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Original Article

Fast-Dissolving Oral Films: Formulation Strategies, Evaluation Parameters and Recent Advances

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ABSTRACT

Fast-dissolving oral films (FDOFs), also known as orodispersible films (ODFs), are thin polymeric dosage forms designed to disintegrate or dissolve rapidly in the oral cavity, generally without requiring water. These formulations have gained considerable attention as alternatives to conventional tablets, capsules and liquid dosage forms, particularly for individuals who experience difficulty swallowing solid medicines. The performance of oral films depends on the selection of suitable film-forming polymers, plasticizers, active pharmaceutical ingredients (APIs), sweeteners, flavouring agents and other functional excipients. The solvent-casting method is widely discussed in the literature because of its simplicity and suitability for laboratory-scale development, while hot-melt extrusion, printing and other manufacturing approaches offer alternative opportunities. Evaluation involves physical appearance, thickness, weight variation, folding endurance, mechanical strength, surface pH, drug content uniformity, disintegration, dissolution and stability. Recent developments include improved taste-masking systems, natural polymer-based films, nanotechnology-assisted formulations, quality-by-design approaches and three-dimensional printing. However, challenges involving drug loading, moisture sensitivity, dose uniformity, scale-up and long-term stability remain important. This review examines the formulation principles, preparation methods, quality evaluation and emerging developments of fast-dissolving oral films, with particular emphasis on the comparative roles of natural and synthetic polymers. The review also identifies opportunities for further research in developing patient-friendly, stable and reproducible oral film formulations.

Keywords: Fast-dissolving oral films, orodispersible films, film-forming polymers, solvent casting, taste masking, disintegration time, drug release, formulation evaluation

INTRODUCTION

Oral drug administration is one of the most widely used routes of drug delivery because it is convenient, generally acceptable to patients and suitable for numerous therapeutic agents. Conventional tablets and capsules remain important dosage forms; however, some patients experience difficulty swallowing them. This problem, known as dysphagia, may occur in paediatric and geriatric populations and in individuals with certain medical conditions. Liquid formulations can address some swallowing difficulties, but they may present challenges involving dose measurement, portability, palatability and physical or chemical stability.

Fast-dissolving oral films have emerged as an alternative dosage form intended to simplify medication administration. They are thin, flexible polymeric sheets containing a drug and suitable excipients. When placed on the tongue or another appropriate oral mucosal surface, the film interacts with saliva, hydrates and disintegrates or dissolves, releasing the incorporated drug.

Early reviews described oral strip technology as a promising platform for rapid drug release, local oral delivery and selected buccal drug delivery applications [1,2]. More recent reviews have expanded the discussion to include patient acceptability, advanced manufacturing, improved taste masking and quality-by-design approaches [3–5].

An important distinction must be made between rapid disintegration and rapid systemic absorption. A film may disintegrate quickly without producing faster absorption or greater bioavailability than a conventional dosage form. Drug solubility, permeability, gastrointestinal absorption, formulation composition

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and the intended route of administration all influence therapeutic performance.

Similarly, not all oral films are designed for the same purpose. Some disintegrate rapidly and are swallowed with saliva, while others are designed to adhere to oral mucosa or release a drug over a longer period. Therefore, formulation design must begin with a clearly defined therapeutic objective.

The purpose of this review is to examine the formulation strategies, preparation methods, evaluation parameters and recent advances associated with fast-dissolving oral films, particularly the influence of natural and synthetic film-forming polymers on product performance.

2. Objectives of the Review

The principal objectives are:

1. To explain the basic principles and pharmaceutical applications of fast-dissolving oral films.
2. To describe the functions of polymers, plasticizers and other formulation ingredients.
3. To compare natural and synthetic film-forming polymers.
4. To discuss common preparation methods and their advantages and limitations.
5. To review important physical, mechanical and pharmaceutical evaluation parameters.
6. To examine taste-masking approaches and recent technological developments.
7. To identify formulation challenges and potential areas for future research.

3. Methodology of Literature Review

This article follows a narrative review approach. Relevant literature can be identified through databases and scholarly search platforms, including PubMed, PubMed Central, Google Scholar and ScienceDirect.

Suggested search terms include “fast-dissolving oral films,” “orodispersible films,” “oral thin film formulation,” “film-forming polymers,” “solvent casting,” “taste masking,” “disintegration time,” “drug dissolution” and “oral film stability.”

Foundational publications from 2009–2013 and more recent reviews published from 2021 onward are relevant to understanding the development of the technology and current research directions. Important publications include the reviews by Dixit and Puthli [1], Bala and colleagues [2], Salawi [3], Jacob and colleagues [4], and the review on orodispersible films from conception to quality by design [5].

For a formal systematic review, a reproducible search strategy, explicit inclusion and exclusion criteria, screening records and a method for assessing study quality would be required. The present narrative review does not claim to be a systematic review or to have exhaustively screened all available publications.

4. Overview and Classification of Fast-Dissolving Oral Films

Fast-dissolving oral films are typically composed of a water-compatible polymer matrix containing an API and selected excipients. Their thin structure provides a large surface area relative to their volume, which can facilitate rapid contact with saliva.

The performance of a film depends on its dimensions, thickness, polymer composition, porosity, wettability, mechanical properties and drug distribution. A suitable formulation must balance rapid disintegration with sufficient strength to withstand manufacturing, packaging, transportation and handling.

4.1 Orodispersible films

Orodispersible films are intended to disintegrate or dissolve rapidly in the oral cavity. Their contents are commonly released into saliva and subsequently swallowed. These films are particularly relevant when ease of administration and avoidance of water are important.

4.2 Mucoadhesive buccal films

Mucoadhesive buccal films are designed to adhere to the inner cheek or another appropriate oral mucosal surface. Depending on the formulation, they may provide local treatment or facilitate drug absorption through the mucosa. Unlike rapidly disintegrating films, some buccal films are deliberately designed to remain in place for an extended period.

4.3 Sublingual films

Sublingual films are placed beneath the tongue to facilitate drug release at the sublingual mucosa. Depending on the API and formulation, absorption through the oral mucosa may contribute to systemic exposure. This route is not suitable for every drug, and rapid disintegration alone does not establish sublingual absorption.

4.4 Immediate-release and modified-release films

Immediate-release films are designed to release their drug relatively rapidly. Modified-release oral films, by contrast, may use specialised polymers or multilayer structures to regulate drug release. These categories should not be treated as interchangeable because they have different formulation requirements.

5. Advantages and Limitations

5.1 Advantages

Fast-dissolving oral films offer several potential benefits:

1. **Convenience:** They can generally be administered without water.
2. **Ease of administration:** Their thin, flexible structure may be useful for patients who have difficulty swallowing conventional solid dosage forms.
3. **Portability:** Individually packaged films can be convenient to carry.
4. **Dose presentation:** A manufactured film can provide a defined dose when content uniformity and manufacturing controls are adequate.
5. **Potential for improved acceptability:** Flavouring and sweetening systems may help reduce unpleasant taste.
6. **Flexible formulation design:** Different polymers and manufacturing processes allow adjustment of disintegration, strength and drug release.

These advantages are consistent with the potential applications described in early and contemporary reviews [1–5]. However, actual patient preference and adherence depend on the drug, flavour, film texture, dosing requirements and the intended population.

5.2 Limitations

The technology also has limitations. The small size and limited mass of an oral film can restrict the quantity of drug that can be incorporated. This may be particularly challenging for APIs requiring large doses.

Moisture-sensitive ingredients can complicate manufacturing and storage. Some drugs have a bitter taste or an unpleasant mouthfeel, requiring additional formulation strategies. Films may also become brittle, sticky or mechanically weak if the polymer-to-plasticizer ratio and moisture content are unsuitable.

Additional challenges include uniform distribution of the drug, reproducibility between batches, packaging requirements, manufacturing scale-up and the need to establish appropriate quality specifications.

6. Formulation Ingredients and Their Functions

The composition of an oral film must be selected according to the physicochemical properties of the API and the required performance of the final dosage form.

6.1 Active pharmaceutical ingredient

The API is the therapeutically active component. Its dose, solubility, stability, taste, particle size and compatibility with excipients influence formulation design.

Drugs intended for oral films should be assessed for their suitability for the intended route and dose. A highly bitter drug may require taste masking, while a poorly water-soluble drug may require solubilisation or particle-engineering strategies.

The API should also remain chemically stable during mixing, drying, storage and administration. Drug-excipient compatibility studies are therefore important during development.

6.2 Film-forming polymers

Film-forming polymers provide the structural matrix of the formulation. They influence film formation, flexibility, tensile strength, disintegration, drug release and moisture sensitivity.

An ideal polymer should be suitable for pharmaceutical use, form a uniform film, possess acceptable mechanical properties and be compatible with the API and other excipients.

Common synthetic or semisynthetic polymers include hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), polyvinyl alcohol (PVA), polyvinylpyrrolidone (PVP) and selected grades of polyethylene oxide.

Natural or naturally derived materials include pullulan, starch, sodium alginate, gelatin and selected cellulose derivatives of natural origin. Their properties differ according to molecular weight, grade, substitution, source and processing conditions.

6.3 Plasticizers

Plasticizers improve flexibility and reduce brittleness by modifying interactions within the polymer matrix. Examples include glycerol, polyethylene glycol and propylene glycol, subject to suitability for the particular formulation.

An insufficient quantity of plasticizer may produce a brittle film, whereas an excessive quantity can produce a soft, sticky film with reduced handling strength. The optimum concentration must therefore be established experimentally.

6.4 Sweeteners and flavouring agents

Sweeteners and flavours are added to improve palatability. Examples of sweeteners include sucralose, saccharin sodium and suitable sugar alcohols. Flavour selection depends on the API, intended population and compatibility with the formulation.

Sweeteners and flavours cannot always conceal strong bitterness on their own. The effectiveness of a taste-masking system depends on the concentration of the drug released into saliva, the drug's taste threshold and the duration of oral exposure.

6.5 Saliva-stimulating agents

Certain food-grade acids, such as citric acid, may be incorporated when appropriate to stimulate salivation. Increased saliva production may support wetting and swallowing, but the effect depends on concentration, taste, tolerability and the target population.

6.6 Other excipients

Colours, surfactants, solubilising agents, preservatives and pH-adjusting agents may be used when justified. Their inclusion should be based on formulation need rather than routine addition.

All excipients must be appropriate for the intended route, dose and patient population. Excipients suitable for one product or age group are not automatically suitable for another.

7. Natural Versus Synthetic Film-Forming Polymers

Polymer selection is one of the central decisions in oral film development because the polymer matrix governs both processing and final product performance.

Natural polymers may offer advantages related to availability, biodegradability and consumer interest in naturally derived ingredients. However, their properties can vary with source, extraction and purification. Microbial quality, impurities and batch-to-batch consistency must also be considered.

Synthetic and semisynthetic polymers often provide more predictable material specifications and well-characterised formulation behaviour. Nevertheless, their suitability depends on grade, concentration, cost, regulatory status and compatibility with the drug.

Table 1: Comparison of Selected Film-Forming Polymers

Polymer	Category	Potential advantages	Important limitations
Pullulan	Microbially derived polysaccharide	Good film-forming properties and clarity	Cost and moisture sensitivity may require consideration
Starch	Natural polysaccharide	Availability and potential low cost	Film strength and flexibility may require modification
Sodium alginate	Naturally derived polysaccharide	Hydrophilic and useful in selected polymer blends	Swelling and film integrity depend on formulation conditions
Gelatin	Protein-based polymer	Film formation and flexibility under suitable conditions	Source-related variability and sensitivity to environmental conditions
HPMC	Semisynthetic cellulose derivative	Versatile film formation and established pharmaceutical use	Performance varies by viscosity grade and concentration
HPC	Semisynthetic cellulose derivative	Useful film formation and compatibility in selected systems	Grade and concentration influence mechanical behaviour
PVA	Synthetic polymer	Film strength and flexibility can be adjusted	Processing and dissolution properties depend on grade
PVP	Synthetic polymer	Hydrophilicity and use in polymer blends	Hygroscopicity and mechanical performance require assessment

Source note: This is a qualitative synthesis of polymer characteristics discussed in the oral-film literature, including Dixit and Puthli [1], Bala and colleagues [2], Salawi [3] and Jacob and colleagues [4]. It is not a universal performance ranking.

7.1 Importance of polymer blending

Combining two or more polymers can improve film properties when their individual characteristics are complementary. For example, one polymer may provide rapid hydration while another improves strength or handling.

However, polymer blending can also produce undesirable effects, including phase separation, increased drying time or altered drug release. Compatibility and performance must therefore be verified through suitable experimental studies.

7.2 A critical comparison

Natural polymers should not automatically be considered superior because of their origin, nor should synthetic polymers automatically be considered more effective. A meaningful comparison requires evidence from films prepared under comparable conditions.

Important variables include polymer concentration, molecular weight, plasticizer level, API loading, drying conditions, film thickness and storage humidity. Differences in these variables can confound comparisons between published studies.

A useful direction for future research is to compare natural and synthetic polymers using standardised evaluation methods and clearly reported formulation compositions.

8. Methods of Preparation

Several manufacturing approaches have been described for oral films. The most appropriate method depends on the polymer, drug stability, required production scale and desired film characteristics.

8.1 Solvent-casting method

Solvent casting is widely discussed as a method for preparing oral films, especially during laboratory-scale formulation development [1–4].

The general procedure involves the following stages:

1. **Preparation of the polymer solution:** The selected polymer is dispersed or dissolved in a suitable solvent system.
2. **Addition of excipients:** The plasticizer, sweetener, flavour and other compatible excipients are incorporated.
3. **Drug incorporation:** The API is dissolved or uniformly dispersed, depending on its solubility and stability.
4. **Mixing and deaeration:** The mixture is homogenised and air bubbles are reduced to minimise defects.
5. **Casting:** A measured quantity of the mixture is spread over a suitable flat surface.
6. **Drying:** Solvent is removed under controlled conditions.

7. **Peeling and cutting:** The dried film is removed and divided into units of the intended dimensions.
8. **Packaging:** Films are packed in protective packaging appropriate to their stability requirements.

Advantages: The process is relatively straightforward, allows formulation variables to be adjusted and is suitable for preparing films for laboratory evaluation.

Limitations: Drying can be time-consuming, residual solvent must be controlled where relevant, and uneven casting may cause thickness variation or nonuniform drug distribution.

8.2 Hot-melt extrusion

Hot-melt extrusion involves processing compatible materials through a heated extruder to form a continuous film or related dosage structure. It may reduce or eliminate the need for a casting solvent.

The method can be useful for suitable thermoplastic polymers and may support continuous production. However, the API and excipients must tolerate the processing temperature and mechanical stress. Thermal degradation and changes in the physical state of the drug require particular attention.

8.3 Semisolid casting

In semisolid casting, a suitable polymer-containing mass is prepared and spread as a layer before drying or further processing. This approach may be useful for selected formulations, but viscosity control, layer uniformity and drying behaviour can complicate production.

8.4 Printing-based manufacturing

Printing technologies can deposit measured quantities of formulation material in predefined patterns. Depending on the method, they may support personalised dimensions, drug loading or multilayer structures.

Three-dimensional printing has been identified as an emerging area in the oral-film literature [4]. However, printer compatibility, material viscosity, drying, dose uniformity, production speed and regulatory requirements remain important considerations.

Table 2: Comparison of Preparation Methods

Method	Main advantage	Main limitation
Solvent casting	Accessible and suitable for formulation screening	Drying and solvent-control requirements
Hot-melt extrusion	Potential for continuous production	Heat-sensitive ingredients may be unsuitable
Semisolid casting	Useful for selected viscous formulations	Uniform spreading and drying may be challenging
Printing-based methods	Potential for customisation and multilayer designs	Equipment, material and validation requirements

9. Evaluation Parameters of Fast-Dissolving Oral Films

Evaluation is necessary to establish whether a formulation has suitable physical integrity, dose uniformity, drug-release behaviour and stability. No single test is sufficient to establish overall product quality.

Specific methods and acceptance criteria should be justified for the formulation and intended use. The following tests are commonly discussed in the literature [2–5].

9.1 Physical appearance

Films are visually examined for colour uniformity, transparency or opacity, smoothness, cracks, air bubbles, visible particles and other defects.

A uniform appearance may indicate satisfactory casting and drying, but visual inspection cannot confirm chemical stability or drug content uniformity.

9.2 Thickness

Thickness is measured at multiple locations using an appropriate thickness gauge or micrometer. The mean and variation between measurements are recorded.

Consistent thickness supports reproducible handling and can help reduce variability in dose when the drug is distributed uniformly throughout the film. Thickness alone, however, does not establish dose uniformity.

9.3 Weight variation

Individual films of defined dimensions are weighed, and the mean weight and variability are calculated.

Weight variation can help identify inconsistent casting or cutting. It is an indirect quality indicator and should not replace a drug content assay.

9.4 Folding endurance

Folding endurance assesses the ability of a film to withstand repeated folding under a defined procedure before breaking.

The test is commonly used during formulation screening to compare flexibility. However, the result depends on the folding method, sample dimensions, film thickness and operator technique. A standardised procedure is therefore important.

9.5 Tensile strength and percentage elongation

Mechanical testing measures how a film responds to applied force.

Tensile strength describes the stress a film withstands before failure, while percentage elongation indicates its extension relative to its original length. Young's modulus may also be used to characterise stiffness.

These measurements provide more quantitative information about mechanical behaviour than folding endurance alone. Their relevance is particularly high when films must withstand manufacturing, packaging and handling.

9.6 Surface pH

Surface pH is assessed by contacting the film with a small amount of suitable aqueous medium and measuring the pH using an appropriate method.

The purpose is to identify formulations that may cause undesirable local irritation. A surface-pH measurement is a screening tool rather than a complete assessment of oral safety or tolerability.

9.7 Drug content and content uniformity

Drug content is determined using a validated analytical method appropriate to the API, such as UV-visible spectrophotometry or high-performance liquid chromatography.

A defined film unit or representative sample is extracted, and the amount of drug is quantified. Content uniformity is especially important when each film represents a single dose.

Uniform thickness and weight do not guarantee uniform drug distribution. Drug content must be evaluated directly using a suitable method, with appropriate analytical validation and acceptance criteria.

9.8 Disintegration time

Disintegration time measures the period required for a film to break apart or lose its structural integrity under defined test conditions.

The result depends on the testing apparatus, liquid volume, temperature, agitation and the operational definition of disintegration. Consequently, results from different studies may not be directly comparable unless their methods are similar.

Published reviews report different proposed targets and test procedures for oral films. Jacob and colleagues discuss generic quality attributes, including disintegration and dissolution, while other reviews highlight limitations in harmonised testing requirements [4,5].14 Nov 2026

A single universal disintegration limit should not be assumed to apply to every film. The specification should reflect the product's intended use, relevant compendial or regulatory expectations and the validated test method.

9.9 In vitro dissolution

Dissolution testing evaluates the release of the API into a defined liquid medium over time. Samples are collected at predetermined intervals and analysed using an appropriate analytical method.

The percentage of drug released can be calculated as:

Percentage drug released = (Amount of drug released / Total drug content) × 100

Dissolution profiles help compare formulations and assess the influence of polymers, plasticizers and other excipients on drug release.

Rapid disintegration does not necessarily mean complete or rapid drug dissolution. The drug may have poor aqueous solubility, or the formulation may contain components that delay its release.

9.10 Moisture content and moisture uptake

Moisture content can influence flexibility, brittleness, stickiness and stability. It may be measured using a validated loss-on-drying method or a suitable moisture-analysis technique.

Moisture uptake can be studied by exposing films to controlled humidity and determining the change in weight. The results help identify packaging requirements and potential storage risks.

9.11 Stability studies

Stability studies evaluate changes in appearance, drug content, degradation products, moisture, mechanical properties and dissolution over time under specified storage conditions.

Study design should be appropriate to the product, packaging and applicable regulatory requirements. Accelerated studies can help identify potential weaknesses, but they do not automatically replace long-term stability data.

Table 3: Evaluation Parameters and Their Significance

Parameter	Purpose	Main interpretation
Appearance	Identify visible defects	Supports physical quality assessment
Thickness	Measure dimensional consistency	Helps assess film uniformity
Weight variation	Compare unit weights	Detects casting or cutting variability
Folding endurance	Assess flexibility	Screens resistance to repeated folding
Tensile strength	Measure resistance to applied stress	Characterises mechanical strength
Surface pH	Screen potential local pH concerns	Supports formulation suitability assessment
Drug content	Quantify API in a sample	Assesses assay and dosage accuracy
Content uniformity	Assess drug distribution between units	Supports dose consistency
Disintegration time	Measure loss of film integrity	Evaluates rapid breakdown under defined conditions
Dissolution	Measure drug release into a medium	Characterises release performance
Moisture studies	Evaluate water-related changes	Supports packaging and stability decisions
Stability studies	Assess quality over time	Supports shelf-life determination

10. Taste-Masking Strategies

Taste is a major factor affecting acceptability, particularly for drugs with pronounced bitterness. Since oral films disintegrate directly in the mouth, the formulation may expose the taste buds to the drug before swallowing.

Taste masking should therefore be considered during early formulation design rather than added only after other characteristics have been optimised.

10.1 Sweeteners and flavours

Sweeteners and flavours are simple approaches for improving palatability. They can reduce the perception of unpleasant taste but may be insufficient for strongly bitter drugs.

Their selection should account for the intended patient population, dose, taste profile and stability.

10.2 Polymer-based taste masking

Selected polymer coatings or matrices can reduce the immediate release of a bitter API in saliva while allowing release under subsequent conditions. The system must be designed carefully so that taste masking does not unacceptably delay drug availability.

10.3 Complexation

Complexation with suitable agents, such as cyclodextrins in appropriate formulations, can alter the availability of a drug for interaction with taste receptors. Whether complexation is effective depends on the drug, complexing agent, binding behaviour and formulation conditions.

10.4 Ion-exchange resins and encapsulation

For compatible drugs, ion-exchange resins or encapsulation techniques may reduce the amount of free drug released in the oral cavity. These approaches may improve palatability but can increase formulation complexity and require additional characterisation.

10.5 Assessment of taste masking

Taste masking should be evaluated using a scientifically and ethically appropriate approach. Potential methods include validated instrumental techniques, drug-release testing in simulated saliva and, where permitted and justified, controlled human taste assessment.

Instrumental testing can support formulation development but cannot fully reproduce human taste perception. Human testing requires appropriate ethical approval and safeguards.

11. Recent Advances in Fast-Dissolving Oral Films

Recent reviews describe several directions for improving oral-film formulation, manufacturing and product quality [3–5].

11.1 Quality by design

Quality by design (QbD) provides a structured approach to product development. It begins with defining the target product profile and identifying critical quality attributes, material attributes and process parameters.

Design-of-experiments methods can help investigate interactions between formulation variables. This approach may improve understanding and reproducibility, although its usefulness depends on appropriate experimental design and data analysis.

11.2 Three-dimensional printing

Three-dimensional printing offers potential for preparing films with customised dimensions, multilayer structures or different drug distributions. Jacob and colleagues identify printing as one of the emerging developments in orodispersible film technology [4].

11.3 Nanotechnology-assisted films

Nanoparticles and other nanoscale carriers may be incorporated into films to modify drug solubility, stability or release. This strategy may be useful for selected poorly soluble or sensitive compounds.

However, the incorporation of nanoparticles introduces additional questions concerning particle distribution, aggregation, excipient compatibility, safety and release behaviour. Claims of enhanced bioavailability require appropriate experimental and clinical evidence rather than relying solely on improved in vitro dissolution.

11.4 Natural polymer-based formulations

Interest in naturally derived materials has encouraged research into polysaccharides and other biopolymers for oral films.

Potential benefits include availability and opportunities to modify film properties through polymer blending. However, natural origin does not establish pharmaceutical suitability. Batch consistency, microbial quality, impurities, stability and performance must be evaluated.

11.5 Patient-centred formulation development

Patient acceptability depends on more than rapid disintegration. Film size, taste, texture, ease of removal from packaging and suitability for the intended patient group can all influence use.

Research should therefore evaluate patient-related outcomes where feasible, rather than assuming that a formulation with favourable laboratory properties will necessarily improve adherence.

11.6 Improved manufacturing and packaging

Process control, reproducible drying, automated cutting, in-line inspection and protective unit packaging may improve product consistency.

Moisture-barrier packaging is particularly relevant for films that absorb water from the environment. Packaging selection should be supported by stability data rather than determined only by appearance or cost.

12. Challenges and Future Perspectives

Despite the potential benefits of fast-dissolving oral films, several technical and scientific issues remain.

Drug loading: The small dimensions of a film can limit the amount of API that can be incorporated without compromising thickness, taste or mechanical integrity.

Stability: Moisture, temperature, light and interactions between ingredients may affect physical properties or chemical integrity. Appropriate packaging and stability studies are essential.

Standardisation: Differences in disintegration methods, dissolution conditions, sample dimensions and mechanical testing can make direct comparison between studies difficult.

Scale-up: A formulation that performs well in a small laboratory batch may behave differently during continuous manufacturing. Drying uniformity, casting speed, cutting accuracy and process control become increasingly important at larger scales.

Clinical relevance: Laboratory improvements in disintegration or dissolution do not automatically establish faster clinical onset, improved bioavailability or better adherence. These outcomes require suitable evidence.

Future research could address these limitations through standardised test methods, comparative polymer studies, improved taste masking, validated

manufacturing controls and stronger links between in vitro performance and clinical outcomes.

A particularly useful research direction is a structured comparison of natural and synthetic film-forming polymers. Studies should report polymer grade, concentration, plasticizer content, API loading, manufacturing conditions, film dimensions and test procedures. Reporting these details would improve reproducibility and help determine whether observed differences are attributable to polymer type or other formulation variables.

13. Critical Discussion

The available literature establishes fast-dissolving oral films as a versatile dosage-form platform, but the evidence must be interpreted carefully.

First, the advantage of administration without water is clear as a practical formulation characteristic. However, improved patient adherence should be demonstrated for the intended product and population rather than assumed from convenience alone.

Second, polymer selection involves a balance between mechanical integrity and rapid disintegration. A highly flexible film may become sticky, while a strong film may hydrate too slowly. The optimal formulation is therefore not necessarily the one with the highest value for a single evaluation parameter.

Third, taste masking can improve acceptability but may interfere with release if the drug is retained too strongly in the formulation. Formulation studies should assess palatability alongside disintegration, dissolution and drug content.

Fourth, recent manufacturing approaches such as printing may enable customisation, but their practical value depends on reproducibility, throughput, material compatibility and regulatory requirements. Conventional solvent casting remains a relevant method for initial formulation screening.

Finally, published research would be more comparable if common evaluation methods and reporting practices were adopted. Standardisation would strengthen the evidence base and support more meaningful comparisons between natural and synthetic polymers.

These observations suggest that future oral-film development should focus on a balanced set of critical quality attributes rather than maximising rapid disintegration in isolation.

CONCLUSION

Fast-dissolving oral films represent a promising dosage-form approach for delivering selected medicines conveniently without the need for water. Their performance depends on the compatibility of the API with the polymer matrix, appropriate excipient selection, controlled manufacturing and comprehensive quality evaluation.

Natural and synthetic film-forming polymers both offer useful formulation possibilities, but neither category is universally superior. Polymer selection must be based on mechanical strength, flexibility, hydration, drug-release characteristics, stability, reproducibility and pharmaceutical suitability.

Solvent casting remains an accessible method for laboratory-scale development, while hot-melt extrusion and printing technologies offer additional manufacturing possibilities for suitable formulations. Evaluation should include physical, mechanical, pharmaceutical and stability characteristics, with drug content uniformity and dissolution being particularly important for establishing dosage-form quality.

Taste masking, quality-by-design methods, nanotechnology and patient-centred design are important areas of continuing development. Nevertheless, claims regarding improved bioavailability, faster therapeutic action or increased adherence require appropriate evidence.

Overall, further research using standardised evaluation methods and carefully controlled comparisons of natural and synthetic polymers could improve the reproducibility, quality and practical applicability of fast-dissolving oral films.

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