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Fast-Dissolving Oral Thin Films – A Review

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ABSTRACT

Orodispersible films are also known as fast-dissolving oral films, are thin polymeric dosage forms designed to disintegrate or dissolve rapidly in the mouth, usually without water. After placement on the tongue or oral mucosa, saliva wets the film and hydrates its polymer matrix, allowing it to break and release the active pharmaceutical ingredient (API). Depending on the formulation and intended route, the released drug may be swallowed or absorbed through the buccal or sublingual mucosa. Orodispersible films performance depends on API dose, solubility, stability, taste, polymer selection, plasticizer concentration, manufacturing method and packaging. Common preparation methods include solvent casting, semisolid casting, hot-melt extrusion, coating or spraying, and emerging additive-manufacturing approaches. Evaluation generally covers appearance, thickness, mass variation, mechanical strength, surface pH, drug content and uniformity, disintegration, dissolution, microbial quality where applicable, and stability. Although Orodispersible films can improve convenience for selected people who have difficulty swallowing or need a dosage form that does not require water, they are not suitable for every drug. High-dose APIs, poor drug solubility, processing sensitivity, dose-uniformity challenges and specialised packaging can limit development. This review summarises the terminology and classification of Orodispersible films, formulation ingredients, API selection considerations, manufacturing technologies, critical quality attributes, evaluation approaches, applications, advantages, limitations and recent advances. Emphasis is placed on matching film design to the drug's properties and intended release route, while applying risk-based development and quality-by-design principles to support consistent, stable and acceptable products in appropriate, evidence-based clinical contexts when clinically appropriate.

Keywords: Orodispersible film; fast-dissolving film; mouth-dissolving film; hot-melt extrusion; quality by design; patient-centric drug delivery.

INTRODUCTION

Orodispersible films are thin, flexible polymer-based dosage forms designed to disintegrate or dissolve rapidly in the mouth, generally without water. On contact with saliva, the film hydrates and its polymer matrix breaks down, making the active pharmaceutical ingredient (API) available for swallowing or, when specifically designed, absorption through the oral mucosa. Orodispersible films are being developed as alternatives to conventional tablets and capsules because they can be portable and easy to administer. They may be useful for selected children, older adults and people who have difficulty swallowing solid medicines. Their unit-dose presentation can help when water is unavailable. However, convenience alone does not establish clinical superiority: suitability depends on the drug's dose, solubility, stability, taste and intended route. Rapid film disintegration does not necessarily mean faster drug dissolution or increased bioavailability. Formulation development must balance rapid disintegration with adequate mechanical strength. A film must withstand manufacture, cutting, packaging, transport and handling, yet hydrate in the mouth. Polymer type and concentration, plasticizer level, drug particle properties, sweeteners, flavours, saliva-stimulating agents and tastemasking systems influence performance. Moisture sensitivity, dose uniformity, unpleasant taste, limited drug-loading capacity and packaging needs are common challenges. Research explores solvent casting, hot-melt extrusion, multilayer films and three-dimensional printing. Evaluation extends beyond appearance and disintegration to drug content, content uniformity, mechanical properties, dissolution, stability and patient acceptability. Quality-by-design principles can help identify critical material attributes and process parameters. Orodispersible films offer a versatile patient-focused platform, but reliable products require sound formulation, validated manufacturing, quality controls and performance assessment[1].

Historical Development and Terminology

Fast-dissolving dosage forms became alternatives to traditional oral solid dosage forms toward the end of the twentieth century. In the early stages, a lot of effort was put into developing orally disintegrating tablets. Later, thinner films and strips were created, which offered the same ease of use but with fewer issues like tablets breaking apart or being hard to swallow. The review articles show how this development has taken place and point out that oral thin films are a newer type of fast-acting oral medication[2].

Terms like oral thin film (OTF), fast-dissolving oral film (FDOF), fast-dissolving film, mouthdissolving film, oral dissolving film, oral disintegrating film, and orodispersible film are often used in similar or overlapping ways. In this review, the term Orodispersible films is used as a general term, while FDOF and OTF are used when talking about the quick-dissolving or thin-film features specifically[3].

An important difference is between films meant mostly to break down and let the medicine go down for swallowing, and films made to stay in the mouth or under the tongue. The latter might purposely include mucoadhesive polymers and can be designed to stay in contact with the mucosa for a longer time. So, film design should start by clearly knowing the therapy route and the desired product features, not just focusing on how it's made[4].

Rationale and Need for Orodispersible Films

The main reason for developing Orodispersible films is to make it easier to give oral medicine. Conventional tablets and capsules need to be swallowed and usually require water. This can make traveling more troublesome and may be hard for people who have trouble swallowing. Orodispersible films can be taken without needing a glass of water, making them a useful option for certain patients[5].

Rapid breakdown can also be helpful when you need the effect to start quickly. The mouth creates a wet area where a thin, water-loving layer can quickly absorb moisture. A dissolved part can be swallowed, and some medicines with the right physical and chemical features might be absorbed through the mouth lining. The degree to which a drug is absorbed into the body can vary depending on the specific drug and how it's made, and you can't just assume it will be better just because it dissolves quickly[6].

Another rationale is dose-form differentiation. A films can give a strong, properly made single dose while also providing the feeling and way it is given of a liquid or something that breaks apart quickly. It can also be made into a small, portable device that cuts down on the need for extra tools used with certain liquid mixes[7].

From a development point of view, films offer a versatile way to mix polymers, plasticizers, tastemasking ingredients, sweeteners, and other useful additives. This flexibility is an advantage, but it also means there are more factors that need to be managed when creating a formula[8].

Applications

Orodispersible films have several potential applications, depending on the active ingredient, dose, stability, taste and intended release profile.

1. Systemic drug delivery: Selected low- or moderate-dose medicines used for pain, allergies, nausea, cough and cold symptoms, gastrointestinal disorders and some central nervous system conditions may be formulated as Orodispersible films. Rapid disintegration alone does not guarantee faster onset or higher bioavailability.

2. Local oral delivery: Buccal or mucoadhesive films can maintain contact with oral mucosa for local treatment.

3. Sublingual delivery: Films placed under the tongue may support mucosal absorption of suitable drugs; this differs from films that simply disintegrate and are swallowed.

4. Nutraceutical and emerging applications: Research includes selected herbal extracts, nutraceuticals, probiotics and vaccine-related formulations. These remain formulation-dependent research areas and require evidence of compatibility, stability, dose accuracy and quality.

5. Patient-centred use: Orodispersible films may be convenient for selected children, older adults and people with swallowing difficulties, or when water and portability are concerns. Handling ability, prescribed dose, excipient safety, taste and clear administration instructions must be considered[9,10,11].

Advantages

1. Administration without water: Orodispersible films can be taken without a glass of water, improving convenience during travel or when water is not readily available.

2. Easier administration: The thin dosage form may be easier to take than conventional tablets or capsules for selected patients who experience swallowing difficulties.

3. Potential improvement in acceptability: Small size, rapid disintegration, and the option to add sweeteners and flavours may improve the user experience when the formulation is well designed.

4. Unit-dose convenience: Each correctly manufactured film can contain a defined dose, avoiding the measuring step needed for many liquid medicines.

5. Portability and discreet use: Films are lightweight, compact, and generally easy to carry. 6. Rapid wetting and disintegration: The large surface-area-to-volume ratio can support rapid contact with saliva, although it does not guarantee faster dissolution or greater absorption of every drug.

7. Formulation flexibility: Polymer blends, plasticizers, taste-masking systems, and multilayer designs can be selected to tailor film properties and drug release.

8. Multiple delivery designs: Depending on the active pharmaceutical ingredient and intended site, films can be designed for immediate release, local oral action, buccal or sublingual delivery, or selected modified-release applications.

9. Potential for dose personalisation: Printing and other advanced manufacturing methods may enable customised doses or multilayer designs in specialised settings, although validation and regulatory requirements remain important.

10. Avoidance of some tablet-related problems: Films do not require tablet compression and may avoid tablet breakage or friability issues; however, films have their own mechanical and moisture.

related limitations[12,13,14.]

Disadvantages

1. Limited drug-loading capacity: The thin film has limited space for drug, so high-dose medicines may be difficult to formulate without making the film thick or uncomfortable.

2. Moisture sensitivity: Films may absorb moisture and become sticky or soft, while excessive drying can make them brittle; suitable packaging and storage are important.

3. Taste-masking difficulties: Bitter or unpleasant-tasting drugs can reduce acceptability, and tastemasking must not interfere with drug release.

4. Mechanical fragility: Films may tear, crack, fold, or stick during manufacture and handling if their polymer and plasticizer balance is not appropriate.

5. Drug-selection constraints: Poorly water-soluble drugs may dissolve slowly even when the film disintegrates quickly, and some drugs may be unsuitable for heat- or solvent-based processes.

6. Dose-uniformity challenges: Drug settling, uneven coating, variable thickness, and cutting errors can cause differences in the amount of drug in individual films.

7. Packaging and manufacturing costs: Individual high-barrier packaging and specialised equipment may increase production costs, particularly for advanced manufacturing methods.

8. Need for extensive evaluation: Content uniformity, disintegration, dissolution, mechanical properties, stability, and acceptability must be checked; Orodispersible films are not automatically better than tablets or liquids for every medicine[15,16.]

Classification and Routes of Oral Film Delivery

A. Classification by route of administration.

1. Oral-cavity fast-disintegrating films: Placed on the tongue, these films break down rapidly and are generally swallowed with saliva.

2. Buccal films: Placed against the inner cheek; they may provide local action or allow drug absorption through the buccal mucosa.

3. Sublingual films: Placed under the tongue for selected drugs that can be absorbed through the sublingual mucosa[17,18.]

B. Classification by function and release behaviour.

1. Immediate-release films: Disintegrate quickly and release the drug for swallowing.

2. Mucoadhesive films: Contain polymers that help the film adhere to oral mucosa for longer contact.

3. Sustained-release films: Designed to release drug over an extended period at the intended site.

4. Taste-masked films: Use sweeteners, coatings, complexes or encapsulation to reduce unpleasant taste.

5. Multilayer or bilayer films: Separate incompatible ingredients or combine layers with different functions or release profiles.

The selected route and class determine polymer choice, film thickness, drug loading, residence time, release profile and sensory properties. A rapidly disintegrating film therefore requires a different design from a mucoadhesive film intended to remain in place[19,20.]

Table 1. Classification of orodispersible films by route and function

Basis of classification	Type of film	Description / key feature
Route of administration	Oral-cavity fast-disintegrating film	Placed on the tongue; rapidly disintegrates and is generally swallowed with saliva.
Route of administration	Buccal film	Placed against the inner cheek; intended for local action and/or absorption through buccal mucosa.
Route of administration	Sublingual film	Placed under the tongue to support mucosal absorption of suitable drugs.
Release behaviour	Immediate-release film	Disintegrates rapidly and releases drug for swallowing or subsequent absorption.
Release behaviour	Mucoadhesive film	Uses mucoadhesive polymers to prolong contact with oral mucosa.
Release behaviour	Sustained-release film	Designed to release drug over an extended period at the intended site.
Special formulation design	Taste-masked film	Uses sweeteners, coatings, complexation or encapsulation to reduce unpleasant taste.
Special formulation design	Bilayer / multilayer film	Separates incompatible ingredients or combines layers with different functions or release profiles.

Biopharmaceutical and API Selection Considerations

1. Choosing the right API is one of the first and most important decisions when building an Orodispersible films. Traditional fast-dissolving films work best for medicines that have small or medium amounts because the film isn't very big and needs a lot of polymer and other inactive ingredients. Some studies say that high drug amounts can be reached, but there are still limits on how much can be safely given[21.]

2. Water solubility is an important factor because even if a film breaks down quickly, it doesn't mean the drug will dissolve fast if it doesn't mix well with water. If the API stays hard and doesn't get wet well, the medicine might break apart too fast, but the drug might not dissolve quickly enough. So, methods like using amorphous solid dispersions, making cyclodextrin complexes, reducing

particle size to nanoscale, adding surfactants, and choosing the right salt form can be useful when the drug's properties support these approaches[22].

3. Other important features to consider are the dose, melting point, particle size, how much it absorbs moisture, its pKa value, logP value, how stable it is chemically, different crystal forms it can take, its taste, how well it works with polymers, and how it reacts to heat or organic solvents. Some medicines have a bad taste that can be unpleasant or annoying.This happens because the drug touches the taste buds before it is swallowed, which can make it feel worse[23].

4. A good preformulation process should look at how the active ingredient and other ingredients interact, find out the right amount of medicine needed for each film, check how well the medicine dissolves in the right liquid, test the taste, and figure out how the system reacts to heat and humidity before choosing how to make the product[24].

Composition of Orodispersible Films

An Orodispersible films is a multicomponent matrix. The film-forming polymer gives the structure; plasticizers make it more flexible; sweeteners and flavors make it taste better; saliva-stimulating agents help with wetting; surfactants can help with wetting or spreading; fillers and processing aids change how it is handled; and taste-masking agents reduce the API's contact with taste receptors[25].

Each component's level needs to be carefully adjusted for the best result, not just pushed to the highest possible amount. Too much polymer can make the product thicker, stickier, and take longer to break apart. Too much plasticizer can make the film sticky or not strong enough. Too much sweetener or flavor can change how something feels in your mouth, how concentrated it is, or how well it stays the same over time. So, the makeup of a formulation needs to be seen as a balanced system where key quality features can be measured[26].

Table 2. Major formulation components used in Orodispersible films

Component	Examples	Primary function	Important considerations
Film-forming polymer	HPMC, HPC, pullulan, PVA, NaCMC, maltodextrin, pectin, gelatin	Forms continuous film matrix; controls hydration and release	Grade, molecular weight, viscosity, concentration, compatibility
Plasticizer	Glycerol, propylene glycol, PEG	Improves flexibility and reduces brittleness	Excess may cause tackiness or lower strength
Sweetener	Sucrose, sorbitol, xylitol, high-intensity sweeteners	Reduces bitterness and improves palatability	Taste profile, dose, stability, oral tolerance
Flavour	Mint, fruit flavours, vanillin-type flavours	Improves sensory acceptance	Compatibility and masking efficiency
Surfactant	Polysorbates and suitable surfactants	Improves wetting/dispersibility	Taste, foaming, compatibility
Saliva stimulant	Selected organic acids	May promote wetting and saliva secretion	pH and mucosal tolerability
Taste-masking agent	Polymer coating, cyclodextrin, microencapsulation	Reduces drug exposure to taste receptors	Must not compromise intended drug release
API	Low/moderate-dose drug	Provides therapeutic activity	Dose, solubility, stability, bitterness, dose uniformity

Film-Forming Polymers

Film-forming polymers are the main structural ingredients in Orodispersible films. Hydrophilic polymers are very helpful because they quickly react with saliva and can create a smooth, continuous film. Materials that are often talked about include hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), pullulan, polyvinyl alcohol (PVA), sodium carboxymethyl cellulose, maltodextrin, starch derivatives, alginates, pectin, and gelatin[27].

HPMC is commonly used because it can create clear and flexible films, and it comes in various types. The thickness of the solution, how thick the film forms, how strong it is, and how it breaks apart all depend on its viscosity grade. Pullulan is appreciated because it can form films and dissolve quickly, but its cost and how well it holds up physically might influence how often it is used. Pectin and cellulose derivatives offer chances for making natural or semi-synthetic products, but they can create different feelings in the mouth and change how they break down in the body based on their size and how much they've been altered[28].

Polymer blending is often used when one type of polymer isn't able to offer the right mix of strength, flexibility, and quick hydration. A tougher polymer can be mixed with a quicker-dissolving polymer, and a natural polymer can be combined with a synthetic or semi-synthetic polymer to make things easier to process. It's important to check how well the materials work together and how they behave when mixed, because the way the polymers interact can greatly affect the structure of the final film[29].

Natural polymers are appealing because they are easy to get and people generally think they are safe for the body. However, they can differ between batches, be sensitive to microbes, and have inconsistent molecular weights. Synthetic and semi-synthetic polymers can offer more reliable performance in pharmaceutical applications. The final decision should be made based on clear quality standards instead of whether an excipient is natural or man-made[30].

Plasticizers and Other Functional Excipients

Plasticizers make the molecules in a polymer chain less sticky to each other and help the material become more flexible. Plasticizers that are often talked about are things like glycerol, propylene glycol, polyethylene glycol, and some materials that are based on citrate. Their focus influences how strong something is when stretched, how much it can stretch before breaking, how well it holds up when folded, how sticky it feels, and how much water it can absorb[31].

Sweeteners are often used because many APIs have a bitter taste. Sugars and polyols, along with high-intensity sweeteners, can be chosen based on the amount needed, the flavor they provide, and how well they hold up under different conditions. Flavouring agents are added to help balance the sweetener and make the bitterness less noticeable. Certain acids that help increase saliva can make a medicine dissolve faster and feel like it's working quicker, but these acids need to be safe to use with the active medicine and the mouth[32].

Surfactants can help water spread better on drugs that don't mix well with water and can also spread hydrophobic particles more evenly. Surfactant levels need to be kept in check because they can influence taste, foaming, how films look, and the physical strength of materials. Other ingredients might also be added, such as colorings, substances that prevent oxidation, materials that help maintain the right pH level, substances that keep the product safe for longer, and materials that fill space, depending on the mix and purpose of the product[33].

Taste Masking and Palatability

Taste plays a big role in how acceptable an Orodispersible films is because the form stays in the mouth while it breaks down. A strong medicine that works well in a regular tablet might not be good enough when taken as an orally disintegrating tablet because it could dissolve too quickly in the mouth. Reviews often point out that hiding the taste is a major problem when making the formula[34].

Taste masking can be done in different ways. One way is to use sweeteners and flavors. Another is to coat the drug with a polymer or to put it into tiny capsules. You can also mix the drug with other substances to hide its taste. Some methods involve changing the pH or using materials that don't dissolve easily. Additionally, the active ingredient can be added to small particles before making the final product. The choice of selection is based on the API dose, how well it dissolves, the desired way it releases, and the manufacturing conditions[35].

An important rule is that taste masking should not stop the drug from working once it is swallowed. A good system makes sure that not much drug is present in saliva while it's in the mouth for a short time, but it lets the drug release properly when it reaches the stomach or the right lining in the body. So, taste masking needs to be checked along with dissolution, and if needed, also with how well the medicine works in the body[36].

Palatability evaluation may involve using trained people to taste and assess, electronic devices that detect taste, and laboratory tests that check how taste is hidden. Patients or end-users should be taken into account during development because a good taste, smooth texture, how it feels in the mouth, the size of the film, and how easy it is to handle can all affect how well people stick to using the product in real life[37].

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Manufacturing Technologies

Solvent casting is the most commonly used method for preparing Orodispersible films in both laboratory and industries. In a usual process, the polymer is mixed or spread in a proper solvent, other ingredients are added, the active substance is included while mixing carefully, air is removed from the mixture, the liquid is spread to a certain thickness, the solvent is taken out by drying, and the final sheet is divided into individual doses[38].

The quality of a cast film is greatly influenced by factors like the thickness of the solution, how much solid material is in it, how well the ingredients are mixed, the space between the casting tools, the temperature used to dry the film, how long it is dried, the movement of air, and the properties of the material being used as a base. Trapped air can cause problems and lead to uneven distribution of the dose. Uneven drying can cause differences in thickness and create stress inside the material. So, moving from small-scale experiments in a beaker or lab casting plate to a continuous process needs a deep understanding of the process, not just bigger equipment[39].

Semisolid casting can be used with mixtures that make a proper gel or paste. Hot-melt extrusion (HME) doesn't require removing volatile solvents, making it a good option for APIs and polymers that can withstand heat. However, high temperatures and shear forces can lead to material breakdown or changes in the solid state, which is why it's important to study how materials react to heat[40].

Spraying and other methods of applying materials can form thin films with controlled layers. These methods could be helpful when it's possible to achieve accurate low doses and even spread of the dose. Printing techniques have also been looked into for making custom dosages and multi-layer designs[41].

1. General mechanism of an orodispersible film

FILM PLACED IN ORAL CAVITY
↓
SALIVA WETTING AND HYDRATION
↓
POLYMER SWELLING / MATRIX BREAKDOWN
↓
DISINTEGRATION + DRUG DISSOLUTION
↓
SWALLOWING AND/OR OROMUCOSAL ABSORPTION
↓
LOCAL OR SYSTEMIC THERAPEUTIC EFFECT

2. General manufacturing workflow

API + POLYMER + EXCIPIENTS
↓
PREFORMULATION / COMPATIBILITY ASSESSMENT
↓
PREPARATION OF POLYMER SOLUTION OR MELT
↓
API INCORPORATION + MIXING + DEAERATION
↓
CASTING / EXTRUSION / DEPOSITION
↓
DRYING OR COOLING
↓
FILM SHEET INSPECTION
↓
CUTTING INTO UNIT DOSES
↓
INDIVIDUAL HIGH-BARRIER PACKAGING
↓
FINISHED PRODUCT TESTING

3. Quality-by-design workflow for Orodispersible films development

QUALITY TARGET PRODUCT PROFILE (QTPP)
↓
IDENTIFY CRITICAL QUALITY ATTRIBUTES (CQAs)
↓
IDENTIFY MATERIAL ATTRIBUTES + PROCESS PARAMETERS
↓
RISK ASSESSMENT / FMEA / ISHIKAWA
↓
DESIGN OF EXPERIMENTS (DoE)
↓
DEFINE DESIGN SPACE + CONTROL STRATEGY
↓
PROCESS VALIDATION / CONTINUOUS MONITORING
↓
ROBUST FINISHED PRODUCT

Table 3. Comparison of major manufacturing methods

Method	Principle	Advantages	Limitations	Best suited for
Solvent casting	Polymer solution/dispersion is cast and dried	Simple, flexible, widely used, good film quality	Drying time; solvent/moisture control; scale-up issues	Most immediate release Orodispersible films
Semisolid casting	Gel/paste is spread and dried	Useful for viscous systems	Thickness control and drying can be difficult	Selected polymeric matrices
Hot-melt extrusion	Thermoplastic polymer/API mixture is processed without solvent	Solvent-free, continuous potential, useful for solid dispersions	Heat/shear stress; thermal stability required	Thermally stable APIs and polymers
Spraying/deposition	Formulation is deposited in thin layers	Potential for layer control	Uniformity and equipment complexity	Low-dose and specialized systems
3D printing	Digital deposition creates defined geometry/layers	Personalization, multilayer and complex designs	Equipment, validation, scale and regulatory challenges	Personalized or advanced films

Emerging Manufacturing and Drug-Loading Technologies

Three-dimensional printing is one of the most important new technologies that has been talked about in recent Orodispersible films reviews. Printing could allow for custom doses, intricate shapes, layered structures, and keeping mixed ingredients separate when they don't work well together. This method could be useful for personalised medicine and for creating polypill-like treatments[42].

Hot-melt extrusion is another way to mix poorly soluble drugs with polymer materials and make films without using any solvents. Amorphous solid dispersions form when the drug and polymer mix well together and the process is carefully managed. The main risks during development include thermal degradation, leftover crystallinity, changes in the polymer's molecular weight, and not having good control over how long the material stays in the system[43].

Nanoparticles, nanocrystals, cyclodextrin complexes, and lipid-based carriers can be added to films to help drugs spread better or dissolve more easily. These systems make the process more complicated and need extra testing to check things like particle size, how particles stick together, how evenly the ingredients are spread, and how the product releases its active parts over time[44].

Multilayer and bilayer films can separate incompatible APIs or combine immediate and modified release. They also allow for the physical separation of the taste-masking layers from the layers that contain the drug. The review articles mention that using multiple layers is a promising approach for handling active ingredients that don't work well together[45].

Critical Quality Attributes and Evaluation

The evaluation of the Orodispersible films must show that the final product meets all the required physical, mechanical, chemical, biopharmaceutical, and sensory characteristics. Common tests include checking appearance, measuring thickness, looking at weight differences, checking drug content, ensuring content is uniform, testing how well it holds up when folded, measuring how much force it can handle before breaking, checking how much it stretches, testing the pH of the surface, measuring moisture levels, seeing how quickly it breaks apart, checking how well it dissolves, measuring how much it swells, and testing how well it sticks to mucous membranes if applicable, along with stability[46].

Thickness and mass differences offer easy ways to check how consistent the manufacturing process is. However, they cannot replace testing for purity and consistency because the way medicine is spread out can change due to settling, clumping, or layers forming when it dries. Therefore, dose uniformity should be directly evaluated[47].

The pH of the surface is important for films that are meant to touch the inside of the mouth. A formula that is too sour or too bitter on the surface can cause discomfort or not be well received. Moisture content affects how flexible, sticky, strong, and stable something is. Hygroscopic films may require high-barrier packaging[48].

Table 4. Common evaluation parameters

Parameter	What it indicates	Typical interpretation	Development importance
Appearance	Visual quality and defects	Uniform, intact, acceptable surface	Basic product quality
Thickness	Dimensional uniformity	Consistent thickness across units	Affects dose, dissolution and handling
Weight variation	Unit mass consistency	Low variability preferred	Process consistency
Drug content/content uniformity	Dose accuracy	Within specification	Critical attribute quality
Tensile strength	Resistance to breaking	Adequate strength for handling	Packaging and transport
Percent elongation	Flexibility	Adequate deformation before failure	Reduces cracking
Folding endurance	Repeated folding resistance	Higher endurance generally indicates flexibility	Practical handling
Moisture content	Water in film	Controlled level required	Affects stability and mechanics
Surface pH	Mucosal compatibility	Near oral-tolerable range	Patient comfort
Disintegration	Time to lose film integrity	Rapid for fast-dissolving films	Key performance attribute
Dissolution	Rate/extent of API release	Product-specific profile	Biopharmaceutical performance
Stability	Change during storage	Acceptable within shelf life	Shelf-life assignment

Evaluation of Orodispersible Films

Appearance and visual inspection
↓
Thickness measurement
↓
Weight variation
↓
Drug content determination
↓
Content uniformity
↓
Surface PH
↓
Moisture content
↓
Tensile strength
↓
Percentage elongation
↓
Folding endurance
↓
Disintegration time
↓
Dissolution and Drug release study
↓
Swelling study
↓
Mucoadhesive strength
↓
Palatability and Taste Evaluation
↓
Stability study
↓
Final quality assessment of Orodispersible Films

Mechanical and Physical Evaluation

Tensile strength shows how much force is needed to tear the film, and percent elongation tells how much the film can stretch before it breaks. Folding endurance is a straightforward way to test how flexible something is. A strong Orodispersible films needs to be tough enough to cut and handle, but also flexible enough to avoid breaking when it's packaged and used[49.]

How a material behaves mechanically depends a lot on factors like the size of the polymer molecules, how much polymer is present, the kind and amount of plasticizer used, the moisture left behind, and how the material is dried. Using more plasticizer makes the material more flexible, but if you use too much, it can make the material weaker when stretched. High moisture can act like a plasticizer and alter the mechanical properties during storage[50.]

Visual appearance is also a quality attribute. Films should look even and smooth, without cracks, bubbles, or noticeable specks, and shouldn't have big differences in thickness, unless the film is meant to have a specific, planned pattern. The product can be made transparent or not transparent depending on how it is designed[51.]

Disintegration, Dissolution and Drug Release

Disintegration time shows how fast the film breaks down and loses its shape in a specific test setup. Because Orodispersible films have a big surface area, they can break down very quickly. Nevertheless, disintegration and dissolution are distinct phenomena. A movie might split apart quickly while a medicine that doesn't dissolve well takes longer to break down[52.]

Dissolution testing should be chosen based on how the product works. For films that release the medicine right away, the method should tell the difference between different versions while showing how well they release the medicine quickly. When testing buccal

or mucoadhesive films, it's important to take into account how long the film stays in place, how long it takes to release the medicine, and the conditions inside the mouth. There isn't one single way that works for every Orodispersible films[53].

Drug release can be affected by how the polymer absorbs water, how the drug moves through the material, how the polymer breaks down, how well the drug dissolves, the size of the drug particles, and how the active ingredient interacts with the surrounding material. Mathematical modeling can help compare how different release mechanisms work, but choosing the right model should be based on proper data, not trying to make sense of incomplete or limited dissolution results[54].

Packaging and Stability

Orodispersible films usually have a large surface area compared to their size, which makes them easily affected by moisture in the environment and how they are handled. Packaging is an important part of the dosage form and not just something that comes after the main part. Individual pouches, strip packs, and other high-protection systems can help keep the film safe from moisture, air, and physical damage[55].

Stability studies need to check things like how the product looks, its active ingredient levels, any breakdown products that form, how evenly the contents are spread, moisture levels, how it holds up physically, and how well it breaks down or dissolves over time. If the film is hygroscopic, changes in moisture can affect how flexible it is and how it dissolves, even if the API test results are still good. Packaging should be chosen based on how sensitive the whole product is to moisture and oxygen[56].

The temperature and humidity levels while storing something can also affect how the polymer relaxes and how the plasticizer moves around. Stability-indicating analytical methods are needed for chemical testing, and physical tests should ensure the film stays safe and usable for giving to patients during its entire shelf life[57].

Quality by Design Approach

Quality by design offers a structured way to create Orodispersible films. The process starts with a Quality Target Product Profile (QTPP), then identifies critical quality attributes (CQAs), along with the material properties and process factors that can influence those CQAs[58].

For an Orodispersible films, possible CQAs include how evenly the dose is distributed, how thick the film is, how strong the film is, how quickly it breaks apart, how well it dissolves, the amount of leftover solvent, the moisture level, the active ingredient content, any breakdown products, and how it looks and feels. Material characteristics involve the type of polymer, the size of the active ingredient particles, the amount of plasticizer used, and the moisture content in the raw materials. The process involves setting parameters like how long to mix, the temperature to use, the thickness of the cast, the conditions for drying, and the settings for cutting[59].

Risk assessment tools like Ishikawa diagrams and failure mode and effects analysis help find variables that pose a high risk. Design of experiments can be used to look at how different factors interact and find a strong range of conditions for the formulation. The control strategy should link the requirements for raw materials, the checks done during production, and the tests on the final product[60].

A QBD approach is especially helpful when scaling up because it transforms the development process from trying things randomly to having a clear understanding of how different factors in the product and manufacturing process affect its performance[61].

Bioperformance and Patient Acceptability

The possible benefit of an Orodispersible films in terms of how the drug moves through the body depends on the API, the way it is made, and the method it is given. Fast breaking apart of a solid medicine can make it available for the body to use quicker, but it doesn't always mean the body gets more of the medicine overall. Taking medicine under the tongue or in the mouth can help avoid breakdown in the stomach or first-pass metabolism, which is useful for certain drugs.However, if a film dissolves quickly and is swallowed, it acts like a regular immediate-release pill[62].

Patient acceptability is multidimensional. Taste, sweetness, how it feels in the mouth, the size of the film, how easy it is to take off the package, how flexible it is, and how people feel about any leftover stuff all play a role. Recent reviews show that the user's experience should be part of the development process, not just thought about after the product is made[63].

Evaluation should therefore include both instrument-based tests and assessments based on sensory or patient-related factors when it is suitable. A movie that is very strong and breaks down quickly might still not work well if it has a bad taste or leaves something unwanted behind[64.]

Limitations and Development Challenges

1. Limited drug-loading capacity: The small area and thin structure of a film can make high-dose drugs difficult to accommodate. Increasing drug loading may increase thickness, impair flexibility, affect taste, and reduce dose uniformity[65.]

2. Moisture sensitivity: Hydrophilic polymers can absorb environmental moisture, making films sticky, soft, or unstable. Excessive drying may instead make them brittle. Protective unit-dose packaging and controlled storage conditions may therefore be needed[66.]

3. Taste-masking challenges: Bitter or unpleasant-tasting drugs can reduce acceptability. Tastemasking methods must limit drug exposure in the mouth without preventing the intended drug release. 4. Mechanical-property trade-offs: A film must be strong enough for manufacture, cutting, packaging, and handling while still disintegrating quickly. Excessive plasticizer may cause tackiness or lower strength, whereas insufficient plasticizer can cause brittleness.

5. Manufacturing and scale-up: Uneven casting, drying, drug settling, air bubbles, thickness variation, and cutting errors can affect product quality. Process controls are needed to ensure reproducible batches[67.]

6. Drug-specific limitations: Poorly water-soluble APIs may disintegrate with the film but dissolve slowly. Drugs that are heat-sensitive or solvent-sensitive may not suit particular manufacturing methods.

7. Packaging and cost: High-barrier individual packaging can add material and production costs. Advanced methods such as hot-melt extrusion or 3D printing may require specialised equipment and process validation.

8. Need for comprehensive testing: Content uniformity, dissolution, stability, residual solvent where relevant, mechanical strength, and patient acceptability must be assessed. Orodispersible films are not automatically superior to tablets or liquids; the best dosage form depends on the drug and patient needs. Regulatory classification and requirements must be addressed for the intended product[68.]

Recent Advances and Future Perspectives

Recent reviews show that Orodispersible films research is focusing more on patient-centered approaches and using more advanced technology. Three-dimensional printing, multilayer structures, nanoparticulate drug loading, and QbD-based development are more and more being talked about as methods to solve the problems with traditional casting[69.]

Personalized films could eventually let doctors adjust the dose, shape, flavor, and how the medicine is released for each patient. These systems might be especially useful when you need to adjust the dose easily. However, making personalized manufacturing work in real life needs strong quality checks, reliable printing processes, and the right rules and regulations in place[70.]

Advanced methods for hiding tastes are probably going to stay a big focus of research. Using microencapsulation, polymer barriers, sensory improvements, and fast-release methods could let bitter medications be given in helpful amounts without making the medicine less appealing to patients[71.]

Another possible future step is combining digital manufacturing with process analytical technology. Checking the coating's thickness, moisture, temperature, and makeup as it's being made can help make the production process smoother and less inconsistent. The general direction is moving toward a combined way of developing products where material science, process engineering, sensory science, and biopharmaceutics are all looked at together[72.]

Table 5. Key development challenges and potential approaches

Challenge	Why it occurs	Potential development approach
High API dose	Limited film area and high excipient requirement	Dose reduction where clinically appropriate; higherloading matrices; multilayer design
Bitter taste	Rapid drug exposure in saliva	Encapsulation, polymer barriers, complexation, optimized sweetener/flavour system
Brittleness	Insufficient plasticization or excessive drying	Optimize plasticizer and residual moisture; polymer blending
Tackiness	Excess plasticizer/moisture	Adjust plasticizer, drying and packaging
Poor dissolution	Low API solubility	Particle engineering, solid dispersion, surfactants or complexation
Dose non-uniformity	Sedimentation, aggregation or casting variability	Control viscosity, particle size, mixing and drying; in-process controls
Moisture sensitivity	Large surface area and hydrophilic polymers	High-barrier unit-dose packaging and humidity control
Scale-up variability	Casting/drying and process changes	QbD, process characterization and robust operating ranges

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