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A REVIEW ON ORAL DISINTEGRATING FILMS: A NOVEL DRUG DELIVERY SYSTEM

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ABSTRACT

The oral route remains the most preferred mode of drug administration due to its convenience, patient compliance, and ability to accommodate various drug candidates. However, conventional oral dosage forms face limitations such as difficulty in swallowing, delayed onset of action, and reduced bioavailability due to first-pass metabolism. Oral disintegrating films (ODFs) have emerged as an innovative drug delivery system addressing these challenges. Designed to rapidly disintegrate and dissolve upon contact with saliva, ODFs enable quick drug absorption through the oral mucosa, ensuring enhanced bioavailability and faster therapeutic action. This review explores the anatomy of the oral epithelium, formulation considerations, types of drugs suitable for ODFs, and the advantages they offer over traditional dosage forms. Additionally, various manufacturing techniques such as solvent casting, hot melt extrusion, and rolling methods are discussed. The study highlights the role of polymers, plasticizers, saliva- stimulating agents, and taste-masking components in optimizing film properties. While ODFs present numerous advantages, including ease of administration and improved patient adherence, formulation challenges such as taste masking, drug loading capacity, and stability must be addressed for broader pharmaceutical applications.

KEYWORDS: Fast Dissolving Films, Sublingual Route, Higher Bioavailability, Dysphagia.

INTRODUCTION

Oral route of administration is the most convenient and preferred route of administration among the various other delivery system. More than 70% of drugs are available in the market in the form of oral drug delivery system due to pain avoidance and versatility (to accommodate various types of drug candidates).[1]

There has been a tremendous amount of effort put into developing novel drug delivery systems over the last two decades (NDDS). The reason for this technological advancement is the relatively low development cost and time required for introducing an NDDS when compared to introducing a new chemical entity. Conventional or classical therapy has some limitations as well, such as the difficulty of swallowing tablets in the case of oral dosage forms, the difficulty of patient compliance among paediatric and geriatric patients, the difficulty of taking these dosage forms without water while traveling, and these systems also show less absorption, resulting in a slow onset of action. A novel drug delivery system, such as designing a sublingual delivery of a drug, is one of the better solutions to these problems. Because of its thin membrane and large veins, the sublingual mucosa is relatively permeable. Because of the high blood flow, the sublingual mucosa allows for rapid absorption and immediate bioavailability of drugs. Because rapid absorption is possible, a rapid onset of action may be observed.[2]

Oral disintegrating films first introduced in the market as breath fresheners and personal care products such as dental strips and soap strips. However, they are introduced in the United States and European pharmaceutical markets for therapeutic effect. Oral disintegrating films are most advance form of solid dosage form due to various reasons like flexibility, improved efficacy of API (Active Pharmaceutical Ingredient), dissolution and disintegration within 1 minute with the help of less amount of saliva as compared to dissolving tablet. Thin films have the potential to allow the development of sensitive drug targets that may otherwise not be possible in tablets or liquid formulations.[3]

Approximately one-third of the population, primarily the elderly and children, has swallowing difficulties, resulting in poor adherence to oral tablet drug therapy and reduced overall therapy effectiveness. A new sublingual fast-dissolving dosage form, such as a fast dissolving tablet or fast-dissolving film, has been developed that combines the benefits of ease of dosing with the convenience of dosing in the absence of water or fluid.[4]

Anatomy of Oral Epithelium

The mouth cavity provides a highly special environment in which to administer medication. The oral epithelium prevents first pass metabolism and permits direct medication entry into the systemic circulation. The mouth cavity's epithelium and skin are relatively similar, with a few minor variations in keratinization, protection, and the lubricating mucus that covers the surface. Oral epithelium permeability is 4-1000, several times more than skin permeability.[5]

The mouth cavity is divided into two regions:

a. Outer vestibule- bounded by lips and cheeks.
b. mouth cavity proper- separated from the vestibule by the alveolus bearing the teeth and gingiva

Mucosal Layers

The oral mucosa contains following three layers of cells:

- Stratified squamous epithelium- This is the oral epithelial outermost layer. The contact between connective tissue and epithelium is known as the basement membrane.
- Lamina propria- a connective tissue presents below basement membrane.
- Sub mucous membrane- consists of the inner most layer of the oral epithelium.[6]

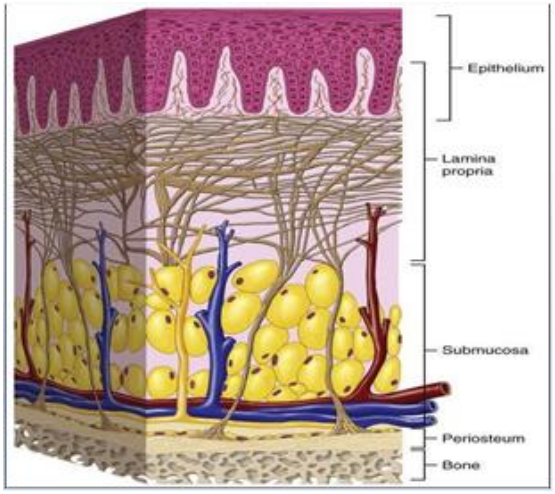

Fig. 1: Anatomy of epithelium.

In this study, oral films film was designed to deliver drug through oral mucosa in order to produce fast onset of action.

Release mechanism involved: the solid single-unit dosage form which are made of a water dissolving polymer, allows the dosage form to rapidly hydrate, adhere and dissolve when

placed on the tongue in the oral cavity to provide local or systemic drug delivery. The large surface area available in the film dosage form allows rapid wetting by saliva, quick disintegration, dissolution and absorption of drug directly enter into the systemic circulation without undergoing first-pass hepatic metabolism with increased bioavailability. In such cases bioavailability of drug is significantly greater than those observed from conventional tablet dosage form.[7]

Fig. 2: Pictorial representation of administering an oral films film inside the mouth cavity.

Drugs for Oral Administration

The drugs selected for films should possess good stability in saliva and water with low dose. The film should consist of 1-25% w/w of the drug. Small dose molecules are the best candidates to be incorporated in Oral fast dissolving film. Multi vitamin sup to 10% w/w of dry film weight was incorporated in the films with dissolution time of less than 60seconds. It is always useful to have micronized API which will improve the texture of the film and also for better dissolution and uniformity in the fast-dissolving film.[8]

These substances can belong to any class. Antiulcer, antiasthma tics, 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-, antiallergic, antepileptic, anxiolytics, sedatives, and erectile dysfunction medications. alzheimer's, anti emetic, neuroleptics, cardiovascular agents, analgesics.[9]

Table No. 1: Class of drugs used in oral films.

Category	Examples
Anti-emetics	Ondansetron, Granisetron, Palonosetron, Dronabinol, Aprepitant, Ramosetron, Trimethobenzamide, Nabilone
Serotonin inhibitors	Fluoxetine, Sertraline, Paroxetine, Fluvoxamine, Citalopram and

	Alaproclate 5HT3 antagonists Alosetron,
5HT3 antagonists	Alosetron, Ondansetron, Granisetron, Palonosetron, Ramosetron and Tropisetron
Anti-epileptics	epileptics Carbamazepine, Clonazepam, Diazepam, Divalproex sodium, Fosphenyloin, Gabapentin, Lamotrigine, Levetiracetam.
Anti-migraines	Almotriptan, Dihydroergotamine Mesylate, Eletriptan, Frovatriptan, Naratriptan
Dopamine D1 and D2 antagonists	Amisulpride, Bromperidol, Cabergoline, Domeperidone, Fenoldopam, Halopiridol, Metoclopramide, Metopimazine, Pergolide
No tropics	Almitrine, Dimesylate and Raubasine, Cevimeline Hydrochloride, Co dergocrine Mesylate, Donepezil, Galantamine, Gingko Biloba Extract (Eg: b 761), Memantine
Statins	Atorvastatin, Cerivastatin, Fluvastatin, Lovastatin,

Criteria For Oral Films Film[10]

- Thin elegant films are available in sizes and shapes.
- Un-obstructive in nature
- Quick disintegration and rapid drug release
- It should dissolve or crumble in the mouth in a matter of seconds, eliminating the need for water when swallowing.
- The film should impact a pleasant after taste.
- Suitable for use with agents that disguise tastes
- Minimise or eliminate residue in the mouth following oral delivery.
- Display minimal susceptibility to environmental factors including humidity and temperature.

Advantages of Films[11]

- Ease of administration to patients who refuse to swallow a tablet, such as pediatric, geriatric and psychiatric patients.
- Convenience and accuracy in drug administration when compared to liquid formulations.
- Water is not required for swallowing the dosage form, which is a useful feature for patients who are on the go and do not have easy access to water.
- The good mouth feel property helps to change the basic perception of medication as a "bitter pill,", especially in paediatric patients.
- Rapid dissolution and absorption of the medication, resulting in a rapid onset of action.
- Some drugs are absorbed from the mouth, pharynx and oesophagus as saliva passes down into the stomach, increasing drug bioavailability.
- It offers the benefits of liquid formulations in the form of solid dosage form.

- Pregastric absorption can improve bioavailability and, as a result of lower dosage, clinical performance by reducing unwanted effects.

Disadvantages of Oral Films[12,13]

- It is not possible to deliver medications that irritate the mucosa or are unstable at buccal pH by this route.
- Only drugs required in lower dose can be delivered through this dosage form.
- Most drugs have bitter taste and taste masking is highly recommended.
- It shows fragile and granular property affecting its appearance.
- Special packaging is required to ensure stability and safety of product.

Components of mouth dissolving films

A mouth-dissolving film is a thin film with an active ingredient that has a surface area of 5 20 cm2. The immediate dissolution in water or saliva is achieved via a special matrix made of water-soluble polymers. A typical composition includes the following elements:[14]

Table No. 2: Composition of strip.

Si.No	Composition of Strip	Quantity
1	Active pharmaceutical agent	1-25%
2	Film-forming polymer	40-50%
3	Plasticizer	0-20%
4	Saliva stimulating agent	2-6%
5	Sweetening agent	3-6%
6	Flavouring agent	10%
7	Colouring agent	1%

A. Active Pharmaceutical Ingredient (API)

The active pharmaceutical ingredient makes up 1-30% w/w of the film's unique composition. Since it is typically difficult to include high doses of medications into fast dissolving films, it is always best to utilise low doses of the active pharmaceutical ingredient. Improved dissolution and homogeneity in the fast-dissolving film are also benefits of using micronized APIs.[15]

B. Polymers

The foundation of film formulations are polymers, and there are several types of polymers that can be used to create oral films. To get the required film qualities, these polymers can be used separately or in combination with other polymers. The foundation of film formulations is polymer, and different polymers can be used to create oral films.[16] To get the required

film qualities, these polymers can be used separately or in combination with other polymers. It is necessary that the polymers used be non-toxic, non-irritating, and devoid of leachable contaminants. For the preparation of the film, both natural and synthetic polymers are used.[17,18]

C. Plasticizer

Plasticizers are liquids that are added to materials, mainly elastomers or resins, to increase their softness, flexibility, and ease of processing by lowering the polymer's glass-transition temperature.[19] Pharmaceutical plasticizers are a class of auxiliary materials that spark interest in enhancing the functionality of various dosage forms used in medicine.[20] In order to enhance heat processing, adjust drug release from polymeric systems, and enhance the dosage form's mechanical characteristics and surface appearance, plasticizers are incorporated into pharmaceutical polymers.[21]

D. Saliva Stimulating Agent

The purpose of using a saliva stimulating chemical is to speed up saliva production in order to facilitate the faster dissolution of the oral film within the oral cavity. The salivary glands are stimulated to generate more saliva by these saliva stimulating substances. Within the range of 2–6%, these agents can be administered singly or in combination. Ascorbic acid, tartaric acid, lactic acid, citric acid, and malic acid are often used saliva-stimulating substances. Citric acid is the most favoured among them.[22]

E. Sweetening Agent

Sweeteners are now a necessary component of pharmaceutical and food items that are meant to dissolve or disintegrate in the mouth. Sweeteners are typically used to cover up the bitter taste of some medications. You can add natural or artificial sweeteners separately or in combination to increase the oral films film's palatability. While saccharin, cyclamate, aspartame, sucralose, alitame, and neotame are artificial sweeteners, natural sweeteners include dextrose, glucose, sucrose, maltose, galactose, xylose, ribose, and corn syrup solids.[22]

F. Flavouring Agent

By adding flavour to the formulation, flavors improve acceptance. The type of medicine to be included in the formulation determines which taste to use. Flavouring agents include synthetic flavour oil, oleo resins, and extracts made from different plant components, such as leaves,

flowers, and fruits. Any flavour can be added, including acidic fruit flavours like lemon or orange, strong mints like peppermint, spearmint, wintergreen, cinnamon, and clove, and essential oils or water-soluble menthol extracts. Chocolate, vanilla, and fruit essences including pineapple, cherry, apple, and raspberry are examples of flavours.[12]

G. Colouring agents

FD&C colours, EU colours, natural colouring agents and natural juice concentrates, pigments such as titanium dioxide, silicon dioxide, and zinc oxide, and custom Pantone-matched colours are all available.[23]

Manufacturing Methods

Fast-dissolving films can be made using the following processes:

1. Solvent casting
2. Semi solid casting
3. Hot melt extrusion
4. Solid dispersion extrusion
5. Rolling method

1. Solvent Casting

The oral fast dissolving films are prepared by dissolving strip forming agents, plasticizer and saliva stimulating agent in the distilled water, then solution is continuous stirred on magnetic stirrer and kept for 1 hour to remove all the air bubbles entrapped. Meanwhile, in the separate container remaining water soluble excipients i.e. sweetening agent, disintegrating agent, saliva stimulating agent, flavor and drug are dissolved with constant stirring. When the stirring is over both the solutions are mixed together with stirring for another 1 h on magnetic stirrer. Then keep the solution stationary for 1 hr to let the foams settle down. The resulting formulation is casted on a suitable platform and is dried to form a film. The film is preferably air-dried or dried under oven then the film is carefully removed.[24]

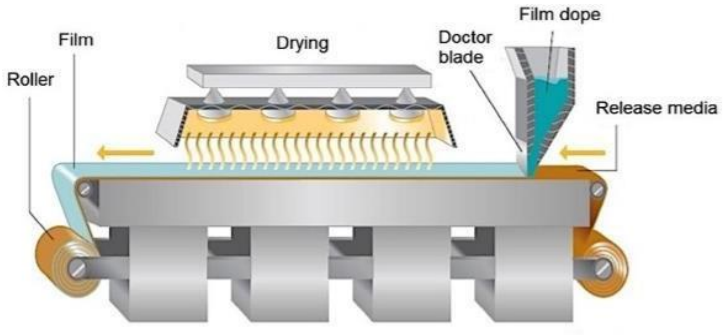

Fig. No. 3: A Solvent casting film system.

2. Semi-solid casting technique

In the semisolid-casting method, a solution of the water-soluble, film-forming polymer is prepared. The resulting solution is added to a solution of acid insoluble polymer (e.g., cellulose acetate phthalate and cellulose acetate butyrate), which is previously prepared in ammonium or sodium hydroxide. The appropriate amount of plasticizer is added to obtain a gel mass. The prepared gel mass is cast into films or ribbons using a controlled heat source. The thickness of the film is controlled between 0.015–0.05 in.[23]

3. Hot melt extrusion method

The drug is first mixed with carriers in solid form in the hot melt extrusion method. The mixture is then melted by an extruder equipped with heaters. Finally, the dies shape the melt into films. There are some advantages to using hot melt extrusion.

- A reduction in the number of operational units
- Better content uniformity
- An anhydrous process.[25]

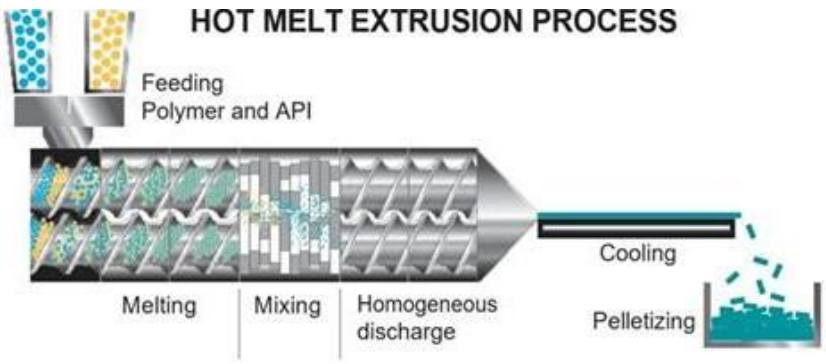

Fig. no. 4: Hot melt extrusion process.

4. Solid Dispersion Extrusion

Solid dispersion extrusion use HME-like method. One or more API is dispersed in an inert

carrier in solid state in the presence of amorphous hydrophilic polymers. The immiscible components are then extruded with the drug, forming solid dispersions that finally shaped into films by dies.[26]

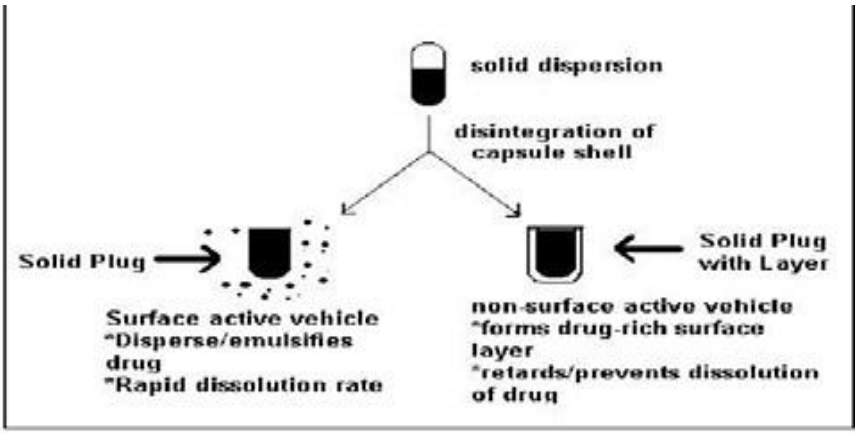

Fig. No. 5: solid dispersion extrusion process.

5. Rolling method

In the first instance, a pre-blend is made with foil packaging, polar dissolvable polymers and other additional medications. In the pre-blend, add the appropriate amount of medication. The medication is pre-mixed to create a stable grid. The mixture collected is provided for in the roller. The film is shaped and extracted by a roller aid. Using managed base drying is then dried wet film. The film is divided into the size and type necessary. The drum should be rolling with different rheological characteristics.[27]

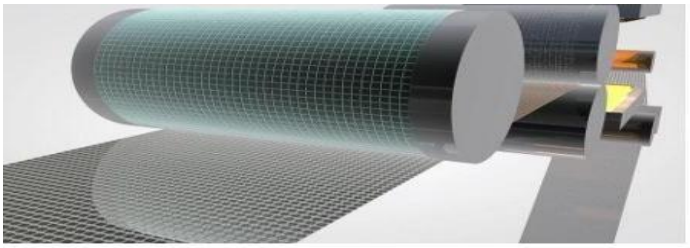

Fig. No. 6: Rolling method.

Packaging[28]

In the pharmaceutical industry, the package chosen must be adequate for preserving the product's integrity. To protect the dosage of other fast dissolving dosage forms, expensive packaging, specific processing, and special care are required during manufacturing and storage. Fast-dissolving films come in a variety of packaging options. For films, single packaging is required. The most common packaging format is an aluminium pouch.

1. Foil, paper, or plastic pouches

The flexible pouch is a packaging concept capable of providing not only a temperature-resistant package, but also, through proper material selection, a package with a high degree of environmental protection. During the product filling operation, a flexible pouch is typically formed using either vertical or horizontal forming, filling, or sealing equipment. Single pouches or aluminum pouches can be used

2. Single pouch and Aluminum pouch

Soluble film drug delivery pouches are peelable pouches for "quick dissolve" soluble films with high barrier properties. The pouch is clear to allow for product display. Using a two-structure combination allows one side to be clear while the other uses a low-cost foil lamination. The foil lamination allows virtually no gas or moisture transmission. For nutraceutical and pharmaceutical applications, the package offers a flexible thin film alternative. The single-dose pouch protects both the product and the dosage. The most common type of pouch is an aluminium pouch.

3. Blister card with multiple units

The blister container is made up of two parts: the blister (the formed cavity that holds the product) and the lid stock (the material that seals to the blister). Heat-softening a sheet of thermoplastic resin and vacuum-drawing the softened sheet of plastic into a contoured mould are used to create the blister package. After cooling, the sheet is removed from the mould and transported to the packaging machine's filling station.

Evaluation Parameters

1. Thickness

The patch's thickness was measured using a digital Vernier Calliper with a minimum count of 0.01 mm at various locations on the film. The patch's thickness was measured at three different locations, and an average and standard deviation were calculated.[29]

2. Weight variation

Weight variation of the films was determined by weighing three films of (2cm x 2cm) individually, from each batch of the formulation and the average weight was calculated. An Electronic balance was used for this purpose. The individual weight should not deviate significantly from the average weight.[30]

3. Folding endurance

Folding endurance was determined by repeated folding of the film at the same place till the strip breaks. The number of times the film is folded without breaking was computed as the folding endurance value.[29]

4. Tensile strength

Tensile strength is the maximum stress applied to a point at which the strip specimen breaks. It is calculated by the applied load at rupture divided by the cross-sectional area of the strip as given in the equation below[31]

$$\text{Tensile strength} = \frac{\textit{Load at breakage}}{\textit{Strip thickness} \times \textit{Strip width}}$$

5. Percentage elongation

Strain is the term used to describe how much a material extends when subjected to stress. In essence, strain is the film's distortion divided by the substrate's initial dimension. In general, The longer the film, the more plasticizer there is in it.[32] The formula used to calculate it is

$$\% \text{ Elongation} = \frac{\textit{Strip's length increase}}{\textit{Initial length of strip}} \times 100$$

6. Drug content uniformity

The film (2cm x 2cm) was cut at three different places with nominal drug content. Each film was dissolved in 100ml of phosphate buffer pH 6.8 (stimulated saliva fluid) for 20 minutes with continuous shaking to obtain a homogenous solution. 10ml of the above solution was filtered to remove polymer residues if any and the filtrate obtained was made up to 100ml with phosphate buffer pH 6.8 in a volumetric flask and the absorbance was measured using UV visible spectrophotometer.[33]

7. Surface pH

A 4 cm^2 part of the film was cut, and it was placed in distilled water for an hour in a glass tube to swell to measure the surface pH of the film. The combined glass electrode of the pH meter was then brought close to the film's surface, and it was given a minute to acclimatize before measuring the surface pH. The average values of the three replicated experiments were recorded.[34]

8. In vitro dissolution studies

The release studies of pregabalin from the oral films film were carried out using USP type II

(paddle) dissolution apparatus under sink conditions. 500ml of phosphate buffer of pH 6.8 was used as the dissolution medium and the temperature was maintained at 37±0.5°C. The paddle rotation rate was 100 rpm. 5ml of samples were pipetted at regular intervals of 30 seconds till the end of 5 minutes and the samples were measured at 207 nm using UV visible spectrophotometer. From the absorbance obtained the cumulative percentage drug release was calculated.[35]

CONCLUSION

Oral disintegrating films (ODFs) represent a significant advancement in pharmaceutical drug delivery, offering enhanced patient compliance, rapid disintegration, and improved bioavailability. Designed to address the needs of populations with dysphagia, including pediatric, geriatric, and psychiatric patients, ODFs provide a convenient, water-free administration route while reducing the risk of choking. The formulation of ODFs incorporates a range of polymers, plasticizers, taste-masking agents, and surfactants, ensuring stability, efficacy, and patient acceptability. Their formulation, manufacturing advancements, and innovative drug delivery technologies have expanded their therapeutic applications. Despite some limitations, ongoing research continues to enhance their stability, drug-loading capacity, and patient acceptance, making ODFs a promising dosage form in modern pharmaceuticals.

DISCUSSION

Oral Disintegrating Films (ODFs) have emerged as a transformative solution in drug delivery, addressing several limitations of conventional oral dosage forms, especially for populations with swallowing difficulties such as pediatric, geriatric, and psychiatric patients. This review effectively highlights the multifaceted benefits and challenges associated with ODFs.

A major advantage of ODFs is their rapid disintegration and onset of action. The thin film, composed primarily of water-soluble polymers, disintegrates within seconds upon contact with saliva, enabling faster absorption through the oral mucosa. This bypasses the gastrointestinal tract and avoids first-pass hepatic metabolism, thereby increasing drug bioavailability and effectiveness. Such characteristics are particularly valuable in emergency conditions (e.g., antiemetics, antiepileptics) where swift therapeutic action is required.

The formulation of ODFs is complex and requires a careful balance of components. Polymers like HPMC, PVA, and natural alternatives provide mechanical strength and disintegration properties. Plasticizers enhance flexibility, while saliva-stimulating agents, sweeteners, and

flavors improve the overall mouthfeel and patient acceptability. However, incorporating drugs with poor solubility or unpleasant taste remains a significant formulation challenge. Efficient taste-masking and the inclusion of only low-dose drugs (<30 mg) are crucial, as high drug loading may compromise film integrity.

The article also presents a thorough evaluation of manufacturing techniques such as solvent casting, hot melt extrusion, and rolling methods. Solvent casting remains the most commonly used due to its simplicity and reproducibility. However, hot melt extrusion and solid dispersion methods are gaining prominence for their ability to improve drug solubility and content uniformity.

Packaging plays a vital role in the stability of ODFs, as they are sensitive to humidity and mechanical stress. Single-unit aluminium pouches are often preferred for their protective properties, ensuring long-term product integrity.

Despite their numerous advantages, ODFs face certain drawbacks. Drugs that irritate the mucosa, require high doses, or are unstable at buccal pH are not suitable for this delivery system. Additionally, the films are fragile and require special packaging, increasing production costs.

Future prospects for ODFs include expanding their use for systemic therapies, vaccines, and macromolecules like peptides and proteins. Advancements in nanotechnology, mucoadhesive agents, and smart polymers may overcome existing limitations and further broaden the therapeutic scope of this novel drug delivery system.

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