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A Dragon Fruit Peel Mucilage-Based Fast-Dissolving Oral Film for Scopolamine Hydrobromide Delivery.

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ABSTRACT: **Background**: Motion sickness is associated with sensory conflict and commonly causes nausea and vomiting. Scopolamine is effective for prophylaxis; however, conventional oral administration may be inconvenient during travel. The present study aimed to develop a fast-dissolving oral thin film (FDOF) of scopolamine hydrobromide using dragon fruit peel mucilage as a natural film-forming polymer.Materials and

Methods: Films were prepared by the solvent-casting technique using dragon fruit peel mucilage, HPMC, sodium alginate, plasticizer, and surfactant. Twelve preliminary formulations were prepared and evaluated for film-forming characteristics. The optimized formulation was characterized for physicomechanical properties, surface pH, moisture content, transparency, drug content, disintegration, and in-vitro drug release.

Results: Formulation F12 demonstrated excellent film formation, flexibility, peelability, and uniformity. It exhibited thickness of 0.112 ± 0.003 mm, folding endurance of 327.67 ± 3.51 folds, drug content of 99.33 ± 0.76%, disintegration time of 18.00 ± 1.00 s, and 91.80 ± 1.15% transmittance. Cumulative drug release reached 98.40% within 10 min.

Conclusion: The optimized scopolamine hydrobromide FDOF demonstrated satisfactory mechanical properties, rapid disintegration, excellent drug uniformity, and rapid drug release, indicating its potential as a convenient oral dosage form for motion-sickness management.

INTRODUCTION

Motion sickness is a common neurophysiological disorder caused primarily by a conflict among visual, vestibular, and somatosensory information involved in the perception of movement and spatial orientation. It may occur during travel by automobile, bus, aircraft, or ship and may also be induced by amusement rides, simulators, virtual-reality environments, and visually perceived motion. The clinical manifestations include nausea, vomiting, pallor, sweating, increased salivation, dizziness, headache, fatigue, drowsiness, and general malaise. Although motion sickness is generally self-limiting, its symptoms can significantly impair travel, occupational performance, training, and quality of life. It may be particularly important in aviation, maritime, military, and other occupational environments where impaired alertness and performance can have safety implications.[1,2]

The pathophysiology of motion sickness is most commonly explained by the sensory-conflict or neural-mismatch theory. Under physiological conditions, the central nervous system integrates information received from the semicircular canals and otolith organs of the vestibular apparatus with visual and proprioceptive signals to maintain an appropriate representation of body

movement and orientation. When these sensory inputs are inconsistent, abnormal neural processing may activate autonomic and emetic pathways, producing the characteristic symptoms of motion sickness. Reading during vehicle travel is a typical example in which visual information indicates relative stability while the vestibular system detects acceleration and changes in direction. Repeated exposure may promote habituation and adaptation, thereby reducing susceptibility in some individuals.[1,2]

Pharmacological management of motion sickness is generally directed toward prevention because established nausea and vomiting can be difficult to control. Scopolamine (hyoscine) is an established prophylactic agent that acts primarily through central antimuscarinic mechanisms and inhibits cholinergic transmission involved in vestibular-mediated nausea. Clinical evidence supports its efficacy in preventing motion-sickness symptoms, although adverse effects such as dry mouth, drowsiness, blurred vision, and other anticholinergic effects may occur.[2,3] A recent systematic review and meta-analysis of randomized controlled trials reported that scopolamine significantly reduced nausea compared with placebo, further supporting its therapeutic value in motion sickness.[4]

Despite its effectiveness, the clinical utility of scopolamine is influenced by its route of administration. Conventional oral administration requires swallowing and gastrointestinal absorption, which may be inconvenient when a patient is already nauseated or travelling without access to water. Vomiting may also interfere with retention and absorption of an orally administered dose. Transdermal scopolamine provides sustained drug delivery and is useful for prolonged travel; however, its onset is relatively delayed because the patch generally needs to be applied several hours before exposure. These limitations create an opportunity for alternative dosage forms that provide convenient, accurately controlled dosing while addressing the practical difficulties associated with conventional administration.[2,5]

Fast-dissolving oral thin films (FDOFs), also known as orally disintegrating films, have emerged as a patient-oriented drug-delivery platform for rapid and convenient administration. These systems consist of thin polymeric matrices containing the drug and suitable excipients. After placement in the oral cavity, the film is rapidly wetted by saliva and undergoes hydration, disintegration, and drug release. The released drug may subsequently be swallowed for gastrointestinal absorption and, depending on its physicochemical properties and formulation design, a proportion may also be absorbed through the oral mucosa.[6,7] Their administration without water, portability, small size, and ease of use make oral thin films particularly attractive for patients experiencing nausea, difficulty swallowing, or limited access to water.[6-8]

The application of FDOFs to motion-sickness therapy is therefore rational because symptoms commonly develop while an individual is already travelling. A thin film can be administered directly in the mouth without requiring water or conventional swallowing of a tablet. Rapid disintegration may facilitate prompt drug release, while accurate low-dose drug loading is particularly relevant for potent drugs such as scopolamine. However, the potential therapeutic advantage of an oral thin film should be evaluated through formulation-specific parameters rather than assumed solely from rapid disintegration, since the extent of transmucosal absorption depends on drug permeability, dose, formulation composition, residence time, and other physiological factors.[6,7]

Polymers constitute the principal structural components of oral thin films and strongly influence film thickness, flexibility, tensile strength, hydration, disintegration, drug release, and stability. Hydrophilic polymers are particularly useful because they facilitate rapid interaction with saliva. Common film-forming polymers include hydroxypropyl methylcellulose, hydroxypropyl cellulose, polyvinyl alcohol, polyvinylpyrrolidone, pullulan, alginate, pectin, and other polysaccharides.[6-9] However, increasing polymer concentration may improve mechanical strength while simultaneously delaying hydration and disintegration. Consequently, optimization is required to achieve an appropriate balance between mechanical integrity and rapid drug release.

Natural polymers have attracted increasing interest because of their biocompatibility, biodegradability, renewable origin, and potential to provide film-forming and hydration properties. Plant-derived mucilages, gums, pectins, and polysaccharides can be used as alternatives or complements to synthetic polymers in oral-film systems.[8,9] Nevertheless, natural polymers may exhibit variability in composition, molecular weight, viscosity, moisture content, and functional characteristics due to differences in botanical source, maturity, extraction procedure, and processing conditions. Appropriate extraction, characterization, standardization, and formulation optimization are therefore essential for achieving reproducible pharmaceutical performance.

Dragon fruit (*Hylocereus* spp.) peel is a promising agro-industrial source of polysaccharides and pectin. Although commonly discarded as fruit-processing waste, the peel contains substantial amounts of pectic substances and other polysaccharides with useful functional properties. Recent studies have demonstrated successful extraction and characterization of pectin from red dragon fruit peel, including its potential for biodegradable film formation.[10] Other investigations have also characterized

water-soluble polysaccharide fractions from dragon fruit materials, supporting their potential as functional polymeric resources.[11] Utilization of dragon fruit peel as a pharmaceutical excipient may therefore combine formulation functionality with waste valorization and sustainable-material development.

A major challenge in natural-polymer-based oral thin-film development is obtaining adequate mechanical strength without compromising rapid hydration and disintegration. Polymer blending provides a rational approach by combining complementary characteristics of two or more polymers. A natural polymer may contribute swelling, hydration, biodegradability, and film-forming properties, whereas another polymer may improve flexibility, mechanical strength, casting characteristics, and uniformity. Optimization of the polymer ratio can consequently influence critical quality attributes including film thickness, tensile strength, folding endurance, drug content, disintegration time, and drug-release behavior.[6-9]

Accordingly, the present study focuses on the development and optimization of a fast-dissolving oral thin film of scopolamine hydrobromide using a blend of natural polymers for motion sickness relief. The research aims to combine the established therapeutic potential of scopolamine with the convenience of oral thin-film technology and the functional and sustainability-related advantages of natural polymers. Systematic optimization of the natural-polymer blend is expected to facilitate the development of a film possessing acceptable mechanical properties, uniform drug content, rapid disintegration, and satisfactory drug-release characteristics. The study therefore explores a patient-centric and potentially sustainable approach for the delivery of scopolamine hydrobromide in motion-sickness management.

MATERIAL AND METHOD

METHOD

Scopolamine hydrobromide (pharmaceutical-grade gift sample) was obtained from TajPharma India Ltd., Vapi, Gujarat, India. Fresh Hylocereusundatus fruits were procured from a local market for mucilage extraction. HPMC and sodium alginate were used as film-forming polymers, while glycerol and PEG-400 served as plasticizers. Tween 80 and Poloxamer 188 were incorporated to improve drug dispersion. Suitable sweeteners and flavors were added for palatability. Analytical-grade chemicals were procured from Merck and Qualigens Fine Chemicals, India. Ethanol (95%), distilled water, simulated saliva fluid (pH 6.8), and phosphate buffer were used.

Preformulation Studies

Preformulation studies of scopolamine hydrobromide were performed to establish its physicochemical and analytical characteristics before formulation development. Organoleptic properties including color, odor, and physical appearance were evaluated. Solubility was determined in distilled water, simulated saliva fluid (pH 6.8), and ethanol. The absorption maximum (λmax) was identified by UV–Visible spectrophotometry. A calibration curve was prepared using concentrations of 2–10 µg/mL to establish linearity. Drug–excipient compatibility was assessed by FTIR spectroscopy using pure drug, individual excipients, and drug–mucilage physical mixtures to identify potential interactions. [12].

Optimization of Formulation

The present investigation was undertaken to develop and optimize scopolamine hydrobromide fast-dissolving oral thin films (FDOFs)usingdragon fruit peel mucilage as a natural film-forming polymer. A systematic trial-based optimization approach was employed to investigate the effect of formulation variables on the physicochemical and in vitro performance of the films. The independent formulation variables studied were dragon fruit peel mucilage concentration, secondary polymer concentration, and plasticizer concentration. HPMC or sodium alginate was used as the secondary polymer, while glycerol or PEG-400 was used as the plasticizer.

The formulation variables were varied within the selected ranges to obtain films with suitable mechanical strength, flexibility, rapid disintegration, uniform drug content, and satisfactory drug release. The optimized formulation was selected based on the overall physicomechanical and in vitro performance of the prepared films.

Table 1. Variables Studied

Code	Independent Variable	Investigated Range
X_1	Dragon fruit peel mucilage concentration (% w/v)	1–2

Code	Independent Variable	Investigated Range
X_2	HPMC or sodium alginate concentration (% w/v)	0.5–1
X_3	Glycerol or PEG-400 concentration (% w/w of total polymer)	15–30

The dependent variables evaluated during optimization included film thickness, folding endurance, tensile strength, disintegration time, drug content uniformity, and percentage drug release. Process parameters such as drying temperature (40 ± 2 °C), drying time (24 h), casting conditions, and other preparation conditions were maintained constant.

Preparation of Fast-Dissolving Oral Thin Films

Fast-dissolving oral thin films were prepared by the solvent casting method. Accurately weighed dragon fruit peel mucilage (1–2% w/v) was dispersed in distilled water and stirred continuously using a magnetic stirrer until a homogeneous dispersion was obtained. The dispersion was allowed to hydrate for 4–6 h to ensure complete swelling of the mucilage.

HPMC or sodium alginate (0.5–1% w/v) was dissolved separately in distilled water and slowly incorporated into the hydrated mucilage dispersion with continuous stirring to obtain a uniform polymer blend. Glycerol or PEG-400 (15–30% w/w of total polymer) was then added gradually and mixed for 30 min. Tween 80 or Poloxamer 188 (0.2–0.5% w/v) was incorporated as a surfactant to improve wetting and drug dispersion.

Scopolamine hydrobromide equivalent to 0.6 mg per unit film was accurately weighed, dissolved in a minimal quantity of distilled water, and slowly incorporated into the polymeric mixture under continuous stirring. Sweetening and flavoring agents were added as required. The final film-forming solution was stirred for an additional 30 min and allowed to stand for 15–20 min to remove entrapped air bubbles. . [13]

Evaluation of Fast-Dissolving Oral Thin Films

Physicomechanical Evaluation

Thickness

The thickness of individual films was measured at three different positions, including the center and two corners, using a calibrated micrometer screw gauge. The mean thickness was calculated from the recorded measurements. Uniform film thickness was considered important for ensuring consistent drug loading and dosing.

Weight Variation

Individual film units measuring 2 × 2 cm^2 were weighed separately using a digital analytical balance with a sensitivity of 0.1 mg. The mean weight was calculated, and the percentage deviation from the mean was determined to assess weight uniformity.

Folding Endurance

Folding endurance was determined by repeatedly folding the film at the same position until the film developed visible cracks or broke. The number of folds required to cause breakage was recorded as the folding endurance. Folding endurance greater than 300 folds was considered indicative of satisfactory flexibility and mechanical strength.

Tensile Strength and Percentage Elongation

The mechanical properties of the films were determined using a Brookfield Texture Analyzer. Film strips of uniform dimensions were fixed between two clamps, and force was applied until the film broke. Tensile strength and percentage elongation at break were determined from the recorded force and elongation values using standard equations.

Physicochemical Evaluation

Surface pH

The surface pH of the films was determined to assess their compatibility with the oral mucosa. Each film was moistened with a few drops of distilled water and allowed to equilibrate for 1 min. The pH was then measured by placing a calibrated pH

electrode in contact with the film surface. A near-neutral surface pH was considered desirable to minimize the possibility of mucosal irritation.

Moisture Content

The moisture content of the films was determined by accurately weighing the films and placing them in a desiccator containing anhydrous calcium chloride at room temperature for 24 h. The films were subsequently reweighed, and the percentage moisture loss was calculated using the difference between the initial and final weights.

Transparency

The transparency of the prepared films was evaluated using a UV–Visible spectrophotometer. The film samples were placed appropriately in the spectrophotometer, and transmittance was measured at 600 nm. Film transparency was determined from the recorded absorbance/transmittance values.

Drug Content and Content Uniformity

Drug content and content uniformity were determined by dissolving individual 2 × 2 cm^2 film units in 100 mL of simulated saliva fluid (pH 6.8) with continuous stirring until complete dissolution. The resulting solution was filtered and analyzed using a Thermo Scientific Vision One UV–Visible spectrophotometer at the predetermined wavelength maximum (λmax) of scopolamine hydrobromide. The drug concentration was determined using the regression equation obtained from the standard calibration curve. At least three film units from each formulation batch were analyzed to determine drug content uniformity.

In Vitro Performance Studies

Disintegration Time

The disintegration time of the films was determined by placing an individual film in a Petri dish containing 10 mL of simulated saliva fluid (pH 6.8) maintained at 37 ± 0.5 °C. The time required for complete disintegration of the film without visible residue was recorded. A disintegration time of less than 30 s was considered desirable for a fast-dissolving oral thin film.

In Vitro Dissolution Study

The in vitro dissolution study was performed using a USP Type II (paddle) dissolution apparatus. Phosphate buffer (pH 6.8), 300 mL, was used as the dissolution medium and maintained at 37 ± 0.5 °C. The paddle speed was maintained at 50 rpm.A single 2 × 2 cm^2 film containing the predetermined dose of scopolamine hydrobromide was placed in the dissolution medium. Samples were withdrawn at predetermined time intervals of 1, 2, 3, 5, and 10 min. The withdrawn samples were filtered and analyzed spectrophotometrically at the predetermined λmax. An equal volume of fresh dissolution medium was immediately added after each withdrawal to maintain the dissolution volume and sink conditions.The percentage cumulative drug release was calculated from the drug concentration determined at each sampling interval and plotted against time to obtain the drug release profile.[14].

RESULT

Preformulation Studies

Preformulation studies confirmed that scopolamine hydrobromide is a white to off-white, odorless, crystalline, free-flowing powder with favorable aqueous solubility. The drug exhibited a λmax of 252 nm in simulated saliva fluid (pH 6.8). The calibration curve showed a linear concentration-dependent response over 2–10 μg/mL, supporting the suitability of UV–Visible spectrophotometry for quantitative drug analysis.

Table 2. Summary of Preformulation Results of Scopolamine Hydrobromide

Preformulation Parameter	Result/Observation
Color	White to off-white
Odor	Odorless
Physical state	Crystalline powder

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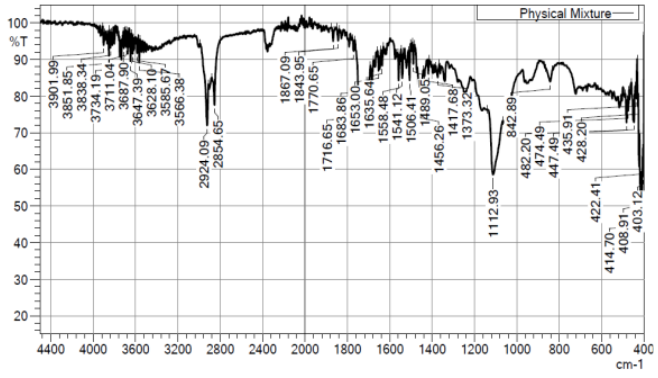
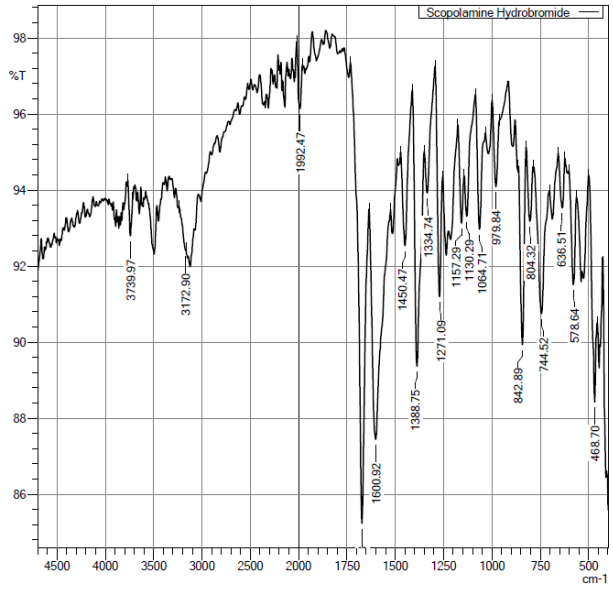
Preformulation Parameter	Result/Observation
Texture	Fine and free-flowing
Solubility in distilled water	Freely soluble
Solubility in simulated saliva fluid (pH 6.8)	Freely soluble
Solubility in ethanol	Soluble
λmax	252 nm
Calibration range	2–10 µg/mL
Regression	0.9997

Drug-Excipient Compatibility Studies

FTIR spectrum confirmed characteristic functional groups of Scopolamine Hydrobromidewithout structural alterations, indicating drug identity, purity, and compatibility.



(A)



(B)

FTIR spectrum of ScopolamineHydrobromide(A) and physical mixture(B)

Formulation Development and Optimization of Fast-Dissolving Oral Thin Films

Twelve preliminary batches (F1–F12) of scopolamine hydrobromide fast-dissolving oral thin films were prepared by the solvent casting method using dragon fruit peel mucilage as the primary polymer and HPMC or sodium alginate as secondary polymers. The concentrations of mucilage (1.0–2.0% w/v), secondary polymer (0.5–1.0% w/v), plasticizer (15–30% w/w), and surfactant (0.2–0.5% w/v) were varied to obtain suitable film characteristics.

The formulations were evaluated for surface smoothness, flexibility, peelability, cracking, stickiness, and overall film-forming ability. Low polymer and plasticizer levels resulted in brittle films, whereas higher concentrations produced thicker, sticky, or slowly drying films. Polymer-blend formulations showed improved film characteristics. Among all batches, F12 exhibited excellent film formation, smoothness, flexibility, peelability, and uniformity without cracking or stickiness and was therefore selected as the optimized formulation for further evaluation.

Table 3. :Composition of Preliminary Formulation Batches

Formulation	Dragon Fruit Peel Mucilage (% w/v)	HPMC (% w/v)	Sodium Alginate (% w/v)	Plasticizer (% w/w of total polymer)	Surfactant (% w/v)	Film Formation
F1	1.0	0.5	–	15	0.2	Slightly brittle
F2	1.0	1.0	–	20	0.2	Smooth, moderately flexible
F3	1.5	0.5	–	20	0.3	Uniform, good flexibility
F4	1.5	1.0	–	25	0.3	Smooth, flexible
F5	2.0	0.5	–	25	0.3	Thick, slightly sticky
F6	2.0	1.0	–	30	0.3	Thick, flexible
F7	1.0	–	0.5	20	0.3	Slightly opaque
F8	1.0	–	1.0	25	0.3	Uniform, acceptable strength
F9	1.5	–	0.5	25	0.3	Flexible, moderate peelability
F10	1.5	–	1.0	30	0.5	Thick, slower drying
F11	1.5	0.5	0.5	25	0.3	Smooth, flexible, uniform
F12	1.5	1.0	0.5	25	0.3	Excellent film formation

Selection of Optimized Batch

The optimized formulation was selected on the basis of the overall balance between film-forming ability, mechanical properties, flexibility, peelability, and anticipated fast-dissolving performance. F12 was composed of 1.5% w/v dragon fruit peel mucilage, 1.0% w/v HPMC, 0.5% w/v sodium alginate, 25% w/w plasticizer, and 0.3% w/v surfactant. Each 2 × 2 cm^2 film was designed to contain 0.6 mg of scopolamine hydrobromide.F12 exhibited excellent surface smoothness, flexibility, peelability, and uniformity without visible cracking or stickiness. The formulation also fulfilled the predefined targets for folding endurance,

disintegration time, drug content, and drug release according to the available study criteria. Consequently, F12 was selected as the optimized formulation and subjected to further physicomechanical, physicochemical, drug content, disintegration, dissolution, and stability evaluation.

Table 4. Composition and Selection Criteria of Optimized Formulation F12

Parameter	Optimized F12
Scopolamine hydrobromide	0.6 mg/2 × 2 cm² film
Dragon fruit peel mucilage	1.5% w/v
HPMC	1.0% w/v
Sodium alginate	0.5% w/v
Plasticizer	25% w/w of total polymer
Surfactant	0.3% w/v
Film appearance	Excellent
Surface smoothness	Excellent
Flexibility	Excellent
Peelability	Excellent
Cracking	Absent
Stickiness	Absent
Folding endurance	>300 folds
Disintegration time	<30 s
Drug content	85–115%
Drug release	Rapid

Figure 2. Optimized Oral Thin Filmformulation

Evaluation of Fast-Dissolving Oral Thin Films

The optimized fast-dissolving oral thin film exhibited satisfactory physicomechanical, physicochemical, and in vitro performance characteristics. The film showed a uniform thickness of 0.112 ± 0.003 mm and a mean weight of 86.57 ± 0.50 mg, indicating good casting uniformity. The folding endurance was 327.67 ± 3.51 folds, confirming excellent flexibility and mechanical resistance. The film exhibited a tensile strength of 2.65 ± 0.08 N/mm² and 23.00 ± 1.20% elongation, demonstrating an appropriate balance between strength and flexibility. The surface pH was 6.53 ± 0.04, indicating good suitability for oral mucosal application. Moisture content were 3.92 ± 0.18%,while transmittance was 91.80 ± 1.15%**,** confirming satisfactory physical stability and transparency. The optimized film demonstrated excellent drug uniformity, with 99.33 ± 0.76% drug content and 0.77% RSD. The film rapidly disintegrated within 18.00 ± 1.00 s and achieved 98.40% cumulative drug release within 10 min, confirming its fast-dissolving characteristics.

Table 06. Evaluation of Fast-Dissolving Oral Thin Films

Evaluation Parameter	Result (Mean ± SD)
Film thickness	0.112 ± 0.003 mm
Film weight	86.57 ± 0.50 mg
Folding endurance	327.67 ± 3.51 folds
Tensile strength	2.65 ± 0.08 N/mm²
Percent elongation	23.00 ± 1.20%
Surface pH	6.53 ± 0.04
Moisture content	3.92 ± 0.18%
Transparency	91.80 ± 1.15%
Mean drug content	99.33 ± 0.76%
Content uniformity (% RSD)	0.77%
Disintegration time	18.00 ± 1.00 s

In-Vitro Drug Release Study

The optimized fast-dissolving oral thin film demonstrated a rapid drug-release profile, with 34.80% scopolamine hydrobromide release within 1 min**,** increasing to56.70%, 73.90%, and 91.60% at 2, 3, and 5 min, respectively. At 10 min, 98.40% cumulative drug release was achieved. The rapid release corresponded with the short disintegration time of the film and may be attributed to the hydrophilic nature of the polymeric matrix and the low dose of scopolamine hydrobromide. These findings confirm the suitability of the optimized formulation for rapid dissolution and prompt drug availability.

Table 07. In-Vitro Drug Release Profile of Optimized Oral Thin Film

Time (min)	UV Absorbance	Drug Concentration (µg/mL)	Cumulative Drug Release (%)
1	0.046	0.70	34.80
2	0.073	1.12	56.70
3	0.093	1.45	73.90
5	0.114	1.78	91.60
10	0.121	1.88	98.40

Overall, the optimized F12 fast-dissolving oral thin filmexhibited uniform physical characteristics, adequate mechanical strength, acceptable physicochemical properties, excellent drug-content uniformity, rapid disintegration, and 98.40% drug release within 10 min**,** supporting its suitability as a fast-dissolving oral film formulation for scopolamine hydrobromide.

CONCLUSION

The present study successfully developed and optimized a fast-dissolving oral thin film of scopolamine hydrobromide using dragon fruit peel mucilage as a natural film-forming polymer in combination with HPMC and sodium alginate. Among the twelve preliminary formulations, F12 demonstrated the most favorable film-forming characteristics, including excellent smoothness, flexibility, peelability, uniformity, and absence of cracking or stickiness. The optimized film exhibited satisfactory physicomechanical properties, with a thickness of 0.112 ± 0.003 mm, folding endurance of 327.67 ± 3.51 folds, tensile strength of 2.65 ± 0.08 N/mm², and 23.00 ± 1.20% elongation. The surface pH of 6.53 ± 0.04 and moisture content of 3.92 ± 0.18% indicated acceptable physicochemical characteristics. Excellent drug-content uniformity was achieved, with 99.33 ± 0.76% drug content and 0.77% RSD. The film rapidly disintegrated within 18.00 ± 1.00 s and exhibited 98.40% cumulative drug release within 10 min. Overall, the optimized F12 formulation demonstrated suitable mechanical properties, rapid disintegration, uniform drug distribution, and rapid drug release. The findings indicate that dragon fruit peel mucilage can serve as a promising natural polymer for oral thin-film development and that the optimized scopolamine hydrobromide film has potential as a convenient dosage form for motion-sickness management. Further stability and in-vivo studies are warranted to establish its long-term performance and therapeutic applicability.

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