Review Article



Fast Dissolving Oral Films: A Revolutionary Approach in Oral Drug Delivery Systems

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ABSTRACT

The oral route is the most favored method for administering therapeutic agents due to its affordability and simplicity. Administration results in elevated levels of patient adherence. The most widely used oral solid dosage forms are capsules and tablets. Numerous Patients, especially pediatric and geriatric ones, often struggle to swallow tablets and hard gelatin capsules, which leads them to avoid taking their medication. Medications as directed. Challenges in swallowing or dysphasia affect about 35% of the general population. In certain instances, like motion sickness, an abrupt allergic reaction or cough, anxiety about choking, and a lack of water, the act of swallowing tablets or capsules might become challenging. To address these challenges, various rapid-dissolving medication delivery systems have evolved. Oral fast-dissolving films represent a relatively new dosage form where a thin film is created using hydrophilic polymers, which quickly disintegrate on the tongue or in the buccal cavity. The movie addresses the risk/fear of choking. A perfect movie ought to possess qualities such as enjoyable flavor, great stability, simplicity to manage and use, and no water needed for application.

Keywords: Drug delivery systems, oral thin film, oral drug and 3D printing techniques.

INTRODUCTION

ral fast-dissolving film (FDF) represents an innovative method to enhance consumer acceptance through quick dissolution and the ability to self-administer without the need for water or chewing. The demand for non-invasive delivery systems persists because of patients' low acceptance and adherence to current delivery methods, the restricted market size for pharmaceutical companies and drug applications, along the high expenses associated with managing diseases. About one-third of the population, especially the elderly and children, experiences difficulties in swallowing, leading to poor adherence to oral tablet medications and consequently diminishing the overall effectiveness of the therapy¹. A new orally fast-dissolving dosage form like the fast-dissolving tablet or fast-dissolving film has been created that provides the benefits of easy dosing and the convenience of dosing without the need for water or any fluid. The majority of current fast-dissolving drug delivery systems are solid tablets that are created to dissolve or disintegrate in the patient's mouth in just a few seconds or minutes, without requiring any drinking or chewing ⁴. Nonetheless, the apprehension regarding swallowing solid tablets and the choking hazard for specific patient groups persists even with their rapid disintegration/dissolution periods. The film alleviates the risk/fear of choking. The creation of a rapidly dissolving film also opens the door for market expansion; many types of medications (such as neuroleptics, cardiovascular agents, pain relievers, antihistamines, antiasthma tic medications, and drugs for erectile dysfunction) can be seen as suitable options for this delivery method²⁻⁵. Administering drugs through the oral mucosa is a promising method when aiming for a quick onset of effects or enhanced bioavailability for medications with significant first-pass metabolism. Consequently, there is an increasing focus on creating alternative dosage forms, such as orally fast-disintegrating strips, which enable a quickly dissolving medication to be absorbed directly into the systemic circulation via the oral mucosa. These types of dosage forms are also suitable for children, older patients with difficulty swallowing, and when potable liquids are not available. Nonetheless, besides formulation factors, the characteristics of the active ingredient must be suitable to ensure drug delivery into the systemic circulation following intraoral administration. The oral mucosa consists of a top layer of stratified squamous epithelium, beneath which is the basement membrane, followed by the lamina propria and, at the innermost level, the submucosa³ (Table 1).

Advantages: 6-7

- The oral cavity has a large surface area, leading to rapid dissolution and disintegration of oral dosage forms.
- There is no risk of choking.
- Oral fast-dissolving films (OFDFs) are solid unit dosage forms, providing accurate dosing and great precision.
- Pregastric absorption improves the bioavailability of the drug, requiring fewer doses and enhancing patient compliance.
- OFDFs do not require water for swallowing, making them more acceptable for dysphagic patients.
- They provide a good mouth feel.
- Oral films are flexible and less fragile compared to OFDFs, making them easy to transport, handle, and store.



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- They bypass first-pass metabolism by directly absorbing from the buccal mucosa, reducing side effects and doses.
- Fast-dissolving films disintegrate immediately on the tongue without water, releasing one or more active pharmaceutical ingredients (APIs).
- The stability of the dosage form is enhanced.

Disadvantages:7

Unstable drugs at buccal pH cannot be administered.

- This route is not suitable for administering drugs that • irritate the mucosa.
- A drug with a small dose requirement can only be administered.
- Most drugs have a bitter taste, necessitating the use of taste masking.
- OFDFs are fragile and require special packaging to protect them from water.

| Property | Flash release | Muco adhesive melt release | Muco adhesive Sustained release |
|-------------------------|-------------------------------------|--|--|
| Area (cm ²) | 2-8 | 2-7 | 2-4 |
| Thickness (µm) | 20- 70 | 50- 500 | 50- 250 |
| Structure | Film single layer | Single or multilayer system | Multilayer system |
| Excipients | Soluble, highly hydrophilic polymer | Soluble, hydrophilic polymer | Low/non-soluble polymer |
| Drug phase | Solid solution | Solid solution/suspended drug particle | Suspension or solid solution |
| Application | Tongue (upper plate) | Gingival or buccal region | Gingival (or other regions of the oral cavity) |
| Dissolution | Maximum sixty second | Disintegration in few mins, forming a gel | Maximum 8 - 10 hours |
| Site of action | Systemic or local | Systemic or local | Systemic or local |

Table 1: Properties of the Oral Films³⁵

Constraints of oral film⁸⁻¹⁰:

- High doses are not feasible.
- The drug should be administered in low doses.
- It should possess high oral bioavailability.
- Oral films come with costly packaging.

Special features of oral films¹¹⁻¹⁵:

- Extremely thin films offered in different dimensions and forms
- Discreet
- Quick release and speedy breakdown
- Superior muco adhesive properties

Applications:16-19

- **a.** Oral films are favored for localized effects as well as for alleviating pain, allergies, sleep issues, and CNS disorders.
- b. Dissolvable films are suitable for topical use in wound care as pain relievers or antimicrobial substances.
- c. Oral films can be used to improve the bioavailability of drugs with low bioavailability.
- d. Concealing the flavor of bitter medications

e. Soluble films contain sensitive substances that permit a regulated release upon contact with biological fluids or serve as isolation barriers to separate various reagents, facilitating a timed reaction with a diagnostic tool.

Formulation consideration²⁰⁻²¹:

From a regulatory standpoint, all the recipients utilized in the formulation and developments of oral films are considered safe (GRAS listed) and must receive approval for use in oral pharmaceutical dosage forms. The size of oral thin films ranges from 1-20cm² (depending on the dosage and drug quantity included.

Drug²² (Active pharmaceutical ingredient):

Various kinds of APIs can be effectively integrated into the oral strip technology. Micronized API can enhance the film's texture as well as the dissolution and consistency of the oral fast-dissolving film. Various molecules can be integrated into the delivery system. The flavor of a bitter medication must be concealed; for this purpose, cyclodextrins or resins can be utilized as they inhibit the direct interaction of the active pharmaceutical ingredient with saliva. It comprises cough/cold treatments (antitussives, expectorants), anxiety medications, CVS drugs, throat pain, erectile dysfunction medications. antihistamines. antiasthmatics. gastrointestinal issues, nausea, pain relief, and CNS (antiparkinson's medications).



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The ideal properties of a drug for the development of oral strip formulation:

- i. The drug should have a low dose.
- ii. The dug has extensive high first-pass metabolism.
- iii. It should be non-bitter.
- iv. It should have a quick onset of action.
- v. The dug should have high solubility and high permeability (BCS class I).

Polymers ²³⁻²⁶:

Polymers are essential in the creation of films. Hydrophilic polymers are utilized in the formulation to ensure that the film dissolves quickly in the mouth, allowing the drug to enter systemic circulation through dissolution upon contact with saliva in the buccal area. The polymers may be utilized individually or together in a film to achieve the desired characteristics of the film. The strength of a film relies on the kind and quantity of polymer used in the formulation. Nowadays, both natural and synthetic polymers are utilized in the oral cavity. Natural polymers are safe, effective, and free from side effects, making them more favored than synthetic polymers.

Ideal properties of the polymers used in the oral film ²⁷:

- Polymers should be nontoxic and non-irritant
- It should be non-bitter
- Polymers should be tasteless
- It should be devoid of leachable impurities
- It should be inexpensive and readily available
- It should not be an obstacle in the disintegration time
- It should have good wetting and spread ability property
- It should exhibit sufficient peel, shear, and tensile strength
- It should have a sufficient shelf life
- It should not cause secondary infection in the oral cavity.

Composition and Formulation of Fast Dissolving Oral Films²⁸

The creation of FDFs includes the complex implementation of aesthetic and functional attributes like taste masking, rapid dissolution, visual appeal, and mouth feel, among others. Regarding regulatory considerations, all excipients utilized in OS formulation must be Generally Recognized as Safe and should have approval for use in oral pharmaceutical dosages. **Film Forming Polymers:** Water-soluble polymers serve as film formers, offering quick disintegration, pleasant mouthfeel, and enhanced mechanical strength to the films. The durability of the strip relies on the kind of polymer and the quantity present in the formulations. Water-soluble polymer films stick to the buccal mucosa and quickly release medication into the systemic circulation. There are various polymers available for film preparation, with pullulan, gelatin, and hypromellose being the most frequently utilized. Generally, at least 45% w/w of the polymer should be included based on the overall weight of the dry film ²⁹. Instances of water-soluble polymers are: Pullulan, Gelatin, guar gum, Xanthum gum, Hydroxyl propyl methyl cellulose, Modified starches, Hydroxyl ethyl cellulose, and so forth.

Drug Category: This technology can potentially deliver a range of active pharmaceutical ingredients. Nonetheless, due to the constraints on the size of the dosage form, incorporating high-dose medications into films is challenging. Various categories of medications can be created as rapidly dissolving films, such as antiulcer agents, antiasthmatics, antitussives, expectorants, antihistamines, NSAIDs, and more.

Plasticizers: A plasticizer is an essential component of the oral films. The choice of plasticizer relies on its compatibility with the polymer as well as the kind of solvent used in the film-casting process. It contributes to enhancing the film's flexibility and lessens its brittleness. Plasticizer greatly enhances the properties of the strip by lowering the glass transition temperature of the polymer. Usually, plasticizers are utilized at concentrations of 1 - 20% w/w based on the weight of the dry polymer. Examples comprise: Glycerol, Propylene glycol, Polyethylene glycols of low molecular weight, Citrate derivatives such as triacetin, acetyl citrate, Phthalate derivatives including dimethyl, diethyl, dibutyl variants, Castor oil, etc.

Flavoring agents: The perception of flavor varies from person to person based on ethnicity and personal preference. It was noted that age significantly influences taste preferences. Flavoring agents may be chosen from synthetic flavor oils, oleoresins, and extracts obtained from different parts of plants such as leaves, fruits, and flowers. Examples of flavor oils include peppermint oil, cinnamon oil, and nutmeg oil, while fruity flavors consist of vanilla, cocoa, coffee, chocolate, and citrus. Apple, raspberry, cherry, and pineapple are some examples of fruit essence varieties. The quantity of flavor required to conceal the taste varies based on the type of flavor and its intensity. Coloring agents: Pigments like titanium dioxide or FD&C-approved dyes are added (not surpassing concentration levels of 1% w/w) in OS when certain formulation components or medications are in insoluble or suspended states.

Cooling agents: Substances such as monomethyl succinate can be incorporated to boost flavor intensity and improve the mouthfeel experience of the product. Additional cooling agents such as WS3, WS23, and Utracoll II may also be combined with flavors ³⁰.



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Available online at www.globalresearchonline.net ©Copyright protected. Unauthorised republication, reproduction, distribution, dissemination and copying of this document in whole or in part is strictly prohibited. **Sweetening agents:** Sweeteners have emerged as a vital component of both food items and pharmaceutical products designed to be disintegrated or dissolved in the mouth. The pleasant flavor in formulations is particularly crucial for the pediatric population. Both natural and artificial sweeteners are employed to enhance the taste of the mouth-dissolving formulations. Appropriate sweeteners consist of: (a) Water soluble natural sweeteners: xylose, ribose, glucose, sucrose, maltose, stevioside, etc. (b) Water-soluble artificial sweeteners: sodium or calcium saccharin salts, cyclamate salts, acesulfame-k, etc.

Saliva-inducing agent: The aim of utilizing saliva-inducing agents is to enhance the speed of saliva production, which would assist in the quicker dissolution of the film formulations. Typically, acids employed in food preparation can serve as stimulants for saliva production. Citric acid, malic acid, lactic acid, ascorbic acid, and tartaric acid are some instances of salivary stimulants, with citric acid being the most favored among them.

Surfactants: Surfactants function as solubilizing, wetting, or dispersing agents, allowing the film to dissolve within seconds and promptly release the active agent. Surfactants enhance the solubility of poorly soluble medications in rapidly dissolving buccal films. Some frequently utilized examples include polaxamer 407, sodium lauryl sulfate, benzalkonium chloride, benzthonium chloride, tweens, and spans, among others.

Stabilizers and thickeners: These agents are used to enhance the viscosity and consistency of the dispersion or solution in the strip preparation solution or suspension before casting. Natural gums such as xanthan gum, locust bean gum, carrageenan, and cellulosic derivatives can be utilized at concentrations of up to 5% w.

5. Methods of Preparation - Fast Dissolving Films

Here are the techniques used for producing fast-dissolving films. One or a combination of the following methods can be employed to produce the fast-dissolving films:

- 1. Solvent casting method
- 2. Semisolid casting method
- 3. Hot melt extrusion
- 4. Solid dispersion extrusion
- 5. Rolling method

Generally, the solvent casting method is employed for the manufacture of strips.

1) Solvent Casting Technique

Fast-dissolving films are ideally prepared using the solvent casting technique, wherein the water-soluble components are dissolved to create a clear viscous solution. The drug and additional excipients are dissolved in an appropriate solvent. After mixing both solutions, they are cast into a Petri plate and dried, then cut into pieces of the required size. The characteristics of the API are essential in choosing an appropriate solvent. Water-soluble hydrocolloids utilized for the preparation of RDFs consist of: hydroxyl propyl methyl cellulose (HPMC), hydroxyl propyl cellulose (HPC), pullulan, sodium alginate, pectin, carboxy methyl cellulose (CMC), and polyvinyl alcohol (PVA). Solvents chosen for making a solution or suspension should preferably be selected from the ICH Class 3 solvent list. Certain kinds of equipment, like rollers, are necessary for applying the solution onto an inert substrate. The distance between the roller and the substrate dictates the necessary thickness of the film. The last stage, drying the film, eliminates the solvent and aids in achieving the completed product. Typically, glass, plastic, or Teflon surfaces are employed as a neutral foundation for film casting. When the production technology is moved from a laboratory setting to a manufacturing scale, various issues may arise. These issues may involve the selection of the film's cast, ensuring a consistent thickness of the film, and adequately drying the sample. Choosing the right kind of dryer is essential in the concluding phase of drying. After the films are dried, they undergo cutting, stripping, and packaging. Films can be cut into appropriate sizes and shapes. The standard sizes of films that are generally accessible are 3 x 2 cm2 and 2 x 2 cm².

2) Semisolid casting ³¹

In the semisolid casting process, a solution of a watersoluble polymer that forms a film is created first. The produced solution is mixed with a solution of acid-insoluble polymer (such as cellulose acetate phthalate or cellulose acetate butyrate), which can be made in ammonium or sodium hydroxide. Next, a suitable quantity of plasticizer is added to achieve a gel-like substance. Ultimately, the gel mass is poured into films or ribbons utilizing temperatureregulated drums. The film's thickness measures approximately 0.015-0.05 inches. The proportion of the acid-insoluble polymer to the film-forming polymer must be 1:4.

3) Hot melt extrusion

Hot melt extrusion is frequently utilized to produce granules, sustained-release tablets, and drug-delivery systems for transdermal and transmucosal applications. In the hot melt extrusion technique, the drug is initially blended with carriers in their solid state. Next, the extruder with heating elements melts the blend. Ultimately, the melt is formed into films by the dies. Typically, in RDF design, polymers that have low molecular weight or viscosity, like HPMC E5 or pullulan PI.20, are favored. A mixture of different grades of polymers can also be utilized to attain the desired physical characteristics. Combining high and low-viscosity polymers results in a film that exhibits strong mechanical properties and enhanced drug solubility within the film. The process of manufacturing wafers in the pharmaceutical sector consists of several distinct steps. Typically, the mixture is created initially while regulating temperature and mixing speed. Subsequently, the wafers undergo coating and are dried in a drying tunnel, where the temperature, air circulation, and line speed are monitored



once more. Next, a slitting process occurs, and in the final step, the wafers are punched, bagged, and sealed. Alternative methods for producing oral wafers include spraying processes or extrusion, specifically hot-melt extrusion. Hot-melt extrusion offers several advantages.

Advantages:

- Reduced operational units
- Improved content consistency
- A process without water

Disadvantages:

- Thermal procedures lead to issues with drug/polymer stability
- The flow characteristics of the polymer are crucial for processing
- A restricted selection of polymers is available

Solid dispersion extrusion

The phrase solid dispersion denotes the distribution of one or more active pharmaceutical ingredients (APIs) within an inert carrier in a solid form alongside amorphous hydrophilic polymers utilizing techniques like hot melt extrusion (HME). In this approach, non-miscible elements are extruded alongside the drug, followed by the preparation of solid dispersions. Ultimately, the solid dispersions are formed into films using dies.

Rolling Method

In the rolling technique, a solution or suspension that includes the drug is rolled onto a carrier. The solvent primarily consists of water or a combination of water and alcohol. The film is dried on the rollers and shaped and sized as required.

Electrospinning and 3D Printing Techniques

- 1) Novel technologies
- 2) Printing technologies

Novel technologies such as 3D printing could be used for manufacturing polymeric thin films. It could potentially be a platform for producing the dosage forms beneficial to the individual patient. This could help in creating customized medicine for each patient. Printing technologies are gaining popularity because of their flexibility and cost-effectiveness. The examples include the use of off-the-shelf consumer inkjet printers in which drug-loaded inks are deposited to yield accurately dosed units of pharmaceutical ingredients. The inkiet printing was used for printing active pharmaceutical ingredients on different substrates, whereas the flexographic printing was employed to coat the drug-loaded substrate with a polymeric thin film. Regardless of the various types of printing techniques used, all of them contribute to producing a film with a more homogeneous distribution and accurate dosage of the drug throughout the films. To summarize, printing a drug in dosage form is the

latest intervention for film preparation and it has become a powerful tool to manufacture dosage form with excellent uniformity, speed-ability, and stability³².

XGel

For healthcare and pharmaceutical products, XGeITM film provides unique product benefits. It is made without the use of animals, has religious approval, and is ideal for vegetarians. The film is devoid of GMOs, and continuous production processing allows for a cost-effective and competitive manufacturing platform. Taste masking, coloring, layering, and enteric qualities are all possible with XGeITM films, which also can contain active pharmaceutical ingredients. XGeITM film systems are frequently used to encapsulate any oral dose form and must be soluble in both cold and hot water. XGeITM film is made up of a variety of water-soluble polymers that have been precisely tailored for the application³³.

Soluleaves

This technology is employed to supply a variety of oral delivery films that may incorporate active ingredients, colours, and flavours. Soluleaves[™] films are often designed to dissolve rapidly in contact with saliva, quickly releasing the active ingredients and flavors. For pharmaceutical uses, this method of administration is particularly useful for pediatric or elderly patients who may have difficulty swallowing traditional tablets or capsules. The delivery system is often used for the cough/cold, gastrointestinal, and pain therapeutic areas and also as delivering nutritional products. SoluleavesTM films can also be made to attach to mucous membranes and release the active component over 15 minutes³³.

Wafertab

Wafertab may be a drug delivery system that comes with pharmaceutical actives into an ingestible filmstrip. When the strip comes into contact with saliva in the mouth, the system allows quick breakdown and release of actives. The Wafer tab filmstrip is often flavored for additionally improved taste masking. The active ingredient is carefully dosed and integrated into the body of a prefabricated XGel film, avoiding needless heat and moisture exposure and potentially improving product stability. Wafer tab is often prepared in a variety of shapes and sizes and is a perfect method for delivery of medicines, which require fast release or to be used by patients who have difficulty in swallowing³³.

Foamburst

It's a variation of the Soluleaves technology in which a noble gas is injected into the film during the manufacturing process. This results in a honeycombed film that dissipates quickly, providing a unique tongue feel. Foamburst has attracted interest from food and confectionary manufacturers as a way of carrying and releasing flavors³³.

Evaluation Parameters of Fast-Dissolving Oral Films ³¹

1. Organoleptic evaluation: Specially regulated human taste panels are employed to assess the product. This is



being accomplished by the use of taste sensors in vitro. These invitro taste assessment apparatuses and methodologies are well suited for high throughput taste screening of oral films.

2. Mechanical properties:

- **a.** Thickness: The thickness of the strip can be measured by a micrometer screw gauge at different strategic locations. This is necessary to ensure consistency in the film's thickness because it has a direct bearing on the strip's dosage accuracy.
- **b.** Dryness test/tack test: Tack is the tenacity with which the strip adheres to an accessory (a piece of paper) that has been pressed into contact with the strip.
- **c. Tensile Strength:** Tensile strength is the maximum stress applied to a point at which the strip specimen breaks. It is determined by dividing the applied load at rupture by the strip's cross-sectional area, as shown in the following equation:

Tensile strength = Load at failure x100/Strip thickness x strip width

- **d. Percent Elongation:** When stress is applied, a strip sample stretches, and this is referred to as a strain. In essence, strain is calculated by dividing the strip's deformation by the sample's initial dimensions. In general, the more plasticizer there is in the strip, the longer it becomes.
- % Elongation = Strip length increase × 100 initial strip length
- e. Tear Resistance: Tear resistance of plastic film or sheeting is a complex function of its ultimate resistance to rupture. Very low rate of loading 51 mm (2 in)/min is employed to measure the force to initiate tearing. The tear resistance value in Newtons (or pounds-force) is the highest stress or force (usually determined close to the tearing commencement) needed to tear the specimen.
- f. **Young's Modulus:** Young's modulus or elastic modulus is the measure of the stiffness of the strip. It is shown as follows: the ratio of applied stress to strain in the area of elastic deformation.

Young's modulus = Slope × 100/Strip thickness × Cross head speed

- **g.** Folding Endurance: Folding endurance is determined by repeated folding of the strip at the same place till the strip breaks. The folding endurance value is the number of times the film can be folded without breaking.
- **3. Swelling property:** A film swelling study is conducted using a simulated saliva solution. Each film sample is weighed and placed in a reweighed stainless steel wire mesh. The mesh that holds the film sample is immersed in 15 milliliters of medium in a plastic container. An

increase in the weight of the film is determined at preset time intervals until a constant weight is observed.

The degree of swelling is calculated using the formula-

$\alpha = (wt-wo)/wo$

The weight of the film at time zero is wo, and the weight of the film at time t is wt.

4. Transparency: The transparency of the films can be determined using a simple UV spectrophotometer. Place the film samples on the inside of the spectrophotometer cell after cutting them into rectangles. Determine the transmittance of films at 600 nm. The transparency of the films can be calculated as follows:

Transparency = (logT600)/b = - €C

Where,

T600 is the transmittance at 600 nm,

b=is the film

C=concentration and thickness (mm).

- **5. Contact Angle:** Contact angle measurements are performed at room temperature with a goniometry. A drop of double distilled water was placed on the surface of the dry film. Images of the water droplet were recorded utilizing a digital camera; digital images are analyzed by the image 1.28v software for angle determination.
- 6. Assay/ Content uniformity: This is determined by any standard assay method described for the particular API in any of the standard pharmacopeia. The API content of each strip is estimated to assess content consistency. Content homogeneity is limited to 85-115 percent.
- 7. Disintegration Time: The disintegration time limit of 30s or less for orally disintegrating tablets described in CDER guidance can be applied to fast-dissolving oral strips. Although there are currently no official guidelines for oral rapid dissolving films or strips, this could be utilized as a qualitative guideline during the development stage or for quality control testing. In this study, pharmacopeia disintegration test equipment may be utilized. Strips usually disintegrate after 5-30 seconds.
- 8. *In-vitro* Dissolution Test: Dissolution testing can be performed using the standard basket or paddle apparatus described in any of the pharmacopeia. The dissolution medium will be chosen mostly based on the API's highest dose and sink conditions. Many times dissolution tests can be difficult due to the tendency of the strips to float on the dissolution medium where the paddle system is used. Storage and Packaging of Films A variety of storage and packaging options are available for fast-dissolving films. Drug manufacturers are given product flexibility throughout the packaging stage. Films are pharmaceutical goods that must be packaged in a single container; the most popular packaging shape is an aluminum pouch. The Rapid card is a unique and



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exclusive packaging mechanism created by API, Specifically, for the Rapid films. The fast card can carry three raid films on each side and is the same size as a credit card. It is possible to remove each dose separately (**Table 2**).

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| Table 2: Market Trends and Commercially | ⁴ Available Products (Oral Strips) ³⁴ |
|---|---|
|---|---|

| Product category | Ingredient/s | Indication/applications |
|--|---|--|
| Appetite suppressant | Fucus vesiculosus and guarana extract, Garcinia cambogia | These are top selling natural ingredients associated with weight loss. Cambogia helps to reduce the food intake by suppressing appetite |
| Vitamins and food supplements | Various vitamins, minerals and supplements | It is useful for the people who do not like to pop up the tablets or soluble supplements |
| Breath freshener strip, (Antibacterial strip) | Contain mint flavor and antibacterial agent, cetylpyridinium chloride | It is used as mouth freshener and to stop bad breath |
| Saliva promoting strips | Fruit acid extracts, range of flavors | It is used in the dry mouth as a side effect of the other medications. |
| Labtec GmbH Ondansetron Rapidfilm® | Ondansetron 4 mg and 8 mg. | It is used in the prevention of chemotherapy and radiation- induced nausea and vomiting and prevention of postoperative nausea and vomiting |
| Donezepil Rapidfilm® | Donepezil Hydrochloride 5 mg and 10 mg. | Treatment of mild to moderately severe dementia of the Alzheimer's type |
| Minerals | Chromium | Mineral supplements |
| Natural products | Ginseng, Guarana | Aphrodisiac, Appetite reducer |
| Innozen Inc Chloraseptic® Relief Strips™ | Benzocaine 3 mg, BHT, corn starch, erythritol, FD&C Red 40, hydroxypropyl methylcellulose, malic acid, menthol, monoammonium glycyrrhizinate, cherry flavors, polyethylene oxide, sucralose | Occasional minor irritation, pain, sore throat and sore mouth |
| Loratidine | 10 mg-20 mg | It is a non-sedative antihistaminic agent used to treat the allergy |

FUTURE PERSPECTIVES:

The various negative aspects related to traditional dosage forms, including the difficulty of administration, reduced bioavailability, and patient non-compliance, have driven the creation of innovative polymeric thin films as a rapid drug delivery method. This drug rapid delivery platform is currently monitored by both emerging and established pharmaceutical firms. These companies aim to create various types of thin films for oral, buccal, sublingual, ocular, and transdermal applications.

Consequently, as an alternative to traditional dosage forms, polymeric thin films are anticipated to excel as a dosage form that addresses the restrictions imposed by current dosage forms. The film dosage form faces numerous obstacles throughout the stages of formulation development and production. These matters need to be resolved to enhance the overall formulation, even after moving to large-scale production. The future appears quite bright for film technology in the upcoming years as novel technologies are quickly developed to create thin films.

Storage and Packaging of Films

A variety of storage and packaging options are available for fast-dissolving films. The packaging stage provides product flexibility to the drug manufacturers. Single packaging is mandatory for films, which are pharmaceutical products; an aluminum pouch is the most commonly used packaging format. APR Labtec has developed the Rapid card, a proprietary and patented packaging system, which is specially designed for Rapid films. The rapid card is the same size as a credit card and holds three raid films on each side. Every dose can be taken out individually.

CONCLUSION

Oral fast-dissolving films have surfaced as a groundbreaking trend, and comprehensive research efforts incorporating diverse categories of drugs are emerging in this area. This innovation encompasses a wide range of patients, particularly the elderly, in pediatric medicine. It also provides numerous benefits compared to others. The dosage forms have improved bioavailability and quicker activity. The key application in urgent situations and for transferring patients. Therefore, it can be inferred that oral

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movies with numerous benefits and excellent patient 11. adherence possess bright, advanced possibilities.

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REFERENCES

- Vishali T, Damodharan N. Orodispersible tablets: A review. Research Journal of Pharmacy and Technology. 2020; 13(5):2522-9. https://doi: 10.5958/0974-360X.2020.00449.7
- Dixit RP, Puthli SP. Oral strip technology: Overview and future potential. Journal of controlled release. 2009 Oct 15; 139(2):94-107. https://doi.org/10.1016/j.jconrel.2009.06.014
- Bradoo R, Shahani S, Poojary S, Deewan B, Sudarshan S. Fast dissolving drug delivery systems. Jama India. 2001; 4(10):27-31.
- Prateek S, Ramdayal G, Kumar SU, Ashwani C, Ashwini G, Mansi S. Fast dissolving tablets: a new venture in drug delivery. American Journal of PharmTech Research. 2012; 2(4):252-79.
- Arya A, Chandra A, Sharma V, Pathak K. Fast dissolving oral films: an innovative drug delivery system and dosage form. Int J ChemTech Res. 20101; 2(1):576-83.
- 6. Kulkarni AS, Deokule HA, Mane MS, Ghadge DM. Exploration of different polymers for use in the formulation of oral fast dissolving strips. J Curr Pharm Res. 2010; 2(1):33-5.
- Patil SL, Mahaparale PR, Shivnikar MA, Tiwari SS, Pawar KV, Padm PN. Fast dissolving oral films: An innovative drug delivery system. International Journal of drug discovery and medical research. 2012; 25;1(1):39-41.
- 8. Bhyan B, Jangra S, Kaur M, Singh H. Orally fast dissolving films: innovations in formulation and technology. Int J Pharm Sci Rev Res. 2011; 9(2):9-15.
- 9. Patel H, Patel U, BHIMANI B, DASLANIYA D. Transdermal drug delivery system as prominent dosage forms for the highly lipophilic drugs. The International Journal of Pharmaceutical Research and Bio-Science. 2012; 1(3);102-110.
- Prajapati, B. G., Pharm, M., Naik, M. S., Gol, V. D., & Pharm, B. "Formulation, Optimization & Evaluation of mouth dissolving strips of L-methyl folate calcium. Thesis Master of Pharmacy (M.Pharma), Department of Pharmaceutics and Pharmaceutical Technology, Shree S. K. Patel College of Pharmaceutical Education and Research, Ganpat University, Ganpat Vidyanagar, Mehsana-Gandhinagar Highway, Mehsana, Gujarat, India; 2013.

- Bhyan B, Jangra S, Kaur M, Singh H. Orally fast dissolving films: innovations in formulation and technology. Int J Pharm Sci Rev Res. 2011; 9(2):9-15.
- 12. Patel H, Patel U, BHIMANI B, DASLANIYA D. Transdermal drug delivery system as prominent dosage forms for the highly lipophilic drugs. The International Journal of Pharmaceutical Research and Bio-Science. 2012; 1(3) 12-18.
- Varundev D. Gol. "Formulation, Optimization & Evaluation of mouth dissolving strips of L-methyl folate calcium". [M.Pharma thesis] Department of Pharmaceutics and Pharmaceutical Technology, Shree S. K. Patel College of Pharmaceutical Education and Research, Ganpat Ganpat Vidyanagar-384012. Gujrat, India; 2013.
- 14. Vishwkarma DK, Tripathi AK, Yogesh P, Maddheshiya B. Review article on mouth dissolving film. Journal of global pharma Technology. 2011; 3(1):1-8.
- Rathi V, Senthil V, Kammili L, Hans R. A BRIEF REVIEW ON ORAL FILM TECHNOLOGY. International Journal of Research in Ayurveda & Pharmacy. 2011 Jul 1;2(4).
- Varundev D. Gol. "Formulation, Optimization & Evaluation of mouth dissolving strips of L-methyl folate calcium". [M.Pharma thesis] Department of Pharmaceutics and Pharmaceutical Technology, Shree S. K. Patel College of Pharmaceutical Education and Research, Ganpat Ganpat Vidyanagar-384012. Gujrat, India; 2013.
- 17. Vishwkarma DK, Tripathi AK, Yogesh P, Maddheshiya B. Review article on mouth dissolving film. Journal of global pharma Technology. 2011; 3(1):1-8.
- Rathi V, Senthil V, Kammili L, Hans R. A BRIEF REVIEW ON ORAL FILM TECHNOLOGY. International Journal of Research in Ayurveda & Pharmacy. 2011; 1;2(4) 13-21.
- 19. Siddiqui MN, Garg G, Sharma PK. A short review on "A novel approach in oral fast dissolving drug delivery system and their patents". Adv Biol Res. 2011; 5(6):291-303.
- 20. Peppas NA, Buri PA. Surface, interfacial and molecular aspects of polymer bioadhesion on soft tissues. Journal of Controlled Release. 1985, 1(2):57-65.
- 21. Tabak LA, Levine MJ, Mandel ID, Ellison SA. Role of salivary mucins in the protection of the oral cavity. Journal of Oral Pathology & Medicine. 1982; 11(1):1-7.
- Dixit RP, Puthli SP. Oral strip technology: Overview and future potential. Journal of controlled release. 2009 Oct 15; 139(2):94-107.
- 23. Kulkarni AS, Deokule HA, Mane MS, Ghadge DM. Exploration of different polymers for use in the formulation of oral fast dissolving strips. J Curr Pharm Res. 2010; 2(1):33-5.
- Garsuch V, Breitkreutz J. Comparative investigations on different polymers for the preparation of fast-dissolving oral films. Journal of Pharmacy and Pharmacology. 2010; 62(4):539-45.
- 25. Nagar P, Chauhan I, Yasir M. Insights into Polymers: Film Formers in Mouth Dissolving Films. Drug invention today. 2011,1; 3(12):221-232.
- 26. Corniello C. Quick dissolving strips: from concept to commercialization. Drug Del. Technol. 2006;6(2):68-71.



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- 27. Dixit RP, Puthli SP. Oral strip technology: Overview and future potential. Journal of controlled release. 2009, 15; 139(2):94-107.
- 28. Bhyan B, Jangra S, Kaur M, Singh H. Orally fast dissolving films: innovations in formulation and technology. Int J Pharm Sci Rev Res. 2011 Jul; 9(2):9-15.
- 29. Rowe RC, Sheskey P, Quinn M. Handbook of pharmaceutical excipients. Libros Digitales-Pharmaceutical Press; 2009.
- Wale, A, Weller, PJ., Handbook of pharmaceutical excipients, [Internet]1994, 24,27,352,448. Available from: <u>http://repo.upertis.ac.id/1827</u> /1/Handbook%20of%20Pha rmaceutical%20Ex cipi ents.pdf
- 31. Patel AR, Prajapati DS, Raval JA. Fast dissolving films (FDFs) as a newer venture in fast dissolving dosage forms. Int J Drug Dev Res. 2010 Apr; 2(2):232-46.

- 32. Karki S, Kim H, Na SJ, Shin D, Jo K, Lee J. Thin films as an emerging platform for drug delivery. asian journal of pharmaceutical sciences. 2016 Oct 1;11(5):559-74.
- Bala R, Pawar P, Khanna S, Arora S. Orally dissolving strips: A new approach to oral drug delivery system. International journal of pharmaceutical investigation. 2013; 3(2):67.
- 34. Aggarwal J, Singh G, Saini S, Rana AC. Fast dissolving films: A novel approach to oral drug delivery. International research journal of pharmacy. 2011; 2(12):69-74.
- 35. Patil SL, Mahaparale PR, Shivnikar MA, Tiwari SS, Pawar KV, Padm PN. Fast dissolving oral films: An innovative drug delivery system. International Journal of drug discovery and medical research. 2012;1(1):39-41.

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