



Review article

Innovations in oral thin films: from formulation science to clinical applications

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ABSTRACT

Oral thin films (OTFs), sometimes called fast-dissolving films-have emerged as an innovative, alternative dosage delivery system intended to resolve the drawbacks of traditional oral dosage forms such as tablets or capsules. OTFs are defined as very thin (less than 50 μm), flexible polymeric strips containing an active pharmaceutical ingredient (API), by the United State Food and Drug Administration, and display rapid disintegration without the need for water, dissolved in the oral cavity, enhancing patient compliance in., particular populations including children, geriatrics, and dysphagic patients. Other advantages OTFs offer patients include predictable, swift onset of action; first-pass metabolism avoidance; bioavailability increases and patient convenience, while limitations include drug-loading capacity, fragility, and hygroscopicity. OTFs formulation components are summarized with specific details on; polymers, plasticizers, surfactants, sweeteners and flavouring agents; and OTFs manufacturing processes, including; solvent casting, hot-melt extrusion, electrospinning, and printing technologies. Novel OTFs including; SOLULEAVESTM, FOAMBURSTTM, and XGELTM, helps expanded OTF's many possible uses. Product evaluation parameters (e.g., drug content uniformity, disintegration time, tensile strength, stability) help ensure product quality and effectiveness. They are commercially marketed for; seizure management, migraine relief, smoking cessation, vaccine delivery, and promising applications for probiotics, herbal therapy, and individual medicine. Overall, it represents a novel platform with enormous therapeutic potential for patients and significant opportunities for developments in the future.

Keywords: Oral thin films, Mucoadhesive films, Bioavailability, Drug delivery system.

INTRODUCTION

A thin, flexible, non-friable polymeric film strip with one or more dispersed active pharmaceutical ingredients that is meant to be applied to the tongue for quick disintegration or dissolution in saliva before being swallowed and delivered into the gastrointestinal tract is known as an oral thin film, according to the U.S.FDA. Mucosal thickness at the base of the mouth, tongue, and gums ranges from 100 to 200 μm . The oral mucosal epithelium is a 40–50 cell layer made of proteins and carbohydrates. The mucus, a gel-like substance secreted by the submucosa beneath this layer, is made up of 90–99% water, 1–5% water-insoluble glycoproteins, and additional substances like proteins, enzymes, electrolytes, and nucleic acids [1]. Oral films, also known as oral disintegrating films (ODFs), oral thin films (OTFs), rapid films, fast-dissolving films, or

rapid dissolving films (RDFs), are a cutting-edge drug delivery technology designed to get around the drawbacks of conventional dosage forms. It is possible to administer the medication effectively without swallowing thanks to these thin, flexible sheets that dissolve rapidly in the mouth. Oral films have a quicker onset of action, better bioavailability, less side effects, and increased patient convenience when compared to tablets or capsules [2]. For those who require medication while on the go, they are particularly well-suited because they are compact, lightweight, and simple to use. It may be useful for paediatric, elderly, bedridden, emetic, and patients with conditions that include sudden episodes of coughing or allergic reactions and for local or systemic delivery [3].

Advantages

A greater surface area is available, which facilitates the systemic absorption of APIs and causes them to dissolve and disintegrate quickly in the oral cavity.

Avoid first-pass metabolism and use lower doses for a faster onset of action.

No water is needed while taking medicine.

Increased adherence by patients.

Non-invasive technique.

Not at risk of choking ^[4].

Disadvantages

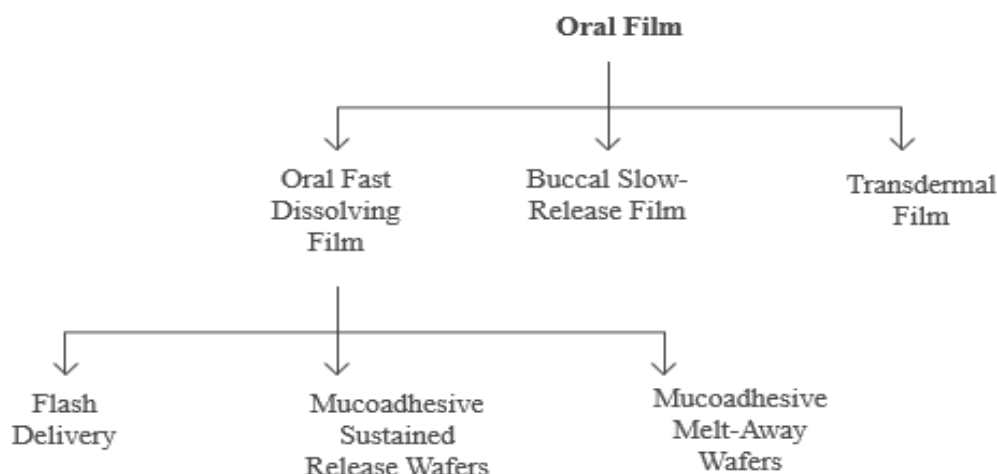
High-dosage drugs cannot be used in the movie.

Prescription medications that irritate the mucosa cannot be used.

Because of its fragility and need for water protection, it needs to be packaged carefully.

By nature, hygroscopic so it difficult to provide long-term protection ^[5].

Classification of oral thin films



Formulation aspects

Active ingredient

A number of drug classes, such as Nonsteroidal Anti-inflammatory Drugs (Meloxicam), expectorants, antitussives, antiulcer drugs (Omeprazole), and antiasthmatics (Salbutamol Sulphate), can be made into mouth-dispersing films.

Water soluble polymers

It serves a purpose as film formers when fast disintegration, acceptable mouth feel, and acceptable mechanical disintegration are all characteristics defined in the requirements of the film properties. The film forming properties Depend on polymer type, the polymer concentration, and the size of the polymer; generally, the larger the polymer size the slower disintegration will be. The common WSPs used are: cellulose ethers: hydroxypropyl methylcellulose (HPMC), carboxymethylcellulose (CMC), methyl cellulose; polyvinyl alcohol (PVP); polyvinylpyrrolidone (PVP K-90); polyethylene glycols; pullulan; gelatine; pectin; sodium alginate; hydroxypropyl cellulose; maltodextrins ^[6].

Plasticizers

The mechanical properties of the films such as tensile strength and elongation have also been achieved through the addition of plasticizers in this work. Their concentration will vary the constituent's property examined. Some plasticizers used include: glycerol, di-butylphthalide, polyethylene glycols, etc.

Surfactant

Surfactants are used multi dimensionally as solubilising agent, emulsification agent, dispersing agent. Non-ionic surfactants are generally preferred. The surfactants used are Tweens, sodium lauryl sulphate, Cremophor, poloxamer.

Saliva stimulating agents

Increase rate of salivary production that would determine disintegration of the rapid dissolving strip formulations. The examples of salivary stimulants are citric acid, malic acid, lactic acid, ascorbic acid, tartaric acid. Among these the one preferred is citric acid ^[7].

Flavouring agents

The quantity of flavouring agent needed for taste masking depends on the flavour and its intensity. The most common flavours are fruity (vanilla, cocoa, coffee, chocolate, citrus), and oils (oil of peppermint, oil of cinnamon, oil of nutmeg). A flavour may be taken from oleo resins, synthetic flavour oils or extracts made from the different sections of a plant (eg. fruit, flowers, etc).

Colouring agents

The colour agents used routinely are FD&C colours, natural colours, and pigments like titanium dioxide. Colour was traditionally chosen by the formulation, and by the colour which would be accepted by the customers in the market.

Sweetening agents

They include polyhydric alcohols (sorbitol and mannitol), fructose, glucose, isomaltose, dextrose, saccharose and others. Artificial sweeteners, respectively both first generation and second generation, i.e., cyclamate, aspartame, acesulfame-K, sucralose, alitame, neotame and saccharin could also be utilized ^[8].

Manufacturing methods

Two types of methods used in preparation of oral thin films.

They are

Conventional methods

Solvent casting method

This process involves dissolving the plasticizer and water-soluble polymer in distilled water. Using a magnetic stirrer, the solution is agitated for two hours and then set aside to eliminate

any trapped air bubbles. The meantime, the excipients and API are dissolved and thoroughly stirred for half an hour. Once the stirring is finished, the two solutions are combined. The solution is then poured onto a level surface that can be used to form a film. After drying, the film is carefully removed [9].

Semisolid casting

With this technique, a solution of an acid-insoluble polymer is combined with a solution of a water-soluble film-forming polymer to create a homogenous, viscous solution (such as cellulose acetate butyrate or phthalate). It is coated on untreated casting film after sonication. Upon drying the film is roughly 0.381-1.27 cm thick. There should be a 1:4 ratio between the acid-insoluble polymer and the film-forming polymer.

Rolling method

This technique involves rolling a drug-containing solution or suspension on a carrier. Water and water-alcohol mixtures make up the majority of the solvent. After drying the film takes on the appropriate size and shape [10].

Hot melt extrusion

The process of combining the API with additional excipients while they are dry is known as hot melt extrusion technology. The molten mass is extruded from the hot melt extruder once the heating process is complete, and the film is cooled before being cut to the appropriate size. This method has the benefit of requiring no solvent at all.

Solid Dispersion Extrusion Technology

In the presence of amorphous hydrophilic polymers, solid dispersion is the process of dispersing one or more APIs in an inert carrier in a solidstate using techniques like Hot melt extrusion. Solid dispersions are prepared by extruding immiscible components with medications in a solid-dispersion manner. With the aid of dies, the solid dispersions are formed into films [11].

Electrospinning and Electro spraying

Both electrospinning and electro spraying are sophisticated methods. When an API-polymer solution is exposed to an electric field during the electrospinning process, high-surface-area nanofibers are created that are compatible with a variety of polymers and dissolve quickly in aqueous media. While droplet size and viscosity determine the film properties, electro spraying uses a high electric field to spray a liquid into fine particles or droplets; at high polymer content, this technique may switch to electrospinning. The two processes provide novel approaches to the creation of oral thin films that dissolve quickly.

Drying of films

The initial drying period lasts ten minutes or less. This time is enough for the volatile solvent to evaporate. After that, controlled reheating ensures even heat distribution and helps form the final shape of the viscoelastic solid. Minor amounts of water can stay without impacting the desired heterogeneity. However, additional drying can be done to lower the solvent content. This

process results in a stable final film formulation with about 6% residual solvent [12].

Non- conventional methods

Inkjet printing

It is primarily divided into Continuous Inkjet Printing (CIP) and Drop-on-Demand Printing (DoD), is a computer-controlled technique that creates digital patterns by ejecting ink droplets. Volatile solvents quickly evaporate to exit the composition in CIP, which uses acoustic waves to break a continuous ink stream into droplets that are then deflected by an electric field to create the desired pattern. DoD uses voltage-induced changes in piezoelectric materials to create pressure waves in the ink chamber, generating droplets only when needed. Although inkjet printing is very accurate and helpful in the pharmaceutical industry, it has drawbacks like high equipment and maintenance costs and the requirement for skilled labor,

Flexographic printing

Drug-containing ink is transferred using a fountain roller to an anilox roller, which regulates the ink quantity, and then sent to a plate cylinder containing the polymer strip, where it is pressure-printed onto the surface. The film is pre-manufactured and dried, preventing heat-induced API degradation. Approximately 530 oral films are produced per minute using this highly efficient method. Large print roller requirements and contamination risk are the main disadvantages [13].

Technologies Soluleavestm™

Oral delivery films made with soluleavestm technology can include active ingredients, colors, and flavours. These films dissolve quickly in saliva and provide rapid release, making them ideal for patients who have trouble swallowing tablets or capsules, such as elderly people or children. These films work well for delivering nutritional supplements and products in therapeutic areas like pain, gastrointestinal, and cough/cold. Furthermore, soulmates films can be designed to stick to mucosal membranes, allowing for a 15-minute controlled release of active ingredients.

Foamburst™

It is a unique soulmates technology variation in which an inert gas is introduced into the film while it is being made. This produces a honeycomb-structured film that dissolves quickly and leaves a unique mouthfeel [14].

Xgel™

Any oral dosage form can be encapsulated using the xgel™ film systems, which dissolve in both hot and cold water. A variety of distinct water-soluble polymers that have been specially tailored for the intended use make up xgel™ film.

Wafer Tab™

The Wafer Tab filmstrip can be flavoured for further improved taste masking and API is dosed accurately and incorporated in the body of a pre-manufactured XGEL™ film allowing the wafer to avoid unnecessary exposure to heat and moisture perhaps increasing stability of the product. It was designed

to offer many possibilities for innovative product design such as bonding together several films with different actives can be produced into any shape and size, and is an ideal system for delivery of medicines which require fast release or for use by a patient who may have swallowing difficulties ^[15].

Micap

In 2004, Micap plc entered into an option agreement in order to combine its microencapsulation technology with Bio Progress' water soluble films. The end development would create additional delivery mechanisms for the global smoking cessation products (SCPs) market worth approximately \$1.4 billion ^[16].

Evaluation

Morphological and organoleptic assessment

Colour, homogeneity, transparency, odour, and texture of the OTFs are evaluated visually (e.g. colour, transparency, and smell) and experientially (e.g. mouthfeel). Their qualities should be examined especially in terms of taste and flavour.

Weight variability

1x1cm² films are cut from each formulation and weight variability is calculated by individual film pieces on a sensitive weighing scale ^[17].

Drug content uniformity

It can be assessed by any of the standard testing methodology included in the standard pharmacopoeia for the specific API. As the API content of each strip is measured, the content uniformity can be assessed. The accepted range for drug content uniformity is 85-115%.

Moisture absorption capacity

The test is conducted under very high humidity conditions to monitor physical stability and physical integrity of the films. After recording the weights of the samples independently, they are put in a desiccator containing an aluminium chloride solution, and exposed to moisture for 3 days. The films are then weighed, and their % moisture absorption capacities are determined using the following formula ^[18].

$$\% \text{ Moisture absorption capacities} = \frac{(\text{Initial Weight} - \text{Final Weight})}{\text{Initial Weight}} \times 100$$

Folding endurance

Folding endurance is determined by - repeated folding of the film in the same area until the film breaks. The folding endurance value will be the number of times the film is folded without breaking.

pH value

It was calculated by dissolving one oral film in 2 ml distilled water and measuring the pH of the resulting solution. The pH was measured using pH paper. Differences were expected since different polymers are used as well the addition of API ^[19].

Thickness

The film thickness was measured by means of a micrometre screw gauge at five positions (central and corner locations) at different pre-determined locations. This will establish

in part uniformity in film thickness which is essential as it directly influences dose accuracy in the film.

Young's Modulus

Young's Modulus is used to measure film stiffness and is expressed as the ratio of applied stress over strain in elastic deformation ^[20].

Swelling Property

The swelling studies of film is conducted by using simulated saliva solution. Each sample film was weighed and placed in the pre-weighed stainless steel wire mesh. The mesh was dissolved in the 15mL of medium in a plastic container. Determine the final weight increase in film at the present time interval until constant weight is obtained (Peh and Wong, 1999).

Tensile strength

Determined by the device, which has two clamps: a movable lower clamp and a fixed upper clamp. The 0.5 x 3 cm film sample is clamped between the two clamps. The elongation and tearing forces are computed ^[21].

Permeation studies

In vitro permeation method across rat abdominal mucosa was studied using a Franz diffusion cell at 37 ± 0.2 °C. Freshly excised rat mucosa was mounted between donor and receptor compartments, with the smooth side facing the donor side. The film was placed on the mucosa and compartments were clamped. The donor compartment contained 3 mL simulated saliva (pH 6.8), while the receptor compartment was filled with 22–25 mL phosphate buffer (pH 7.4) and stirred magnetically. Samples were withdrawn at specific time intervals and analysed at respective wavelengths.

Disintegration test

It is defined as the time (seconds) it takes for a film to break apart after coming in contact with saliva or water. The apparatus for disintegration testing referenced in a pharmacopoeia can be used to measure disintegration times of OTFs. Generally, the disintegration time of the film formulation is often very brief (5-30 s) ^[22].

In vitro dissolution test

Many investigators employed Franz diffusion cells to analyse the drug release from polymeric films, however, the apparatus employed to test the rate of dissolution was improved. The placement of the films is a major challenge in the dissolution rate assay. Therefore, several methods have been described in the literature in which the rate of dissolution of a film is attached to the bottom of the glass container or mixer using a double-sided adhesive tape. In some cases, paddles or basket apparatus are used.

Scanning electron microscopy

One reliable technique for evaluating the surface morphology of a film between multiple excipients and drugs. The researcher retrieved a sample of the film and placed it into a sample holder. Several photomicrographs were taken utilizing tungsten filament as the electron source and at a $\times 1000$ magnification ^[23].

Chemical stability studies

These types of studies examine any possible interactions among excipients in the film. Compatibility studies use Fourier transform infrared spectroscopy (FTIR), Differential scanning calorimetry (DSC), X-ray diffraction, etc.

Stability testing

OTF was held at controlled temperatures of 25 °C/60% RH and 40 °C/75% for 12 months under ICH requirements. Before being stored, OTF should be carefully examined for morphological traits, coupon thickness, tensile characteristics, moisture content, film thickness and dissolution characteristics [24].

Packaging

Special handling, expensive packaging, and special storage are needed for quick dissolving dosage forms, with the single-unit packaging a must. Aluminium pouches are the most prevalent. A patented packaging system, the Rapid card (APR-Labtech) which holds three films on each side and is card size, allows for unit dosing. All packaging must be FDA-approved, non-reactive, tamper-evident, nontoxic, and protect from external environmental factors.

Packaging material

Foil, paper or plastic pouches: Light weight, resistant to tampering and protective; formed and sealed by specialized equipment.

Single and Al foil pouches: One side clear other side laminate foil; protects single dose units, aluminium is the most common.

Blister cards (for multi-units): Plate made with a layer of resin is vacuum-moulded into cavities, filled with dosage, then sealed; provides good moisture protection.

Barrier films for moisture sensitive drugs: materials such as polychlorotrifluoroethylene or polypropylene; these materials can resist moisture as well as vapor or gas; although the clarity of polypropylene is poor [25].

Applications

Vaccines

Administering vaccines orally is difficult. Oral vaccines have low inherent stability and are subject to degradation and metabolism, leading to poor bioavailability. The researchers used

trehalose and pullulan to stabilize therapeutic proteins such as β -galactosidase, in addition to using freeze-drying to improve process stability and air-drying to improve storage stability [26].

Probiotics

Streptococcus salivarius and other probiotics may be able to help treat oral health conditions, such as dental caries brought on by *Streptococcus mutans*. With *S. salivarius* maintaining the integrity of tooth phosphate and xylitol blocking bacterial metabolism, these films lower *S. mutans* populations in vitro [27].

Mental disorders

Oral films with aripiprazole improve dissolution for many mental disorders including schizophrenia, bipolar disorder, autism spectrum disorder and Tourette's disorder. Diazepam buccal films for epilepsy have measurably higher performance and convenience in dosing than other forms. They are particularly beneficial to those patients with psychiatric disorders, paediatric patients and older patients who have swallowing difficulties or stigmas associated with taking medication [28].

Herbal extracts

Oral dissolving (ODFs) of herbal extracts paves a new way for effective drug delivery within the mouth. These ODFs provide a way to deliver drugs without being swallowed, salt an accurate absorption. We explored the use of ODFs for ODFs of traditional herbal extracts, such as *Lagerstroemia speciosa* (anti-diabetic), and *Phyllanthus niruri* (immune), promote therapeutic targeting of diseases. Interestingly, the ODFs of *Panax not ginseng* demonstrated a high level of stability in acidic media and disintegrated rapidly. Furthermore, the ODF could improve the stability, compliance, and convenience of tablets in elderly and chronic patients [29].

Personalized medicine

Atorvastatin, an antifungal medication that lowers cholesterol, was used in the film's development. In order to provide controlled drug release and adhere to oral mucosa, the formulation encapsulated with propylene glycol was then integrated into a 3D-printed mucoadhesive film made of chitosan, PVA, and HPMC [30].

Table 1: phytochemicals test

Name	Company	Use
Sympazan	Aquestive Therapeutics	Seizure
TBX-FREE Oral Strips	Redwood Scientific Technologies	Smoking and Cigarette cessation
QuickStripVax	Rapid dose Therapeutics Corp	Vaccine delivery without Needle
Sebetralstat	KalVista Pharmaceuticals	Acute hereditary angioedema
Rizaport	IntelGenx	Migraine Treatment

CONCLUSION

Oral thin films have quickly entered the pharmaceutical market as a novel and patient-centric drug delivery platform. With fast onset of action, bioavailability advantages, and better adherence, they present exciting possibilities for both systemic and local therapy. Existing marketed products have shown clinical utility, while developing technologies have broaden the possibilities of OTFs in vaccines, probiotics, herbal extracts, and individualized medicine. Overcoming formulation and stability issues, as well as scaling up manufacturing, will ultimately establish the next

generation of OTFs as an official commercial dosage form in contemporary pharmacy practice.

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