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Research Article

Oral Thin Films: Formulation Strategies, Evaluation and Emerging Applications

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ABSTRACT

Oral thin films (OTFs) are soft polymeric dosage forms which are to be administered on the tongue or against the oral mucosa. They can disintegrate quickly to deliver an active pharmaceutical ingredient (API) or they may stay in contact with the mucosa to facilitate local or transmucosal delivery or absorption. Their size, ease of transport and ease of administration without water may be beneficial to individuals who have difficulty swallowing traditional solid dosage forms. The properties of physicochemical property of API, polymer/excipient compatibility, film thickness, moisture content, mechanical strength, disintegration/residence time, drug release and packaging are the criteria that govern the performance of an OTF. Despite the many rapid developments in the polymer and composite industry in recent years, solvent casting is still one of the most widely used methods for developing/d manufacturing. Alternatives for selected materials and product targets are the hot-melt extrusion and electrospinning/printing processes. There are limitations to each method: Solvent casting can be tricky because drying and solvent residue can be problematic; some printing methods expose materials to heat, and electrospinning may require solvents and special equipment. Therefore, the method for evaluating quality must be established on a product-specific basis, as opposed to the use of a single disintegration result. This review aims to discuss the classification of OTFs, excipients, manufacturing processes, quality controls, therapeutic uses, marketed examples and novel technologies. Additionally, it also differentiates between rapidly disintegrating films and mucoadhesive buccal films due to their non-interchangeable performance targets. Characterization needs include harmonization, scale up, moisture protection, palatability, and reproducible scaling of dose distribution and proof of in-vitro/in-vivo correlation. The review is a draft of a review based on published pharmaceutical literature and should be considered a starting point for further searches in the database, reference checking and adaptation to the target journal.

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INTRODUCTION

1. Introduction and advantages

Oral thin films are thin and flexible films which carry one or more active ingredients dispersed and/or dissolved in a polymeric matrix. They are usually placed on the tongue, under the tongue or against the buccal mucosa. Oral thin film is sometimes referred to as oral dispersible film, oral soluble film and oromucosal film; however the intended site of administration and the purpose for release must be clearly defined in the literature. The most common property of Orodispersible films is to be rapidly wetted, disintegrated and dissolved in the small amount of fluid present in the oral cavity. Alternatively, buccal or mucoadhesive films could be formulated to bind to the mucosa for a specific time and then deliver the drug locally or trans-mucosa [1-8]. Patient-centred administration is the primary reason for developing OTFs. A thin film can be packaged into a small unit and given without a glass of water and can be divided into a predetermined unit dose. The properties might be beneficial for children, older people, people with dysphagia, patients who are nauseated and others who have trouble swallowing tablets or capsules. An easier dosage form does not necessarily result in better adherence or clinical outcomes, however, acceptability is affected by taste and texture, size, disintegration, dosing instructions and patient population [1,2,9-13]. The local effects in the oral cavity can occur with OTFs or systemic effects may occur if the drug is swallowed or absorbed through the oral mucosa after the drug is released from the OTF. Absorbed directly through the mucosa is not necessarily subjected to gastrointestinal degradation and hepatic first pass metabolism. This advantage varies in strength with the permeability, degree of ionization, solubility, dose, residence time, and fraction swallowed of the drug. Thus, any bioavailability claims must be based upon pharmacokinetic data for the specific drug and cannot simply be assumed from the dosage form of the drug [4,7,14-18]. Films have added flexibility in shape,

thickness, taste-masking design and can potentially provide dose personalization, when compared to conventional tablets. However, they can also pose problems, such as the degree to which drug can be added in a thin unit, moisture may alter the mechanical properties, taste masking may be challenging, and the film may become brittle with handling or become sticky. Films are not always suitable for every API and since the drug may be unstable in the chosen polymer, solvent or processing temperature [3, 5, 19-22] it is essential to know the properties of the selected film forming material. In this review the formulation and evaluation of oral films with a focus on the relationship between intended use and product design is examined. It includes rapidly disintegrating films and mucoadhesive films, but doesn't classify them as the same dosage form. Manufacturing methods are evaluated by manufacturing principle, suitability and quality risks and scale-up needs. Other novel approaches like printing and structured and multi-layered films are highlighted as potential future opportunities that need to be suitably supported by evidence of reproducibility, stability and clinical utility [6,20-25].

2. Types of oral thin films

Appearance is not the best way to classify OTFs, as they can be used in different ways and applied to different areas. Fast dissolving film/tablet or orodispersible film/tablet is intended to disintegrate quickly in the mouth after they have been placed in the mouth. May liberate the API for local action or for subsequent swallowing and absorption. The formulation is placed under the tongue and a sublingual film is used. A buccal film is a film applied to the inside of the cheek; it can be formulated to dissolve quickly and/or adhere to the mucous membranes. Mucoadhesive films exploit the interaction between the polymers and the mucous membrane to achieve a longer contact time, which may be unidirectional, bilayered or modified in any other way to decrease the amount of drug that is released into the saliva [4,7,14,26-31].

Table 1: Classification of Oral Thin Films Based on Their Intended Function and Performance Requirements.



Film type	Primary design objective	Typical quality priorities	Important caveat
Orodispersible / fast-dissolving	Rapid wetting and disintegration in saliva	Disintegration, dissolution, content uniformity, taste, handling strength	Rapid disintegration does not prove rapid systemic absorption.
Sublingual	Release at the floor of the mouth; possible transmucosal absorption	Dissolution, mucosal compatibility, permeability, dose uniformity	Absorption depends on API properties and contact time.
Buccal / mucoadhesive	Adherence to cheek mucosa for local or systemic delivery	Mucoadhesive strength, residence time, swelling, release, irritation	Long residence and fast disintegration are different targets.
Multilayer / functional film	Separate ingredients or control direction/release	Layer integrity, interlayer adhesion, content distribution, release profile	More complex manufacturing and characterization are needed.
Printed / personalized film	Customized dose, shape or combination	Print accuracy, dose uniformity, mechanical properties, traceability	Technology and regulatory readiness vary by process.

The other useful classification is the immediate release vs modified release. The majority of the commercial orodispersible films are designed for fast release. The modified release technologies involve the combination of drug containing particles and/or polymer matrices or multilayer structures, which are encased in a film. These designs may involve a small and/or easy to use unit in combination with a slower release of the drug, but the intended release mechanism must be validated by suitable dissolution/release testing. The disintegration and release of the drug should be measured separately from a film that disintegrates rapidly but has particles or a matrix with low release rates [32–36].

3. Film-forming polymers and excipients

The polymer will constitute the continuous film matrix and will have a significant effect on characteristics such as tensile strength, flexibility, swelling, wetting, disintegration and drug release. But molecular weight, viscosity, film-forming ability, aqueous solubility, API compatibility, moisture sensitivity and safety for the route and processing should all be taken into consideration when selecting the polymer. Rapidly disintegrating films typically contain only a hydrophilic polymer that will easily absorb water, while mucoadhesive systems can involve a polymer that reacts with mucin and remains attached to the oral mucosa [3,5,7,26,37–42]

Table 2: Film-Forming Polymers and Excipients Used in Oral Thin Film Formulations.

Excipient class	Examples reported in film research	Main function	Selection considerations
Film-forming polymers	Hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), pullulan, polyvinyl alcohol (PVA), maltodextrin, gelatin, sodium alginate, starch derivatives	Create coherent film; govern hydration and mechanical performance	Viscosity, film clarity, flexibility, compatibility, disintegration and residual moisture
Mucoadhesive polymers	Carbomers, chitosan, sodium alginate, cellulose derivatives, polycarbophil	Increase mucosal contact and residence time	Adhesion should be balanced against comfort, hydration and removal
Plasticizers	Glycerol, polyethylene glycol (PEG), propylene glycol, sorbitol	Reduce brittleness and improve flexibility	Excess can increase tackiness, moisture uptake or alter release
Sweeteners and flavors	Sucralose, saccharin, xylitol, mannitol and suitable flavor systems	Improve palatability and acceptability	Must not destabilize API or compromise film integrity



Excipient class	Examples reported in film research	Main function	Selection considerations
Saliva-stimulating agents	Citric acid and other suitable food/pharmaceutical acids	Promote salivation and wetting in selected formulations	May affect pH, taste, API stability and mucosal comfort
Surfactants / solubilizers	Selected pharmaceutically acceptable surfactants and solubilizers	Improve wetting or dispersion of poorly soluble ingredients	Check irritation potential, compatibility and taste
Colorants, preservatives and other auxiliaries	Only where justified and appropriate for route	Appearance, protection or processing	Use the minimum necessary and verify safety and compatibility

Dry polymer films can often be brittle and plasticizers may be necessary. They affect elongation, tensile strength, tackiness, water uptake and disintegration. This effect is not uniform for all polymers; a concentration that works well for one polymer matrix can give too much tack or cause a reduction of tack in another. Hence, the polymer to plasticizer ratio must be optimized on an experimental basis and recorded as an important formulation parameter [3,5,37,43–46].

The API can be used as a solution, suspension, emulsion or as dispersed particles. Selected approach is influenced by solubility, dose, particle size, taste, stability, ionization and polymer affinity. If the API is not very soluble in water, particle size reduction, use of a surfactant, cyclodextrins, solid dispersion, or other interventions to achieve water solubility can also affect the taste, stability and release. It is important that the drug loading is sufficiently uniform throughout the film, especially when a large cast sheet is cut to individual units [19,22,47–51].

In selecting polymers for mucoadhesive films, the mucoadhesive properties are also considered, along with hydration, swelling and residence time. Too much adhesion can cause discomfort and too little adhesion can result in early separation. The in vitro mucoadhesion tests are useful when compared, but the results are subject to the influence of the mucosal substrate, test force, hydration medium, contact time and test geometry. The method should thus be described in sufficient detail to allow its reproduction [7,14,28,52–55].

4. Preparation and manufacturing procedures

4.1 Solvent casting

Solvent casting is commonly employed in the lab for development and has been used for the manufacture of

an oral-film. The polymer is dissolved or dispersed in an appropriate solvent, excipients are added and then the API is added as a solution or suspension. Additives may be required to deaerate the mixture as needed, cast at a controlled thickness onto a surface and dried under controlled conditions. The dry film is then peeled, conditioned, cut into unit dose and finally packaged in moisture-protective film [3,5,20,56–60].

The technique is applicable to heat sensitive APIs as the process of film formation does not have to involve melting the polymer. It also allows for flexible composition and casting area. But slurry viscosity, mixing, air bubbles, sedimentation, casting gap, drying temperature, air flow, humidity and substrate properties have an impact on quality. Gradients, curling, cracking or uneven film properties can result from drying, either through insufficient drying (leaving residual solvent behind) or from harsh drying (causing gradients). These variables need to be controlled and shown to be uniform throughout the web and from batch to batch in a scale up process [5,20,56,58,61–64].

4.2 Hot-melt extrusion

Hot-melt extrusion (HME) involves melting a mixture of API and thermoplastic excipients in a heated barrel and extruding it through a heated die. For making films, the extrudate is formed into a thin film or a ribbon. This process can decrease solvent consumption, promote continuous manufacturing and can also potentially enhance the dispersion of some APIs. The major development variables are feed composition, screw configuration, barrel temperature, screw speed, and residence time, torque, and die design and downstream cooling or thickness control [20,65–70].



It's not the best option for everyone. Some APIs and excipients are heat sensitive and might degrade, the drug might undergo physical changes while melting or cooling. Film dimensions may be influenced by polymer viscosity and die swell, insufficient plasticization causes a brittle film, too much plasticizer makes film handling difficult. Process analytical technology and a quality-by-design approach can help relate material attributes and process parameters to critical quality attributes. Process choice can also affect the properties of the product as shown by comparative work of films cast in solvent and extruded under similar conditions, which can vary in texture, flexibility, moisture response and drug distribution, even though they have identical nominal compositions [65–71].

4.3 Printing technologies

Individualised dose strengths, multilayer structures, combination products and digital manufacturing are being looked into using printing technologies. The two-dimensional printing process can lay down a drug containing ink on to an edible material, whereas three-dimensional or additive methods construct a structure by successively adding material. The methods reported for making pharmaceutical films involve inkjet printing, semisolid extrusion, direct ink writing and other modified printing methods. The selection will be dictated by the properties of the ink, such as its rheological characteristics, wetting and drying of the substrate, stability of the API, and required resolution [20,72-78].

Though print-head performance, droplet or filament consistency, nozzle blockage, layer adhesion, drying between layers, dose mapping and traceability are added quality concerns when using printing. Thermal printing processes may not be applicable with ingredients that are thermolabile and liquid methods need to be managed by controlling solvent evaporation and moisture levels. Demonstrated feasibility does not indicate superiority of casting or extrusion. Validation must include dose uniformity, mechanical integrity, dissolution or disintegration, stability and the reproducibility of the printing process [72–79].

4.4 Other approaches

Other methods are electrospinning, rolling, semi-solid casting and a mixture of manufacturing methods. Electrospinning can produce very porous fibrous structures, which allows for faster absorption of the fluid which may require a proper polymer solution, high voltage, and proper solvent handling. For continuous sheet production, rolling can be useful but it is important to control the thickness, tension and content distribution. For certain materials and multilayer designs, semi-solid casting might be of benefit. The selection of the method should depend on properties of the API and polymer, the desired dose, the desired release, batch size, the availability of equipment and the environmental and safety requirements of the procedure [20,56,80–84].

Table 3: Comparison of Manufacturing Methods Used for Oral Thin Films

Method	Strengths	Main risks / limitations	Best-fit considerations
Solvent casting	Accessible; flexible; widely studied; can suit heat-sensitive APIs	Drying time, solvent residue, moisture gradients, bubbles, shrinkage, batch variability	Early development and APIs compatible with selected solvent/drying conditions
Hot-melt extrusion	Solvent-free potential; continuous processing; good mixing in suitable systems	Heat exposure, energy use, die swell, thermal/physical changes, process complexity	Thermally stable APIs and thermoplastic polymers
2D/3D printing	Dose personalization, multilayering, digital design, potential for on-demand manufacture	Ink rheology, print precision, drying, equipment validation, scale-up	Customized dose or structure where printing adds a demonstrated benefit
Electrospinning	Porous fibrous matrices and rapid wetting potential	Solvent handling, high-voltage equipment, process reproducibility	Research-stage designs where fiber structure provides a useful function
Rolling / semi-solid casting	Potential for continuous or specialized sheet formation	Thickness control, material-specific limitations, less standardized workflows	Selected formulations and manufacturing setups



5. Evaluation parameters and quality by design

Evaluation should be tied to the target product profile, and should be done with OTF. Rapid disintegration is one key performance requirement of a rapidly disintegrating film, while prolonged-residence mucoadhesive film requires different performance requirements. The disintegration time, for instance, plays a crucial role in the orodispersible product, while the adhesion strength and residence time are crucial in the case of a buccal film. In either classification, there are still a few key factors, including dose uniformity and mechanical integrity, chemical stability and appropriate release testing [6,7,85–90].

5.1 Physical and organoleptic evaluation.

Visual and instrumental methods are used to check the appearance, color, transparency and surface defects and odor. This is measured at several points, as there may be local variation which can indicate poor casting or coating control. If drug distribution is not uniform, film area and mass can only be correlated with dose if the contacting objects can be considered to have a constant shape. Surface pH can be evaluated following hydration/wetting, in a set procedure; this is not an indication of the formulation being non-irritating to mucosa. Water activity and moisture uptake and moisture content can be used to determine storage and packaging requirements [6,85,88,91–94].

5.2 Mechanical properties

Mechanical testing is useful to identify if the film is peelable, cuttable, packable and can be administered without any tearing or excessive deformation. Some of the common tests are tensile strength, percentage elongation, Young's modulus, folding endurance, puncture resistance and tack depending upon the film design. The size of the specimen, its conditioning humidity, the speed of the test, the geometry of the grip and the calculation method for stress and strain all affect the results. It is not appropriate to compare values among different studies unless the test conditions and units are sufficiently similar [6,85,89,95–98].

5.3 Disintegration, dissolution and drug release

Disintegration is the breakdown of the film structure and dissolution is the amount of drug transferred into the test media. The mentioned are related but not identical results. The disintegration methods can be visual observation, modified disintegration equipment, imaging methods or sensor-based methods. The small film size must be taken into consideration, as well as limited fluid volumes, floating or sticking and the potential for a traditional tablet apparatus to not replicate oral conditions. Justification and reporting of the medium, agitation and temperature should be justified and should be reported [6,85,99–103].

In the case of films designed for transmucosal delivery, both permeation and residence time must be taken into account when considering drug release. Ex vivo permeation studies can be performed on an appropriate mucosal tissue model and in vitro release can be measured in appropriate diffusion cells or other validated setups. These models must be carefully controlled with regard to tissue source, tissue integrity, receptor media, sink conditions and analytical recovery. The results of in vitro studies are not indicative of clinical bioavailability or therapeutic equivalence [7,14,28,104–107].

5.4 Content uniformity, compatibility and stability

Sampling of individual units should be from relevant areas of the cast sheet or manufacturing run and validated analytical method should be used to determine the content of the drug. Thermal analysis, spectroscopy, chromatography, microscopy or diffraction can be used for compatibility assessment depending on the case. Various tools can be used for the identification of interactions, degradation, crystallinity and phase separation but none of these is fully compatible. Stability studies should include the following parameters: Assay, Degradants, Appearance, Moisture, Mechanical Properties, Disintegration / Dissolution and Package Integrity under justified storage conditions [6,20,85,108–112].

5.5 Quality-by-design

A quality by design approach starts with a quality target product profile, which is used to define critical quality attributes (CQAs), critical material attributes



(CMAs) and critical process parameters (CPPs). OTFs: CQAs can include dose uniformity, tensile properties, moisture content, disintegration or residence time, dissolution, microbial quality (where applicable) and stability. The polymer grade, API particle size, plasticizer grade and solvent properties can be included

in a CMA. CPPs can consist of mixing time, viscosity, casting thickness, drying temperature, extrusion temperature, or screw speed/printing parameters. Interaction screening and designed experiments can be used to determine interactions and operating ranges [20,65,86,113–116].

Table 4: Evaluation Parameters and Quality Attributes of Oral Thin Films

Attribute / test	Why it matters	Method notes / interpretation
Appearance and dimensions	Detect defects and dimensional variation	Define visual standards and sampling locations.
Mass and thickness variation	Support unit consistency and manufacturing control	Measure multiple units and positions.
Drug content / uniformity	Confirms dose delivery per unit	Use a validated assay and appropriate sampling plan.
Tensile strength / elongation	Indicates resistance to handling and flexibility	Report specimen dimensions, humidity and test speed.
Folding endurance / puncture / tack	Supports practical handling and packaging decisions	Select tests that reflect intended use.
Moisture content / uptake	Predicts brittleness, tackiness and stability risk	Control conditioning and storage humidity.
Disintegration / dissolution	Assesses intended rapid breakdown and drug release	Do not treat disintegration as a substitute for dissolution.
Mucoadhesion / residence time	Relevant to buccal or prolonged-contact films	Specify mucosal model, hydration and test conditions.
Compatibility / stability	Detects degradation or physical change	Use multiple complementary analytical methods.
Palatability / mouthfeel	Affects acceptability and correct use	Use ethical, controlled sensory approaches where human testing is justified.

6. Therapeutic uses and commercial products for use.

OTFs are under investigation for antiemetics, analgesics, antimigraine agents, antipsychotics, antihistamines, local oral treatments, among others. The amount required, solubility, taste, stability, and the site and duration of action (local or systemic) affect product development. Some films are made to dissolve quickly and be swallowed; others are prepared to be placed in the mouth or under the tongue. The clinical relevance of a film is defined by the active ingredient and the evidence available for the finished product and not just by the film format [1,4,8,14,117–121].

Prescription and non-prescription film-based products with certain APIs have been mentioned in the literature as examples, including ondansetron, risperidone, aripiprazole, dexamethasone, buprenorphine/naloxone and others as per jurisdiction and date. Approvals and

discontinuations: a product may be approved in one country but not in another, and may be under different brand names in different countries. The name, API concentration, indication, approval authority and whether a product is approved for the market should be checked in a journal manuscript against the official product information and/or regulator databases before publication [1,8,12,122–126].

One of the important reasons involves administration and the difficulties with swallowing and acceptability in children and elderly individuals. However, a small-sized film may present problems when the dose is not suitable, when the film sticks to the packaging and when the patient is misinformed. So, taste masking and a robust packaging system are not added-on features to the product design and are a part of product design. For dose flexibility, unit size variation or digitally manufactured films could prove to be promising, but again,



dose accuracy and ease of use needs to be shown [9–13,72,127–130].

Other bioactive ingredients such as plant extracts, probiotics, vitamins and minerals are also being considered for OTFs. Careful consideration needs to be given to the stability, taste, hygroscopicity, dose capacity and proof of any nutritional or health claims of the

ingredients in this area. The formulation benefits of a thin film cannot be assumed to be equal to the absorption or clinical benefits of the same ingredient/product in the same formulation unless proven. Probiotic films must contain viable counts in their final product and during storage, plant extracts need chemical standardization and batch to batch consistency [131–135].

Table 5: Therapeutic Applications and Development Considerations of Oral Thin Films

Application area	Potential rationale	Development considerations
Pediatric / geriatric administration	May reduce swallowing burden and allow water-free dosing	Dose appropriateness, taste, package opening, caregiver instructions
Antiemetic and acute symptom therapy	Portable dosage form for selected medicines	Stability, onset evidence, dose and clinical equivalence
Buccal / sublingual delivery	Potential local delivery or transmucosal absorption	Permeability, mucosal tolerance, residence time and release
Oral-cavity local therapy	Direct placement near the site of action	Adhesion, local concentration, taste and irritation
Nutraceuticals / vitamins / plant extracts	Convenient unit-dose supplement format	Dose capacity, ingredient standardization, stability and substantiated claims
Personalized dosing	Digital manufacturing may support tailored strengths	Dose accuracy, validation, traceability and regulatory controls

7. Challenges, recent advances and future prospects.

One of the key issues is that there is no universally applicable test protocol. Constructed methods vary in apparatus, media, specimen size, test duration and endpoint definitions. This variability makes it difficult to compare the studies and to draw generalised specifications. A rational approach is to develop a target product profile and to choose validated product relevant tests, and to report procedures in sufficient detail to allow replication [6,85,86,99,136–139].

Another constant problem is moisture. Water may cause the product to become plasticised, or to become tacky if present in excess, or very brittle if present in insufficient amounts. Moisture may also be a factor for the stability of drugs, crystallinity and release. The choice of packaging therefore should be made taking into account its ability to protect from moisture and oxygen, its ability to protect in unit dose form and the shelf life. The selection of high barrier packages may require stability testing, not just based on the type of package [5,20,61,108,140–143].

However, high dose APIs and nutraceutical ingredients that need to be used in a dose of more than a gram are

still dose capacity limited. Various options, such as optimizing potency, expanding the film area within limits of acceptability, using multiparticulate systems or the combination of films with other dosage forms, could be explored, but all alter the product profile. This is also problematic when the API tastes very bitter or is present in high levels. Complexation, coating, ion exchange, sweeteners and flavours can be assessed, but must not interfere with release or lead to an unacceptable excipient exposure [19,22,47,50,144–148].

Recent advances include 3D printing, multi-layer films, films with nanoparticles or drug loaded particles, quality by design and mechanical characterisation with sensors to assist in disintegration testing and personalised film manufacturing. Such innovations can enhance dose flexibility and/or be capable of performing multiple functions. However, while there are some encouraging lab demonstrations, there are still some processes that cannot yet be considered validated for commercial use. The questions that remain to be addressed at the translation of these assays include reproducibility, cost, cleaning, equipment qualification, patient acceptability, regulatory aspect and stability [16,20,72,76,86,149–154].



Sustainability is growing in importance for formulation and manufacturing applications. Sustainability is getting more important for formulation and manufacturing applications. Solvent-free extrusion can help minimize the use of solvent and solvent casting is suitable when it can be used safely and reproducibly to produce the required product. When comparing sustainability, you need to look at energy usage, recycling solvents, waste, materials used, yield, packaging, and the product life cycle. Any manufacturing method that is referred to as environmentally superior has to be considered in terms of system boundaries and be compared with relevant data [20,65,70,80,155-158].

Further work should focus on having standardized test methods, strong in-vitro-in-vivo relationships, better methods for assessing taste and mouthfeel, durable but easy-to-use packaging, and packaging process that maintains dose uniformity at scale. Additional comparisons of different manufacturing methods with the same formulation would help to elucidate the effect of process variables. The dosimetric accuracy and the reproducibility, stability and workflow controls of the personalized films should be reported for personalized films. The setting of targets for residence times and the assessment of tolerability towards the mucosa in addition to the evaluation of drug release should be evaluated for mucoadhesive films [6,7,20,72,85,159–162].

CONCLUSION

Oral thin films are a novel drug delivery system for patient-centred drugs, however, the success of this system requires formulation and manufacturing decisions to be appropriate to a well-defined product objective. Rapidly disintegrating films are designed to achieve good wetting, disintegration, taste and ease of administration, whereas mucoadhesive buccal films are designed to achieve adhesion, residence time, mucosal compatibility and controlled release. The performance of a polymer or plasticizer is a result of the selection of the polymer and plasticizer, API properties, moisture management and manufacturing conditions. Solvent casting is still common and some formulations can be extruded using the hot-melt method or be printed. The physical, mechanical, performance, chemical and

stability properties should be evaluated, and the evaluation methods should be selected for the type of film to be evaluated. Scaling up, patient-relevant evidence and careful translation of emerging technologies to reproducible pharmaceutical products will be critical for future progress.

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