Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/jptcp.v29i04.6496

A COMPREHENSIVE REVIEW ON FAST DISSOLVING ORAL FILMS: A RECENT ADVANCEMENT IN DRUG DELIVERY TECHNOLOGY

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ABSTRACT
Oral fast dissolving films (OFDF) present an innovative approach to improving patient compliance with medications through their rapid dissolution and ease of administration, requiring no water or chewing. This drug delivery system, which utilizes a thin film placed in the mouth, proves highly effective. These films quickly dissolve or disintegrate within seconds once in the oral cavity, eliminating the need for water. They can be formulated with a variety of medications, including analgesics, antihistamines, asthma therapies, antipsychotics, antiemetics, cardiovascular drugs, treatments for erectile dysfunction etc. This technology provides a convenient method of medication delivery, benefiting not only specific groups such as children, the elderly, bedridden patients, and individuals with mental illnesses, but also the general population. Several production methods exist for these oral films, with the buccal cavity being a primary site of application. The buccal cavity, located in the mouth, features a mucosal layer that facilitates rapid drug distribution and absorption into the body. This review thoroughly examines the preparation techniques for oral films, the selection of appropriate polymers for their formulation, the technologies involved, assessment criteria, and the various practical applications of this drug delivery system.

Keywords: Oral fast dissolving films (OFDF), Buccal drug delivery, Novel Drug Delivery System, Pharmaceutical technology

Introduction
The main purpose of a drug delivery system is to release the medication precisely when and where it is needed. The physicochemical properties of the medicinal material and the presence of barriers in the body, such as organ membranes and skin, determine the efficacy of drug distribution. Numerous properties of drugs influence their therapeutic effectiveness. These include, but are not limited to, their size, chemical composition, hydrophilicity, and receptor binding capacities. Suboptimal bioavailability at the target site is a problem for some drugs due to issues including poor organ permeability and low solubility in biological fluids.

Historically, severe illnesses or long-lasting problems have been managed using fast-acting, uncomplicated substances delivered in traditional formats such tablets, capsules, creams, liquids, aerosols, suppositories, injectables, or ointments. However, conventional approaches to drug

delivery frequently result in severe toxicity within the body due to their uncontrolled distribution throughout the body and inadequate regulation of medication release. Furthermore, certain methodologies require such elevated dosages and continuous administration. Therefore, most pharmaceutical companies focus on creating new delivery technologies that boost bioavailability and reduce side effects.

These systems strive to provide optimal performance, adaptability, and regulated release, propelled by breakthroughs in patient adherence, medical effectiveness, extended product durability through controlled medication delivery, and economic factors such as decreased frequency of administration and expenses. Therefore, innovative drug delivery methods are currently experiencing rapid growth and are becoming one of the most rapidly expanding sectors in the pharmaceutical industry.[1]

The significance of developing new drug delivery systems cannot be overstated, given that their very purpose is to improve or surpass the performance of existing medications that rely on conventional systems.

These innovative systems incorporate sophisticated methods and novel ways of medication administration to specifically target, regulate, and adjust drug distribution. The use of innovative medication delivery systems can greatly enhance effectiveness, safety, and patient adherence. The primary goals of novel drug carriers are to transport pharmaceuticals to specific target locations at the desired rate and extent as determined by the body's requirements, as well as to directly monitor the active unit during therapy.

The phrase "drug delivery system" especially refers to systems designed to transport drugs to certain locations and maintain their presence for predetermined periods of time. The major reason for developing new drug delivery methods is to produce long-lasting and controlled medication release, ensuring optimal drug levels while minimizing negative side effects. Illustratively, fast-dissolving drug systems that are administered orally are indispensable in the medical domain, particularly in the areas of paediatrics and geriatrics. These systems provide rapid disintegration or dissolution in saliva without the need for extra liquid.

Furthermore, SEEDDS exhibits potential as a means to improve the solubility of hydrophobic medications in biocompatible liquids for oral administration when implemented appropriately. When taken by mouth, they create mixtures in the fluid of the digestive system, resulting in medications that are broken down into very small particles (micro- or nano-emulsified). These pharmaceuticals are easily absorbed through the lymphatic system, avoiding the initial breakdown in the liver. Osmotic devices, unlike typical oral formulations, employ osmotic pressure as a mechanism to achieve regulated drug administration, independent of gastrointestinal circumstances. [2]

The progress in nanotechnology and the availability of many nanoscale platforms have increased the interest in innovative medication delivery systems. Nanoplatforms, by virtue of their diminutive size at the nanoscale, possess the ability to specifically amass and adhere to designated locations while exhibiting controlled release characteristics. The use of vesicular structures enables effective targeting and precise control over the release of medicines. Several vesicular systems have been created, each providing benefits compared to earlier versions.

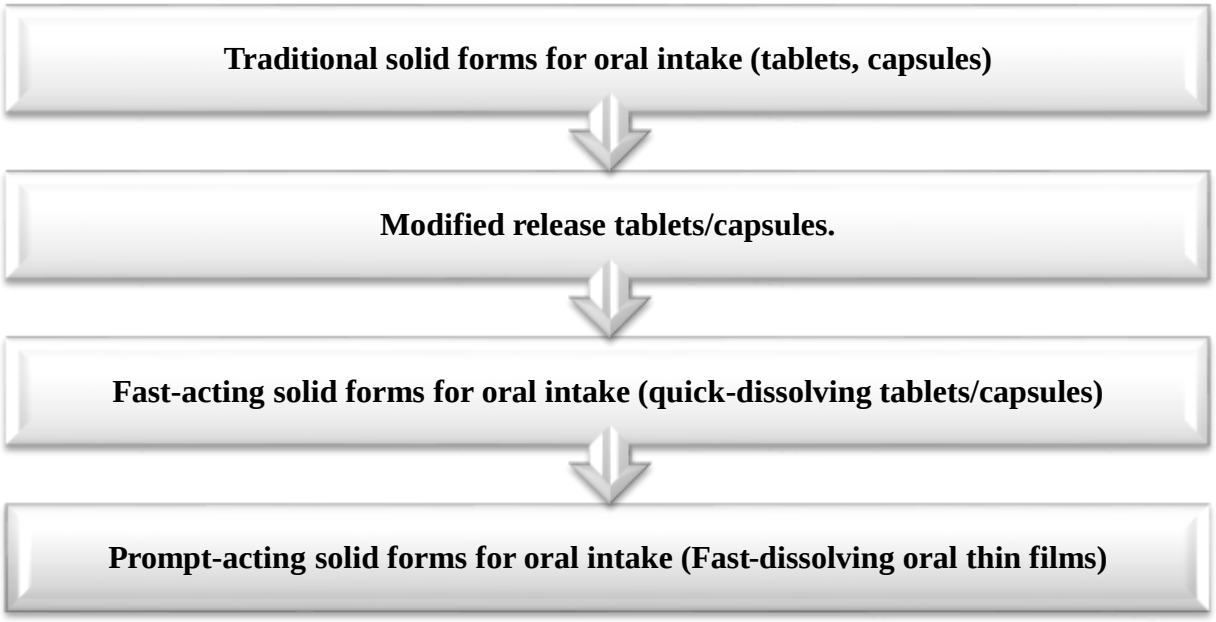

Figure 1: Sequential Illustration for the Creation of Oral Solid Medication Form

Fast dissolving drug delivery systems

Because of its low cost, high patient adherence, and relative ease of use, the oral route of medicine delivery is preferred by pharmaceutical corporations and medical practitioners. The forms of oral solid dosage that are most frequently employed are tablets and capsules. Self-medication methods offer several benefits over alternative approaches, including precise dosing, painless administration, and ease of use.

Nevertheless, these devices pose difficulties, especially for elderly, young, and dysphagic individuals who have difficulties in swallowing, giving rise to worries of asphyxiation. Accurate dosage of liquid formulations, such as syrups, can be challenging.

When water is unavailable, there are other circumstances like kinetosis or allergic reactions that call for innovative oral medication administration devices. To address issues related to swallowing, fast-dissolving drug delivery systems (FDDDS) were developed primarily in the 1970s. Fast-melting/disintegrating tablets (FDTs), also called porous tablets, orodispersible tablets, dissolve or disintegrate in one minute when they come into contact with saliva, eliminating the need for extra liquid or chewing during administration.

This rapid assimilation circumvents the process of first-pass metabolism, providing a more favorable option compared to traditional oral formulations, especially for patients who are susceptible to nausea, vomiting, or are bedridden.

However, concerns related to FDTs such as the potential for suffocation, expensive packaging, inadequate formulations leading to unpleasant tastes, fragility, and challenges in manufacturing and transportation, instigated the development of FDOFs. FDOFs, which are frequently called oral strips or wafers, were initially developed as breath strips to assist with oral hygiene. As time has passed, they have become available without a prescription or as over-the-counter remedies. Oral strips, which originate from the concept of FDTs, are ingested without the need for water or digestion. They can be administered via the buccal, sublingual, or intragastric routes, allowing for the potential to induce localised or systemic effects. [3]

FDOFs provide several benefits compared to conventional oral forms. These include a faster dissolution rate resulting from a larger surface area and quick disintegration, which improves the absorption of lipophilic and insoluble medicines, hence boosting their bioavailability. Enhancing bioavailability is achieved by bypassing the first-pass effect and directly entering the bloodstream. Moreover, administering medication orally without the need for water overcomes the bad taste and removes the potential danger of choking. This medication delivery technology offers improved

stability, precise dosing, and simplified manufacture, transportation, and packaging.[4]

Significant characteristic of fast dissolution drug delivery systems

- ❖ One notable characteristic of rapid dissolving drug delivery systems is their ability to facilitate streamlined administration, which is particularly beneficial for patients with cognitive impairments or individuals who demonstrate noncompliance.
- ❖ Elimination of water requirement
- ❖ Resolution of the unpleasant taste commonly associated with specific medications.
- ❖ Produces a pleasurable sensation by leaving minimal to no residue in the mouth following ingestion.
- ❖ Capable of reproducing the benefits of liquid medications through the use of solid formulations
- ❖ Cost-effectiveness.
- ❖ The design is slim and visually appealing.
- ❖ Reduced susceptibility to environmental variables including humidity and temperature

Classification of fast dissolving technology

There are essentially three ways to classify fast-dissolve technologies, which will help keep things organised:

- ❖ Lyophilized systems
- ❖ Compressed tablet based systems
- ❖ Fast dissolving oral film

Lyophilized systems

Lyophilized systems refer to substances or materials that have been freeze-dried to remove moisture and create a stable, dry product.

This system has shown unparalleled success compared to all others in terms of sales volume, sales value, and the number of global product approvals. Making tablet-shaped units using a mould or blister pack to combine a medicinal liquid or solution with extra structural excipients is the technology used in these systems. The tablet-shaped units are formed by executing this procedure. The next step is to freeze and lyophilize the units or tablets within the mould or packaging. The end products have very high porosity, which allows water or saliva to penetrate quickly and breaks down very quickly.

The dose handling capacity of these systems varies based on the solubility of the active components. It is possible to get a dosing capability that is slightly lower for soluble medications as compared to certain tablet-based systems. Tablet-based treatments are slower to break down than these units, which have the flexibility to include a wide variety of taste-masked ingredients and display faster disintegration, respectively.

Compressed tablet-based systems

This method employs conventional tablet technology in which excipients are compressed directly. Tablet technology's hardness and friability are subject to variation contingent upon the manufacturing process implemented. This leads to discrepancies in the efficacy of disintegration processes and the stipulations for packaging. Packaging designs that provide product protection, such as those provided by PackSolv and CIMA Labs, may differ in specification from those of more simplistic high-density polyethylene (HDPE) bottles or blisters. The expedited disintegration of fast dissolving tablets, as opposed to conventional tablets, is due to the incorporation of superdisintegrants or water-soluble excipients that facilitate the swift ingress of water into the tablet core. Biovail Fuisz Technology departs from the tablet method by creating drug-infused candy floss using the proprietary Shearform technique. For tableting, this candy floss is then mixed with other ingredients. These systems are capable of processing significant quantities of pharmacological substances, including coated particulates intended to obscure their flavour. However, their rate of

disintegration may be comparatively delayed when compared to lyophilized or thin film dosage forms. An increasing number of technology organisations, branded corporations, and generic pharmaceutical companies have adopted the loose compression tablet method internally to create generic fast-dissolving dosage forms and line extensions.

Fast dissolving oral film

The therapeutic material in a fast-dissolving oral film (FDOF) dissolves rapidly in saliva, usually within seconds, without the need for water or chewing. The film is very thin.

The gold standard of solid dosage forms for oral administration, fast-dissolving oral films (FDOFs) provide increased convenience and versatility. Without the need for chewing or water, they improve the efficacy of active pharmaceutical ingredients (APIs) by quickly dissolving in the mouth when exposed to saliva.

The rapid absorption and easy accessibility of the medications are caused by the increased permeability and blood flow in the oral mucosa, which can be four to a thousand times higher than in the outermost layer of skin.

FDOFs provide benefits for various patient populations, including paediatric patients, the elderly, bedridden individuals, those afflicted with vomiting or diarrhoea, and those experiencing abrupt allergic reactions or episodes of wheezing. By utilising water-soluble polymers that rapidly degrade in the mouth or tongue, these films facilitate the transportation of the drug to the bloodstream via the oral mucosa [5].

Medications that undergo extensive first-pass metabolism and require low dosages to be more bioavailable are designed with fast-dissolving drug delivery systems in mind [6].

Developed towards the end of the 1970s, these systems offered an alternative to the more traditional solid oral dose forms, including tablets, syrups, and capsules. People who have trouble swallowing, whether they are young or old, are the target audience for these products.

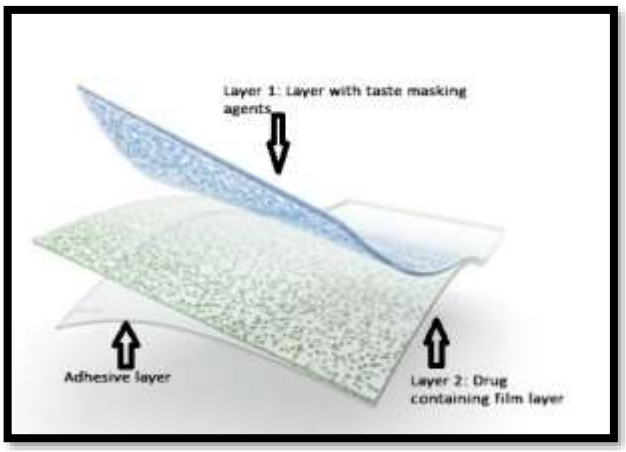

Figure 2: Oral thin film

Oral fast-dispersing dosage forms are solid formulations that decompose or dissolve rapidly in the mouth, producing a suspension or solution that does not necessitate the addition of water. Dysphagia, or trouble swallowing, affects people of all ages, although it is more common among the elderly. Traditional forms, such as tablets and capsules, may also present with same difficulties. Dysphagia is linked to a range of medical diseases, such as stroke, Parkinson's disease, AIDS, thyroidectomy, head and neck cancer therapy, and neurological abnormalities like cerebral palsy. The primary complaints frequently revolve around the tablet's dimensions, followed by subsequent apprehensions concerning its texture, form, and taste. Tablet ingestion difficulties are a common occurrence among paediatric and elderly patients, as well as travellers who may face water scarcity restrictions.

Notion behind oral dissolving film

- ❖ The structure of this delivery system is a thin film.
- ❖ When placed on the tongue, it dissolves quickly, increasing the drug's bioavailability by avoiding first pass metabolism. [7].
- ❖ Increased surface area promotes quick breakdown and absorption in the mouth.
- ❖ When seen in the mouth, quickly dissolving films take on a texture similar to cotton candy. [8].

Classification of oral films

Oral films can be categorised into three distinct groups:

- ❖ Flash release/fast dissolving films are designed to be applied to the tongue
- ❖ Mucoadhesive melt away films are intended for application to the gingival or buccal region.
- ❖ Mucoadhesive sustained release films that stick to the buccal mucosa. [9].

Property/sub type	Flash release Wafer	Mucoadhesive melt-away wafer	Mucoadhesive sustained release wafer
Area (cm2)	2-8	2-7	2-4
Thickness (mm)	20-70	50-500	50-250
Structure	It comprises of just one layer.	either a single layer or many layers	usually consists of several layers
Excipients	makes use of very hydrophilic, soluble polymers	makes use of hydrophilic, soluble polymers	Contains low/non-soluble polymers
Drug phase	Contains the medication in a solid form.	Has the medication in either a solid solution or suspended particles.	Mixes the medication into a solid solution or suspension.
Application	positioned on the upper palate or tongue	applied to the buccal or gingival area	positioned inside the mouth cavity on the gingival and other areas
Dissolution	Rapidly dissolves, with a maximum of 60 seconds	Disintegration in a few min	Provides a prolonged dissolving period of up to eight to ten hours.
Location of the action	functions locally or systematically	functions locally or systematically	Provides systemic or local pharmacological effects

Figure 3: Categories of Oral-Films [10, 11]

Advantages of orally FDFs [12]

These fast dissolve films have a number of benefits, including

- ❖ Quick breakdown and dissolution in the mouth is made possible by the large surface area of ODFs. The ability to dissolve and break down the films quickly in the mouth is one of numerous advantages of the fast dissolving films.
- ❖ They provide convenient options for dosage.
- ❖ Rapid disintegration or dissolution results in a swift initiation of action, which is particularly advantageous in situations such as pain.
- ❖ ODFs can be administered in the absence of water, rendering them convenient for use in any location and at any time.
- ❖ Because they help with swallowing tablets, oral dissolving films are particularly helpful for elderly and young patients, as well as those with dysphagia or cognitive problems. They are also

beneficial for those who are feeling queasy or nauseous.
- ❖ There is no danger of asphyxiation linked to ODFs.
- ❖ ODFs are malleable, portable, and simple to transport, handle, and store, which improves their stability.
- ❖ They are highly efficient in situations that demand extremely fast action, such as motion sickness or allergic attacks.
- ❖ ODFs, in comparison to liquid formulations, guarantee accuracy in the administered dosage.
- ❖ The amount of medication that may be absorbed when given orally is increased when it is directly absorbed through the highly vascularized oral or buccal mucosa, which prevents the drug's early breakdown in the liver.
- ❖ Sublingual and buccal administration using thin film can expedite the drug's effects, decrease the required dosage, and improve the drug's effectiveness and safety.
- ❖ ODFs promote improved patient compliance.

Disadvantages of orally FDFs
- ❖ Medications that provoke irritation to the oral mucosa cannot be effectively delivered through this method.
- ❖ Medications that irritate the mucous membranes of the mouth cannot be given through this method
- ❖ Additionally, because the buccal cavity has a small surface area, only small amounts of drugs can be effectively administered. Formulating drugs with high doses into thin films, such as Rifampin (600mg) and Ethambutol (1000mg), presents challenges.[13]
- ❖ Stability issues, such as ductility and the absorption of moisture, may arise when storing thin films.
- ❖ Specialized packaging is essential to guarantee the stability and safety of the products.

Anatomy and physiology of oral mucosa

The oral mucosa has been the subject of several in-depth analyses of its makeup and functions. Each layer of the oral mucosa- the basement membrane, connective tissues, and epithelium—contributes to its unique characteristics. Different from one another are these layers. There are many areas that have both keratinized and non-keratinized epithelium, such as the posterior surface of the tongue, the floor of the mouth, the alveolar mucosa, the vestibule, the lips, and the cheeks.

The hard palate and other less pliable areas of the mouth, on the other hand, are mostly composed of keratinized epithelium. As they migrate towards the surface, epithelial cells undergo morphogenesis, a process by which they change shape and proliferate. In rabbits, dogs, and humans, the buccal epithelium can range in thickness from 500 to 800 μm.

The basement membrane provides a structural basis for adhesion between the epithelium and the connective tissues by separating them. Mechanical robustness is a critical function of the connective tissues beneath the mouth mucosa. The tall, cylindric tissues are lined with collagen fibres, smooth muscles, and blood vessels; they are called the lamina propria. You can find them in non-keratinized tissues. The anterior, posterior, buccal, and infraorbital arteries are branches of the external carotid artery that bring blood to the oral mucosa.

Mucus, a gel-like substance mainly composed of glycoproteins that are insoluble in water, coats the whole oral cavity. Mucus protects the cells below by acting as a hydrogel and a viscoelastic barrier. It is composed of water, proteins, enzymes, glycoproteins, electrolytes, and nucleic acids. The chemical characteristics of mucus vary according to its site of genesis in the body.

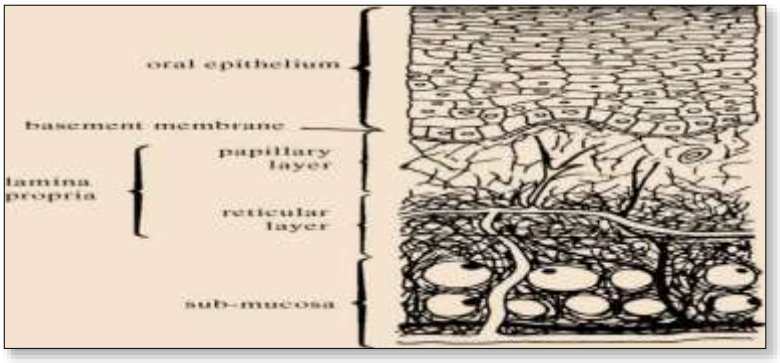

Figure 4: Anatomy of the oral mucosa

Formulation considerations

Determining the mechanical characteristics of films requires careful formulation, which includes adjusting for a lower glass transition temperature [15]. Oral dissolving films (ODFs) must be developed with careful attention to balance performance and aesthetic factors, such as flavour masking, fast dissolve, appearance, and mouth feel. Drug-loaded fast-dissolving films (FDFs) have a single-dose capacity of 30 mg and are typically best sized between 1 and 20 cm2. [15].

S. No	Ingredient	Concentration (%)
1.	**Drug**	1-30
2.	**Film Forming Agent**	40-50
3.	**Plasticizer**	0-20
4.	**Saliva Stimulating Agent**	2-6
5.	**Sweetening agent**	3-6
6.	**Flavouring agent**	q.s
7.	**Colouring agents**	q.s

Figure 5: Composition of FDOFs [16]

Active Pharmaceutical ingredient (API)

Any class of medicine with pharmacological effects that can be given orally or through the buccal mucosa is considered an active pharmacological substance [17–18]. When choosing a medication, the following qualities are ideal:

- ❖ Pleasant taste
- ❖ Requires a low dosage (<30mg).
- ❖ The optimal range for its molecular weight is between small to moderate.
- ❖ It ought to have the ability to permeate the oral mucosal tissue, be stable, and dissolve in both water and saliva.

Film Forming Polymers [19]

About forty to fifty percent of the film's total mass consists of polymers, the primary component of FDOFs. Nonetheless, they can be raised by up to 65% w/w to achieve specific characteristics. These polymers are essential to the film's strength and endurance, ensuring that no damage will occur during handling or transit. The durability of the film is contingent upon the specific composition and concentration of polymers employed in its formulation. The physicochemical properties of certain polymers are crucial in determining how quickly the prepared film breaks down. Polymers with

higher molecular weights tend to have slower disintegration rates. Hydrophilic polymers are the ones used in oral strips the most since saliva rapidly degrades them. Depending on the needs, polymers can be used alone or in combination, and both synthetic and natural options are available.

Ideal properties of film-forming polymers include:

- ❖ Non-toxic and non-irritating properties.
- ❖ Hydrophilic nature
- ❖ Excellent ability to form films.
- ❖ Good wetting and spreading capabilities.
- ❖ Widely accessible and affordable.
- ❖ Low molecular weight.
- ❖ Extended shelf life.
- ❖ Tasteless and colorless attributes.
- ❖ Non-inductive of secondary infections in the oral mucosa refers to the absence of causing or promoting additional infections in the oral lining.

Commonly used natural polymers in Oral disintegrating film

S. no.	Class	Example
1.	Carbohydrate	Pullalan, pectin, sodium alginate, maltodextrin, Sodium starch glycolate (SSG)
2.	Proteins	Gelatin
3.	Resin	Polymerized rosin (novel film former)

Commonly used synthetic polymers in Oral disintegrating film

S. no.	Class	Example
1.	Cellulose derivatives	Hydroxypropyl methylcellulose (E3, E5, E15, K3, K15, K50), Methylcellulose (A3, A6, A15), Carboxy methylcellulose secekol- 30, Sodium carboxymethyl cellulose, Microcrystalline cellulose, Croscarmellose sodium (CCS).
2.	Vinyl polymer	Poly vinyl pyrrolidone (K-90, K-30), Poly vinyl alcohol, poly ethylene oxide
3.	Acrylic polymer	Eudragit (RD-100, 9, 10, 11, 12 and RL-100)

Figure 6: Commonly used natural and synthetic polymers

Plasticizers [20-21]

Fast-dissolving films require plasticizer because it reduces brittleness and promotes flexibility. It enhances the film-forming characteristics of the polymer by lowering its glass transition temperature. It is possible to drastically alter the glass transition temperature of polymers by manipulating their chemical composition and the quantity of plasticizers. When making a film, the plasticizer is selected according to how it reacts with the polymer and the solvent. Polymers are made stronger by adding plasticizers to them, which improve their flow. The typical range for plasticizer concentrations in polymers is 0% to 20% w/w by weight. However, if not applied correctly, they can cause film defects like as peeling, splitting, and cracking. Some plasticizers can potentially affect the absorption rates of drugs. Some examples of plasticizers are

S. no.	Example
1.	Glycerol
2.	Propylene glycol
3.	Polyethylene glycol
4.	Phthalate derivatives like dimethyl, diethyl and dibutyl phthalate
5.	Castor oil
6.	Citrate derivatives like tributyl, triethyl, acetyl citrate, triacetin

Figure 7: Commonly used plasticizers in Oral disintegrating film

Sweetening Agents [22-23]

Sweeteners are now essential components in formulations designed to break down or dissolve in the mouth. Incorporating flavors and sweeteners into the formulation is crucial for effectively concealing the sensory perception of taste. Whether used alone or in combination, sweeteners typically range from 3 to 6% w/w. To create films that dissolve quickly, a mix of natural and artificial sweeteners is used. Polyhydric alcohols like sorbitol, mannitol, and isomalt can enhance the texture and provide a refreshing coolness to food products.

Nevertheless, it is crucial to restrict the utilization of natural sugars in such concoctions, particularly for individuals adhering to dietary restrictions or those suffering from diabetes. As a result, artificial sweeteners have become increasingly popular in food and pharmaceutical products.

Acesulfame-K and sucralose have sweetness intensities that are more than 200 and 600 times higher than sucrose's, respectively. With sweetness levels that surpass 2000 and 8000 times that of sucrose, neotame and alitame are considerably sweeter. The composition of oral strips containing valdecoxib has included aspartame.It is well known that the bitter taste of fast-dissolving films containing ondansetron and diclofenac, respectively, can be covered up by neotame and sucrose.

S. no.	Sweetening agent	Example
1.	**Natural sweeteners**	Xylose, ribose, glucose, galactose, fructose, dextrose, sucrose, maltose
2.	**Artificial sweeteners**	**First generation:** Saccharin, Cyclamate and Aspartame
		Second generation: Acesulfame-K, Sucralose, Alitame, and Neotame

Figure 8: Commonly used natural and artificial sweetners in oral disintegrating film

Saliva-stimulating Agent [24]

By stimulating saliva production, saliva stimulants accelerate the disintegration of fast-dissolving films (FDFs). Saliva production is frequently stimulated by acids. Examples are

S. no.	Example
1.	Citric acid
2.	Malic acid
3.	Lactic acid
4.	Ascorbic acid
5.	Tartaric acid

Figure 9: Commonly used Saliva-stimulating Agent in oral disintegrating film

Among these options, citric acid is the one most typically chosen. Common concentrations for these agent range from 2 to 6 percent, and they are often used either alone or in combinations.

Flavoring Agents [25]

It takes flavours to cover up the harsh or unpleasant taste of the combined drug. What kind of active pharmaceutical ingredient (API) is being utilised determines the flavour and its strength, which in turn determines how much is needed. It is possible to add flavours to the formulation at up to 10% weight content. The flavour that is perceived just after administration and for at least 10 minutes afterward determines whether or not the patient accepts the dosage form. As such, selecting the right flavouring agent is crucial. Flavouring agents can be created from a wide variety of plant components, including leaves, fruits, flowers, and oleo resins, as well as artificial flavour oils. Some taste oils include nutmeg, peppermint, spearmint, and cinnamon. Flavours of fruit can be detected in cocoa, vanilla, coffee, chocolate, and citrus.In addition, the fruit essences of pineapple, apple, cherry and raspberry are examples of different kinds.

Colouring Agents [26]

Colouring agents are flavor-driven additives used to a composition to enhance colour. Fast-dissolving oral films and other pharmaceutical preparations generally use FD & C approved colourants; titanium dioxide is the most commonly used choice. However, the colouring ingredient should not be added in excess of 1% of the total weight.

Technologies used in manufacture of FDFs [30]:

Various techniques are employed to create formulations for fast dissolving films.

1. Casting and drying
A. Solvent casting
B. Semisolid casting.
2. Freeze dried wafer
3. Extrusion
A. Hot melt extrusion.
B. Solid Dispersion Extrusion
C. Rolling method.

Casting and drying

A. Solvent Casting Method

When it comes to the production of films that dissolve quickly, the solvent casting method is typically considered to be among the most commonly used procedures. The first step in dissolving water-soluble polymers is to heat them to sixty degrees Celsius and spin them in water at a thousand

revolutions per minute (rpm).

Individually, each of the other ingredients, including colours, flavour enhancers, and sweeteners, are dissolved at the same time. Both solutions are then thoroughly combined by stirring at a rate of one thousand revolutions per minute after the previous step has been completed. The next step is to mix the created solution with the API, which needs to be dissolved in the appropriate solvent. Once the vacuum system is activated, all of the trapped air is removed. After the procedure is complete, the solution is transformed into a film. It is then let to dry before being cut into pieces with the specified dimensions.

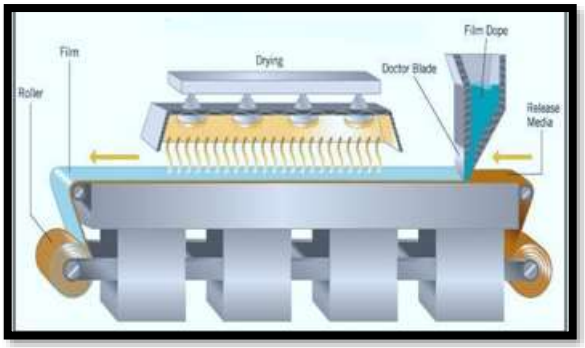

Figure 10: Solvent Casting System

The process involves several key steps:

- **Preparation of the casting solution:** Initially, the strip-forming agents and plasticizer are dissolved in distilled water. This solution is then continuously mixed on a magnetic stirrer for up to 4 hours, followed by an additional hour to remove any trapped air bubbles [9-12].
- **Deaeration of the Solution:** In a separate container, other water-soluble excipients, including sweeteners, saliva-stimulating agents, flavors, and the active medication, are dissolved while constantly stirring for 45 minutes. The solutions are then combined and stirred for another hour. Afterward, they are left to sit for an hour to allow any foam to settle.
- **Transfer of Solution into Mold:** The resulting mixture is cast onto a suitable platform, where it is allowed to dry to form a film.
- **Drying the Casting Solution**: Ideally, the film is air-dried or placed in an oven for drying before gentle removal.
- **Cutting** It involves dividing the fast dissolving film into individual pieces to ensure each has the right drug dosage.This method involves precise steps to create rapidly dissolving oral films.
- **Packaging** It is the process of placing these film pieces into containers, like pouches or blister packs, to protect them, provide dosing information, and maintain their quality.

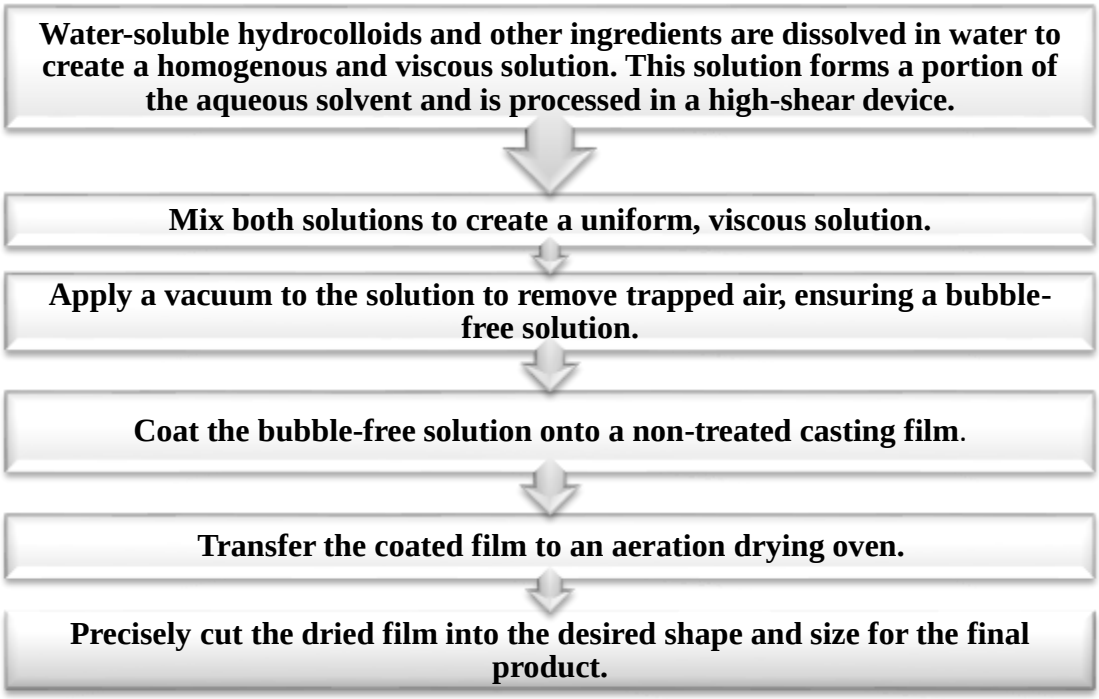

Figure 11: Sequential Illustration for the Creation of FDF'S by solvent casting method

Advantages

- ❖ Offers improved transparency and uniform thickness in comparison to extrusion methods.
- ❖ There are no flaws, such die lines, and the finished film looks well-polished.
- ❖ Better physical characteristics and increased flexibility are displayed by it. While varying thicknesses can be achieved to meet the needs of API loading and dissolution, the best range for the final film thickness is usually between 12 and 100 micrometres.

Disadvantages

- ❖ The polymer needs to be able to dissolve in water or a solvent that evaporates easily.
- ❖ To obtain a stable solution, it is necessary to have a minimum amount of solid material and a viscosity that is appropriate.
- ❖ It should be possible to produce a film that is uniform and extract it from the casting substrate.

B. Semi solid casting

It is a casting process in which material being cast is in a partially solid state, usually in the form of a slurry or a mushy consistency.Film materials made of acid-insoluble polymers are the primary targets of this method. Soluble polymers are first dissolved in water. After that, a separate acid-resistant polymer solution is added to the one that has been produced. Both solutions are combined well. The last step in making a viscous mass is adding the right amount of plasticizer to the blended solution. The next step involves using temperature-controlled drums to transfer the gel bulk onto films or ribbons. Typically, the thickness of the film is kept within the 0.015 to 0.05 inch range. A ratio of one to four between acid-insoluble and film-forming polymers is ideal. Polymers that do not show insolubility in acidic solutions include cellulose acetate butyrate and cellulose acetate phthalate.

Freeze dried wafer

Dehydration lowers the water content and surrounding pressure of freeze-dried wafers, which are also called Lyophilization or Cryodessication. Because of this, the material's water can go straight from a solid to a gas. Products made by lyophilization have a lot of surface area, a lot of porosity, they dissolve quickly, and they are more absorbable and bioavailable.

Extrusion

A. Hot-Melt Extrusion

The first step in hot melt extrusion is to use carriers to help form a mass. The first step is to combine the drug with carriers to form a compressed material, which is subsequently dried. The next step is to feed the dehydrated particle material into the extruder. Each of the four sections of the extruder has its own temperature range: 800°C in zone 1, 1150°C in zone 2, 1000°C in zone 3, and 650°C in zone 4. To ensure the granules are processed properly in the extruder barrel, the screw speed is set to 15 revolutions per minute (rpm). This speed is maintained for a duration of approximately 3-4 minutes, ensuring sufficient melting of the mass. The material that is forced out through a small opening, known as the extrudate, is subjected to a temperature of 650°C. Subsequently, the material is compacted into a cylindrical form using a calendar, leading to the creation of a film. Hot melt extrusion has numerous advantages, including a decreased number of operating components, little product loss, scalability, water-free processing, absence of organic solvents, shorter mixing time and temperature for the drug and carrier, and improved content consistency.

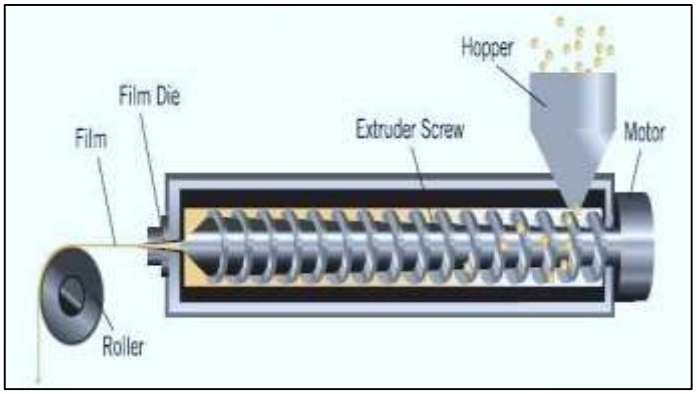

Figure 12: Film Extrusion System

Advantages

- ❖ Eliminates the necessity of solvents or water.
- ❖ It's possible that the API's compressibility features won't be as apparent.
- ❖ It functions as a highly effective substitute for drugs that have low solubility.
- ❖ It achieves a more consistent distribution by vigorously mixing and agitating.
- ❖ Requires a lower amount of energy in comparison to high-shear methods.

Disadvantages

- ❖ High temperatures employed in the process can result in thermal degradation.
- ❖ The polymer's rheological properties are crucial for its processing.
- ❖ There is a scarcity of appropriate polymers.
- ❖ The excipients ought to be devoid of any volatile solvents or water.

B. Solid-Dispersion Extrusion

Solid-dispersion extrusion is the method used to produce solid dispersions by means of extrusion. This method entails dissolving the medication in a heated polymer solution to create a solid dispersion that is ideal for loading the medicament. To begin with, the medicine is dissolved in a liquid solvent that is compatible with it. Subsequently, the resultant solution is mixed with the liquefied polymer. This can be achieved at temperatures below 70°C without the necessity of extracting the liquid solvent. By using this method, a solid dispersion is produced. Finally, dyes are integrated into the solid dispersions to create films.

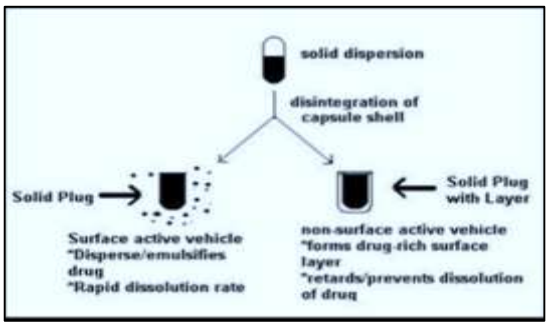

Figure 13: Solid Dispersion Technique

C. Rolling-Method

For the rolling method to work, the drug solution and the film-forming polymer solution must be mixed precisely. Next, the solution or suspension is processed using rollers. Important rheological parameters must be satisfied by the solution or suspension. Before being split into the required sizes and shapes, the film is dehydrated on the rollers.

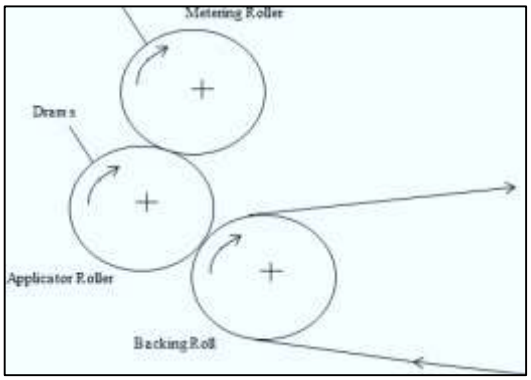

Figure 14: Three Roll-coating

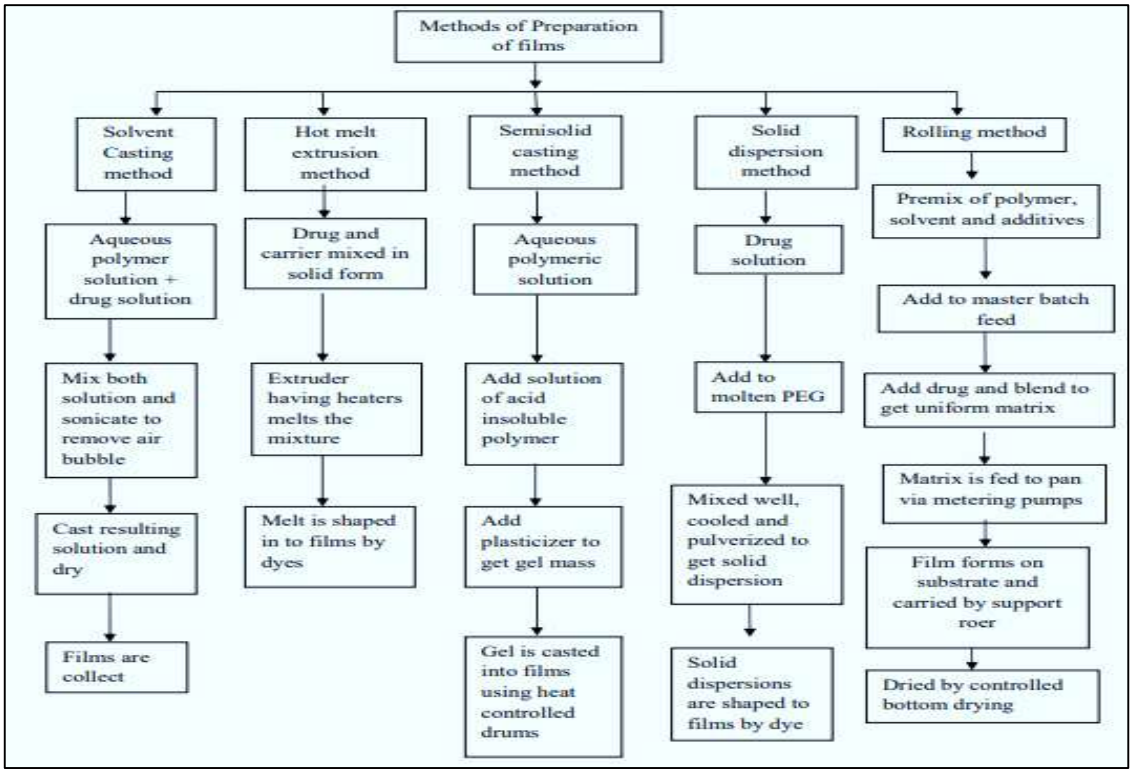

Figure 15: Flow Chart for manufacturing of Fast Dissolving Film

Patented technologies for oral dissolving films [31]

- ❖ SOLULEAVES
- ❖ WAFERTAB
- ❖ FOAMBURST
- ❖ XGEL
- ❖ MICAP

Soluleaves

Various oral delivery films containing active ingredients, colours, and flavours are manufactured using this method. When exposed to saliva, the specially designed Soluleaves^{TM} films dissolve rapidly, allowing the active chemicals and flavours to be released. If your product needs to dissolve quickly in your mouth, edible films are the way to go. This method of administration is especially helpful in the pharmaceutical sector for elderly and children patients who have difficulty swallowing regular tablets. The administration of nutritional products, pain treatment, gastrointestinal disorders, coughs and colds, and other therapeutic domains can all benefit from this delivery method. In addition, Soluleaves^{TM} films can stick to mucosal membranes and release the active ingredient slowly over 15 minutes.

Wafertab

One approach to pharmaceutical medication administration is the use of consumable filmstrips, and one such method is the Wafertab^{TM}. When bioactive components come into touch with saliva in the mouth, this approach allows them to disintegrate and release them quickly. You can further boost WafertabTM filmstrips' capacity to mask bad flavours by injecting them with your favourite flavours. The active ingredient is precisely measured and incorporated into a premanufactured XGelTM film's composition, protecting it from unnecessary exposure to heat and moisture and perhaps increasing the product's stability. By making it easier to adhere several films containing different active components, the Wafertab^{TM} method enables varied product formulation. For those who have trouble swallowing or who need medications with a rapid release, WafertabTM is a great option because of its adaptability to different shapes and sizes.

Foamburst

An inert gas is inserted into the film during the manufacturing process of Foamburst^{TM}, making it a unique adaption of the Soluleaves^{TM} technology. The resulting film has a honeycombed structure and breaks down quickly, giving it a unique taste and texture when swallowed. This innovation has been spotted by the food and candy industries as a way to transmit and release flavours.

XGel

Healthcare and pharmaceutical products can benefit greatly from the XGel^{TM} film. It is suitable for vegetarians and those who follow religious dietary restrictions because it is not sourced from animals. Not only that, but the product is free of GMOs, and the continuous production process makes it possible to manufacture it efficiently and competitively. Taste, colour, layering, and enteric qualities can all be achieved by customisation of the XGel^{TM} film. Not only that, it can include active pharmacological ingredients. A wide variety of oral dosage forms can be encapsulated in XGel^{TM} film systems, and these systems dissolve in water at both low and high temperatures, demonstrating their remarkable adaptability. A combination of water-soluble polymers, XGel^{TM} film has been fine-tuned for its particular application.

Micap

Micap plc and Bio Progress had an opportunity to combine their water-soluble film and microencapsulation technological capabilities in 2004. Innovative distribution strategies for smoking cessation products (SCPs) in the $1.4 billion worldwide industry will be the primary emphasis of the coordinated efforts.

Some of Marketed Products of ODFs are listed below [32]

S. no.	Brand name	Manufacturer/ distributor	API (strength)	Uses
1.	Eme film	Delvin formulations pvt ltd	Ondansetron 4 mg	Nausea & vomiting
2.	Listerine cool mint pocket packs	Pfizer	Mint crystals	Mouth freshner
3.	Niquistin stripes	Omega pharma ltd	Nicotine 2.5 mg	Anti-smoking
4.	Zupelnz stripes	Monosol Rx	Ondansetron 8 mg	Ondansetron
5.	Spiromont	Monosol Rx	Montelukast 10 mg	Asthma& allergy
6.	Sildenafil citrate film	Alpha pharma health care	Sildenafil 50 mg	Erectile function
7.	Tadalafil stripes	Alpha pharma health care	Sildenafil 20 mg	Erectile function
8.	Vitamin D3	Zim laboratories	Calciferol 2,000 I.U	Calcium supplement
9.	Benadryl	MC Neil consumer health care	Diphenhydramine 25 mg	Antihistamine
10.	Tri aminic	Novartis	12.5 mg	Antiallergic

Figure 15: List of Marketed Products of ODFs

Packaging of Fast Dissolving Film

Choosing packaging that properly maintains product quality is of the utmost importance when thinking about the pharmaceutical industry. To ensure the correct dosage of rapidly dissolving dosage forms, it is necessary to use expensive packaging materials, precise processing procedures, and careful handling both during production and storage. A variety of packaging choices are available with fast-dissolving films; special packaging is required for pharmaceutical products. The most popular option among these formats is the aluminium pouch. The Rapid card is a proprietary and trademarked packaging solution developed by APR-Labtec for Rapid films. You may fit up to three Rapid films on each side of the Rapid card, which is about the size of a credit card. Dosage for each film can be precisely measured using this method [33].

The selected material must possess the following characteristics: -

- ❖ It should provide protection to the product against environmental factors.
- ❖ It must be approved by the FDA.
- ❖ It should comply with applicable tamper-resistant standards
- ❖ The substance must be non-toxic.
- ❖ The substance must not have a chemical reaction with the product.
- ❖ It must not react with the product
- ❖ The substance should not impart any flavour or odour to the product.

Diverse packaging types

- ❖ Foil, paper or plastic pouches.
- ❖ Single pouch and Aluminum pouch.
- ❖ Blister card with multiple units.

Foil, paper or plastic pouches

Flexible pouches manufactured from materials such as plastic, paper, or foil can be utilised to accomplish packaging solutions. These pouches offer a combination of temperature resistance and environmental protection, provided that appropriate materials are chosen. Typically, these pouches are formed, filled, or sealed utilising vertical or horizontal machinery during the product filling process. They are available as aluminium pouches or as individual pouches.

Aluminium pouch and single-use pouch

The Transport of Drugs via Soluble Films to store "quick dissolve" soluble films with outstanding barrier properties, a specialist container called a pouch was developed. The things are made more visible through the use of transparency. One side of the material remains see-through while the other is coated with an economical foil lamination; this technique is called a dual-structure combination. Impressive gas and moisture barrier qualities are offered by this foil lamination. To ensure the safety of the drug and the dosage, the packaging offers a thin and flexible film alternative that is perfect for pharmaceutical and nutraceutical uses. The most popular and recommended choice is the aluminium pouch.

Blister card containing several units

There are two primary parts to a blister container: the blister itself (which creates the empty space to hold the contents) and the lid stock (which closes the blister). The blister package is made by first making a sheet of flexible thermoplastic resin, and then shaping it into a predetermined shape using a vacuum. After the sheet has cooled, it is taken out of the mould and moved to the packing machine's filling station. The contents are placed into the semi-flexible blister, which has now taken its shape, and then the backing material is heat-sealed to seal it. The desired amount of protection should dictate the choice of film; aluminium foil is commonly used for lids. In most cases, the hollow is made of a plastic material that is designed to keep the dosage form dry.

Barrier Films

Water is a major enemy of pharmaceutical preparations, hence high barrier coatings are an absolute must. Polypropylene and polychlorotrifluoroethylene (PCTFE) film are two of the many materials that can be used to achieve moisture protection. Stress cracking is not an issue for polypropylene, and the material also provides excellent gas and vapour barrier properties. But the lack of transparency is still a problem.

Evaluation of the Films [34]

Thickness

A micrometre screw gauge or a calibrated digital Vernier calliper are the usual tools for evaluating film thickness.Typically, three measurements are obtained from each batch, and the average is computed. The evaluation should be carried out at five specific positions, encompassing the four corners and the central area. Ensuring a consistent thickness throughout the film is essential as it directly affects the uniformity of the drug content.

Folding endurance test

The endurance value is evaluated through the repetitive bending of film specimens, which have dimensions of 2.5 × 2.5 cm2, at a fixed spot to a 180° angle until they either fracture or show a visible crack. The folding endurance value is calculated based on the film's capacity to endure several folds without fracturing or exhibiting obvious fissures. Folding endurance measures the fragility of a film, where a higher value signifies increased mechanical resilience. The concentration of plasticizer has an indirect impact on the folding endurance value, as it influences the mechanical strength.

Weight variation

Three randomly selected films, each measuring 2.5 × 2.5 cm^2, were selected from each film formulation. Using an electronic balance, every film was evaluated separately, and the mean weight

for each group was calculated.

DrynessTest/Tack Tests

Film drying is evaluated in eight phases: set-to-touch, dust-free, tack-free (surface dry), dry-to-touch, dry-hard, dry-through (dry-to-handle), dry-to-recoat, and print-free. These tests are also known as tack tests. In this case, tack refers to the degree of adhesiveness that a strip retains on a surface, like paper, following friction. In addition, specific instruments are available to carry out these assessments.

Tensile Strength

Tensile strength is the maximum amount of tension that a certain area can endure before the film sample breaks. The strength of the film is calculated by dividing the force exerted at the site of rupture by the cross-sectional area of the film.

$$\textbf{Tensile Strength} = \frac{\textbf{Load at failure } \times \textbf{100}}{\textbf{Film width } \times \textbf{Film thickness}}$$

Percent elongation

When a film sample (2.5×2.5 cm^2) is subjected to stress, it undergoes deformation, which is known as strain. Strain refers to the alteration in the shape of a strip prior to its fracture as a result of applied stress. The measurement is conducted using Hounsfield universal testing equipment. Typically, the elongation of the strip increases with an increase in the plasticizer content. The calculation is determined using the formula:

$$\%\ \boldsymbol{Elongation} = \frac{\textbf{Increase in length of strip}}{\textbf{Initial length of strip}} \times \textbf{100}$$

Tear resistance

Tear resistance in plastic films or sheets is a multifaceted characteristic that pertains to the material's overall ability to withstand ripping. The tearing process is initiated by exerting force at a slow rate of 51 mm (2 inches) per minute. The tear resistance value, given in Newtons or pounds-force, indicates the maximum stress or force needed to initiate ripping, usually happening during the early stages of the tearing process.

Young's modulus

Young's modulus, or elastic modulus, quantifies the rigidity of a substance. The term refers to the ratio of stress applied to the amount of strain experienced in the area of elastic deformation. This ratio characterises the material's ability to withstand external forces without undergoing deformation.

Hard and brittle strips exhibit a significant tensile strength and Young's modulus, but have limited elongation.

$$\textbf{Young's modulus} = \frac{\textbf{Slope } \times \textbf{100}}{\textbf{Strip thickness } \times \textbf{Crossheadspace}}$$

Surface pH

The surface pH was assessed by placing the film on a Petri plate and moistening it with 0.5 ml of phosphate buffer. The film remained undisturbed for a period of 30 seconds. Subsequently, the pH of the formulation was determined by placing the pH metre electrode in contact with its surface and allowing it to stabilise for a period of 1 minute. Every formulation was subjected to three trials, and the mean outcome was recorded. The film's surface pH should be about neutral, ideally with a value of 7.

Percentage Moisture Loss

Percent moisture loss is used as a measure for assessing a film's ability to absorb moisture from its environment. Usually, this attribute is evaluated by measuring the initial weight of six films from each formulation and then placing them in a desiccator containing calcium carbonate for a period of three days. Subsequently, the films are retrieved and subjected to repeated weighing until a stable weight is achieved for each film. The calculation of moisture loss is determined using the following formula:

$$\textbf{Percentage moisture loss} = \frac{\textbf{Initial weight} - \textbf{Final weight}}{\boldsymbol{Initial\ weight}} \times \mathbf{100}$$

Optimally, the moisture content in a film should be below 5%.

Organoleptic test

The essential sensory characteristics that a rapid dissolving formulation should possess are hue, aroma, and palatability. Since the formulation will break down in the mouth, it should have desirable sensory and taste qualities. The use of colour in a formulation enhances its acceptability among patients. Additionally, oral films intended for youngsters should include an appealing colour. Therefore, it is important for the formulation to have a consistent and visually appealing colour. Colour can be assessed by visual examination. Another sensory characteristic is the smell. The flavour utilised in the composition should impart a pleasant scent to the product. The scent of the polymer, medicine, and any other ingredient should be concealed by employing a flavouring agent. Evaluating taste is a crucial consideration as well. Special human taste panels are employed to assess the flavour. Studies utilising electronic tongue measurements have also documented the ability to differentiate between varying amounts of sweetness in taste masking formulations. The electronic tongue technique operates based on the premise of potentiometric titration procedure. Liquid samples can be directly analysed, but solid samples must first be dissolved in an appropriate solvent before analysis. In this procedure, the reference electrode and sensors are immersed in a beaker containing a test solution for a duration of 120 seconds. The E tongue software is then used to measure and record the potentiometric difference between each sensor and the reference electrode.

Contact angle

Contact angle measurement is a reliable method for predicting the wetting behaviour, disintegration time, and dissolution of oral film. The measurements are conducted using a goniometer manufactured by AB Lorentzen and Wettre in Germany. It is important to note that the measurements must be carried out at the standard room temperature. The water utilised for measuring contact angle should be distilled twice.A small amount of double distilled water is applied onto the surface of a dry film. Water droplets are captured with a digital camera during a time frame of 10 seconds after they are deposited. The angle determination of digital photographs can be performed using the imageJ 1.28v software (NIH, USA).

Transparency

A straightforward method to assess the transparency of an oral film is by use a basic ultraviolet (UV) spectrophotometer. The film sample is positioned on the inner surface of the spectrophotometer cell. The transparency of films is determined by a calculation method as follows.

$$\textbf{Transparency} = \frac{(\textbf{log T600})}{\boldsymbol{b}} = -€\mathbf{c}$$

T_{600} represents the transmittance at a wavelength of 600 nm. The variables b and c correspond to the film thickness (measured in millimetres) and concentration, respectively.

Scanning electron microscopy

Electron microscopy can be employed to examine the surface morphology of a film formed by various excipients and drug scans. To capture images of the film sample, it should be positioned in the sample holder. By utilising a tungsten filament as an electron source and setting the magnification to ×1000, several photomicrographs can be obtained.

Disintegration test

Disintegration time is the period it takes for an oral film to start breaking apart when it comes into contact with water or saliva. It is preferable for fast dissolving films to have a disintegration time between 5 and 30 seconds. In order to determine the time it takes for the film strip to break down, a square film measuring 2.5 × 2.5 cm2 is placed in a Petri dish containing 25ml of phosphate buffer

solution with a pH of 6.8. The duration required for the film to fully disintegrate is recorded. Measurements are conducted three times, and the mean values are presented.

***In-vitro* dissolution test**

An in-vitro dissolution test is a laboratory procedure that measures the rate at which a chemical dissolves in a liquid medium, without the involvement of a living creature. Dissolution is the process by which a certain amount of a pharmaceutical substance dissolves in a solution within a defined timeframe, under controlled parameters of liquid/solid contact, temperature, and solvent concentration. The in vitro dissolution investigation was performed using the USP dissolution equipment II, specifically the Paddle with sinker configuration. Each film was attached to a metal wire slab and placed at the bottom of the dissolution vessel. The dissolution experiments were conducted at a temperature of 37±0.5°C, with a stirring rate of 50 revolutions per minute in 900 millilitres of phosphate buffer solution at a pH of 6.8. Films measuring 2.5 × 2.5 cm2 were used to administer the dosage. At regular intervals of 30, 60, 90, 120, 150, and 180 seconds, 5 ml samples of the dissolving fluid were taken and substituted with equivalent volumes of phosphate buffer (pH 6.8). The gathered samples were passed through a 0.45 μm Whatman filter paper and subsequently examined using spectrophotometry.The absorbance values were transformed into concentrations by utilising a standard calibration curve derived from experimental measurements conducted on a UV spectrophotometer. The results were presented as the average of three concentrations of the same type.

Drug content

Content uniformity is evaluated by quantifying the concentration of the active pharmaceutical ingredient (API) in each individual strip. The drug concentration was ascertained by dissolving the formulated rapidly-dissolving film, measuring 2.5×2.5 cm2 in size, in 100 ml of phosphate buffer solution with a pH of 6.8. A 1 ml aliquot was extracted and then diluted to a final volume of 10 ml using phosphate buffer solution with a pH of 6.8. The solution was subsequently purified using a Whatman filter paper and examined using a UV spectrophotometer at the specified wavelength to quantify the concentration of the medication in the film. The range for content homogeneity is defined as 85-115%. The drug content was evaluated by calculating the mean of three measurements.

Permeability Studies

Although the permeability of the mouth mucosa is significantly higher (4-1000 times) than that of the skin, it is crucial to carry out permeation experiments. These tests frequently employ a modified Franz diffusion cell in conjunction with porcine buccal mucosa. The Franz diffusion cell consists of two compartments, namely the donor and receptor compartments, separated by the mucosa. The size of the mucosa is adjusted to match the proportions of the opening of the receptor compartment. The receptor compartment is filled with a phosphate buffer solution having a pH of 6.8. The temperature is maintained at a precise range of 37 ± 0.2°C, and a magnetic bead is used to stir the solution at a speed of 50 rpm in order to achieve thermodynamic equilibrium. A film sample is dampened with artificial saliva and brought into touch with the mucous membrane. The donor compartment is filled with 1 cc of synthetic saliva fluid, which has a pH of 6.8. At regular intervals, samples are taken out and substituted with an equivalent amount of new medium. An appropriate analytical approach can be used to determine the percentage of drug that has entered.

Stability Studies

Stability testing must be carried out in accordance with the criteria set forth by the International Conference on Harmonisation (ICH). The formulation was enclosed using a specific method, which included first wrapping it in parchment paper and then enclosing it in aluminium foil. Subsequently, the gift was placed inside a glass container. Stability experiments were conducted on the optimised formulation to assess its stability in terms of physical appearance, drug content, and drug release properties. The investigations entailed subjecting the samples to a controlled temperature of 40 ± 2 °C, along with a relative humidity of 75 ± 5%, for a period of 3 months. Specimens were collected at regular time intervals of 0, 30, 60, and 90 days for analysis.

Applications of Fast Dissolving Films in Pharmaceutical Administration [35]

Delivery of medications through the oral mucosa via buccal, sublingual, and other mucosal routes using fast-dissolving films (FDFs) may become a favoured approach for treatments that need to be absorbed quickly. This encompasses therapies for pain mitigation, allergic reactions, sleep disturbances, and disorders affecting the central nervous system. Dissolvable film dosage forms (FDFs) have recently become a trendy way for people to take vitamins and use personal care items. The confectionery and dental care sectors were the first to use these Film-Dissolving Films (FDFs) as breath strips.

Topical applications

For wound treatment and similar uses, soluble films provide an effective alternative to traditional methods of administering active substances like antibiotics or painkillers.

Gastro retentive dosage systems

Researchers are looking at soluble films as a possible delivery strategy for chemicals with varying molecular weights, including those that are water-soluble and those that are poorly soluble. These films may have important uses in the treatment of gastrointestinal diseases since they can be activated by changes in pH or enzyme secretions in the intestines.

Diagnostic devices

When exposed to biological fluids, soluble films can transport delicate reagents and release them in a regulated fashion. In addition, they can be used as isolation barriers, effectively separating various reagents so that a diagnostic device can use timed reactions.

Conclusion

Fast Dissolving films have proven to be effective drug delivery systems due to their beneficial characteristics such as rapid drug absorption, high bioavailability, ease of use, and bypassing the first-pass effect in the gastrointestinal tract and liver. Advances in fabrication techniques and formulation strategies using both natural and synthetic polymers have significantly improved the practical applications of oral films. Additionally, incorporating active ingredients into nanoparticles or inclusion complexes, which are uniformly or non-uniformly distributed within the films, enhances bioadhesion to the targeted oral mucosa and improves both the solubility and permeability of the drugs. This ultimately leads to better drug absorption and increased bioavailability. However, several challenges still hinder the widespread industrialization and commercialization of these promising oral films. Future research should focus on developing innovative formulations that increase drug loading rates while ensuring biocompatibility and biodegradability. Additionally, existing production techniques need to be adapted to produce these advanced oral films more efficiently, with reduced processing time and higher output.

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