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Review Article

Oral Disintegrating Film: A Review

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ABSTRACT

Oral disintegrating films (ODF) hold great promise for novel and inventive drug delivery methods. Because it is flexible and comfortable to use, mouth dissolving film is the most advanced oral solid dosage form available. Mouth dissolving films are oral solid dosage forms that, when placed in the mouth without water or chewing, dissolve and disintegrate within a minute. With this dosage form, the drug can avoid the first pass metabolism, potentially increasing its bioavailability. Mouth dissolving films have the ability to reduce dosage, improve the onset of action, and get rid of choking anxiety. Plasticized hydrocolloids and taste-masking agents for APIs are laminated using solvent casting and semisolid casting techniques in the formulation of mouth-dispersing films, yielding both functional and visual characteristics. The most widely used technique is solvent casting because of its superior physical properties, finely glossy films produced, and excellent thickness uniformity. Mouth dissolving films are evaluated according to several parameters, such as thickness and physical attributes like disintegration and dissolution time. An overview of formulation methods, packaging, evaluation standards, and some commercially available mouth dissolving film products are given in this review.

INTRODUCTION

Alternative routes are the most preferred route of drug administration because they have various advantages over other drug delivery routes, but oral drug delivery systems still need improvement due to several disadvantages associated with certain patient classes, including geriatrics, paediatrics children, and patients with aphasia who

have difficulty swallowing or chewing solid dosage forms and are associated with many diseases. Among other factors, the palatability of paediatric oral dosage forms is one of the most important factors influencing adherence. Solid dosage forms are widely used by adults and adolescents, but younger children tend to prefer liquid dosage forms that are easier to swallow.¹

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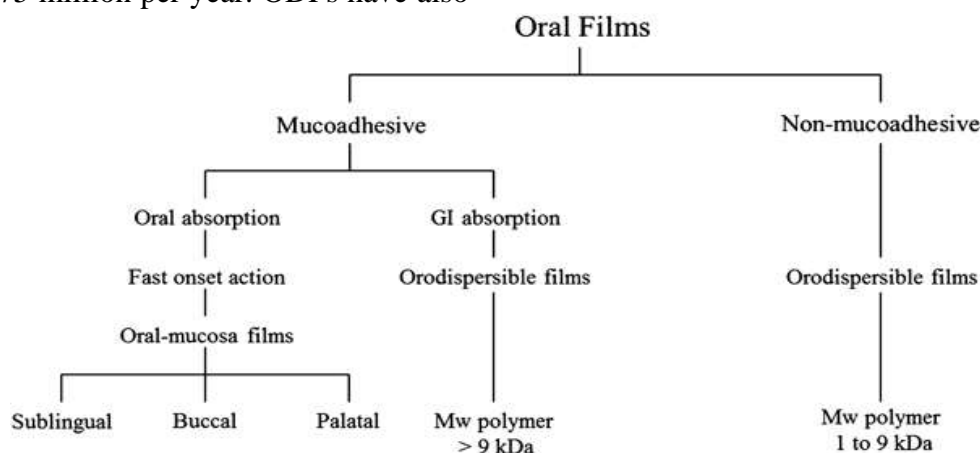


Conventional oral solid dosage forms like tablets, capsules are always preferred by patients over liquid dosage forms. Constantly changing lifestyle and interest demand more patient-friendly dosage forms. Patient's disinterest in taking medicines which are difficult to swallow resulted in the origination of the concept of orally disintegrating solid dosage forms in 1970. Orally disintegrating solid dosage forms when placed upon tongue disintegrate within few seconds to form suspension which can be swallowed easily without water.² The first commercial ODF, a mouth freshener, was developed in 2001 by Pfizer under the name "Listerine", and has a sales volume of more than \$175 million per year. ODFs have also

been developed in an attempt to relieve various conditions such as colds, coughs, smoking addiction, allergies, vomiting, pain, nausea, anxiety, constipation, and Alzheimer's disease.³

SALIENT FEATURES:4

- Simplicity of administration for mentally ill, incapacitated, and uncooperative patients.
- Do not need any water and unpleasant taste of the drugs disappears.
- Possibility of offering liquid medication's benefits in the form of solid preparation.
- Flexible and accommodating of current processing and packaging.
- Economical.



ADVANTAGES:

Compared to other oral dosage forms, oral films have the following unique advantages:

Due to its large surface area, which reduces dosage intervals and enhances therapy's onset of action, efficacy, and safety profile, it dissolves and disintegrates quickly in the oral cavity.

- Compared to ODTS, oral films are less brittle, more compliant, and flexible.
- Simple to handle, store, and transport.
- Every strip or film ensures accuracy in the dose administered.
- OTFs are a realistic substitute for traditional oral dosage forms like tablets and capsules, which are widely accepted by pharmaceutical companies and customers.

- Patients with motion sickness, dysphagia, recurrent emesis, and mental illnesses should consider oral film.⁵

DISADVANTAGE:

Medication that is unstable at buccal pH cannot be given.

- This route cannot be used to administer medications that irritate the mucosa.
- Only small doses of medications can be administered.
- Taste masking: Since most medications have an unpleasant taste, taste masking is necessary.
- Special packaging is required because it needs to be waterproof. ⁶

COMPOSITION OF MOUTH DISSOLVING FILM

Performance attributes of the ODF include taste masking, mouthfeel, physical appearance, and quick dissolution. Each of the ingredients listed below should be FDA-approved for use in oral dosage forms and generally advised as safe (GRAS).⁷

- Active pharmaceutical ingredient (API)
- Polymer
- Plasticizer
- Sweetening agent
- Flavouring agent
- Saliva stimulating agent
- Colouring agent
- Thickening agent

Concentration of component 8

Sr. No	Ingredients	Amounts
1	Drug	1-30%
2	Film-forming polymer	40-50%
3	Plasticizer	0-20%
4	Saliva stimulating agent	2-6%
5	Sweetening agent	3-6%
6	Flavouring agent	Q. S
7	Surfactant	Q. S
8	Colours	Q. S
9	Filler	Q.S

Active pharmaceutical agents:

Pharmaceutically active substances that can be given orally or through the buccal mucosa are referred to as active pharmaceutical agents. These substances can belong to any class. Antiulcer, antiasthmatics, expectorants, and antiepileptics etc. The medication dosage should be less than 20 mg/day for the most effective formulation. Many different types of medications, including those for erectile dysfunction, anti-Alzheimer's, antiemetic, neuroleptics, cardiovascular agents, analgesics, antiallergic, antiepileptic, anxiolytics, sedatives, and erectile dysfunction medications.

The following are the ideal qualities of a drug to choose:

- The medication should taste good.
- The medication to be included should be taken at a low dosage—generally, less than 30 mg.
- It should be preferred to use the medication with a smaller and moderate molecular weight.
- The medication needs to be soluble and stable in both water and saliva.
- It should be able to penetrate oral mucosal tissue and be partially unionised at the pH of the oral cavity.⁹

Examples of suitable drug molecules and its category ⁸

Category	Examples
Anti-emetics	Ondansetron, Granisetron, Palonosetron, Dronabinol, Aprepitant, Ramosetron, Trimethobenzamide, Nabilone,
Serotonin inhibitors	Fluoxetine, Sertraline, Paroxetine, Fluvoxamine, Citalopram and Alaproclate
5HT3 antagonists	Alosetron, Ondansetron, Granisetron, Palonosetron, Ramosetron and Tropisetron
Anti-epileptics	Carbamazepine, Clonazepam, Diazepam, Divalproex sodium, Fosphenytoin, Gabapentin, Lamotrigine, Levetiracetam.
Anti-migraines	Almotriptan, Dihydroergotamine Mesylate, Eletriptan, Frovatriptan, Naratriptan.
Dopamine D1 and D2 antagonists	Amisulpride, Bromperidol, Cabergoline, Domperidone, Fenoldopam, Haloperidol, Metoclopramide, Metopimazine, Pergolide.
Nootropics	Almitrine, Dimesylate and Raubasine, Cevimeline Hydrochloride, Cogergocrine-Mesylate, Donepezil, Galantamine, Gingko Biloba Extract (Eg: b 761), Memantine.
Statins	Atorvastatin, Cerivastatin, Fluvastatin, Lovastatin,

	Pitavastatin, Pravastatin, Rosuvastatin and Simvastatin
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Film Forming Polymer:

Water-soluble polymers give films their rapid disintegration, pleasing mouthfeel, and mechanical strength, which makes them useful as film formers. The kind and quantity of polymer used in the formulations determines how sturdy the strip is. Many different polymers can be used to prepare films; the most widely used ones are pullulan, gelatine, and Hypromellose. Water-soluble polymers comprise a variety of substances, such as modified starches, PVPK30, guar gum, xanthan gum, pullulan, gelatine, and so on. HPMC E3/E5/E6/E15.

Ideal properties of the polymers used in the oral film:

- Polymers should be non-toxic, non-irritant, and non-bitter.
- Polymers should be tasteless
- It should be devoid of leachable impurities
- It should be inexpensive and readily available.¹⁰

Plasticizers:

An essential component of the formulation is the plasticizer. It lessens the strip's brittleness and aids in enhancing its flexibility. Plasticizer lowers the polymer's glass transition temperature, which greatly enhances the strip's characteristics. The choice of plasticizer will be based on how well it works with the polymer and what kind of solvent was used to cast the strip. When a plasticizer is used, the polymer's flow improves and its strength glycerol is increased. Some of the frequently used plasticizer excipients are phthalate derivatives, such as dimethyl, diethyl, and dibutyl phthalate, and citrate derivatives, such as tributyl, triethyl, acetyl citrate, triacetin, and castor oil. The concentration of plasticizers used is typically 0-20% w/w of dry polymer weight. On the other hand, improper use of plasticizers can cause the film to split, peel, and crack.¹¹

Saliva stimulating agent:

The goal of employing saliva stimulating agent is to boost salivary flow, which will facilitate the FDF's quicker disintegration. Acids are typically used to stimulate saliva production. Among the few salivary stimulants, citric acid is the most favoured. Other examples include malic acid, lactic acid, ascorbic acid, and tartaric acid. One can use these agents in combination or alone, ranging from 2 to 6%.¹²

Sweetening Agent:

Sweeteners have grown in importance in both food and pharmaceutical products that are meant to dissolve or disintegrate in the mouth. Both artificial and natural sweeteners are used to increase the mouth-dissolving formulations palatability. Among the acceptable sweeteners are:

- Natural sweeteners that dissolve in water, such as xylose, ribose, glucose, sucrose maltose etc.
- Artificial sweeteners that dissolve in water, such as acesulfame-K, sodium or calcium saccharin salts, etc.
- Aspartame, a dipeptide-based sweetener.¹³

Flavouring agent:

The type and strength of the flavour determine how much flavouring is needed to cover up the taste. Fruity flavours (vanilla, cocoa, coffee, chocolate, citrus) and flavour oils (peppermint, cinnamon, and nutmeg) are frequently used. Additionally, flavours can be selected from oleo resins, artificial flavour oils, and extracts made from different plant parts, such as fruits, flowers, etc.¹⁴

Surfactants:

Surfactants are used as dispersing, wetting, or solubilizing agents to dissolve films quickly and release active ingredients right away. Surfactants also help poorly soluble medications become more soluble in quickly dissolving buccal films. Among the frequently utilized are tweens and spans,



sodium lauryl sulphate, benzalkonium chloride, benzethonium chloride, and poloxamer 407.

Colouring agent

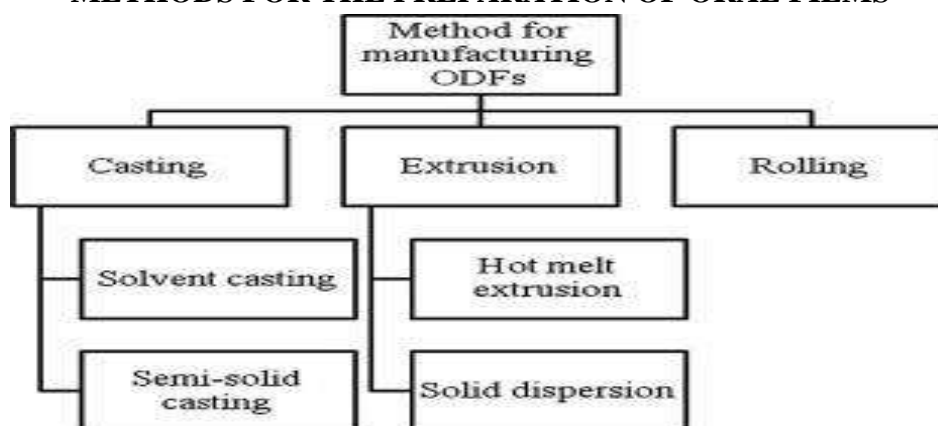
Colouring agents are wide variety of colours are offered, including custom pan tone-matched hues, FD&C and EU colours, natural colouring agents, and natural juice concentrates. Pigments like titanium oxide, silicon dioxide, and zinc dioxide are also available. The concentration levels of all of these colouring agents shouldn't go above 1% w/w. When certain drugs or formulation

ingredients are present in an insoluble or suspension form, these agents are added.

Thickening agent:

The purpose of the thickening and stabilizing agents is to increase the viscosity of the formulation and the consistency of the solution or dispersion. The addition of thickening agents occurs at a 5% w/w concentration. Examples include cellulose derivatives, locust bean gum, xanthan gum, and carrageenan, among other natural gums. Additionally, a tiny amount is added to enhance ODF's properties.¹⁵

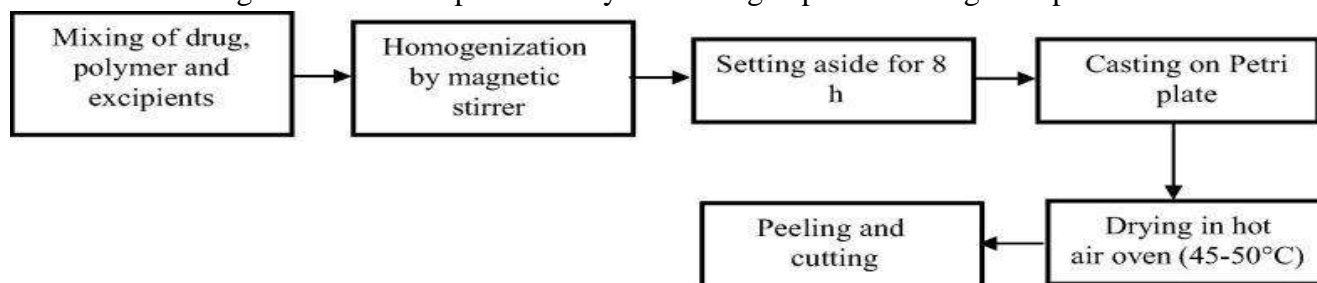
METHODS FOR THE PREPARATION OF ORAL FILMS



Solvent casting method:

The most popular technique for producing ODFs is solvent casting, which involves dissolving drug, polymers, and water-soluble excipients in de-ionized water. High shear forces produced by a

shear processor are then applied to produce a homogenous mixture. To produce high-quality films, the prepared solution is then poured onto a Petri plate, and the solvent is allowed to dry by being exposed to a high temperature.¹⁶



Film-forming polymer is typically soaked in the proper solvent for an entire night when using the solvent casting technique. The kind of API that needs to be included in ODF determines which solvent is best based on important physicochemical characteristics of the API, like melting point, shear sensitivity, and polymorphic

form. Before a formulation is finalized, the drug's compatibility with the solvent and other excipients is also taken into consideration. Entrapment of air bubbles during formulation can cause prepared films to become less uniform. Therefore, the mixture is deaerated with the assistance of a vacuum pump.¹⁷

Semi-solid casting method:

In semisolid casting method firstly a solution of water-soluble film forming polymer is prepared. The resultant mixture with an acid-insoluble polymer solution (such as cellulose acetate butyrate or phthalate) that was made using sodium or ammonium hydroxide. After that, the right quantity moulded into the film or ribbons. The film has a thickness of between 0.015 and 0.05 inches. The acid insoluble polymer to film-forming polymer ratio needs to be 1:4. 18

Hot melt extrusion:

Since the early 1980s, the pharmaceutical industry has been using hot-melt extrusion, or HME. Granules, sustained-release tablets, and transdermal and transmucosal drug delivery systems are frequently made with HME. Low production quantities, environmental issues, and instability brought on by erratic variables like polymer chain relaxation, moisture absorption or loss, and polymer-plasticizer interaction during storage are possible outcomes of oil-drying fibers (ODFs) made using the solvent-casting method. On the other hand, HME techniques offer benefits like easy shaping, fewer units of operation, less product waste, the ability to scale up, compatibility with drugs that are sensitive to moisture, and effective solubility enhancement for poorly soluble APIs. HME techniques, however, are expensive and call for specialized tools.19

Solid-dispersion extrusion:

When one or more APIs are dispersed using techniques like HME in an inert carrier in a solid state with amorphous hydrophilic polymers present, the process is referred to as solid dispersion. Solid dispersions are created by extruding immiscible components with medication in a process known as solid-dispersion extrusion. Dies are used to form the solid dispersions into films. A suitable liquid solvent is used to dissolve the medication. Without eliminating the liquid solvent, this solution is

added to the melt of polyols, such as polyethylene glycol, that is produced below 70 °C. It's possible that the chosen solvent or drug solution won't mix well with the polyethylene glycol melt. The liquid solvent used may have an impact on the drug's polymorphic form that precipitates in the solid dispersion.20

Rolling method:

When using the rolling method, the suspension is first made of a polymer that forms a water film and a mixture of alcohol and water with other excipients, but not APIs, to process the rheological properties. After being prepared, the suspension went through the metering roller. The amount of suspension in the roller is continuously moved to the mixers through the use of a controlled valve and metering pump. The metering pump is now used to add the API to the suspension-containing mixture. Both the metering roller and the applicator roller, which apply the film, determine its thickness. Ultimately, a backing roller is used to carry the formed film away. The film is then allowed to dry by using controlled bottom drying without the use of external air. Following that, the film is allowed to dry on its surface using controlled bottom drying when there is no external air present.21

Technologies involved in oral disintegrating film:

Soluleaves™:

A variety of oral delivery films with active ingredients, colors, and Flavors can be created using technology. When Soluleaves™ films come into contact with saliva, they can be made to dissolve quickly, releasing the flavours and active ingredients. Because of this feature, edible films are a great way to deliver a wide variety of products that need to be released quickly in the mouth. For pharmaceutical purposes, this mode of administration is particularly helpful for elderly or paediatric patients who might have trouble swallowing regular pills or capsules. The delivery

system can be applied to nutritional product delivery as well as the therapeutic areas of cough/cold, gastrointestinal, and pain. Additionally, Soluleaves™ films have the option of adhering to mucous membranes and releasing the active ingredient gradually over 15 minutes.

Wafertab™:

The Wafertab drug delivery system includes an edible filmstrip containing pharmaceutical active ingredients. The system releases the active ingredients of the strip quickly when it comes into contact with saliva in the mouth. For even more effective taste masking, the Wafertab™ filmstrip can be flavoured. An XGel™ film that has already been manufactured has its active component carefully dosed and incorporated into its body to protect it from unnecessary heat and moisture exposure, potentially enhancing product stability. A plethora of imaginative possibilities for product design is made possible by the Wafertab™ system, which bonds together multiple films containing different active ingredients. Because Wafertab™ comes in a range of sizes and shapes, it's a great way to administer medications that need to be released quickly or for patients who have trouble swallowing.

Foamburst:

This unique version of Soluleaves™ technology involves the introduction of an inert gas into the film while it is being produced. As a result, a honeycomb-structured film is produced, which dissolves quickly and produces a strange mouthfeel. Manufacturers of foods and confections are interested in using Foamburst™ as a way to release and carry flavors.

XGel™:

For pharmaceutical and healthcare products, XGel™ film offers the following special product benefits: The film is free of genetically modified organisms (GMOs), approved for religious reasons, and suitable for vegetarians. Its non-

animal origin and continuous production processing offer a competitive and cost-effective manufacturing platform. XGel™ film can include active pharmaceutical ingredients and can be taste-masked, colored, layered, and have enteric properties. Any oral dosage form can be encapsulated in the XGel™ film systems, which are soluble in both hot and cold water. A variety of distinct water-soluble polymers that have been specially tailored for the intended application make up XGel™ film.²²

Characterization and Evaluation:

Specialized, controlled human taste panels are used for this. This in-person taste study uses human participants. ODFs are tested in-vitro using taste sensors for screening. In-vitro techniques and technologies are adequate and suitable for high-throughput taste sensing of such dosage forms. The sweetness and efficacy of taste-masking agents are assessed using both in-vitro and in-vivo techniques.

1. Thickness test:

A calibrated digital micrometer is used to measure a film's thickness, and the mean average is subsequently calculated. Usually, the calculation takes the mean of three readings from each batch. A film's weight variation can be computed in triplicate by cutting the film and weighing each film. Since thickness uniformity directly correlates with the film's dose accuracy, it is imperative to confirm.²³

2. Dryness test/tack test:

The purpose of this test is to determine a film's adhesiveness to a piece of paper sandwiched between strips. Tack is the obstinacy with which the film sticks to the paper or any other object pressed in between the films. The film drying process can be divided into approximately eight stages: dust-free, dry through, tack-free, dry print-free, dry hard, dry-to-touch, and dry-to-recoat. These tests can also be used to evaluate oral fast-disintegrating films. Generally, they are used to

assess the dryness of films in the paint industry. Some newly developed instruments can also be used to perform tack or dryness tests.²⁴

3. Tensile strength:

To evaluate the elasticity and strength of the optimized film formulation, a tensile test is conducted. The strain on the material at the moment of breakage, known as the elongation-to-break (or ultimate elongation), indicates the material's toughness and stretchability before breaking. The films' mechanical performance and end-use handling qualities are determined by these parameters. The specimens' thickness is measured using a standard micrometre screw gauge. The tensile properties were then ascertained by applying five specimens to a tensile tester. MPa is the unit of measurement for tensile stress, and % elongation is the unit of strain.²⁵

$$\text{Tensile strength} = (\text{Load at breakage}) / (\text{strip thickness}) \times \text{strip width}$$

4. Percent elongation:

The prepared film is pulled using a pulley system. The pulling force of the pan is increased by progressively adding weights until the film broke. The distance a pointer travelled before the film break was used to calculate the elongation. Using the formula, the percent elongation was determined.²⁶

$$\text{Percent Elongation} = L1/L0 \times 100$$

Where

L1= increase in the length,

L0 = Initial length

5. Stability study:

It explains the significance of physical stability for pharmaceutical products and how to evaluate it for ointments, tablets, capsules, emulsions, solutions, and suspensions. Aluminium foil is used to package the selected formulas so that the film is perfectly and fully covered. After that, they were maintained in a humid environment for 4–8 weeks at 40°C and 75% relative humidity. During this

time, their physical traits and in vitro drug release were evaluated regularly.²⁷

6. Young's Modulus:

The strip's elasticity or stiffness is indicated by its elastic modulus, also known as Young's modulus. Plotting the stress-strain curve allows for the calculation of strip deformation. It can be calculated using the following formula and is expressed as the ratio of applied stress over strain in the elastic deformation region.²⁸

7. Disintegration Test:

The disintegration of orally fast dissolving films requires USP disintegration apparatus. The disintegration time limit of 30 seconds or less for orally disintegrating tablets described in CDER guidance can be applied to fast-dissolving oral strips. Disintegration time vary depending on the formulation but typically the disintegration ranges from 5 to 30 sec. Although, no official guidance is available for oral fast disintegrating films strips.²⁹

8. In-vitro dissolution studies:

The In-vitro dissolution study is carried out in 500 ml pH 6.8 phosphate buffer using (USP) XIV basket apparatus II at 37.0 ± 0.5°C and at 50 rpm. Each square cut film sample (dimension: 2cm x 2cm) is submerged into the dissolution media and appropriate aliquots were withdrawn at 1, 2, 3, 4, 5, 6, 7-, 8-, 9-, and 10-minute time intervals and again replaced with same volume of dissolution media. The sample are filtered through Whatman filter paper for all the batches and analysed spectrophotometrically at 272 nm. Sink conditions is maintained throughout the experiment. The dissolution test was performed in triplicate for each batch.³⁰

Packaging:

In the pharmaceutical industry the package selected must satisfactorily safeguard the integrity of the product. Specific processing, expensive packaging, and special care are recommended during manufacturing and storage for protection of the dosage of other rapid dissolving dosage forms.



For branding purposes and to meet industry regulations, converters may choose to print information directly onto the film unit doses before packaging. Criteria that require special attention includes the need for unit dose packaging, barcode labelling, and the content in guidelines for use, child-resistant seals, and senior-friendly packaging.

The material selected must have the following characteristics:

- They must be FDA approved
- They must protect the preparation from environmental conditions.
- They must meet applicable tamper-resistant requirement.
- They must not be reactive with the material utilized in preparing films.
- They must be non-toxic.²⁸

Application:

Oral mucosal delivery via Buccal, sublingual, and mucosal route by use of ODFs could become a preferential delivery method for therapies in which rapid absorption is desired, including those used to manage pain, allergies, sleep difficulties, and central nervous system disorders. ODF evolved over the past few years from the confection and oral care markets in the form of breath strips and became a novel and widely accepted form by consumers for delivering vitamins and personal care products.

1. Gastro retentive dosage systems:

Dissolution of the films could be triggered by the pH or enzyme secretions of the gastrointestinal tract, and could potentially be used to treat gastrointestinal disorders.

2. Diagnostic devices:

Dissolvable films may be loaded with sensitive reagents to allow controlled release when exposed to a biological fluid or to create isolation barriers for separating multiple reagents to enable a timed reaction within a diagnostic device.

3. Taste masking:

An important aspect of thin film drug delivery technology is the masking of the often bitter and poor taste of drug formulations.

4. Vaccination:

Rotavirus vaccine is a room temperature stable quick-dissolving oral thin film delivery system for vaccines that will make vaccinations almost as simple as freshening your breath.³¹

CONCLUSION

The present review shows that oral disintegrating films are one of the novel approaches in the field of pharmaceutical sciences. In comparison to conventional dosage forms, they have better acceptance and patient compliance and no choking risk, which is linked to improved safety and efficacy. The main motivation for the development of ODFs was to address the challenge that paediatric, geriatric, and psychiatric patients with dysphagia faced when swallowing conventional oral dosage forms. Due to their importance, ODFs are currently widely available for conditions like pain, allergies, acidity, hypertension, and more. One of these dosage forms main benefits is that it can be administered without the need for water, which satisfies the needs of the target population who prefer convenience in drug administration. It also avoids the hepatic metabolism, which improves the therapeutic response.

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