International Journal of Advances in Pharmaceutics
E-ISSN: 2320-4923; P-ISSN: 2320-4931
Journal DOI: https://doi.org/10.7439/ijap **Research Article**

Design, Development and characterization of fast dissolving oral films for rapid delivery of Loratadine

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***Article History:**
Received: 14/07/2026
Revised: 01/08/2026
Accepted: 03/08/2026
DOI: https://doi.org/10.7439/ijap.v15i2.5924

Abstract

Fast dissolving oral films (FDOFs) represent an innovative drug delivery system that disintegrates rapidly in the oral cavity without water, enhancing patient compliance and therapeutic onset. Loratadine, a second-generation antihistamine for allergic rhinitis and chronic urticaria, suffers from poor aqueous solubility, limiting dissolution and onset of action. Developing FDOFs of Loratadine offers a promising approach to improve drug release and acceptability.

The present study aimed to design, develop, and characterize Loratadine FDOFs using the solvent casting technique. Hydroxypropyl methylcellulose (HPMC E15 and HPMC E5) served as film-forming polymers, with polyethylene glycol 400, glycerin, and propylene glycol as plasticizers. Tween 80 was incorporated as a surfactant, while citric acid and sodium saccharin acted as saliva-stimulating agent and sweetener, respectively. Prepared films were evaluated for physical appearance, thickness, weight variation, folding endurance, surface pH, tensile strength, drug content, disintegration time, in vitro drug release, and stability under ICH guidelines.

All formulations yielded smooth, flexible, uniform films with satisfactory mechanical properties. Among them, formulation F3 demonstrated optimal performance, showing uniform drug content, excellent folding endurance, rapid disintegration, and highest cumulative drug release. Accelerated stability studies at 40 ± 2°C/75 ± 5% RH for 90 days revealed no significant changes in physicochemical properties, confirming good stability.

In conclusion, the optimized Loratadine FDOF exhibited rapid disintegration, efficient drug release, satisfactory mechanical strength, and excellent stability. This formulation represents a promising alternative to conventional oral dosage forms, with potential to improve patient compliance and provide rapid therapeutic action in allergic disorders.

Keywords: Loratadine; Fast dissolving oral film; Solvent casting; HPMC E15; HPMC E5; Oral drug delivery; Drug release; Stability study

1. Introduction

Allergic disorders, including allergic rhinitis, chronic urticaria, allergic conjunctivitis, and other hypersensitivity reactions, are among the most prevalent chronic conditions worldwide [1]. These disorders result from an exaggerated immune response to environmental allergens such as pollen, dust mites, animal dander, mould spores, and certain foods. The release of histamine from mast cells plays a central role in the pathophysiology of allergic reactions, producing symptoms such as sneezing, rhinorrhoea, nasal congestion, itching, watery eyes, and skin irritation. The increasing prevalence of allergic diseases has created a growing demand for effective, safe, and patient-friendly drug delivery systems capable of providing rapid symptomatic relief [2].

Loratadine is a long-acting, second-generation antihistamine that selectively antagonizes peripheral histamine H_1 receptors, thereby preventing the biological effects of histamine without producing significant central nervous system sedation. Owing to its efficacy and favourable safety profile, Loratadine is widely prescribed for the treatment of seasonal and perennial allergic rhinitis, chronic idiopathic urticaria, and other allergic conditions [3]. Although clinically effective, Loratadine belongs to the Biopharmaceutics Classification System (BCS) Class II, exhibiting low aqueous solubility and high membrane permeability. Its poor aqueous solubility limits dissolution in

gastrointestinal fluids and may delay the onset of therapeutic action. Therefore, formulation approaches that enhance dissolution are of considerable pharmaceutical interest [4].

Conventional oral dosage forms such as tablets and capsules remain the most commonly prescribed formulations because of their convenience and manufacturing simplicity. However, these dosage forms may present swallowing difficulties for paediatric, geriatric, and dysphagic patients. They also require water for administration and may exhibit delayed drug release due to the time needed for tablet disintegration and dissolution. These limitations have stimulated the development of alternative oral dosage forms that improve ease of administration while providing a faster onset of action [5].

Fast dissolving oral films have emerged as an attractive oral drug delivery system capable of overcoming many of the limitations associated with conventional dosage forms. These thin, flexible polymeric films rapidly hydrate and disintegrate upon contact with saliva, releasing the incorporated drug without the need for water. Their ease of administration, rapid disintegration, portability, accurate dosing, and improved patient acceptance make them particularly suitable for paediatric, geriatric, bedridden, and dysphagic patients. In addition, rapid dissolution may enhance the onset of therapeutic action and improve treatment outcomes in conditions requiring prompt symptom relief [6].

The performance of fast dissolving oral films depends largely on the choice of film-forming polymer, plasticizer, surfactant, and other excipients [7]. Hydroxypropyl methylcellulose (HPMC) is one of the most widely used polymers because of its excellent film-forming ability, biocompatibility, non-toxicity, and rapid hydration. HPMC E15 contributes mechanical strength, whereas HPMC E5 promotes rapid hydration and film disintegration [8]. Plasticizers such as polyethylene glycol 400, glycerin, and propylene glycol improve flexibility and reduce brittleness, while surfactants such as Tween 80 enhance drug wettability and facilitate dissolution of poorly water-soluble drugs. Citric acid stimulates saliva secretion, and sodium saccharin improves taste masking, thereby enhancing patient acceptability [9].

The solvent casting method is one of the most widely employed techniques for preparing fast dissolving oral films because it is simple, economical, reproducible, and capable of producing uniform films with consistent drug distribution [10]. Following solvent evaporation, thin polymeric films with desirable mechanical and dissolution characteristics are obtained. The quality of the films is subsequently assessed through physicochemical characterization, including thickness, weight variation, surface pH, folding endurance, tensile strength, drug content uniformity, disintegration time, in vitro drug release, and stability studies. These parameters collectively determine the suitability of the formulation for oral administration [11].

The present study was undertaken to design, develop, and characterize fast dissolving oral films of Loratadine using HPMC E15 and HPMC E5 as film-forming polymers prepared by the solvent casting method [12]. The formulations were systematically evaluated to identify an optimized film with desirable mechanical properties, rapid disintegration, enhanced drug release, and satisfactory stability. The findings of this investigation are expected to contribute to the development of an effective oral film formulation capable of improving patient compliance and providing rapid relief from allergic symptoms [13].

2. Materials and Methods

2.1 Materials

Loratadine was obtained as a gift sample from a reputed pharmaceutical manufacturer. Hydroxypropyl methylcellulose (HPMC E15 and HPMC E5) was used as the film-forming polymer. Polyethylene glycol 400 (PEG 400), glycerin, and propylene glycol (PG) were used as plasticizers. Tween 80 was used as a surfactant, citric acid as a saliva-stimulating agent, and sodium saccharin as a sweetener. Dichloromethane and methanol were used as the solvent system for film preparation. All chemicals and reagents were of analytical reagent (AR) grade and were used without further purification. Double-distilled water was used throughout the study.

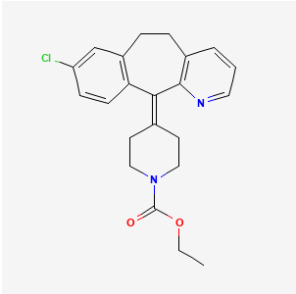

Figure 1. Structure of Loratadine

2.2 Preformulation Studies

Preformulation studies were performed to determine the physicochemical characteristics of Loratadine prior to formulation development.

2.2.1 Identification of Loratadine

The drug was identified by evaluating its organoleptic properties, melting point, solubility profile, UV-visible spectroscopy, and Fourier Transform Infrared (FTIR) spectroscopy.

2.2.2 Organoleptic Evaluation

Loratadine was examined visually for colour, odour, appearance, and physical nature.

2.2.3 Melting Point Determination

The melting point was determined using a digital melting point apparatus by the capillary tube method. Approximately 2–3 mg of Loratadine was filled into a sealed capillary tube and heated gradually until complete melting occurred. The observed melting point was compared with the reported value.

2.2.4 Solubility Study

The solubility of Loratadine was evaluated in distilled water, methanol, ethanol, acetone, chloroform, and dimethyl sulfoxide (DMSO). Approximately 10 mg of the drug was added separately to 10 mL of each solvent, shaken for 30 minutes, and observed visually for dissolution.

2.2.5 UV Spectrophotometric Analysis

A stock solution of Loratadine (100 µg/mL) was prepared in methanol. Appropriate dilutions were prepared and scanned over the wavelength range of 200–400 nm using a UV–Visible spectrophotometer to determine the maximum absorption wavelength (λ_{max}). A calibration curve was constructed by plotting absorbance against concentration.

2.2.6 Fourier Transform Infrared (FTIR) Spectroscopy

Drug–excipient compatibility was evaluated using FTIR spectroscopy. Samples of pure Loratadine and physical mixtures with excipients were mixed with potassium bromide, compressed into pellets, and scanned in the range of 4000–400 cm^{-1}. The spectra were compared to identify any significant changes in characteristic functional group peaks.

2.2.7 Formulation Design of Fast Dissolving Oral Films

Five formulations (F1–F5) were prepared by varying the concentration of HPMC E15 and HPMC E5 while maintaining constant amounts of the remaining ingredients.

Table 1: Composition of Loratadine Fast Dissolving Oral Films

Ingredients (mg)	F1	F2	F3	F4	F5
Loratadine	10	10	10	10	10
HPMC E15	200	175	150	125	100
HPMC E5	0	25	50	75	100
PEG 400	20	20	20	20	20
Glycerin	10	10	10	10	10
Propylene glycol	10	10	10	10	10
Citric acid	5	5	5	5	5
Sodium saccharin	5	5	5	5	5
Tween 80	5	5	5	5	5
Dichloromethane : Methanol	q.s. (1:1)	q.s. (1:1)	q.s. (1:1)	q.s. (1:1)	q.s. (1:1)

2.2.8 Preparation of Fast Dissolving Oral Films

Fast dissolving oral films were prepared by the solvent casting method. The required quantities of HPMC E15 and HPMC E5 were dispersed in the dichloromethane:methanol (1:1) solvent system under continuous magnetic stirring until a clear polymeric solution was obtained. PEG 400, glycerine, and propylene glycol were added as plasticizers, followed by Tween 80, citric acid, and sodium saccharin.

Loratadine was dissolved separately in a small quantity of the solvent system and added slowly to the polymer solution with continuous stirring to obtain a homogeneous casting solution. The resulting solution was allowed to stand to remove entrapped air bubbles and then poured into clean, leveled glass Petri dishes. The films were dried at room temperature for 24 hours. After complete drying, the films were carefully peeled from the casting surface and cut into uniform squares of appropriate dimensions, each containing the required dose of Loratadine. The films were wrapped individually in aluminium foil and stored in a desiccator until further evaluation.

2.3 Evaluation of Fast Dissolving Oral Films

2.3.1 Physical Appearance

The prepared films were visually inspected for colour, transparency, smoothness, flexibility, and the presence of cracks or air bubbles.

2.3.2 Thickness

Film thickness was measured at five different positions using a digital micrometer screw gauge, and the average value was recorded.

2.3.3 Weight Variation

Individual films of identical dimensions were weighed using a digital analytical balance, and the average weight was calculated.

2.3.4 Surface pH

The films were moistened with distilled water, and the surface pH was measured using a calibrated digital pH meter.

2.3.5 Folding Endurance

Folding endurance was determined by repeatedly folding the same film at the same location until it broke. The number of folds required to break the film was recorded.

2.3.6 Tensile Strength

Mechanical strength was determined using a tensile strength tester. Tensile strength was calculated from the force required to break the film divided by its cross-sectional area.

2.3.7 Drug Content Uniformity

Each film was dissolved in methanol, filtered, suitably diluted, and analysed spectrophotometrically at the predetermined λmax. Drug content was calculated from the calibration curve.

2.3.8 In Vitro Disintegration Time

The film was placed in a Petri dish containing 10 mL of phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C. The time required for complete disintegration was recorded.

2.3.9 In Vitro Drug Release

Drug release studies were performed using the USP dissolution apparatus (Type II paddle) containing 900 mL of phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C and stirred at 50 rpm. Samples (5 mL) were withdrawn at predetermined intervals, filtered, and analysed using a UV–Visible spectrophotometer. An equal volume of fresh dissolution medium was replaced after each sampling.

2.3.10 Stability Studies

The optimized formulation was packed in aluminium foil and subjected to accelerated stability testing according to ICH Q1A(R2) guidelines at 40 ± 2°C and 75 ± 5% relative humidity for 90 days. Samples were evaluated initially and after 30, 60, and 90 days for physical appearance, thickness, drug content, folding endurance, surface pH, disintegration time, tensile strength, and in vitro drug release.

2.4 Statistical Analysis

All experiments were carried out in triplicate, and the results are expressed as mean ± standard deviation (SD). Statistical comparisons among formulations may be performed using one-way analysis of variance (ANOVA), with $p < 0.05$ considered statistically significant.

3. Results

3.1 Drug–Excipient Compatibility Studies

3.1.1 Fourier Transform Infrared (FTIR) Analysis

The FTIR spectra of pure Loratadine and its physical mixtures with HPMC E5 and HPMC E15 were compared to evaluate drug–excipient compatibility. The characteristic absorption peaks of Loratadine were retained in the physical mixtures without any significant shift, disappearance, or formation of new peaks, indicating the absence of chemical interactions between the drug and the selected polymers. These findings confirmed the compatibility of Loratadine with HPMC E5 and HPMC E15 and demonstrated the suitability of these polymers for the development of fast dissolving oral films.

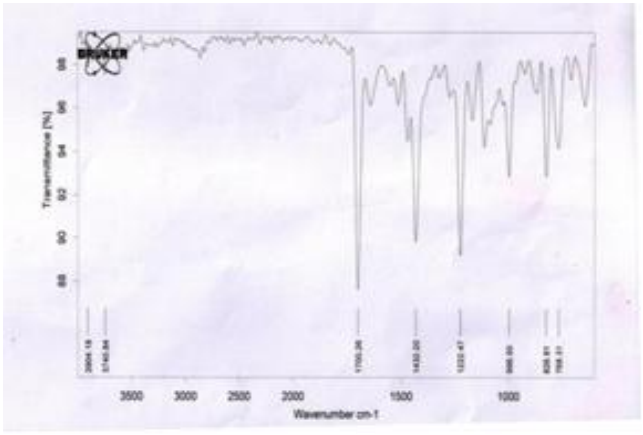

Figure 2: FTIR Spectrum of Loratadine

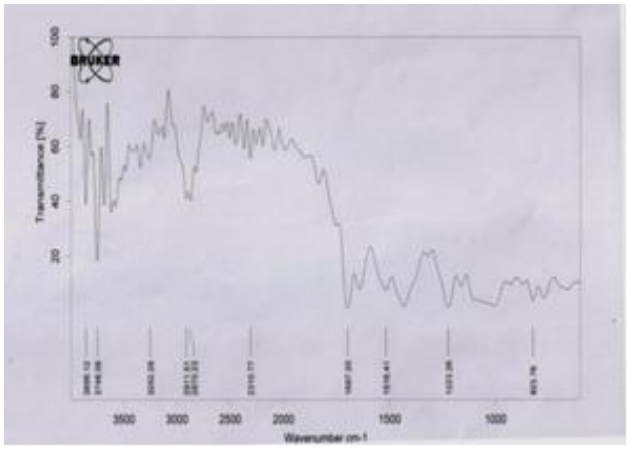

Figure.3: FTIR Spectrum of Loratadine with HPMCE5

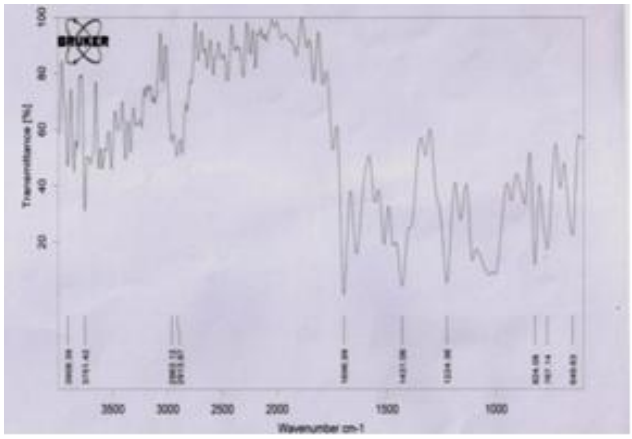

Figure .4: FTIR Spectrum of Loratadine with HPMCE15

3.1.2 Differential Scanning Calorimetry (DSC)

DSC thermograms of pure Loratadine and its physical mixtures with HPMC E5 and HPMC E15 exhibited similar endothermic melting peaks. No appreciable change in the melting temperature of Loratadine was observed after mixing with the polymers, confirming that the crystalline nature of the drug remained unchanged. The DSC results further supported the compatibility of Loratadine with the selected excipients and indicated that no significant physicochemical interaction occurred during formulation development.

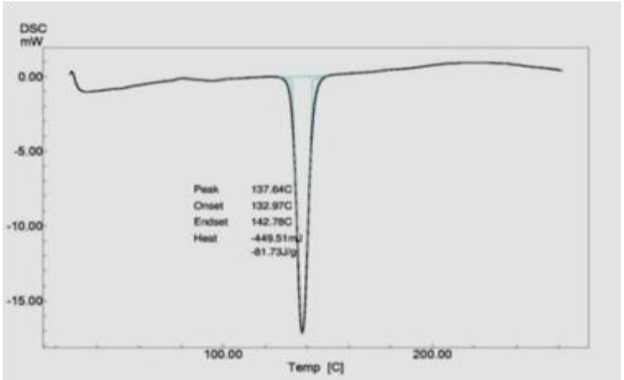

Figure .5: DSC Thermogram of Loratadine

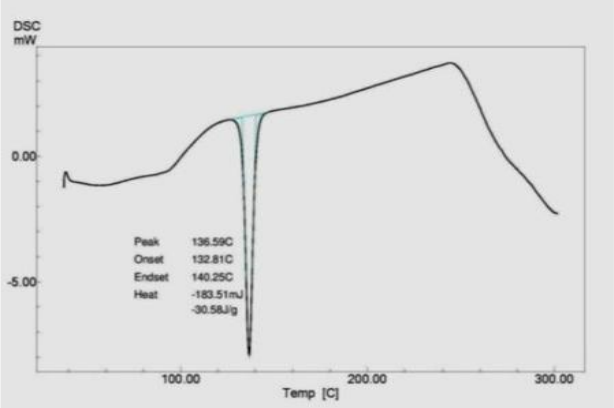

Figure 6: DSC Thermogram of Physical Mixture of Loratadine and HPMCE5

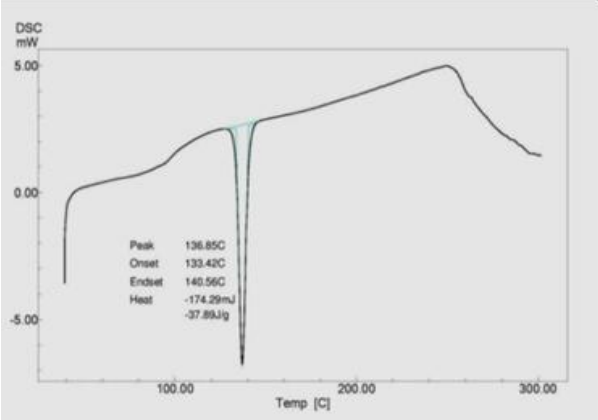

Figure.7: DSC Thermogram of physical mixture of Loratadine and HPMCE15

3.2 Evaluation of Loratadine Fast Dissolving Oral Films

3.2.1 Physical Appearance

All prepared formulations (F1–F5) were smooth, flexible, and free from cracks, air bubbles, and visible drug crystals. Formulations F3 and F4 showed superior transparency and flexibility, indicating improved film formation due to the optimized combination of HPMC E15 and HPMC E5.

3.2.2 Thickness

Film thickness ranged from 0.15 ± 0.01 to 0.20 ± 0.01 mm. The slight variation among formulations was attributed to differences in polymer concentration. The solvent casting technique produced films of uniform thickness, ensuring consistent drug loading and dose uniformity.

3.2.3 Weight Variation

The weight of the prepared films ranged from 112 ± 2 to 121 ± 2 mg. The low variation in film weight demonstrated uniform distribution of the casting solution and confirmed the reproducibility of the manufacturing process.

3.2.4 Surface pH

The surface pH of all formulations ranged from 6.70 ± 0.05 to 6.80 ± 0.03, which is close to the physiological pH of saliva. These values suggest that the films are unlikely to cause irritation to the oral mucosa and are suitable for buccal administration.

3.2.5 Folding Endurance

The folding endurance values varied between 215 ± 5 and 298 ± 7 folds. Formulation F3 exhibited the highest folding endurance, indicating excellent flexibility and mechanical strength. The optimized polymer composition and plasticizer concentration contributed to improved resistance to repeated folding without cracking.

3.2.6 Drug Content Uniformity

Drug content ranged from 96.25 ± 0.85% to 99.42 ± 0.63%, demonstrating uniform distribution of Loratadine throughout the films. The optimized formulation (F3) exhibited the highest drug content, confirming efficient incorporation of the drug during the solvent casting process.

3.2.7 Tensile Strength

The tensile strength of the prepared films ranged from 1.95 ± 0.08 to 2.38 ± 0.06 N/mm². Formulation F3 showed the highest tensile strength, indicating an optimum balance between polymer concentration and plasticizer content. The films possessed sufficient mechanical strength for handling, packaging, and transportation.

3.2.8 Percentage Moisture Content

Moisture content was found to be between 4.23 ± 0.15% and 5.18 ± 0.20%. The relatively low moisture content suggests reduced susceptibility to microbial contamination and improved storage stability. Formulation F3 exhibited the lowest moisture content among all formulations.

3.2.9 In Vitro Disintegration Time

The disintegration time of the films ranged from 24 ± 1 to 46 ± 2 seconds. Formulation F3 showed the shortest disintegration time (24 ± 1 seconds), demonstrating rapid hydration and film disintegration due to the optimized ratio of HPMC E15 and HPMC E5. These findings indicate the suitability of the optimized formulation for rapid drug delivery through the oral cavity.

3.2.10 In Vitro Drug Release

All formulations exhibited rapid dissolution, with cumulative drug release increasing over time. Formulation F3 showed the highest drug release, achieving 99.4% within 10 minutes, whereas F1 exhibited the slowest release profile (92.3%). The enhanced dissolution of F3 can be attributed to the optimized polymer composition, rapid hydration of the film matrix, and improved wetting effect of Tween 80. These results demonstrate the effectiveness of the optimized formulation in providing rapid drug release suitable for immediate therapeutic action.

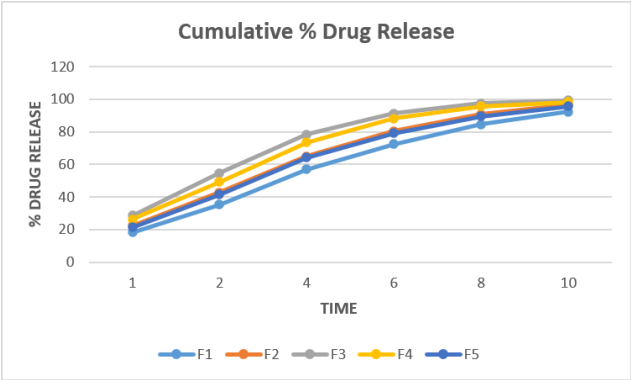

Figure 8: Comparison of cumulative % drug release of films F1-F5

3.3 Stability Studies

The optimized formulation (F3) was subjected to accelerated stability testing at 40 ± 2°C/75 ± 5% RH for 90 days. No significant changes were observed in physical appearance, thickness, weight variation, surface pH, folding endurance, drug content, disintegration time, or in vitro drug release during the study period. Drug content decreased only slightly from 99.42 ± 0.63% to 98.35 ± 0.67%, while drug release at 10 minutes remained above 98%. These findings indicate that the optimized formulation maintained its physicochemical integrity and performance under accelerated storage conditions, confirming its excellent stability and suitability for further pharmaceutical development.

Table 2. Summary of Evaluation Results of Loratadine Fast Dissolving Oral Films (Mean ± SD, n = 3)

Evaluation Parameter	F1	F2	F3	F4	F5
Physical appearance	**White, smooth**	**White, smooth**	**Transparent, smooth**	**Transparent, smooth**	**Slightly opaque, smooth**
Thickness (mm)	0.20 ± 0.01	0.18 ± 0.01	0.17 ± 0.01	0.16 ± 0.01	0.15 ± 0.01
Weight variation (mg)	121 ± 2	118 ± 2	116 ± 1	114 ± 2	112 ± 2
Surface pH	6.70 ± 0.05	6.72 ± 0.04	6.80 ± 0.03	6.78 ± 0.05	6.76 ± 0.04
Folding endurance	215 ± 5	248 ± 6	298 ± 7	285 ± 6	252 ± 5
Tensile strength (N/mm²)	1.95 ± 0.08	2.12 ± 0.07	2.38 ± 0.06	2.29 ± 0.05	2.01 ± 0.08
Moisture content (%)	5.18 ± 0.20	4.82 ± 0.18	4.23 ± 0.15	4.41 ± 0.16	4.76 ± 0.17
Drug content (%)	96.25 ± 0.85	97.83 ± 0.74	99.42 ± 0.63	98.84 ± 0.69	97.66 ± 0.72
Disintegration time (sec)	46 ± 2	35 ± 2	24 ± 1	27 ± 1	31 ± 2
Cumulative drug release at 10 min (%)	92.30 ± 0.52	96.80 ± 0.48	99.40 ± 0.45	98.30 ± 0.49	95.70 ± 0.56

Data are expressed as mean ± standard deviation (SD) (n = 3).

4. Discussion

The present study successfully developed and characterized Loratadine fast dissolving oral films using the solvent casting technique. The formulation was designed to overcome the limitations associated with the poor aqueous solubility of Loratadine and the inconvenience of conventional oral dosage forms, particularly for paediatric, geriatric, and dysphagic patients. The prepared films were systematically evaluated for their physicochemical, mechanical, and in vitro performance characteristics to identify the optimized formulation.

Preformulation studies confirmed the suitability of Loratadine for oral film formulation. The organoleptic properties, melting point, and solubility profile were consistent with the reported characteristics of the drug. FTIR analysis demonstrated that all characteristic functional group peaks of Loratadine were retained in the physical mixtures with HPMC E15 and HPMC E5, indicating the absence of significant drug–excipient interactions. Similarly, DSC thermograms showed no appreciable change in the melting endotherm of Loratadine after mixing with the polymers, confirming the compatibility of the drug with the selected excipients and the stability of the formulation.

The solvent casting method produced smooth, flexible, and uniform films without cracks, air bubbles, or visible drug crystals, demonstrating the suitability of the selected formulation process. The transparency and flexibility observed in formulations containing both HPMC E15 and HPMC E5 indicated that the combination of these polymers promoted better film formation than either polymer alone. Uniform thickness and minimal weight variation among the formulations further confirmed the reproducibility of the manufacturing process and ensured uniform drug distribution.

Surface pH values of all formulations remained close to the physiological pH of saliva, indicating that the films are unlikely to produce irritation following administration in the oral cavity. Mechanical evaluation demonstrated satisfactory tensile strength and folding endurance for all formulations. The optimized formulation (F3) exhibited the highest folding endurance and tensile strength, suggesting that the selected polymer ratio and plasticizer concentration produced films with sufficient flexibility and mechanical integrity for handling, packaging, and transportation.

Drug content analysis confirmed uniform distribution of Loratadine throughout the films, indicating

efficient mixing during formulation. The high drug content observed for formulation F3 reflects the effectiveness of the solvent casting technique in achieving homogeneous incorporation of the drug within the polymer matrix.

Rapid disintegration is one of the principal requirements of fast dissolving oral films. In the present study, all formulations disintegrated within one minute, while formulation F3 exhibited the shortest disintegration time of 24 seconds. The rapid hydration of HPMC E5, together with the hydrophilic nature of the polymer matrix and the presence of saliva-stimulating agents, facilitated quick penetration of dissolution medium into the film, resulting in rapid film erosion and drug release.

The in vitro dissolution study demonstrated rapid release of Loratadine from all formulations. The optimized formulation (F3) achieved approximately 99% cumulative drug release within 10 minutes, indicating excellent dissolution performance. The enhanced release may be attributed to the combined effects of rapid polymer hydration, increased surface area of the thin film, improved wetting by Tween 80, and uniform drug dispersion within the polymeric matrix. These characteristics are particularly advantageous for Loratadine, a BCS Class II drug, where dissolution is the rate-limiting step for absorption.

Accelerated stability studies performed under ICH conditions (40 ± 2°C/75 ± 5% RH) for 90 days demonstrated that the optimized formulation maintained its physical appearance, drug content, mechanical properties, disintegration time, and drug release profile throughout the storage period. The minor changes observed in drug content and mechanical parameters remained within acceptable limits, indicating that the formulation possesses satisfactory physicochemical stability and adequate shelf-life characteristics.

Among the prepared formulations, F3 consistently demonstrated superior performance with respect to film quality, mechanical strength, drug content, rapid disintegration, dissolution behaviour, and stability. The optimized balance between HPMC E15 and HPMC E5 provided sufficient film strength while maintaining rapid hydration and drug release. Overall, the findings indicate that the developed fast dissolving oral film is a promising dosage form for Loratadine and has the potential to improve patient convenience, compliance, and therapeutic effectiveness compared with conventional oral formulations.

5. Conclusion

The present investigation successfully designed, developed, and characterized fast dissolving oral films of Loratadine using the solvent casting method. Preformulation studies confirmed the identity, purity, and compatibility of Loratadine with the selected excipients, supporting their suitability for formulation development.

The prepared films exhibited satisfactory physicochemical characteristics, including uniform appearance, acceptable thickness and weight variation, near-neutral surface pH, excellent mechanical strength, high drug content uniformity, rapid disintegration, and efficient in vitro drug release. Among the five formulations, formulation F3 demonstrated the best overall performance, showing superior flexibility, highest drug content, shortest disintegration time, and nearly complete drug release within 10 minutes.

Accelerated stability studies conducted at 40 ± 2°C/75 ± 5% RH for 90 days confirmed that the optimized formulation remained physically and chemically stable, with no significant changes in its quality attributes. These findings indicate that the developed fast dissolving oral film provides a stable, effective, and patient-friendly dosage form for the rapid delivery of Loratadine.

Overall, the optimized formulation offers several advantages over conventional oral dosage forms, including ease of administration without water, rapid drug release, improved patient compliance, and the potential for faster therapeutic action. Future investigations should include taste-masking evaluation, ex vivo permeation studies, in vivo pharmacokinetic and pharmacodynamic assessment, long-term stability testing, and scale-up studies to establish the clinical applicability and commercial potential of the developed Loratadine fast dissolving oral film.

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