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ORAL DISINTEGRATING FILMS: A REVIEW ON RECENT PERSPECTIVE ON EFFECTIVE DRUG DELIVERY

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ABSTRACT

The confines of traditional techniques are being broken by modern formulation research. Active constituents can now be supplied with a level of achievement, bioavailability, and flexibility like before in the trade. By merit of their quick disintegration and ability to be administered without water or chewing, fast disintegrating or oral dissolving films (ODFs) is one unique strategy to strengthen user adoption. For the population who have trouble swallowing unit oral drug delivery forms, such as Tablets and Capsules, this unique style of delivery system offers simplicity. The ODFs frameworks are typically manufactured of hydrocolloids with biopolymers being underlined because they're hypoallergenic, compostable and exhibit qualities that are advantageous for this utilization. Buccal dissolving films are evaluated for their parameters like thickness, weight variation, moisture content and physical properties like folding endurance, disintegration and dissolution time. The review article describes numerous composition strategies and subsequent assessments when applied to the mouth-dissolving film preparations.

KEYWORDS: Buccal dissolving films, Disintegration, Dissolution, Bioavailabilty.

INTRODUCTION

The oral pathway is the perfect and the most common approach of administering because of its systemic effect and therapeutic effect. Due to its therapeutic and systemic effects, oral administration is the ideal and most preferred method. Additionally, it is the most popular method because it has an easy administration process and a low cost of therapy. This includes non-invasiveness, adaptability, patient acceptance, self-medication, pain avoidance, and precise dosing. Altering the dosing patterns will also be simple. Most elderly, young, nauseated, bedridden, and noncompliant patients have trouble swallowing the traditional oral dosage form and fail to take their medication as directed. However, a few restrictions for elderly, young, or dysphagic individuals, as well as for those who have trouble swallowing, as well as for animals. According to estimates, 50% of the population has this issue, which ultimately increases the risk of non-compliance and unsuccessful treatment.[1,2]

For juvenile and elderly patients who have trouble ingesting oral solid dosage forms, oral rapid disintegrating medication delivery systems were first created as a substitute for tablets, capsules, and syrups.

Therefore, this is the purpose for which oral disintegrating systems were created. These disintegrating films are designed to target medication absorption directly through the oral mucosa, avoiding first-pass metabolism and into the systemic circulation. ODFs has achieved significance in the pharmaceutical sector due to its unique traits and quick disintegration time of just a few seconds to a minute. The design of ODFs allows for the incorporation of many different medications for their pharmacological effects, such as antitussive, anti-epileptic, anti-asthmatic, and expectorant. The temperature and humidity are high.[2]

These dose forms either disintegrate or dissolve in the mouth in around 3 minutes. Due to improved patient compliance, oral fast-dissolving dosage forms have begun to acquire appeal and acceptability as innovative drug delivery systems. Mouth-dispersing tablets and fast-dissolving films make up oral fast-elimination dose forms. Mouth-dispersing tablets have a number of drawbacks, including the fact that they leave residues in the mouth that make the mouth feel gritty and provoke choking fears in some people. To solve these issues with mouth-dispersing tablets, researchers studied fast-dissolving films, also known as oral disintegrating films, which are a new drug delivery technique for oral pharmaceutical administration. The creation of fast-dissolving oral films for medicine delivery did not employ the transdermal patch technology. The thin film acting as the delivery mechanism is put in the size of a postage stamp to the person's tongue or other epithelial region, where it instantly absorbs saliva to hydrate the area. The film then quickly breaks down and dissipates, releasing the medication to permeate by the oral epithelial layer. The vast film's surface area, which

quickly becomes wet when confronted with the humid oral environment, is principally responsible for the film's swift dissolving action.

Anatomy of Oral Cavity

Grabbing the environment offered for medication delivery requires an understanding of the structure and anatomy of the oral cavity. The oral mucosa prevents first-pass metabolism and permits direct medication entry into the systemic circulation. The epithelium of the oral cavity resembles the skin relatively closely, with a few minor exceptions in terms of keratinization and the protective and lubricating mucus that coats its surface. On average, epithelial tissue is four to thousand times more porous than skin. The outer region of the oral cavity, which is divided into two sections by the hard and soft palates, the surface of the mouth, and the tonsils, as well as the lips, cheeks, and oral vestibule, has all been investigated for the systemic distribution of pharmaceuticals either through various pharmaceutical products of varied ration. Oral medicine delivery and dosage forms have long been acknowledged as the most popular administration method.

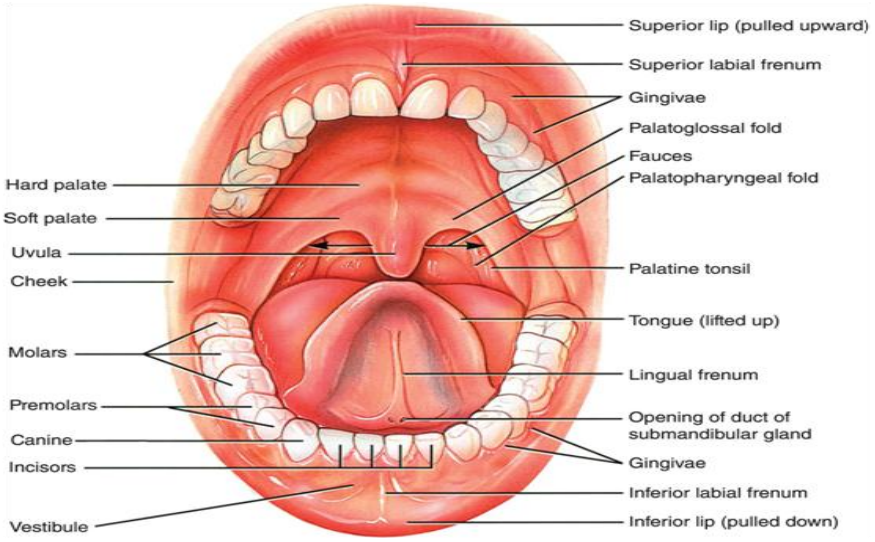
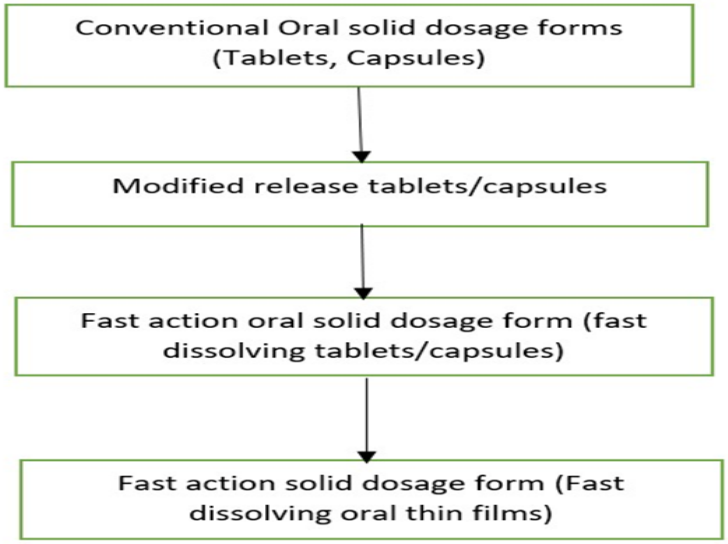


Fig. Oral Cavity.

Flowchart for Development of Oral Solid Dosage Forms



Fast Dissolving Films

In the relevant literature, oral films, sometimes known as oral wafers, are a collection of flat films that are placed within the mouth. Over the past several years, breath strips known as oral thin films (OTFs) or oral strips (OS) have grown from confection and oral care businesses to become a unique and well-liked delivery method for vitamins and personal care items.

On the basis of the transdermal patch technology, quick deliquesces films are a kind of oral drug delivery device, were created for delivery of the medicine. It consists of a

thin film that is applied to the individual's tongue or other tissue of mucosal and immediately moistened by saliva present. The film then quickly breaks & disintegrates to release the medication for absorption by the oral mucosa.

Hydrophilic polymers are used to create fast-dissolving oral films, which quickly disintegrate on the soft palate or buccal cavity and release the medicine into bloodstream when they come into contact with liquid. An innovative replacement for the conventional pills, capsules, and liquids frequently seen in prescription and over-the-counter drugs is the fast-dissolving oral film. Thin-film strips are primarily intended to be administered orally, either inside the mouth (internal) or beneath the tongue (sublingual) cheeks.[3]

By skipping the first pass effect, these drug delivery techniques increase the absorption of the medication. The medication can reach bloodstream by the buccal, sublingual, or intestinal routes as the thin oral film dissolves.

Features of Oral Disintegrating Films

A thin film the size and shape of a postage stamp makes up this delivery technique. Oral films that dissolve quickly leave a nice mouthfeel and an acceptable taste after dissolving in the tongue, like cotton candy. The unhindered oral film dissolves quickly. In comparison to tablets & other conventional oral solid dosage forms. Film dissolves on the top of the tongue in a matter of seconds, bypassing first-pass metabolism, which may boost the drug's bioavailability. Oral films that dissolve quickly should be less sensitive to environmental factors like humidity and temperature.

Necessary Characteristics Of The Drug To Be Chosen

1. A medication need to taste good & medicine should have a tiny molecular weight and size.
2. In both water and saliva, the medicine should be well-soluble and stable.
3. It ought to be just barely unionized at the pH of a buccal cavity.
4. Low environmental sensitivity should be a property of the medicine.
5. It should be capable of penetrating oral mucosal tissue.
6. The maximum recommended therapeutic dose of the medication is 40mg.[5]

Advantages of Oral Disintegrating Films

1. Water is not required for administration.
2. Especially useful for geriatrics and paediatrics with trouble swallowing.
3. Bypassing the hepatic first-pass effect, which results in a rapid beginning of action and enhanced bioavailability.
4. Lowering the dose improves the drug's efficacy and safety profile while minimizing negative effects.
5. They are adaptable and lightweight, making them simple to handle, carry, and store.
6. Simplicity of dosing for individuals with mental illness, handicapped, recalcitrant, on reduced liquid intake programmes, or queasy.
7. Helpful in conditions requiring an ultra-rapid commencement of the action, such as motion sickness, severe discomfort, quick allergic reaction, asthmatic attack, and coughing.
8. Longer-lasting stability since the medicine stays in solid dose form until it is ingested.
9. Dosage accuracy versus liquid formulations.
10. Pleasant mouthfeel, little or no aftertaste, and minimal or no residue.

Disadvantages of Oral Disintegrating Films

1. It is impossible to incorporate high doses.
2. It is impossible to make excessively bitter medications.
3. Dose uniformity presents a technological difficulty.
4. They need particular packaging to ensure the stability and security of the products.
5. This route cannot be used to provide medications that irritate the oral mucosa.

Applications of Oral Dissolving Formulations

1. Oral films are given for local action, as well as to treat discomfort, problems falling asleep, allergies, and CNS diseases.
2. Topical applications of dissolvable films, such as analgesics or antimicrobials, are possible for wound treatment.
3. Sensitive reagents are put onto dissolvable films to either form obstacles for many chemicals' isolation to allow for a scheduled response with a diagnostic tool or to enable controlled release when subjected to biological fluids.
4. Oral films can improve the bioavailability of medications that aren't very bioavailable.[7]

Some Marketed Preparations of Odf's

COMMERCIALIZED ORAL THIN FILM PRODUCTS		
Brand name	**Type of formulation**	**Application**
Zolmitriptan Rapidfilm®	Zolmitriptan oral disintegrating films (ODF)	Migraine
Setofilm®	Ondansetron ODF	Nausea
KP106	D-amphetamine ODF	ADHD
Onsolis™	Fentanyl buccal soluble films	Breakthrough pain (cancer)
RapidFilm®	Ondansetron and donepezil ODF	Nausea; psychosis
Triaminic Thin Strips	Phenylephrine and diphenhydramine ODF	Cough and cold
Suboxone®	Buprenorphine and naloxone (sublingual film)	Opiod dependance
Pedia-Lax™Quick Dissolve Strip	Sennosides ODF	Constipation
Gas-X Thin Strips	Simethicone (sublingual film)	Bloating and gas
Sudafed PE quick dissolve strips	Phenylephrine ODF	Cough and cold

Oral Films Consists Of Active pharmaceutical ingredients

The amount of API in the oral film composition ranges from 1-30% w/w. The use of low-dose pharmaceutical ingredients is advised because it is challenging to combine high doses of medication into an oral film that dissolves quickly. The minerals, vitamins, and supplement industries dominate the demand for thin oral films. The oral strip technique can successfully incorporate many types of API. Depending on the desired final release profile, API can be milled, loaded as particles or nanocrystals, or micronized. Drugs' bitter tastes must be covered up before API is added to the formulation of an oral film. A variety of methods are employed to improve flavour, some of which involve combining and co-processing excipients with good, agreeable flavour with bitter API. The "obscuration technique" is the name given to this procedure.

A few examples of APIs are Azatidine Maleate 1mg, Nicotine 2mg, Loperamide 2mg etc.

Plasticizer

Plasticizer lessens the film's brittleness while increasing flexibility and mechanical properties, including tensile strength and elongation. The key additives inside this oral film are plasticizers. By decreasing polymer's glass transition temperature, the plasticizer greatly enhances characteristics of the strip. It is important to choose a plasticizer that is compatible with the oral film's polymers, medication, and other excipients. The plasticizer can boost the polymer's strength and flow. The use of an improper plasticizer causes the film to split, crack, and peel.

Plasticizers are employed in concentrations ranging from 0 to 20% weight per weight of the dry polymer.

The oral films are made with a variety of plasticizers, including polyethylene glycol, glycerol, propylene glycol and dibutyl phthalate.

Film forming polymers

Polymers are crucial to the development of a film.

In order for the film to break down quickly in the mouth cavity and transport the drug towards the systemic circulation when it comes into contact with saliva in the buccal cavity, hydrophilic polymers are mostly employed in the preparation. To achieve the desired film qualities, film-forming polymers can be used singly or in combination.

polymer used in the formulation, including its type and volume affect how robust the film is. In the oral cavity, both biological and manmade polymers are utilized. Natural polymers are favoured over synthetic polymers since they are more efficient, safe, and don't cause negative effects. The soluble in water polymers give the film excellent mechanical qualities, quick disintegration, and a pleasant mouthfeel.

Examples of Natural polymers are Starch, Pectin, Gelatin, Sodium alginate etc. & few examples of Synthetic polymers are HPMC, Polyvinyl alcohol (PVA), Sodium Carboxy methyl cellulose etc.[10]

Sweeting agents

The formulation intended to dissolve or disintegrate in the oral cavity now primarily consists of sweeteners. The creation of rapid-dissolving films involves the use of both artificial and natural sweeteners. In the formulation, sweeteners are utilized in concentrations ranging from 3 to 6% by weight.

Mannitol, sorbitol, and isomalt are examples of polyhydric alcohols that can be combined since they also offer a cooling feeling and a satisfying taste.

Glucose, ribose, xylose, sucrose, maltose and dextrose are among the natural sweeteners utilized.

The artificial sweeteners aspartame, sodium/calcium saccharin salts, and cyclamates salts are utilized in oral films.

Saliva altering agents

These substances are used to increases salivation in order for the oral film can dissolve more easily and disintegrate more quickly within the oral cavity.

Utilizing saliva-stimulating chemicals will boost saliva production, which will help the formulations for rapid dissolving films dissolve more quickly. Typically, saliva is stimulated by the acids that are employed in meal preparation. Within 3-6%w/w of an oral strip, these medications are administered singly or in combination.

The principal saliva-stimulating chemicals utilized in the creation of oral films include citric acid, tartaric acid, and ascorbic acid.

By comparing the amounts of accelerated circulation and resting circulation at the same time and under the same conditions, salivation stimulation can be assessed.

Flavouring agents

The compounds that are added to a formulation to add flavour are called flavouring agents. The sort of medicine that will be included in the formulation mostly determines the flavour choice. When a medication is taken for the first time & after the taste of the preparation persists for at least a few seconds, the initial flavour quality is perceived 10 minutes, is the major factor in determining whether an individual will accept an oral dissolving/disintegrating formulation. The type and strength of the flavour will largely determine how much flavour should be applied to cover the taste.

10% weight-to-weight of flavouring ingredients is utilized in the recipe.

The formulation can have a US-FDA-approved flavour added based on the preferences of people; the preferences for Flavors alter with age; elderly people tend mint or orange flavours, while youngsters choose strawberry fruit or raspberry flavours. A flavouring agent ought to work well with the medication and other substances in various age groups.

Colouring agents

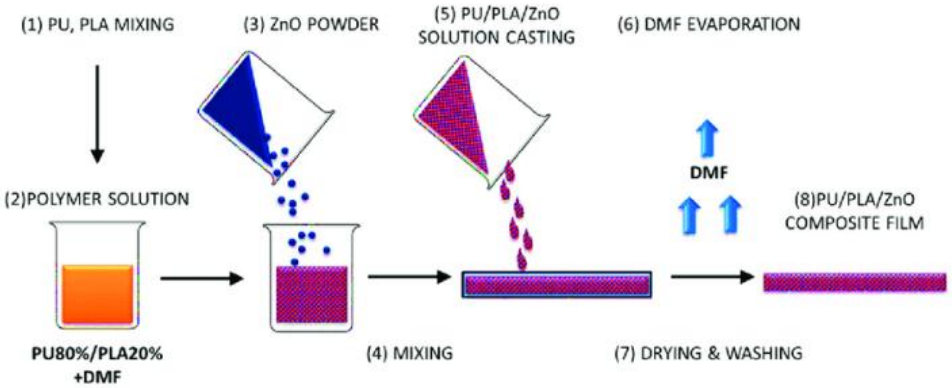
The fast-dissolving film contains a colouring ingredient that has received FD and C approval. The fast-dissolving film uses a colouring ingredient at a concentration of 1% w/w. The most common colouring ingredient in the composition is titanium dioxide. [4]

Surfactants

They are employed as dispersing or moistening agents. Surfactant is utilised to break down the film quickly and distribute the active ingredient. A surfactant can make medications that aren't very water soluble more soluble in quickly dissolving oral films. For instance, benzalkonium chloride, tweens and spans.

Approaches for Preparation

Solvent casting method: In this method, API and excipient are dissolved in a suitable solvent, whereas water-soluble polymers are soluble in water. Then the two solutions are combined and stirred, and the final step is casting the mixture into a petri dish that has been dried and cut in accordance with the specifications.[9]



Scheme 1. Schematic illustration of the solvent casting method used for PU/PLA/ZnO composite fabrication.

Semisolid Casting: To begin the process, a solution of a film-forming polymer that is water soluble must first be created. A solution of an acid-insoluble polymer (such as cellulose acetate phthalate) that was made in ammonium or sodium hydroxide is combined with the resultant solution.

After that, the proper quantity of plasticizer is added to produce a gel mass. Finally, the gel mass is molded into

the films or ribbons using heat-controlled drums. The thickness of the film ranges from 0.015 to 0.05 inches.

Hot melt extrusion: In this procedure, the medication and carriers are first combined in solid form. The mixture is then melted by a heater-equipped extruder. Finally, the dies form the melt into films.

The process of hot melt extrusion has some advantages.
- A decrease in operation units
- Greater homogeneity of content
- A procedure that is anhydrous

Extrusion of solid dispersions: In this technique, drug and immiscible components are extruded together before solid dispersions are made. Finally, dies are used to mold the solid dispersions into films.

Rolling Method: In this method, a drug-containing the suspension or solution is rolled onto the transport. Water and an alcohol-water mixture make up the majority of the solvent. The film is cut into the desired sizes and shapes after it has dried on the rollers.

Mouth Dissolving Film Analysis Using Physicochemical Techniques

Physical factors

Physical factors are crucial since they are applied to the final dosage form, providing information about the consistency between batches and helping to preserve the final formulation's visual appeal. Technical rules from other industries, for example, the plastic sector, can be pre-owned as models because the USP only specifies a test of tensile strength for surgical sutures and patches.

Mechanical factors

- **Test for dryness and tact**

The firmness with which the film adheres to any piece of paper placed in touch with the strip is known as tack, whereas the ability to measure the solvents or water content in the film is known as dryness. It has been determined there are eight separate phases in the drying process for films: Film that is established, dust-free, tack-free, dry-to-touch, dried hard, dry-through, dry to recoat, and dry imprint less. These qualities can currently be measured using much different equipment. At the lab scale, you can accomplish this by pressing your thumb against the film.

- **Tensile strength**

The greatest stress that can be given to a film specimen before it breaks is known as the tensile strength, and it may be calculated using the impact stress using the equation below, determine the cross-sectional area of the fragmented film at rupture as the average of three measurements. The tensile force (N)/cross-sectional area of the sample (mm^2) is the formula for determining tensile strength (N/mm^2).

- **% Elongation**

Deformation comes in the form of elongation. Anything under stress simply changes shape, and a texture analyser can be used to quantify this change. In other words, a sample deforms, lengthens, or elongates when it is subjected to tensile stress. The following formulae can be used to determine it by evaluating the length increase of the film following tensile measurement:
(L-L0) X 100 / (L-L0) = Percent Elongation
L0 = starting length, and L = finished length.

- **Young's Modulus**

The stiffness of a film is measured by its elastic or Young's modulus. The techniques used to calculate tensile strength might also be applied in this situation. In the zone of elastic deformation, the corresponding ratio of tensile stresses to strain is used to express it:
Cross Head Speed x 100/Film Thickness x Slope = Young's Modulus
A tough and frangible film exhibits a superior Young's modulus & tensile strength with little elongation.

- **Tear Resistance**

Plastic film or sheeting's tear resistance is a complicated based on the final rupture's resistance. Force needed to start tearing is essentially measured using a very modest loading rate of 51 mm (2 in.) /min. Tear resistance value is estimated in Newtons (or pounds-force) and represents the stress concentration or force (which is typically obtained close to the beginning of tearing) needed to tear the object.

- **Folding tenacity**

Film flexibility is a crucial physical qualification required for simple application on the administration site. The elasticity of the film may be quantitatively measured in terms of folding perseverance by repeatedly folding it at a 180° inclination of the plane within the same plane until it fragments or by folding it 300 times without shattering. The number of folds a film can withstand before breaking is used to compute its folding durability value. [6]

Altered physical characteristics

a) Appearance

Any produced film can be examined to see if it seems transparent or opaque. Surface qualities are often determined through visual inspection; however, tools like microscopes can also be utilized.

b) Thickness

Micrometre screw gauges can be used to measure the produced film's thickness at various key spots. Five measurements of the film's thickness should indeed be taken, each instance commencing in the centre and working forth from all four edges. before calculating the mean thickness. It is crucial to confirm uniformity in the film thickness because it has a direct impact on the strip's dosage accuracy.

c) Variation in weight
Each film must be weighed individually & then the average weights should be determined. The particular weight of the film is then lessened by the weight of the films as a whole. A significant weight fluctuation suggests that the procedure used was ineffective and suggests that the medication content was likely not uniform.

d*)* Contact angle
At room temperature, the contact angle could be determined with a goniometer. You can accomplish this by taking a film which is dry and dabbing a droplet of distilled water on its surface. Digital cameras can capture photographs of droplets of water 10 seconds after they had plummeted. On both sides of the descent, the contact angle could be measured, and an average is taken.

e) Moisture content
The level of moisture has an impact on how fragile and friable films are. In essence, the product's ingredients control how much moisture is present in a given film. Generally, moisture content testing equipment, to ascertain how much wetness is incorporated in the film, use either the measuring method or the Karl Fisher titration method.

A pre-weighed film of a specific size is typically warmed somewhere between 100 and 120 °C until it reaches a constant weight; weight variations reflect the quantity or degree of moisture present in the film.

% Moisture content= [(Initial weight - Final weight) 100/Initial weight] can be used to compute moisture content.

The optimal moisture content for a film is 5% or less.

Chemical Characteristics
a) Surface pH test
Agar gel with a 1.5% weight-to-volume ratio and pH paper with a pH range of 1 to 11 can be used to measure the surface pH of a film. It is noted and stated that the pH paper's hue has changed. [8]

b) **Time of disintegration**
The film's dissolution and disintegration properties can be inferred from the disintegration time. A film of the required size (2 × 2 cm2) is put inside a stainless-steel wire mesh that has been filled with 25 ml of pH 6.8 simulated salivary fluid. The length of time it requires for a film fragment to rip and disperse is known as the in-vitro disintegration time.

c) Test for in vitro dissolution
Dissolution testing can be performed using any of the typical basket or paddle information that can be gathered in the pharmacopoeia. The sink conditions and API dose will primarily be taken into consideration while choosing the dissolving medium. The dissolution test can occasionally be difficult due to the strip's propensity to float into the liquid that is dissolving when the paddle instrument is engaged.

d) Thermal evaluation
The specimen may be thermographed using a differential scanning calorimeter, which provides data on the medicinal molecules' state inside the film. A modification in the exothermic or the endothermic peak or a broadening of the peak area instantly indicates either recrystallization, phase change, or molecular engagement of a pharmacological molecule contained within the film.

e) Content uniformity and assay
Any acceptable assay methodology specified for the specific API within in the monographs can be used to determine this. By measuring the API content in each individual strip, content consistency is assessed. 85-115%17 is the upper limit of content homogeneity.

In- Vivo testing
Simulating the in vivo disintegration has been attempted using techniques like measuring the analysis of the films' expanding behaviour using the interfacial tension and thermo-mechanical principles.

With the assistance of a tasting panel and live volunteers, in vivo research primarily entails tasting the films and measuring their in vivo disintegration time. The taste of the film is also evaluated using an electronic tongue tester.

Additional tests
Measurements of the polymer solution's viscosity, the homogeneity of the content, and the detection of residual solvents are additional techniques for characterizing and monitoring the quality of ODFs. By using scanning electron microscopy, X-ray diffraction, and near-infrared chemical imaging etc.

CONCLUSION
Several benefits come with medicine delivery via oral thin film. Considering ODFs are simple to ingest and pose no choking hazard, these are indeed an excellent dose form for juveniles and the older. They typically include plasticizers, film-forming polymers, and other excipients that enhance flavour. Determining mechanical characteristics and dissolution behaviour are fundamental characterisation procedures.

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