IJPSR (2025), Volume 16, Issue 11 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 23 May 2025; received in revised form, 22 June 2025; accepted, 28 June 2025; published 01 November 2025

FORMULATION AND EVALUATION OF FAST DISSOLVING ORAL FILM OF COLCHICINE

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Keywords:

Colchicine, Fast-dissolving oral film, Solvent casting method, Patient compliance, Rapid drug release, Bioavailability enhancement, Disintegration time, Acute gout therapy

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ABSTRACT: This study aimed to develop and assess a fast-dissolving oral film (FDOF) for colchicine, targeting enhanced patient compliance and rapid therapeutic onset, particularly for acute gout management. Colchicine, a powerful anti-inflammatory medication, often faces patient adherence challenges due to gastrointestinal side effects and delayed onset in conventional oral forms. FDOFs offer a compelling alternative by dissolving rapidly in the oral cavity without water, improving drug bioavailability and reducing gastrointestinal irritation. The films were formulated using suitable polymers, plasticizers, and super disintegrants through a solvent casting method. Key evaluation parameters included film thickness, folding endurance, disintegration time, drug content uniformity, and *in-vitro* drug release. Results indicated that the optimized films demonstrated rapid disintegration, excellent mechanical strength, and efficient drug release, making this delivery system a promising alternative for colchicine therapy.

INTRODUCTION: Oral drug delivery remains the most common route of administration due to its convenience and patient acceptance. However, conventional forms like tablets and capsules often present challenges, particularly for patients with swallowing difficulties or those needing rapid therapeutic action. Fast-dissolving oral films (FDOFs) have emerged as an innovative solution, offering rapid drug release in the oral cavity without water, enhancing bioavailability and patient compliance. FDOFs possess several advantages, including faster onset of action, improved bioavailability, greater stability compared to liquid forms, and enhanced portability. These thin, flexible films dissolve quickly, making them ideal for patients with dysphagia. Key considerations in their formulation include achieving uniform drug distribution, mechanical strength, rapid disintegration, and pleasant taste.

This study focuses on the development and evaluation of a fast-dissolving oral film for colchicine using the solvent casting method, aiming to achieve rapid disintegration, acceptable mechanical properties, and efficient drug release.

Definition of FDF: Fast dissolving films (FDFs) represent an advanced oral solid dosage form known for their flexibility and ease of use.

They enhance the effectiveness of the active pharmaceutical ingredient (API) by rapidly dissolving in the oral cavity within a short time, requiring only a minimal amount of saliva making them more efficient than conventional fast-dissolving tablets.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.16(11).3120-24

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.16(11).3120-24

Special Features:

- Can be designed in various shapes and sizes.
- Thin, smooth, and attractive appearance.
- Non-intrusive and comfortable in the mouth.
- Quick disintegration or dissolution upon contact with saliva.

Advantages:

- ❖ Eliminates the risk of choking during administration
- ❖ Offers convenient and precise dosing
- ❖ No requirement for water to consume or chew the film
- ❖ Compact size promotes better patient acceptance
- ❖ Provides faster onset of therapeutic action
- ❖ Easy to handle, store, and transport
- ❖ Enhances bioavailability for specific active pharmaceutical ingredients
- ❖ Offers improved drug stability compared to liquid forms
- ❖ Effectively masks unpleasant drug tastes

Disadvantages:

1. Sensitive to moisture and must be stored in a dry environment
2. Films are delicate and can easily break or crumble
3. Requires specialized packaging to maintain product stability and protection
4. Limited to incorporating only low-dose drugs

MATERIALS AND METHOD:

Film-Forming Polymers: Polymers form the structural base of the film and contribute to its mechanical strength and disintegration profile. Hydrophilic polymers are widely used, typically at about 45% w/w of the total dry film weight.

Plasticizers: These are added to improve flexibility and reduce brittleness. They enhance the tensile strength and elongation of the film. Selection depends on compatibility with the polymer and the solvent used.

Surfactants: Surfactants help in wetting, dispersing, and solubilizing the drug, ensuring quick disintegration and drug release. Poloxamer 407 is a commonly used surfactant.

Sweetening Agents: Sweeteners improve the palatability of the film. Both natural and artificial types are used in concentrations of 3–6% w/w.

Flavouring Agents: Flavors are included to mask unpleasant drug taste and enhance user acceptance. Typically used at around 10% w/w, the type and amount depend on the drug's bitterness.

Saliva Stimulating Agents: Acids such as citric acid, malic acid, or ascorbic acid are used to promote saliva flow, aiding faster film disintegration. These are generally added in the range of 2–6% w/w.

Method:

Solvent Casting Method:

Preparation of Polymer Solution:

- Weigh the selected polymer (e.g., HPMC E15 – typically 2–5% w/v).
- Disperse it in a small volume of distilled water with continuous stirring (use magnetic stirrer or mechanical stirrer) until a clear, lump-free solution is obtained.
- Allow the solution to stand for 1–2 hours to remove air bubbles.

Addition of Plasticizer:

- Add plasticizer (e.g., glycerine or PEG-400) to the polymer solution under stirring.
- Concentration is usually 10–20% w/w of the dry polymer weight.

Incorporation of Drug (Colchicine):

- Dissolve colchicine (accurately weighed for 0.5 mg per film) in a small volume of ethanol or water depending on solubility.
- Mix the drug solution into the polymer-plasticizer solution with gentle stirring to ensure uniform distribution.

Addition of Sweeteners and Flavouring Agents:

- Add sweeteners and flavouring agents to mask the bitter taste of colchicine.

- Optionally add citric acid to enhance saliva secretion and improve disintegration.

Casting the Film:

- Pour the solution onto a glass, or Petri plate.

Drying:

- Allow the film to dry at room temperature or in a hot air oven at 40–50°C for 6–8 hours.
- Avoid higher temperatures to prevent degradation of colchicine.

Cutting:

- Once dried, cut the film into pieces (e.g., 2 cm × 2 cm) each containing 0.5 mg colchicine.

FIG. 1: SCHEMATIC REPRESENTATION OF THE SOLVENT CASTING METHOD USED FOR THE PREPARATION OF FAST-DISSOLVING ORAL FILMS OF COLCHICINE

Formulation Table:

TABLE 1: COMPOSITION OF FAST-DISSOLVING ORAL FILM OF COLCHICINE PREPARED BY THE SOLVENT CASTING METHOD

Sr. no.	Ingredients	Quantity
1	Colchicine	0.5mg
2	HPMC	50mg
3	Glycerine	2ml
4	Citric acid	2mg
5	Sodium Starch Glycolate	3mg
6	Peppermint oil	1ml
7	Water	q.s.

Evaluation of Fast Dissolving Oral Film of Colchicine:

pH Determination: A 1 cm² film was dissolved in 10 mL distilled water and the pH was measured using a calibrated pH meter. The values, averaged from three readings, were within the acceptable salivary range (6.8–7.4), ensuring mucosal compatibility.

Folding Endurance: A 2×2 cm film was repeatedly folded at the same spot until breakage. The number of folds sustained indicates film flexibility and mechanical strength.

Weight Uniformity: Ten films were individually weighed. The average weight was calculated, and individual values were within ±5% of the mean, confirming uniformity as per pharmacopeial limits.

Thickness Measurement: Film thickness was measured at three points using a screw gauge. The mean value was calculated, ensuring variation remained within ±5%, indicating uniform film formation.

Disintegration Time: Films were placed in simulated saliva (pH 6.8, 37°C), and the time to complete disintegration was visually recorded. All samples disintegrated within 30 seconds, meeting USP standards.

Dissolution Test: Using USP apparatus in phosphate buffer (pH 6.8), drug release was assessed *via* UV spectrophotometry. Over 85% of the drug was released within 5 minutes, confirming rapid dissolution.

Calibration Curve: Standard solutions of colchicine (5–25 µg/mL) were analysed at 243 nm. A linear curve was obtained ($R^2 \geq 0.998$), validating the method for quantifying drug content and release.

IR Spectroscopy: FTIR analysis showed no major peak shifts, indicating no interaction between drug and excipients. Characteristic functional groups were retained, confirming chemical stability of the formulation.

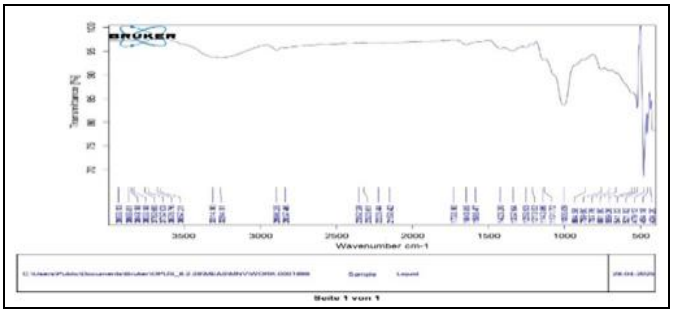

FIG. 2: FTIR SPECTRUM OF COLCHICINE AND OPTIMIZED FILM FORMULATION SHOWING RETENTION OF CHARACTERISTIC PEAKS AND ABSENCE OF DRUG–EXCIPIENT INTERACTION

TABLE 2: EVALUATION PARAMETERS AND RESULTS OF THE OPTIMIZED COLCHICINE FAST-DISSOLVING ORAL FILM

Sr. no.	Evaluation parameter	Result
1	pH	6.68
2	Folding Endurance	4
3	Weight Uniformity	109mg
4	Thickness	1mm
5	Disintegration Time	58 sec
6	Dissolution Test	98.23%

RESULTS AND DISCUSSION: The fast-dissolving oral films (FDOFs) of colchicine were successfully prepared by the solvent casting method using HPMC as the film-forming polymer and glycerine as the plasticizer. The prepared films were smooth, uniform, flexible, and transparent with no visible cracks or air bubbles, indicating uniform distribution of the drug and excipients.

Physicochemical evaluation confirmed the quality and uniformity of the films. The pH of the formulation was 6.68, which lies within the salivary pH range (6.5–7.5), ensuring compatibility with the oral mucosa. Weight uniformity (109 mg) and thickness (1 mm) showed minimal variation, confirming uniformity in film formation. The folding endurance value of 4 demonstrated good flexibility without brittleness. The disintegration time was 58 seconds, indicating that the films dissolved rapidly in the oral cavity without the need for water, ensuring patient convenience and compliance.

The *in-vitro* drug release study in phosphate buffer (pH 6.8) showed 98.23% drug release within 5 minutes, suggesting that the film can provide a rapid onset of action suitable for acute gout therapy. The FTIR spectrum revealed no significant peak shifts, confirming the absence of drug–excipient interactions and chemical stability of colchicine in the formulation. Overall, the optimized film exhibited desirable mechanical strength, rapid disintegration, and efficient drug release. These findings indicate that the developed FDOF of colchicine is a promising alternative to conventional oral dosage forms, offering improved patient compliance and faster therapeutic onset.

CONCLUSION: The developed fast dissolving oral film (FDOF) of colchicine demonstrated promising potential as an effective alternative to conventional oral dosage forms. The formulation showed rapid disintegration, satisfactory mechanical properties, and efficient drug release, which are essential for enhancing patient compliance and therapeutic response. By bypassing the gastrointestinal tract, the film may reduce side effects commonly associated with colchicine. The overall results support the feasibility of using FDOFs for acute conditions such as gout, where rapid onset of action is critical. This novel delivery system offers both clinical and patient-centric benefits.

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How to cite this article:
Mahadik V, Yevale S and Chavan S: Formulation and evaluation of fast dissolving oral film of colchicine. Int J Pharm Sci & Res 2025; 16(11): 3120-24. doi: 10.13040/IJPSR.0975-8232.16(11).3120-24.