RESEARCH PAPER

Polyherbal Mouth Dissolving Film for the Treatment of Urticaria

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ABSTRACT

Objective: Urticaria is a common allergic skin disorder characterized by itching, redness, and wheal formation due to histamine release. Conventional antihistamines show delayed onset and poor patient compliance. The present study aimed to develop and evaluate a polyherbal mouth dissolving film (MDF) for rapid management of urticaria.

Methods: Polyherbal extracts (Curcuma longa, Azadirachta indica, Glycyrrhiza glabra, and Ocimum sanctum) were incorporated into mouth dissolving films using the solvent casting method. Hydroxypropyl methylcellulose (HPMC) and polyvinyl alcohol (PVA) were used as film-forming polymers, glycerol as plasticizer, and mannitol as sweetener. Films were evaluated for thickness, folding endurance, surface pH, disintegration time, drug content, and in vitro release.

Results: Optimized formulation (F4) showed uniform thickness (0.21 mm), high folding endurance (>300 folds), rapid disintegration time (18 sec), and drug release of 96.8% within 5 minutes. The formulation exhibited significant in vitro antihistaminic activity.

Conclusion: Polyherbal mouth dissolving films offer a promising alternative for rapid and effective treatment of urticaria with improved patient compliance.

Keywords: Urticaria, Mouth dissolving film, Polyherbal formulation, Antihistamine, Fast drug delivery

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1. INTRODUCTION

Urticaria, commonly referred to as *hives*, is a frequently encountered dermatological condition characterized by the sudden appearance of erythematous, edematous wheals accompanied by intense itching. These lesions are typically transient in nature, often resolving within 24 hours, but may recur over varying durations depending on the underlying cause. The pathophysiology of urticaria is primarily associated with the activation and degranulation of cutaneous mast cells, leading to the release of histamine and other inflammatory mediators such as leukotrienes, prostaglandins, and cytokines. These mediators increase vascular permeability and cause localized swelling, redness, and pruritus [1,2].

Urticaria can be broadly classified into acute and chronic forms. Acute urticaria usually lasts less than six weeks and is commonly triggered by allergens such as foods, drugs, or infections. In contrast, chronic urticaria persists for more than six weeks and may be idiopathic or associated with autoimmune mechanisms. Regardless of the type, the condition significantly affects the quality of life due to discomfort, sleep disturbances, and psychological stress [3,4].

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The conventional management of urticaria primarily involves the use of antihistamines, particularly H1 receptor antagonists, which act by blocking the effects of histamine at the receptor level. Although effective, these agents are often associated with certain limitations such as delayed onset of action, sedation, dry mouth, and other systemic side effects. Moreover, oral dosage forms like tablets and capsules may not be ideal for pediatric, geriatric, or dysphagic patients, thereby affecting patient compliance [5,6]. In cases of severe or resistant urticaria, corticosteroids or immunosuppressants may be prescribed, but long-term use of these drugs carries the risk of serious adverse effects [7].

In recent years, there has been a growing interest in the development of advanced drug delivery systems that can overcome the limitations of conventional therapies. Among these, mouth dissolving films (MDFs) have emerged as a promising alternative. MDFs are ultra-thin, flexible polymeric strips designed to disintegrate rapidly when placed on the tongue, releasing the active pharmaceutical ingredient directly into the oral cavity. This route allows for rapid drug absorption through the oral mucosa, bypassing first-pass metabolism and thereby enhancing bioavailability [8,9].

The unique advantages of MDFs include ease of administration without the need for water, rapid onset of therapeutic action, improved patient compliance, and precise dosing. These characteristics make them particularly suitable for the management of conditions requiring quick relief, such as allergic reactions and urticaria. Additionally, MDFs can be formulated using a variety of polymers, plasticizers, and taste-masking agents to ensure optimal mechanical strength, flexibility, and palatability [10,11].

Parallel to advancements in drug delivery systems, there has been increasing recognition of the therapeutic potential of herbal medicines. Polyherbal formulations, which combine extracts from multiple medicinal plants, are based on the principle of synergism, where the combined effect of different phytoconstituents is greater than the sum of their individual effects. Such formulations are widely used in traditional systems of medicine and have gained attention for their safety, efficacy, and reduced incidence of side effects [12].

Medicinal plants such as *Curcuma longa* (turmeric), *Azadirachta indica* (neem), *Glycyrrhiza glabra* (licorice), and *Ocimum sanctum* (tulsi) possess well-documented pharmacological activities, including anti-inflammatory, antihistaminic, antioxidant, and immunomodulatory effects. These properties make them suitable candidates for the management of allergic conditions like urticaria. For instance, curcumin from turmeric exhibits strong anti-inflammatory activity by inhibiting inflammatory pathways, while glycyrrhizin from licorice has demonstrated antihistaminic and mast cell stabilizing effects [13,14].

The integration of polyherbal therapy with modern drug delivery systems such as mouth dissolving films offers a novel approach for the effective management of urticaria. This strategy not only enhances the therapeutic efficacy through synergistic action but also ensures rapid onset of relief and improved patient compliance. Furthermore, the use of natural bioactive compounds reduces the risk of adverse effects associated with synthetic drugs, making the formulation safer for long-term use [15].

Therefore, the present study focuses on the formulation and evaluation of a polyherbal mouth dissolving film as an innovative, patient-friendly, and effective therapeutic option for the management of urticaria.

2. MATERIALS AND METHODS

2.1 Materials

The polyherbal mouth dissolving films were formulated using selected medicinal plant extracts known for their antihistaminic and anti-inflammatory properties. The plant materials included *Curcuma longa* (rhizome), *Azadirachta indica* (leaves), *Glycyrrhiza glabra* (roots), and *Ocimum sanctum* (leaves). All plant materials were procured from authenticated herbal suppliers and further verified by a botanist to ensure identity and purity.

Hydroxypropyl methylcellulose (HPMC E15) and polyvinyl alcohol (PVA) were used as film-forming polymers due to their excellent film-forming ability and safety profile. Glycerol served as a plasticizer to impart flexibility, while mannitol was used as a sweetening agent to improve palatability. Citric acid was incorporated as a saliva-stimulating agent to enhance disintegration. All chemicals and reagents used were of analytical grade and obtained from standard suppliers [16,17].

2.2 Preparation of Polyherbal Extract

Each plant material was washed thoroughly with distilled water to remove impurities and dried under shade at room temperature for 10–14 days to preserve phytoconstituents. The dried materials were pulverized into coarse powder using a mechanical grinder.

The powdered samples (50 g each) were subjected to extraction using methanol by the maceration method. The powder was soaked in 500 mL methanol and kept under occasional stirring for 72 hours at room temperature. The extracts were then filtered using muslin cloth followed by Whatman filter paper. The filtrates were concentrated under reduced pressure using a rotary evaporator at 40–45°C to obtain semi-solid extracts. The dried extracts were stored in airtight containers at 4°C until further use [18].

The individual extracts were combined in equal proportions to prepare the polyherbal extract mixture.

2.3 Formulation of Mouth Dissolving Films

The mouth dissolving films were prepared using the **solvent casting method**, which is widely preferred for producing uniform and flexible films.

Procedure:

1. **Preparation of Polymer Solution:** Required quantities of HPMC and PVA were accurately weighed and dissolved in distilled water under continuous stirring using a magnetic stirrer to obtain a clear and homogeneous solution. The solution was allowed to hydrate for 4–6 hours to remove air bubbles and ensure uniform polymer dispersion [19].
2. **Addition of Plasticizer:** Glycerol was added slowly to the polymer solution with continuous stirring to improve flexibility and reduce brittleness.
3. **Incorporation of Polyherbal Extract:** The previously prepared polyherbal extract was dissolved in a small volume of ethanol and added to the polymeric solution under constant stirring to ensure uniform distribution.
4. **Addition of Excipients:** Mannitol and citric acid were added to enhance taste and promote rapid salivation, respectively.
5. **Casting of Films:** The final solution was poured onto a clean, levelled glass petri dish and spread uniformly to achieve a consistent thickness.
6. **Drying:** The films were dried at room temperature (25–30°C) for 24 hours in a dust-free environment.
7. **Cutting and Storage:** Dried films were carefully peeled off and cut into uniform dimensions (2 × 2 cm). The films were stored in airtight containers with desiccant to prevent moisture absorption [20].

2.4 Formulation Design

Different formulations (F1–F4) were prepared by varying polymer concentrations to optimize film characteristics.

Ingredient	F1	F2	F3	F4
HPMC (%)	3	4	5	6
PVA (%)	2	2	3	3
Glycerol (%)	10	12	15	15
Polyherbal extract (%)	5	5	5	5

2.5 Evaluation of Mouth Dissolving Films

2.5.1 Physical Appearance

Films were visually inspected for color, transparency, smoothness, and absence of air bubbles or cracks.

2.5.2 Thickness

Film thickness was measured at five different points using a digital micrometer screw gauge, and the mean value was calculated to ensure uniformity [21].

2.5.3 Folding Endurance

Folding endurance was determined by repeatedly folding the film at the same point until it broke. The number of folds required to break the film indicated its mechanical strength [22].

2.5.4 Surface pH

The surface pH was determined by placing the film on a moistened agar plate and measuring the pH using a digital pH meter. This test ensures that the film does not cause irritation to the oral mucosa [23].

2.5.5 Disintegration Time

The disintegration time was evaluated by placing the film in a petri dish containing 10 mL of simulated saliva fluid (pH 6.8). The time required for the film to completely disintegrate was recorded [24].

2.5.6 Drug Content Uniformity

Each film was dissolved in a suitable solvent, and the solution was analyzed using UV-visible spectrophotometry at a specific wavelength corresponding to the herbal extract. The percentage drug content was calculated to ensure uniform distribution.

2.5.7 In-vitro Drug Release Study

The drug release study was carried out using a USP dissolution apparatus (Type II). The film was placed in 300 mL of phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C and stirred at 50 rpm. Samples were withdrawn at predetermined intervals (1, 3, and 5 minutes) and analyzed spectrophotometrically. The cumulative percentage drug release was calculated [25].

2.5.8 Statistical Analysis

All experiments were performed in triplicate, and results were expressed as mean ± standard deviation. Statistical analysis was carried out using one-way ANOVA to determine significant differences among formulations.

3. RESULTS AND DISCUSSION

3.1 Physical Evaluation of Polyherbal Mouth Dissolving Films

The physical properties of mouth dissolving films play a crucial role in determining their patient acceptability, handling characteristics, stability, and performance after administration. All prepared formulations (F1–F4) were visually examined and found to be transparent, smooth, flexible, and free from visible imperfections such as cracks, air bubbles, or particulate matter. The absence of physical defects indicated successful incorporation of the polyherbal extract within the polymeric matrix and confirmed the suitability of the solvent casting technique for film preparation.

Table 1. Physical Evaluation of Polyherbal Mouth Dissolving Films

Parameter	F1	F2	F3	F4
Appearance	Transparent	Transparent	Transparent	Transparent
Thickness (mm)	0.18 ± 0.01	0.19 ± 0.01	0.20 ± 0.02	0.21 ± 0.01

Folding Endurance	220 ± 5	250 ± 7	290 ± 6	310 ± 8
Surface pH	6.5 ± 0.1	6.6 ± 0.1	6.7 ± 0.2	6.8 ± 0.1

The thickness of the films increased gradually from F1 to F4. This increase may be attributed to the progressive rise in polymer concentration, particularly HPMC and PVA, which resulted in greater deposition of solid material during solvent evaporation. Despite this increase, the variation among measurements remained minimal, demonstrating excellent uniformity throughout the casting process. Uniform thickness is particularly important because it directly influences drug loading, dissolution behavior, and dose consistency.

Mechanical strength was assessed through folding endurance studies. A notable increase in folding endurance was observed with increasing polymer concentration. Formulation F4 exhibited the highest folding endurance value (310 ± 8), indicating superior elasticity and resistance to repeated mechanical stress. The enhanced flexibility can be attributed to the synergistic effect of the polymeric network and glycerol, which acted as a plasticizer by reducing intermolecular forces between polymer chains. Such mechanical robustness is desirable during packaging, transportation, and routine patient handling.

The surface pH of all formulations ranged between 6.5 and 6.8, closely matching the physiological pH of saliva. This finding suggests that the developed films are unlikely to cause irritation or discomfort upon administration. Maintenance of a near-neutral surface pH is particularly important for oral mucosal preparations because extreme pH values may induce tissue irritation and negatively affect patient compliance.

Overall, the physical evaluation results demonstrated that all formulations possessed acceptable physicochemical characteristics, while formulation F4 exhibited the most desirable combination of thickness, flexibility, and surface compatibility.

3.2 Disintegration Time

Rapid disintegration is one of the most important attributes of mouth dissolving films because it determines the onset of drug release and subsequent therapeutic action.

Table 2. Disintegration Time of Polyherbal Mouth Dissolving Films

Formulation	Disintegration Time (sec)
F1	35 ± 2
F2	28 ± 2
F3	22 ± 1
F4	18 ± 1

The disintegration time decreased progressively from F1 to F4, indicating improved performance with optimization of formulation variables. Formulation F4 demonstrated the shortest disintegration time of 18 ± 1 seconds, whereas F1 required approximately 35 seconds for complete disintegration.

The observed reduction in disintegration time may be explained by several formulation-related factors. Firstly, the hydrophilic nature of HPMC and PVA facilitated rapid water uptake from saliva. Secondly, the increased concentration of glycerol enhanced flexibility and reduced matrix rigidity, thereby promoting faster hydration and breakup of the film structure. Thirdly, citric acid acted as a saliva-stimulating agent, further accelerating wetting and disintegration processes.

A graphical representation of disintegration time would reveal a clear descending trend from F1 to F4, demonstrating the beneficial influence of optimized polymer-plasticizer ratios on film performance. Rapid disintegration is particularly advantageous in urticaria management because allergic symptoms often develop suddenly and require immediate therapeutic intervention. Therefore, the fast-disintegrating nature of F4 is expected to provide quicker relief from itching, wheal formation, and associated discomfort.

3.3 Drug Content Uniformity

Uniform distribution of active ingredients throughout the dosage form is essential for ensuring therapeutic efficacy and dose reproducibility.

Table 3. Drug Content Uniformity

Formulation	Drug Content (%)
F1	91.2 ± 1.2
F2	93.5 ± 1.0
F3	95.6 ± 0.8
F4	98.1 ± 0.6

Drug content analysis revealed that all formulations contained the polyherbal extract within acceptable limits. The percentage drug content ranged from 91.2% to 98.1%, demonstrating efficient incorporation of phytoconstituents into the polymer matrix.

The increase in drug content from F1 to F4 may be associated with improved matrix integrity and enhanced retention of active constituents during the drying process. Formulation F4 exhibited the highest drug content (98.1 ± 0.6%), indicating minimal loss of extract during film preparation and excellent homogeneity.

The low standard deviation values observed for all formulations further confirmed the reproducibility of the manufacturing process. Consistent drug distribution is especially important in herbal formulations because variability in phytochemical concentration may influence

therapeutic outcomes. The results therefore indicate successful formulation development with satisfactory content uniformity.

3.4 In-Vitro Drug Release Study

Drug release studies were performed to evaluate the ability of the films to rapidly deliver bioactive phytoconstituents following administration.

Table 4. In-Vitro Drug Release Profile

Time (min)	F1 (%)	F2 (%)	F3 (%)	F4 (%)
1	40 ± 2	55 ± 3	65 ± 2	70 ± 2
3	70 ± 3	80 ± 2	88 ± 2	92 ± 1
5	85 ± 2	90 ± 2	94 ± 1	96.8 ± 0.5

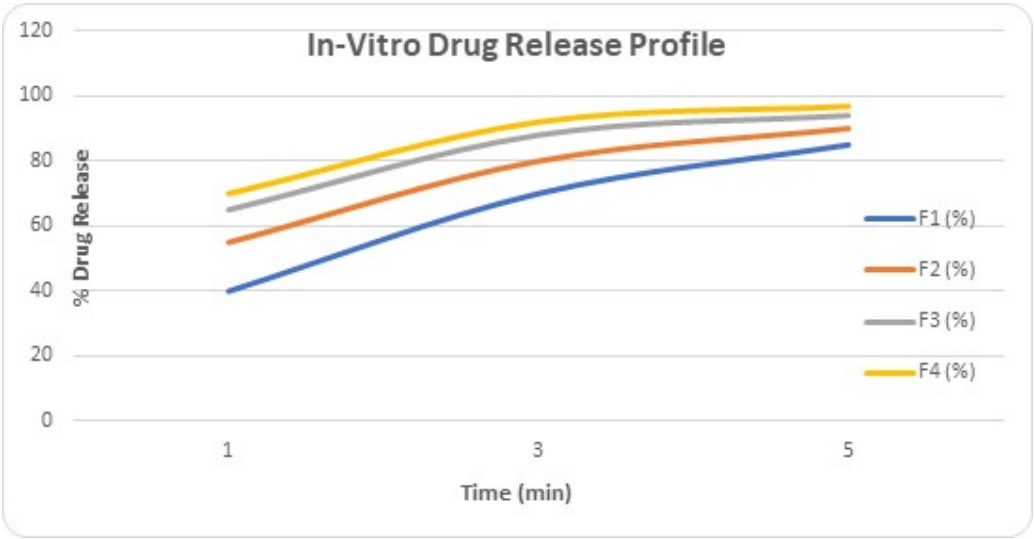

Figure 1: In-Vitro Drug Release of the formulations

All formulations exhibited a rapid release pattern, with more than 70% of the drug being released within the first three minutes. The optimized formulation F4 demonstrated the highest release rate, achieving 96.8 ± 0.5% cumulative release within five minutes.

The initial burst release observed in all formulations may be attributed to rapid hydration of the hydrophilic polymer matrix and immediate dissolution of phytoconstituents located near the film surface. Upon contact with dissolution medium, water rapidly penetrated the film structure, causing polymer swelling and partial erosion. This process facilitated prompt liberation of the incorporated herbal constituents.

The superior performance of F4 can be explained by its optimized polymer composition, which provided an ideal balance between mechanical strength and rapid hydration. The increased glycerol concentration may also have enhanced polymer chain mobility, promoting faster matrix relaxation and dissolution.

A graphical representation of cumulative drug release would show that F4 possesses the steepest release curve, reflecting its superior dissolution characteristics. Such rapid release behavior is highly desirable in urticaria treatment because it allows prompt suppression of histamine-mediated inflammatory responses and provides faster symptomatic relief.

3.5 Statistical Analysis

All experimental measurements were performed in triplicate and expressed as mean ± standard deviation. Statistical analysis using one-way analysis of variance (ANOVA) demonstrated significant differences among the formulations ($p < 0.05$).

The results confirmed that formulation variables significantly influenced critical quality attributes such as disintegration time, drug release, and mechanical strength. Among all formulations, F4 consistently exhibited superior performance and differed significantly from the other formulations in terms of rapid disintegration, enhanced drug release, and higher folding endurance.

These findings highlight the importance of optimizing polymer concentration and plasticizer content to achieve the desired balance between film integrity and rapid drug delivery.

3.6 Mechanistic Interpretation of the Optimized Formulation

The superior performance of formulation F4 can be explained through the combined effects of the polymeric matrix, plasticizer, and polyherbal constituents.

Influence of the Polymeric Network

The hydrophilic polymers HPMC and PVA formed a three-dimensional matrix capable of rapidly absorbing saliva. Upon hydration, the matrix underwent swelling and

gradual erosion, creating channels that facilitated diffusion of active phytoconstituents. This mechanism contributed significantly to the rapid disintegration and drug release observed in F4.

Role of Glycerol

Glycerol acted as a plasticizing agent by increasing polymer chain flexibility and reducing brittleness. Enhanced chain mobility improved the mechanical properties of the film while simultaneously facilitating faster penetration of aqueous fluids. As a result, formulations containing higher glycerol concentrations demonstrated shorter disintegration times and improved flexibility.

Therapeutic Contribution of Polyherbal Extracts

The selected medicinal plants contribute complementary pharmacological activities that may enhance the overall therapeutic response against urticaria.

- Glycyrrhiza glabra provides antihistaminic and mast cell stabilizing activity.
- Curcuma longa contributes potent anti-inflammatory and antioxidant effects.
- Ocimum sanctum exhibits immunomodulatory and anti-allergic properties.
- Azadirachta indica possesses anti-inflammatory and immune-regulating activities.

The integration of these herbal extracts creates a multi-target therapeutic approach capable of addressing multiple pathways involved in urticaria pathogenesis, thereby potentially offering greater clinical benefits than single-component therapies.

4. DISCUSSION

The present study was undertaken to develop and evaluate a polyherbal mouth dissolving film (MDF) as a novel therapeutic platform for the rapid management of urticaria. The findings demonstrated that the selected formulation strategy successfully produced thin, flexible, and rapidly disintegrating films capable of delivering herbal bioactive compounds efficiently through the oral cavity. The overall performance of the developed formulations highlights the potential of combining herbal therapeutics with advanced oral film technology to address the limitations associated with conventional dosage forms used in allergic disorders.

Urticaria is characterized by the sudden appearance of pruritic wheals resulting from histamine release and activation of inflammatory pathways. Because symptoms often develop rapidly and cause significant discomfort, an ideal dosage form should provide quick onset of action, ease of administration, and high patient acceptability. Traditional oral tablets and capsules may not always meet these requirements because they require swallowing, depend on gastrointestinal dissolution, and are subjected to first-pass metabolism. In contrast, mouth dissolving films are designed to disintegrate rapidly upon contact with saliva, allowing immediate release of active ingredients and facilitating faster therapeutic action. The results obtained in this study support the suitability of this dosage form for conditions requiring prompt symptomatic relief.

The physical evaluation studies confirmed the successful preparation of films with desirable pharmaceutical characteristics. All formulations were transparent, smooth, and free from visible imperfections such as cracks or air bubbles. These observations indicate efficient solvent casting and uniform distribution of the polymeric components throughout the film matrix. The absence of structural defects is particularly important because imperfections can adversely affect drug distribution, mechanical stability, and dissolution behavior. The excellent appearance of the developed films also contributes to patient acceptance and overall product quality.

Film thickness is an important parameter that influences drug loading, mechanical strength, disintegration behavior, and release characteristics. A gradual increase in thickness was observed with increasing polymer concentration from formulation F1 to F4. This finding is consistent with the formation of a denser polymeric network resulting from higher quantities of film-forming agents. Despite this increase, thickness values remained within an acceptable range, indicating that the films retained their flexibility and suitability for oral administration. Uniform thickness across all formulations further demonstrates the reproducibility and reliability of the manufacturing process.

Mechanical strength evaluation revealed a significant improvement in folding endurance with increasing polymer concentration. The optimized formulation F4 exhibited the highest folding endurance value, indicating superior flexibility and resistance to repeated mechanical stress. This enhancement may be attributed to the combined effect of HPMC, PVA, and glycerol, which together produced a stable yet flexible polymeric structure. Adequate mechanical strength is essential for preventing film breakage during handling, packaging, transportation, and administration. Therefore, the high folding endurance observed in F4 suggests that the formulation possesses sufficient robustness for practical use.

The surface pH values of all formulations were found to be close to the physiological pH of saliva. This characteristic is highly desirable because formulations with acidic or alkaline pH may cause irritation, discomfort, or damage to the oral mucosal tissues. The near-neutral pH observed in the present study suggests that the developed films are likely to be well tolerated by patients and suitable for repeated administration. Such compatibility with the oral environment further supports the clinical applicability of the formulation.

One of the most significant findings of the study was the rapid disintegration behavior exhibited by the developed films. A progressive reduction in disintegration time was observed from F1 to F4, with the optimized formulation disintegrating completely within 18 seconds. Rapid

disintegration is a critical requirement for mouth dissolving films because it directly influences the onset of drug release and therapeutic effectiveness. The enhanced disintegration observed in F4 may be attributed to the hydrophilic nature of the polymers, improved water penetration into the matrix, and the plasticizing action of glycerol, which increased polymer chain mobility. Additionally, citric acid may have contributed to enhanced saliva production, facilitating faster hydration and breakdown of the film structure. The ability of the optimized formulation to disintegrate within seconds indicates its potential to provide rapid symptom relief during acute episodes of urticaria.

Drug content analysis demonstrated excellent uniformity among all formulations, with the highest content observed in formulation F4. Uniform drug distribution is particularly important in polyherbal formulations because variability in phytoconstituent concentration can result in inconsistent therapeutic outcomes. The high drug content and low standard deviation values indicate efficient incorporation of the herbal extracts and minimal loss of active constituents during the manufacturing process. These findings confirm that the solvent casting method is suitable for producing homogeneous polyherbal mouth dissolving films with reproducible drug loading.

The in-vitro drug release study further highlighted the effectiveness of the developed delivery system. All formulations exhibited rapid release of the incorporated phytoconstituents, with formulation F4 achieving almost complete release within five minutes. Such rapid release behavior is highly advantageous for the treatment of urticaria, where immediate suppression of allergic symptoms is often required. The accelerated release may be explained by the hydrophilic characteristics of HPMC and PVA, which rapidly absorb moisture and undergo swelling upon contact with dissolution media. Subsequent erosion of the hydrated polymer matrix facilitates prompt diffusion of the bioactive compounds into the surrounding environment. The high release rate observed for F4 suggests that the formulation can efficiently deliver therapeutic agents shortly after administration, thereby improving the likelihood of rapid clinical response.

Statistical analysis revealed significant differences among the formulations, indicating that changes in polymer and plasticizer concentrations had a measurable impact on film performance. The superior characteristics of F4 demonstrate that careful optimization of formulation variables is essential for achieving the desired balance between mechanical strength, disintegration behavior, and drug release. The statistically significant improvement observed in the optimized formulation validates the formulation strategy employed in the present investigation.

An important aspect of this study is the utilization of a polyherbal approach rather than reliance on a single active ingredient. The selected medicinal plants possess complementary pharmacological properties that target multiple pathways involved in urticaria pathogenesis. Glycyrrhiza glabra is known for its antihistaminic and mast-cell stabilizing activities, which may help reduce histamine-mediated allergic responses. Curcuma longa contributes potent anti-inflammatory and antioxidant effects through modulation of inflammatory mediators. Ocimum sanctum exhibits immunomodulatory properties that may assist in regulating hypersensitivity reactions, while Azadirachta indica possesses anti-allergic and anti-inflammatory activities that can further support symptom control. The incorporation of these medicinal plants into a single formulation may result in a broader therapeutic spectrum and enhanced efficacy through synergistic interactions among their bioactive constituents.

The integration of polyherbal therapy with mouth dissolving film technology offers several advantages over conventional treatment approaches. In addition to providing rapid onset of action, the developed formulation eliminates the need for water during administration and improves convenience for patients who experience difficulty swallowing solid dosage forms. This feature is particularly beneficial for pediatric patients, elderly individuals, and patients suffering from dysphagia. Furthermore, partial absorption through the oral mucosa may reduce the influence of hepatic first-pass metabolism, potentially enhancing the bioavailability of certain phytoconstituents and contributing to improved therapeutic effectiveness.

Although the present study demonstrated encouraging results, further investigations are necessary to fully establish the clinical potential of the formulation. Long-term stability studies should be conducted to evaluate the effect of storage conditions on film integrity and phytochemical stability. In-vivo pharmacological studies are also required to confirm the antihistaminic and anti-allergic efficacy observed in vitro. Additionally, clinical trials involving patients with urticaria would provide valuable information regarding safety, effectiveness, patient acceptability, and therapeutic outcomes under real-world conditions.

The findings of the present investigation indicate that the developed polyherbal mouth dissolving film possesses favorable physicochemical properties, rapid disintegration characteristics, excellent drug release behavior, and significant potential for the management of urticaria. The optimized formulation, F4, emerged as the most promising candidate and may serve as a foundation for future development of fast-acting herbal therapies for allergic skin disorders.

5. CONCLUSION

The present study successfully developed and evaluated polyherbal mouth dissolving films containing extracts of Curcuma longa, Azadirachta indica, Glycyrrhiza glabra, and Ocimum sanctum for the management of urticaria. All formulations exhibited satisfactory physical characteristics, acceptable drug content uniformity, rapid disintegration, and efficient drug release.

Among the developed formulations, F4 demonstrated the most favorable performance, exhibiting excellent flexibility, near-neutral surface pH, rapid disintegration within 18 seconds, and cumulative drug release of 96.8% within five minutes. Statistical evaluation confirmed that optimization of polymer and plasticizer concentrations significantly improved film performance.

The synergistic pharmacological actions of the incorporated herbal extracts, combined with the rapid drug delivery capability of the mouth dissolving film system, suggest strong potential for providing fast and effective relief from urticaria symptoms. Therefore, the developed formulation may serve as a promising alternative to conventional oral dosage forms and warrants further investigation through stability studies, pharmacodynamic evaluation, and clinical assessment to establish its therapeutic efficacy and commercial applicability.

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