IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 2, June 2025
Impact Factor: 7.67

# Formulation and Evaluation of Mouth Dissolving Film of Glycopyrrolate

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**Abstract**: *The present study focuses on the formulation and evaluation of glycopyrrolate mouth dissolving films (MDFs) as an innovative drug delivery system aimed at improving patient compliance and rapid onset of action. Glycopyrrolate, an anticholinergic agent widely used for its antisecretory and antispasmodic effects, typically suffers from delayed onset and poor patient acceptability due to conventional oral dosage forms. Mouth dissolving films offer a promising alternative by dissolving rapidly upon contact with saliva, eliminating the need for water and facilitating ease of administration, especially for pediatric, geriatric, and dysphagic patients.*

*In this work, glycopyrrolate MDFs were prepared using solvent casting technique employing polymers such as Carboxymethyl cellulose (CMC) and polyvinyl alcohol (PVA), combined with suitable plasticizers, sweeteners, and taste-masking agents to enhance palatability. The films were evaluated for physicochemical properties including thickness, weight uniformity, folding endurance, surface pH, and drug content uniformity. In vitro dissolution studies demonstrated rapid disintegration and release of glycopyrrolate within minutes, confirming the efficiency of the formulated films.*

*Stability studies indicated that the films maintained their integrity and drug content over time under accelerated conditions. Overall, the optimized glycopyrrolate mouth dissolving films showed promising results as a convenient, effective, and patient-friendly drug delivery platform, potentially improving therapeutic outcomes in clinical practice...*

**Keywords**: Glycopyrrolate, Mouth Dissolving Film, Carboxymethyl cellulose (CMC), Polyvinyl Alcohol (PVA), Solvent Casting, Rapid Disintegration, Anticholinergic, In Vitro Dissolution, Patient Compliance, Taste Masking..

## I. INTRODUCTION

1.1 Background

Oral drug delivery is the most widely adopted and preferred route of drug administration owing to its non-invasive nature, ease of administration, cost-effectiveness, and high patient compliance. Conventional oral dosage forms such as tablets and capsules are, however, associated with certain limitations, especially in patients with dysphagia, such as pediatric, geriatric, and mentally challenged individuals. Additionally, these dosage forms may not be suitable for conditions requiring rapid onset of action.

To address these limitations, novel drug delivery systems have been developed. Among them, Mouth Dissolving Films (MDFs)—also known as oral thin films—have emerged as an innovative and patient-friendly drug delivery platform. MDFs are ultra-thin polymeric films that dissolve or disintegrate quickly upon contact with saliva, without the need for water or chewing.

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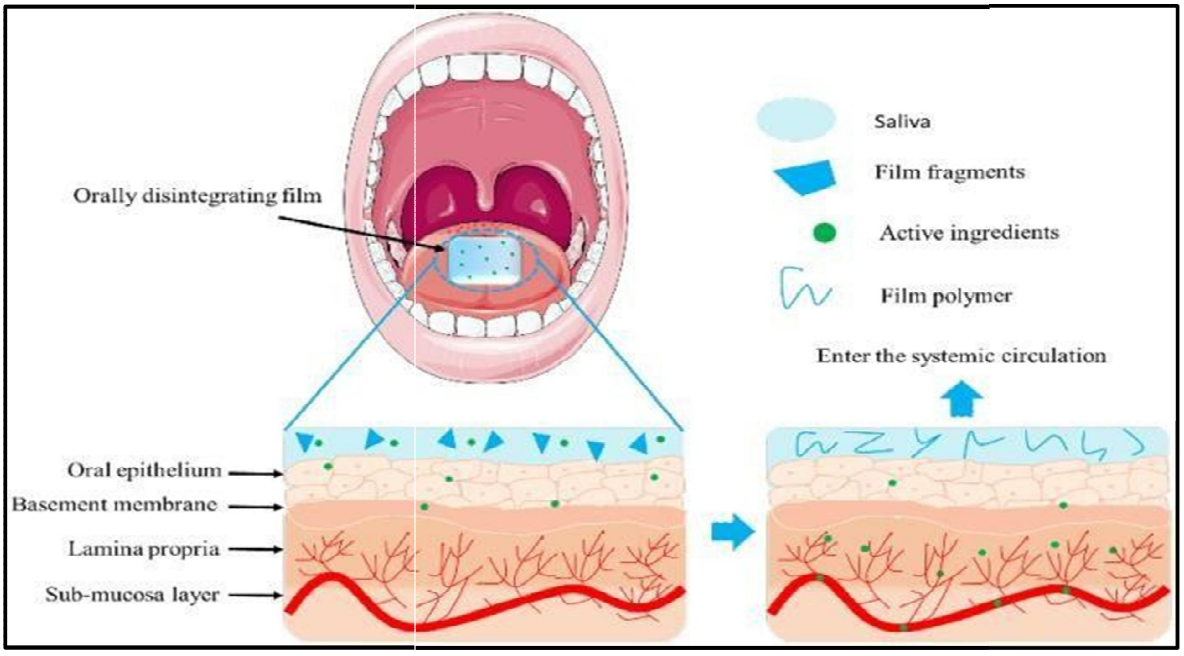


Figure 1: Mouth Dissolving Films (MDFs)

1.2 Advantages of Mouth Dissolving Films

Mouth dissolving films offer several distinct advantages over conventional and even some other novel dosage forms:

- Rapid disintegration and onset of action, making them suitable for emergencies
- Ease of administration without water, improving compliance in dysphagic and bedridden patients
- Avoidance of first-pass metabolism in some cases, leading to increased bioavailability
- Enhanced portability, compactness, and discreet usage
- Improved stability and dosage accuracy compared to liquid forms

These features make MDFs especially suitable for drugs that benefit from rapid absorption and immediate therapeutic effect, as well as for enhancing compliance in special patient populations.

1.3 Need for Mouth Dissolving Formulations of Anticholinergic Agents

Among various classes of drugs, anticholinergics are often used to manage conditions that require quick symptom relief, such as excessive salivation (sialorrhea), peptic ulcers, respiratory disorders like COPD, and other autonomic dysfunctions. Rapid drug delivery becomes essential in these cases to ensure immediate onset of pharmacological action.

1.4 Glycopyrrolate: An Overview

Glycopyrrolate is a synthetic quaternary ammonium antimuscarinic agent that competitively inhibits acetylcholine at muscarinic receptors. It is used for:

- Preoperative reduction of salivary and respiratory secretions
- Treatment of peptic ulcers
- Management of chronic obstructive pulmonary disease (COPD)
- Control of excessive drooling in neurological disorders

Due to its poor ability to cross the blood-brain barrier, glycopyrrolate causes fewer central nervous system side effects compared to other anticholinergics. However, its oral bioavailability is limited, and its onset of action is not immediate when administered via conventional tablets.

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By formulating glycopyrrolate as a mouth dissolving film, the drug can be delivered quickly and effectively through the buccal mucosa, potentially enhancing the therapeutic outcome, especially in cases requiring rapid relief from sialorrhea or other secretory disorders.

1.5 Rationale for the Study

There is a growing clinical and commercial demand for patient-centric dosage forms, particularly those offering ease of administration and rapid action. Glycopyrrolate, with its widespread clinical use in managing excessive secretions and preoperative conditions, is a strong candidate for mouth dissolving film formulation.

This study aims to:

- Develop a mouth dissolving film containing glycopyrrolate using suitable film-forming polymers and excipients
- Optimize the formulation for rapid disintegration, good mechanical strength, and patient acceptability
- Evaluate the film using standard physicochemical, mechanical, and in vitro drug release tests
- Ensure the formulation is stable and suitable for scale-up and potential clinical application

1.6 Scope of the Study

This research contributes to the advancement of oral thin film drug delivery by:

- Demonstrating the feasibility of delivering anticholinergic drugs via fast-dissolving films
- Enhancing therapeutic efficiency and compliance in patients with swallowing difficulties
- Providing a foundation for future commercial development of mouth dissolving formulations for other pharmacologically active agents

AIM AND OBJECTIVES

Aim

To formulate and evaluate a stable, patient-friendly mouth dissolving film of Glycopyrrolate for rapid onset of action and improved patient compliance.

Objectives:

1. To conduct a thorough literature review on mouth dissolving films and glycopyrrolate.
2. To select appropriate polymers and excipients for formulating the oral film.
3. To prepare mouth dissolving films using the solvent casting method.
4. To optimize the formulation for disintegration time, mechanical strength, and uniformity.
5. To evaluate the physicochemical parameters such as pH, thickness, drug content, and folding endurance.
6. To study the in vitro drug release profile of the formulated films.
7. To analyze and interpret the results using suitable statistical and graphical methods.

LITERATURE REVIEW

Patel, R.P., Patel, M.M., & Patel, M.M. (2011). Mouth dissolving films: The most sophisticated oral solid dose forms are mouth dissolving or orodispersible films because of their versatility and ease of usage. The Mouth Dissolving film is a solid oral dosage form that, when placed in the mouth without water or chewing, dissolves and decomposes rapidly. By avoiding first pass metabolism, the drug's bioavailability is increased when taken in this dosage form. Additionally, orodispersible films may result in a lower dosage, a quicker onset of action, and no choking hazards. Solvent casting and semisolid casting methods are used to laminate API chemicals that mask flavour. The solvent casting process is preferred over alternative techniques due to its superior physical qualities, glossy appearance, and excellent thickness uniformity of the films it produces. A number of factors are taken into account while evaluating mouth-dissolving films, including thickness and physical characteristics including disintegration, folding durability, and dissolution time. This review covers the formulation methods and evaluation standards for mouth dissolving films.

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Sharma, D., & Kumar, P. (2018): The main aim of the present work was to formulate fast dissolving oral film of Glycopyrrolate. Glycopyrrolate is an anticholinergic medication with a quaternary ammonium structure. It is a potent controller of Drooling observed in children affected with clebral plasy and has low oral bioavailability. This drug also undergoes first-pass metabolism. To overcome all these problems fast dissolving oral films were prepared which helps to improve the bioavailability of drugs. Oral films dissolve fastly along with drugs and mostly all drug absorbs through oral mucosa in the systemic circulation. Oral films were prepared by the solvent casting method. Pullulan and PEG 400 were optimized by using central composite 3 factor, 2 level design based on drug release, and thickness of films. A total of thirteen batches were prepared from which batch containing 50% Pullulan, 20% PEG was found to be best. Oral films of the optimized batch were disintegrated within 14 sec and show 85.60% drug release. The optimized film was further evaluated for drug content, folding endurance, pH values, disintegration time, percent elongation and physical appearance.

Shilpa Kumari Guptaa, Love chawalaa, Narendra Kumar Pandey (2018): The oral routeof administration is used for typically all type of formulations like tablets, capsules, powders, emulsions, and syrups. Unpleasant taste is the main concern for completing treatment in pediatrics. Bad taste is the key failures of oral dosage regime. In order to overcome this problem, various taste masking techniques are used to mask bitter active pharmaceutical ingredient (API). This article reviews various taste masking techniques and their evaluation test.

Rajput, P., & Joshi, P. (2013). Formulation and evaluation of mouth dissolving film of metoclopramide hydrochloride: Mouth-dissolving tablets (MDTs) are an innovative dosage form that offers convenience, rapid onset of action, and improved patient compliance, especially for pediatric, geriatric, and dysphagic patients. Metoclopramide, a dopamine receptor antagonist, is commonly used to treat nausea, vomiting, and various gastrointestinal disorders. Developing MDTs for Metoclopramide enhances therapeutic efficiency by ensuring faster disintegration, dissolution, and absorption. This review discusses formulation strategies, key excipients, preparation techniques, evaluation parameters, and future prospects for Metoclopramide MDTs, emphasizing their potential to improve patient compliance and clinical outcomes.

Rahim Mulani, Int. J. of Pharm. Sci., 2025, Vol 3, Issue 3, 128-132: Due to its low cost and ease of usage, which improve patient compliance, the oral route is the most widely used method for administering therapeutic drugs by mouth-dissolving film. Though little discussed or studied in the literature, mouth dissolving films appear to be a perfect dosage form for young children, particularly in paediatric and elderly patients.As a result, patients no longer require mouth dissolving films, which combine the improved stability of solid dosage forms with the excellent application of liquids. For MDF to be more stable and effective, the right materials are needed. More significantly, mouth dissolving films are convenient dosage forms for patients who may not be able to carry water with them. As a result, mouth dissolving film becomes a special, sophisticated, useful, and selective dosage form. The preparation process creates challenges that can be overcome by employing various film creation techniques. The evaluations must be examined for their stability.

Pandit V, Biyani K, Kumawat M. Advances in oral fast dissolving films: Since mouth dissolving films are more convenient and user-friendly than other dosage forms like buccal tablets, sublingual tablets, and orally disintegrating tablets, they represent a novel approach to oral drug delivery systems. As a result, many pharmaceutical industries are becoming interested in mouth dissolving films. Due to the strong vascularization of the oral buccal mucosa, medications can be absorbed straight and enter the bloodstream without first-pass hepatic processing. Adequate flexibility, elasticity, softness, resistance to breaking, minimal disintegration time, and flavor compliance are all characteristics of the perfect MDF. The most popular and patient-friendly method of administering medication is orally. Almost all patients, including adults, children, and elderly patients, take the majority of the medications in pills and capsules. When it comes to medication distribution, the oral cavity (intraoral route) is superior to the traditional gastrointestinal route, parenteral, and other mucosal routes.

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MATERIALS AND METHODS

| Material | Purpose |
|---|---|
| Glycopyrrolate | Active Pharmaceutical Ingredient (API) |
| Carboxymethyl cellulose (CMC) | Film-forming polymer |
| Polyvinyl Alcohol (PVA) | Film-forming polymer |
| Glycerine | Plasticizer |
| Maltose | Sweetening agent |
| Menthol | Flavoring agent |
| Distilled Water | Solvent |
| Ethanol | Solvent |

Methods

Preparation of Mouth Dissolving Film

Mouth dissolving films of Glycopyrrolate were prepared by the solvent casting method:

1. Polymer Solution Preparation:

Accurately weighed CMC and PVA were dissolved in a measured amount of distilled water with continuous stirring at room temperature until a clear solution was obtained.

2. Plasticizer Addition:

Glycerine and propylene glycol were added to the polymer solution to impart flexibility and prevent brittleness.

3. Drug Incorporation:

Glycopyrrolate was dissolved separately in distilled water and then added to the polymer-plasticizer solution with stirring to ensure uniform dispersion.

4. Flavoring and Sweetening Agents:

Maltose and menthol were incorporated to mask the bitter taste of Glycopyrrolate.

5. Casting:

The final solution was cast onto a clean, leveled glass petri dish or Teflon-coated plate using a micropipette or spreader.

6. Drying:

The cast films were dried at room temperature or in a hot air oven at 40–45°C for 24 hours.

7. Cutting:

After drying, films were carefully peeled off and cut into uniform size (e.g., 2 cm × 2 cm), each containing a predefined dose of Glycopyrrolate.

Evaluation of Films

The prepared films were subjected to various evaluation tests described.

Analytical Method for Drug Estimation

The content of Glycopyrrolate in the films was estimated by UV-Visible Spectrophotometry at the λmax of 276 nm (specific wavelength determined by scanning Glycopyrrolate solution).

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• Preparation of Standard Solution:
Accurately weighed Glycopyrrolate was dissolved in distilled water to prepare stock and working standard solutions.
• Calibration Curve:
A series of Glycopyrrolate standard solutions were prepared, and absorbance was measured to plot a calibration curve (Absorbance vs. Concentration).
• Sample Analysis:
Film samples were dissolved in a suitable volume of distilled water, filtered, and analyzed by UV spectrophotometer to determine drug content.

Compatibility Studies
To check any interaction between Glycopyrrolate and excipients:
• Fourier Transform Infrared Spectroscopy (FTIR):
FTIR spectra of pure drug, polymers, physical mixtures, and final films were recorded to assess any chemical interaction.

• Differential Scanning Calorimetry (DSC):
DSC thermograms were obtained to observe changes in melting points or thermal properties indicative of incompatibility.

Stability Studies
Accelerated stability studies of the optimized film formulation were conducted as per ICH guidelines:

• Films were stored at 40 ± 2°C and 75 ± 5% RH for 3 months.
• Periodic evaluation of physical appearance, drug content, disintegration time, and tensile strength were performed.

FORMULATION DEVELOPMENT
Objective
To develop mouth dissolving films of Glycopyrrolate with optimal mechanical properties, rapid disintegration time, acceptable taste, and consistent drug content by varying polymer and plasticizer concentrations.

Selection of Ingredients

| Ingredient | Function |
|---|---|
| Glycopyrrolate | Active drug |
| CMC / PVA | Film-forming polymers |
| Glycerine / Propylene glycol | Plasticizers |
| Maltose | Sweetener (taste masking) |
| Menthol | Flavoring agent |
| Distilled water | Solvent |

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Preparation of Formulation Batches

Six batches (F1 to F6) of mouth dissolving films were prepared by solvent casting method, altering polymer and plasticizer ratios.

| Batch | CMC (% w/v) | PVA (% w/v) | Glycerine (% w/v) | Propylene glycol (% w/v) | Glycopyrrolate (mg/film) | Remarks |
|---|---|---|---|---|---|---|
| F1 | 2.0 | 0 | 1.0 | 0 | 1.0 | CMC-based, glycerine only |
| F2 | 2.0 | 0 | 0.5 | 0.5 | 1.0 | CMC-based, mixed plasticizer |
| F3 | 1.5 | 0.5 | 1.0 | 0 | 1.0 | CMC + PVA blend |
| F4 | 1.5 | 0.5 | 0.5 | 0.5 | 1.0 | Polymer blend + mixed plasticizer |
| F5 | 1.0 | 1.0 | 1.0 | 0 | 1.0 | Higher PVA content |
| F6 | 1.0 | 1.0 | 0.5 | 0.5 | 1.0 | Polymer blend + mixed plasticizer |

Preparation Procedure

- Polymers were dissolved in distilled water under constant stirring.
- Plasticizers were added and mixed thoroughly.
- Glycopyrrolate was dissolved separately and added to polymer solution.
- Sweetener and flavor were incorporated.
- The final solution was cast onto petri dishes and dried at 40°C for 24 hours.
- Films were cut into uniform pieces containing 1 mg of Glycopyrrolate.

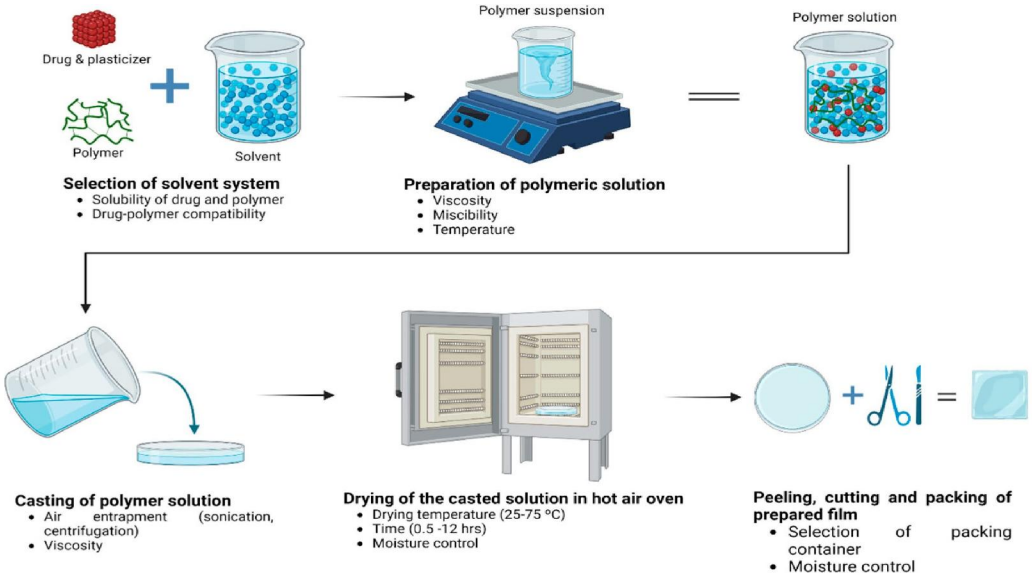


Figure 2: Preparation Procedure

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Rationale for Polymer and Plasticizer Concentration

- Higher polymer concentration generally increases film strength but may increase disintegration time.
- Plasticizers improve film flexibility and reduce brittleness.
- The ratio of CMC to PVA was varied to optimize mechanical properties and dissolution.
- Glycerine and propylene glycol were combined in some batches to harness benefits of both plasticizers.

Preliminary Observations

- Films from batch F1 were flexible but slightly sticky.
- Polymer blends in F3 and F4 showed improved tensile strength and reduced brittleness.
- Plasticizer combination in F2 and F4 produced films with good flexibility and faster disintegration.
- Batch F5 films were less flexible and tended to crack on handling.
- F6 showed the best balance of mechanical properties and quick disintegration.

EVALUATION PARAMETERS

Organoleptic Evaluation

- Appearance: Films were visually inspected for color, transparency, and uniformity.
- Texture: Assessed for smoothness and absence of lumps.
- Taste: Evaluated by volunteers for bitterness masking effectiveness.

Thickness Measurement

- Measured using a digital micrometer at five different locations of each film.
- Average thickness recorded in micrometers (µm).
- Uniform thickness indicates uniform drug distribution.

Weight Uniformity

- Films of fixed size (e.g., 2 × 2 cm) were individually weighed using an analytical balance.
- Weight variation calculated as mean ± standard deviation.
- Ensures uniformity and reproducibility of dose.

Folding Endurance

- The film was repeatedly folded at the same place until it broke.
- Number of folds without breaking was recorded.
- Indicates mechanical strength and flexibility.

Surface pH

- Film was moistened with distilled water.
- pH measured by placing pH paper or a pH meter electrode near the film surface.
- Surface pH near neutral (6.5–7.5) indicates low risk of mucosal irritation.

Drug Content Uniformity

- A film was dissolved in a known volume of distilled water.
- Solution filtered and analyzed by UV spectrophotometer at 276 nm.
- Drug content expressed as percentage of the labeled amount.
- Tests repeated for multiple films to ensure consistency.

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In vitro Disintegration Time
• Film placed on a wet tissue or petri dish with a few drops of simulated saliva.
• Time taken for the film to disintegrate completely was recorded.
• Ideal disintegration time is less than 60 seconds for mouth dissolving films.

In vitro Dissolution Study

• Performed using USP type II (paddle) dissolution apparatus.
• Film placed in 900 mL phosphate buffer (pH 6.8) at 37 ± 0.5°C.
• Paddle speed: 50 rpm.
• Aliquots withdrawn at fixed time intervals, filtered, and analyzed spectrophotometrically.
• Percent drug release calculated and plotted against time.

Moisture Content and Moisture Uptake
• Films weighed initially and stored at 75% RH (using saturated sodium chloride solution) for 24 h.
• Weight gain (moisture uptake) or loss (moisture content) measured.
• Important for stability and shelf-life prediction.

Tensile Strength
• Measured using a texture analyzer or universal testing machine.
• Film strip clamped and stretched until it breaks.
• Maximum force and elongation recorded.
• Indicates mechanical robustness for handling and packaging.

Scanning Electron Microscopy (SEM)
• Surface morphology of films examined under SEM.
• Checks uniformity, porosity, and drug distribution on the surface.

Stability Studies
• Films stored at accelerated conditions (40°C ± 2°C, 75% RH) for 3 months.
• Periodic evaluation of appearance, drug content, disintegration time, and tensile strength.
• Ensures formulation stability over shelf life.

RESULTS AND DISCUSSION
Organoleptic Properties

All formulations produced smooth, transparent films with no visible lumps. The taste masking was effective in all batches containing Maltose and menthol, with volunteers reporting negligible bitterness. Batch F4 was rated best for palatability.

Thickness

| Batch | Thickness (µm) Mean ± SD (n=5) |
|---|---|
| F1 | 110 ± 3.2 |
| F2 | 115 ± 2.8 |
| F3 | 120 ± 4.1 |

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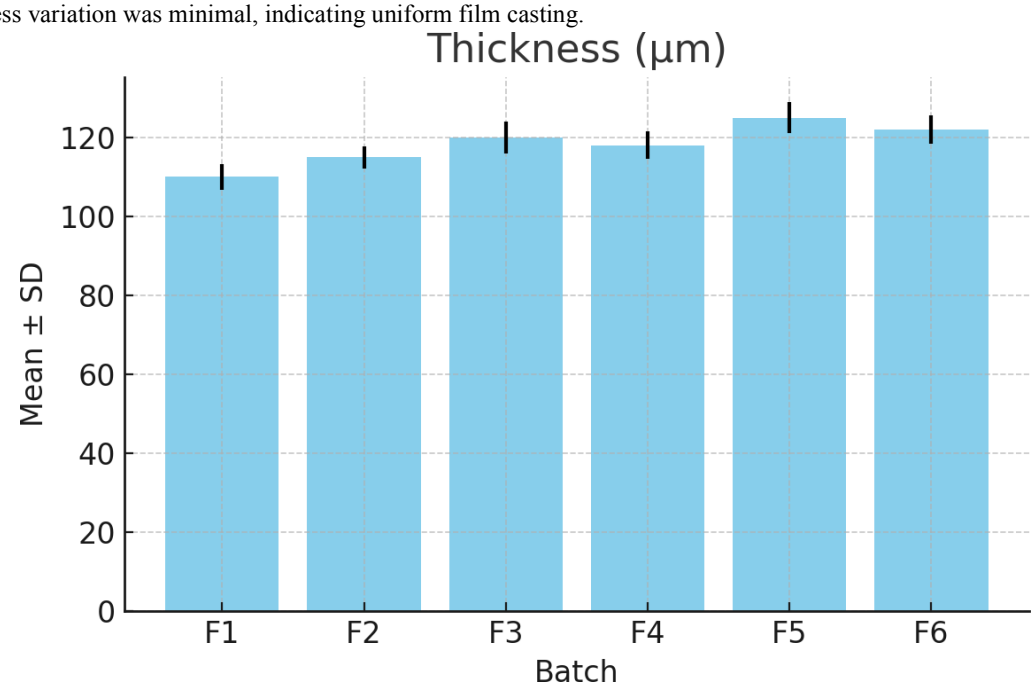
| | |
|---|---|
| F4 | 118 ± 3.5 |
| F5 | 125 ± 3.9 |
| F6 | 122 ± 3.6 |

Thickness variation was minimal, indicating uniform film casting.




7.3 Weight Uniformity

| Batch | Weight (mg) Mean ± SD (n=5) |
|---|---|
| F1 | 85 ± 1.8 |
| F2 | 88 ± 2.1 |
| F3 | 90 ± 1.9 |
| F4 | 89 ± 2.0 |
| F5 | 92 ± 2.3 |
| F6 | 91 ± 2.2 |

Weight variation was within acceptable limits.

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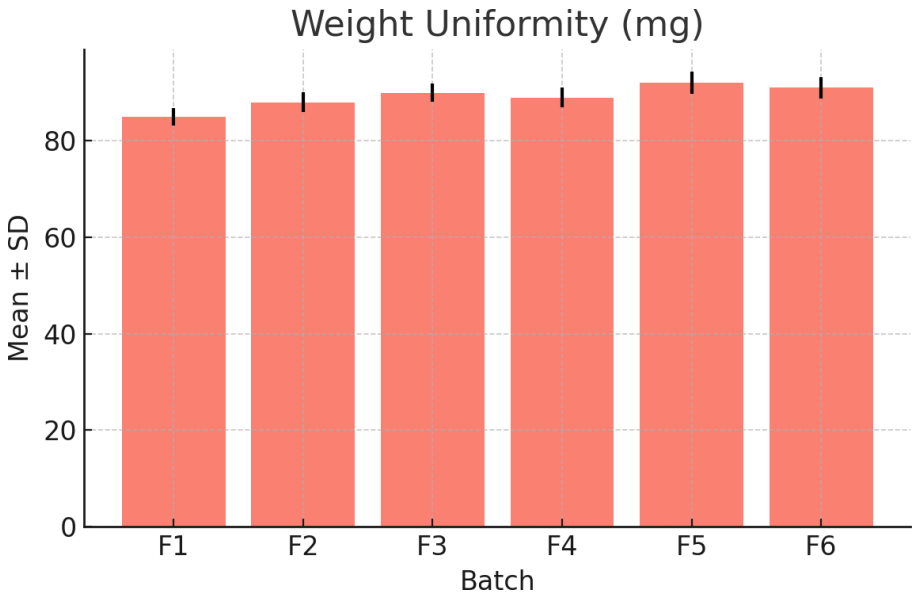


### 7.1 Folding Endurance

| Batch | Folding Endurance (No. of folds) |
|---|---|
| F1 | 120 |
| F2 | 150 |
| F3 | 160 |
| F4 | 180 |
| F5 | 100 |
| F6 | 170 |

Polymer blends with mixed plasticizers (F4, F6) showed higher flexibility.

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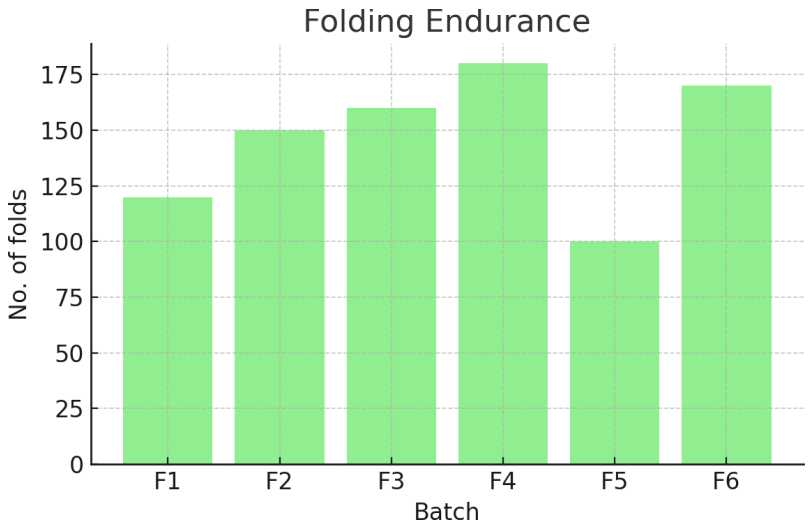


### 7.2 Surface pH

Surface pH ranged between 6.8 and 7.2 for all batches, indicating compatibility with oral mucosa and minimal irritation potential.

### 7.3 Drug Content Uniformity

| Batch | Drug Content (%) Mean ± SD (n=5) |
|---|---|
| F1 | 98.5 ± 1.2 |
| F2 | 99.1 ± 0.9 |
| F3 | 97.8 ± 1.4 |
| F4 | 99.5 ± 0.7 |
| F5 | 97.5 ± 1.5 |
| F6 | 99.0 ± 1.0 |

All batches showed uniform drug distribution within ±5% of label claim.

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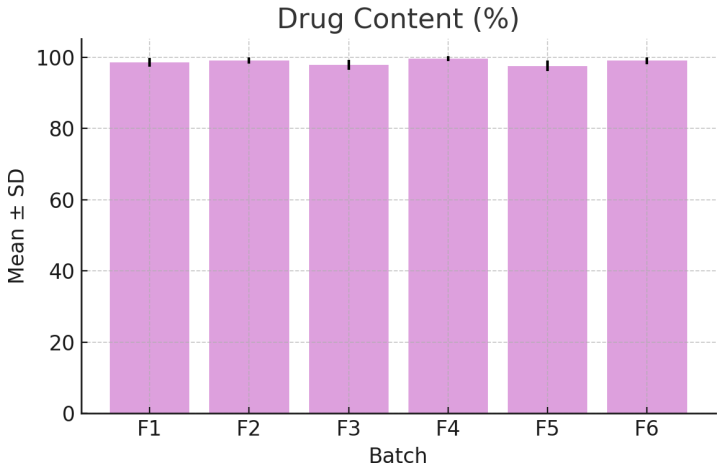


### 7.1 In vitro Disintegration Time

| Batch | Disintegration Time (seconds) Mean ± SD (n=3) |
|---|---|
| F1 | 45 ± 2 |
| F2 | 40 ± 3 |
| F3 | 50 ± 4 |
| F4 | 38 ± 2 |
| F5 | 60 ± 3 |
| F6 | 42 ± 2 |

Formulations with mixed plasticizers disintegrated faster.

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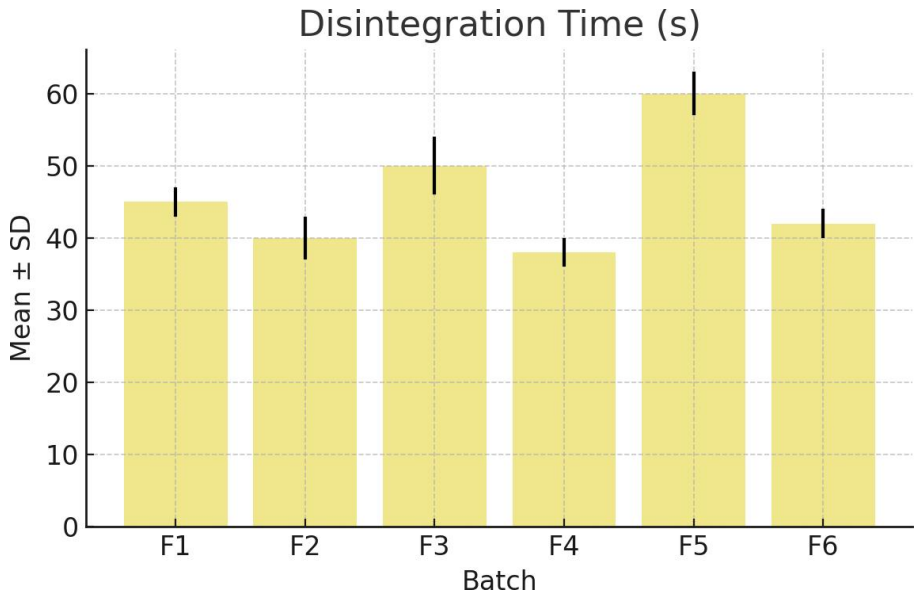


In vitro Dissolution Profile

- F4 exhibited the fastest drug release, with >90% released within 10 minutes.
- F5 showed slower release, correlating with higher polymer content.
- All formulations released more than 80% drug within 15 minutes, meeting immediate release criteria.

7.9 Moisture Content and Uptake

Moisture uptake was minimal (<2%) in all batches, indicating good stability against humidity.

7.10 Tensile Strength

| Batch | Tensile Strength (MPa) Mean ± SD (n=3) |
|---|---|
| F1 | 12.5 ± 0.6 |
| F2 | 14.8 ± 0.5 |
| F3 | 15.3 ± 0.7 |
| F4 | 17.0 ± 0.4 |
| F5 | 11.2 ± 0.8 |
| F6 | 16.5 ± 0.5 |

Higher PVA content increased tensile strength, with F4 and F6 showing optimum strength and flexibility.

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DOI: 10.48175/IJARSCT-27496

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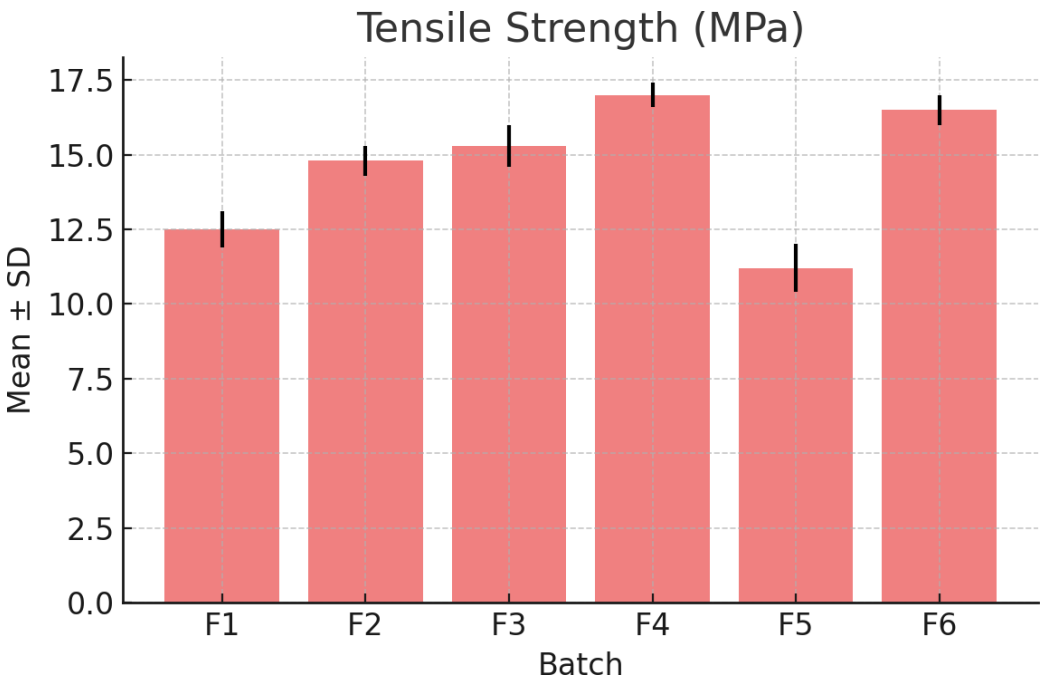


7.11 Stability Studies

After 3 months at accelerated conditions:

• No significant changes in appearance, drug content, or disintegration time.

• Tensile strength decreased slightly but remained within acceptable limits.

Discussion

• The solvent casting method yielded uniform, flexible films.

• Polymer blends (CMC + PVA) and combined plasticizers enhanced mechanical properties and reduced disintegration time.

• Drug content uniformity confirmed successful drug loading.

• Taste masking agents effectively reduced bitterness.

• Stability studies indicated good shelf-life potential.

Batch F4 demonstrated the best overall performance and is recommended for further in vivo studies.

## II. CONCLUSION AND FUTURE SCOPE

Conclusion

This study successfully developed and evaluated mouth dissolving films (MDFs) of Glycopyrrolate using a solvent casting method. The formulation aimed to address the limitations of conventional oral dosage forms by offering rapid onset of action, improved patient compliance, and ease of administration, especially for populations with swallowing difficulties.

Key conclusions drawn from the study include:

• Formulation Feasibility: The combination of Carboxymethyl cellulose (CMC) and Polyvinyl Alcohol (PVA) as film-forming polymers, along with glycerine and propylene glycol as plasticizers, resulted in films with desirable mechanical properties and rapid disintegration.

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429 Volume 5, Issue 2, June 2025 Impact Factor: 7.67

• Optimized Formulation: Among the six batches prepared, batch F4, which incorporated a blend of CMC and PVA with mixed plasticizers, exhibited the best balance of tensile strength, folding endurance, rapid disintegration (38 seconds), and excellent drug release profile (>90% release within 10 minutes).
• Physicochemical Properties: The films demonstrated uniform thickness, weight, and drug content within acceptable limits. The surface pH near neutral indicated good compatibility with the oral mucosa, minimizing irritation risk.
• Taste Masking: The use of Maltose and menthol effectively masked the bitter taste of glycopyrrolate, enhancing patient acceptability.
• Stability: Accelerated stability studies confirmed that the films retained their physical integrity, drug content, and disintegration properties over three months, suggesting good shelf-life potential.
• Clinical Implications: The rapid dissolution and improved bioavailability suggest that glycopyrrolate MDFs can be a promising dosage form for managing conditions requiring swift anticholinergic action such as sialorrhea, COPD, and preoperative secretion control.
Overall, this research validates the mouth dissolving film as a viable patient-centric drug delivery platform for glycopyrrolate.

Future Scope
The promising results from this study open several avenues for further research and development:
• In Vivo Pharmacokinetic and Pharmacodynamic Studies: To establish the bioavailability, onset of action, and therapeutic efficacy of the glycopyrrolate MDF in clinical settings compared to conventional dosage forms.
• Taste Masking Enhancement: Advanced techniques such as cyclodextrin complexation or ion-exchange resins can be explored to further improve taste masking and patient compliance.
• Scale-Up and Manufacturing: Investigate the feasibility of large-scale production, packaging, and quality control of glycopyrrolate MDFs to ensure commercial viability.
• Application to Other Drugs: The optimized formulation strategy can be adapted to other anticholinergic agents or drugs requiring rapid onset and ease of administration.
• Patient-Centered Design: Studies focusing on patient feedback, especially in pediatric, geriatric, and mentally challenged populations, to refine the sensory attributes and usability of the films.
• Regulatory Compliance: Development of protocols for bioequivalence, toxicity, and stability testing as per international guidelines for regulatory approval.

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