- Suitable for storage under normal conditions

4. GRAPH & SPECTRAL ANALYSIS

4.1 UV Spectroscopy

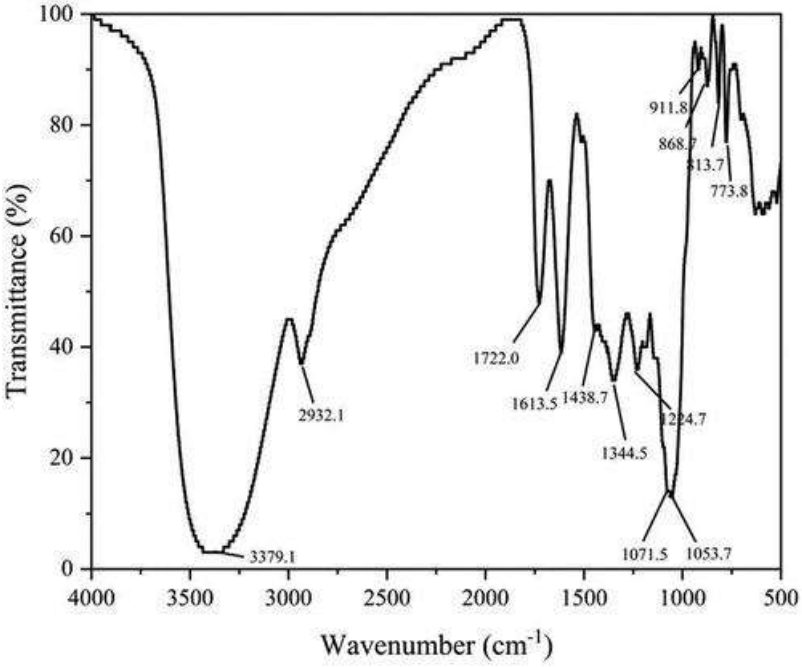


The UV spectrum showed **λmax at 425 nm**.

Interpretation:

- Confirms presence of active phytoconstituents
- Used for quantitative drug estimation
- Indicates purity of extract

4.2 FTIR Spectroscopy



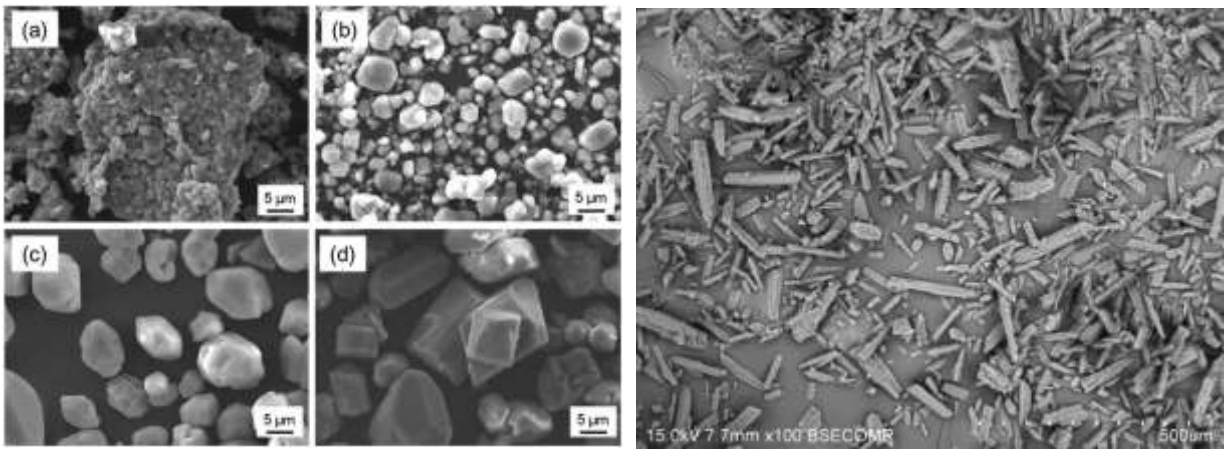
FTIR analysis showed characteristic peaks:

- **O–H stretching (~3200–3500 cm⁻¹)** → Phenols
- **C=O stretching (~1700 cm⁻¹)** → Carbonyl group
- **Aromatic C=C (~1500–1600 cm⁻¹)**

Interpretation:

- Confirms presence of polyphenols and tannins
- No significant shift → **No drug–polymer interaction**
- Indicates formulation compatibility

4.3 SEM Analysis



SEM images showed irregular, porous surface morphology.

Interpretation:

- Porous structure enhances drug release
- Indicates good dispersion of extract
- Supports mucoadhesive behavior

5. DISCUSSION (OVERALL INTERPRETATION)

The developed mucoadhesive Triphala mouthwash successfully addressed the limitations of conventional formulations. The incorporation of mucoadhesive polymers significantly improved retention time, allowing sustained release of active compounds.

The antimicrobial activity confirmed the effectiveness of Triphala against oral pathogens, while physicochemical parameters ensured formulation stability and patient acceptability.

Among all formulations, F3 was identified as the optimized formulation, exhibiting:

- Highest mucoadhesion
- Maximum retention time
- Best antimicrobial activity
- Stable physicochemical properties

6. CONCLUSION

The present study successfully developed a mucoadhesive polyherbal mouthwash containing Triphala for enhanced oral retention and plaque control.

The formulation demonstrated:

- Good physicochemical properties
- Strong mucoadhesive strength
- Prolonged retention time
- Significant antimicrobial activity
- Stability under ICH conditions

The optimized formulation (F3) showed superior performance compared to other formulations. The study concludes that mucoadhesive Triphala mouthwash is a safe, effective, and promising alternative to conventional mouthwashes, with improved therapeutic efficacy and patient compliance.

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