

Oral Disintegrating Films: A Review

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ABSTRACT

The oral route stands out as a preferred method for drug administration due to its cost-effectiveness and ease, contributing to enhanced patient compliance. Some individuals, particularly the geriatric and pediatric populations, encounter difficulties swallowing conventional tablets and hard gelatin capsules. To address this, oral disintegrating drug delivery systems are established as substitutes for tablets, capsules, and syrups. Notably, fast-dissolving oral thin films offer a practical solution for patients such as those in pediatric, bedridden, or developmentally disabled categories, as well as the geriatric population who struggle with a tablet or hard gelatin capsule ingestion. This innovative dosage form involves the creation of thin films consuming water-soluble polymers that quickly disintegrate and dissolve in the mouth cavity. It serves as a substitute stage for those particles that undergo significant metabolism of drugs in the liver. This study provides an overview of numerous dosage form-formulations, preparation approaches, and quality control measures related to fast-disintegrating films.

ARTICLE INFO

Article history:

Received: April 20, 2024

Revised: June 10, 2024

Accepted: June 23, 2024

Keywords:

Fast disintegrating oral films;
Components of formulation;
Characterization and
evaluation; Patient
compliance

To cite this article: Wafa, A., Raihan, R., Zhakfar, A. M., & Sudhakar, C. K. (2024). Oral Disintegrating Films: A Review. *Journal of Natural Science Review*, 2(2), 60-74. DOI: <https://10.62810/jnsr.v2i2.42>

To link to this article: <https://kujnsr.com/JNSR/article/view/42>



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Introduction

Fast-disintegrating drug delivery systems are an essential development in pharmaceutical technology, providing numerous benefits over conventional drug delivery systems; drug delivery from the oral route is widely recognized as a convenient, cost-effective, and favored drug administration method. These drug delivery systems can be applied topically, buccally, sublingually, orally, or by a combination of these routes. This review looks at thin films that are oral from a modern perspective. It provides insight into the industry's expanding global market share due to growing research areas and technological

advancements. Simultaneously, it summarizes the crucial elements linked to formulation design that impact thin-film technology, such as thin-film design, physiological and anatomical constraints, appropriate manufacturing process selection, characterization methods, and the physicochemical characteristics of drugs and polymers. However, certain patient groups, particularly pediatrics and geriatrics, encounter challenges swallowing specific oral formulations such as tablets and hard gelatin capsules. The apprehension of unpleasantness prevents them from quickly consuming these formulations.

To address this issue, some fast-dissolving drug delivery systems (FDDDS) have been advanced. Buccal drug delivery emerges as a significant administration route, offering advantages like escaping the high metabolism of drugs in the liver and minimizing the medicine dilapidation in the GI surroundings. Oral medication in advance drug delivery has evolved from tablets and capsules to improved release of formulations, oral disintegrating tablets, wafers, and most recently, fast-dissolving oral films (Joshua et al., 2016). Fast-disintegrating oral thin films are exceptionally thin films utilizing hydrophilic polymers that swiftly hydrate or adhere when employed on the tongue's surface or in the mouth cavity. The formulations dissolve within seconds, releasing the drug without the need for drinking or chewing. The rich blood supply in the mucosa facilitates rapid absorption, ensuring instant bioavailability of drugs. This immediate bioavailability is achieved by bypassing the first-pass metabolism, making these films particularly suitable for drugs with high metabolism of drug metabolism in the liver, thereby enhancing overall bioavailability. Since oral film technology is still in its infancy, it holds significant promise due to its potential to improve patient compliance (Kanna et al., 2023). The Agency for European Medicines states that prospers films readily dissolve in the mouth cavity. Usually, the films quickly dissolve in less than a minute after coming into touch with saliva. This allows for rapid drug absorption and instant bioavailability. Counting one or more drugs, "a non-brittle, flexible film that is placed on the tongue and quickly dissolves or disintegrates in the saliva before entering the digestive system," is how the Food and Drug Administration of the United States defines the oral disintegrating films. Zuplenz (Ondansetron HCl, 4–8 mg) was the earliest dosage form approved in 2010. The second to be approved was Suboxone, which contains naloxone and buprenorphine. Orally dissolving/disintegrating medication is preferred by four out of five patients over conventional oral solid dosage forms, according to statistics (Ozakar and Ozakar, 2021).

Advantages

- Minimizing the risk of choking
- Bypassing first-pass metabolism, leading to a faster onset of action with lower doses
- Pleasant taste
- High stability
- Eliminating the need for water
- The extensive surface area ensures swift disintegration and dissolution in the oral cavity.

- Convenient management for patients experiencing difficulties such as dysphagia, frequent vomiting, motion sickness, and mental disorders
- Precision in dosage administration (Kanna et al., 2023)

Disadvantages

- Inability to accommodate drugs with high doses
- Rapid release
- Mucoadhesive release
- Mucoadhesive sustained release (Kanna et al., 2023).

Oral Mucosa

Three layers of cells make up the oral mucosa:

- Stratified epithelium: The basement membrane separates this outermost layer in the oral cavity from the connective tissue.
- Lamina propria: Positioned beneath the basement membrane, this layer consists of connective tissue (Waghmare et al., 2023).
- Submucous membrane: Acting as the oral cavity's lowest layer (Fig.1).

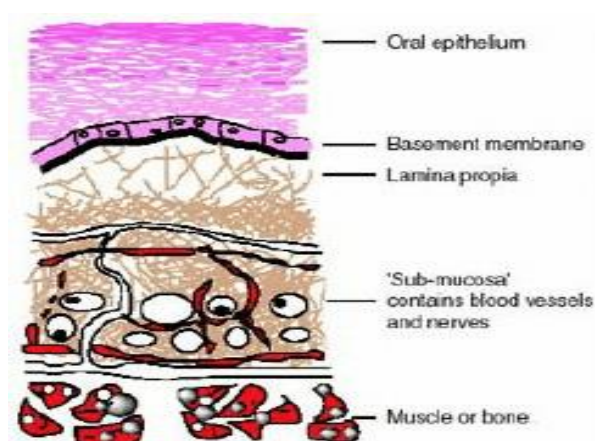


Figure 1. Structure of oral mucosa (Chore & Dighade, 2020)

Composition of Oral Disintegrating Films

Oral softening films are a fine layer with parts ranging from 5 to 20 cm² containing drugs. The formulation allows for loading drugs up to 30 mg. From a supervisory standpoint, for use in oral pharmaceutical dosage forms, all additives contained in the formulation must be licensed for application and generally recognized as safe (GRAS-listed).

Components of Formulation:

- Drug
- Film-forming polymers
- Plasticizers
- Salvia stimulating agents
- Sweetener

- Flavor
- Surfactant
- Colorant

Table 1. Concentration of Component

S. No.	Ingredients	Concentration
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	Flavoring agent	Q. S.
7	Surfactant	Q. S.
8	Colors, Filler	Q. S.

Drug

Typically constituting 1-30% w/w in a standard film, the drug is crucial for active formulation. The incorporation of micronized API is essential to enhance the film's texture and ensure quick dissolution and consistency in the fast-disintegrating film (Nautiyal., 2023). Various drug categories can be adapted for mouth-dissolving films, addressing diverse medical needs (Hartini et al., 2024). These encompass pediatrics (anti-tussive, expectorants), geriatrics (expectorants, antiepileptic), disorders of the gastrointestinal tract (cytostatic therapy), pain management (e.g., migraine), and CNS disorders (Table. 2). The process of absorption requires dissolving the API. The appropriate absorption level may not be achieved if the drug is very hydrophobic, rendering it insoluble in the water-based media. As a result, the drug's lipophilicity and solubility are delicately matched. Passive diffusion is the primary mode of medication absorption. Because of this, the transport of pharmaceuticals over the oral mucosal membranes is significantly influenced by the extent of ionization, partition coefficient, and molecular weight. Bioavailability requires consideration of the pKa of the API and the extent of ionization at room pH. Generally, the hydrophobicity or partition coefficient of the drug determines the degree of absorption, which impacts the solubility of the drug (Karki, 2016).

API Used in Oral Disintegrating Films

- Must be taken at a low dosage
- Its molecular weight must be minimal
- Its taste and sensation in the mouth must be appropriate
- It needs to be soluble in saliva and stable

While choosing the API, consideration must also be given to its potential and therapeutic efficacy. Analgesics, anti-allergic, anxiolytics, hypnotics, sedatives, anti-Alzheimer's,

diuretics, antibacterial, expectorants, anti-asthmatic, anti-cancer, antitussives, anti-epileptics, antihistamines, anti-emetics, antianginal, cardiovascular, and neuroleptics are the best APIs for oral disintegrating films (Ozakar and Ozakar, 2021).

Table 2. Examples of suitable drug molecules and their category

Category	Examples
Anti-emetics	Ondansetron, Granisetron, Plonasetron, Dronabinol, Aprepitant, Ramosetron, Trimethobezamide, Nabilone, Metoclopramide, Dolasetron, Dimenhydramine
Serotonin inhibitors	Fluoxetine, Sertraline, Paroxetine, Fluvoxamine, Citalopram and Alaproclate
5HT ₃ antagonists	Alosetron, Ondansetron, Granisetron, Palonosetron, Ramosetron and Tropisetron
Anti-epileptics	Carbamazepine, Clonazepam, Diazepam, Divalproex sodium, Fosphenytoin, Gabapentin, Lamotrigine, Levetiracetam, Oxacarbazepine, Phenytoin, Primidone and Valproate sodium
Anti-migraines	Almotriptan, Dihydroergotamine Mesylate, Eletriptan, Frovatriptan, Naratriptan, Rizatriptan, Sumatriptan and Zolmitriptan
Dopamine D ₁ and D ₂ antagonist	Amisulpride, Bromperidol, Cabergoline, Domperidone, Fenoldopam, Haloperidol, Metoclopramide, Metopimazine, Pergolide Mesylate, Prochlorperazine, Quetiapine, Ropinirole Hydrochloride, Sulpiride, Tiapride and Zolmitriptan
Nootropics	Almitrine Dimesylate and Raubasine, Cevimeline Hydrochloride, Codergocrine Mesylate, Donepezil, Galantamine, Ginkgo Biloba Extract (Egb 761), Memantine, Nicergoline, Piracetam, Rivastigmine, Tacine And Vinpocetine
Statins	Atorvastatin, Cerivastatin, Fluvastatin, Lovastatin, Pitavastatin, Pravastatin, Rosuvastatin and Simvastatin

Film Forming Polymers

Hydrophilic polymers serve to create films due to their ability to facilitate rapid disintegration, provide a pleasant mouthfeel, and contribute desirable mechanical properties to the films (Maskare et al., 2023). To achieve the favorite film characteristics, such as hydrophilicity, adaptability, mouthfeel, and stability, the polymer is utilized only in a mixture by others (Kamali et al., 2022). The tensile strength of polymers varies depending on the kind and quantity of films used. Choosing the appropriate polymer is one of the most crucial and significant factors in manufacturing oral disintegrating film. At a minimum, 45% of the polymer by weight must exist based on the dry film's total weight; however, 60%–65% is recommended to provide the required characteristics. Notably, as polymer film bases' molecular weight rises, the polymer disintegration rate lowers (Kamali et al., 2022).

The polymers selected for oral thin films must meet the following criteria:

- Non-irritating and non-toxic

- Without impurities
- Have favorable spreadability and wetting property
- Exhibit sufficient tensile, peel, and shear strengths
- Willingly existible and cost-effective
- Low molecular weight and soluble in water
- Display outstanding film-creating ability
- Keep a long shelf life

Plasticizers

A crucial element in the composition of thin oral films, plasticizers play a vital role in enhancing mechanical properties like tensile strength and film elongation while simultaneously reducing brittleness. They contribute to improved flow and increased strength of the polymer (Waghmare et al., 2023). The careful selection of suitable plasticizers is imperative to ensure compatibility with the drug, polymers, and other excipients, preventing splitting, cracking, and peeling issues. Usually employed plasticizers include propylene, glycerol, glycol, acetyl citrate, dimethyl, dibutyl, triethyl, triacetin, polyethylene glycol, diethyl phthalate, and castor oil (Kose et al., 2022).

Salvia Stimulating Agents

Saliva-stimulating agents increase the amount of saliva produced, thereby simplifying the films' quicker disintegration time and dissolution profile. These agents can be employed separately or in combination within the 2-6% range. Lactic acid, citric acid, malic acid, tartaric acid, and ascorbic acid are used, with citric acid being the favored choice (Sayed et al., 2022).

Sweetener

Oral Fast Dissolving Films are sweetened with both artificial and natural sweeteners. The most commonly utilized alcohols are polyhydric ones, like mannitol, sorbitol, maltitol, and isomalt. Moreover, polyhydric alcohols can be combined to give the mouth a pleasant, icy sensation. Moreover, polyhydric alcohols are less dangerous and do not permit a harsh aftertaste in the oral cavity. Except for xylitol and maltitol, which are both somewhat sweeter than sucrose, most polyols have a sweetening capacity that is less than half that of sucrose. In patients with diabetes, the amount of natural sugars used in these products is limited. Artificial sweeteners are, therefore, most commonly used in food and pharmaceutical products. Aspartame and saccharin are typical artificial sweeteners in oral fast-dissolving films (Ozakar and Ozakar, 2021).

Flavor

The kind of API to be utilized determines which flavor is most enjoyable. The flavor that the patient experiences in the initial moments following oral dissolving film consumption and then after at least 10 minutes in the mouth determines whether or not they accept the dose form due to oral disintegration. Thus, selecting a suitable flavoring ingredient is crucial. These agents enhance the flavor of the formulation and are designated from artificial flavor oils,

such as oleo resins or extracts derivative from different plant parts. Whether used singly or in combination, the quantity of flavor incorporated depends on its form and strength (Pandey et al., 2021).

Surfactant

Surfactants are commonly used to raise solubility, dispersibility, and wettability for rapid drug dissolution and release within seconds. Sodium lauryl sulfate, poloxamer 407, benzethonium chloride, and tweens are frequently employed surfactants (Sharma et al., 2020).

Colorant

Frequently used pigments, such as silicon dioxide, titanium oxide, or FD&C-accepted colorant, shouldn't exceed concentrations of 1% (Sharma et al., 2020).

Methods of Preparation

Various methods are employed to prepare fast-disintegrating films, including:

- Solvent casting technique
- Semisolid casting technique
- Hot melt extrusion technique
- Solid dispersion extrusion technique
- Rolling technique (Jana et al., 2024).

Hot melt extrusion and solvent casting are the two most used industrial processes (Celebioglu et al., 2020). In the solvent casting technique, in a volatile solvent, plasticizers and polymers are dissolved, stirred, combined with other ingredients, vacuum-treated to remove air, cast into a Petri dish, and dried in an oven (Fig. 2). After that, the resultant film is sliced to the appropriate size and form (Jana et al., 2024).

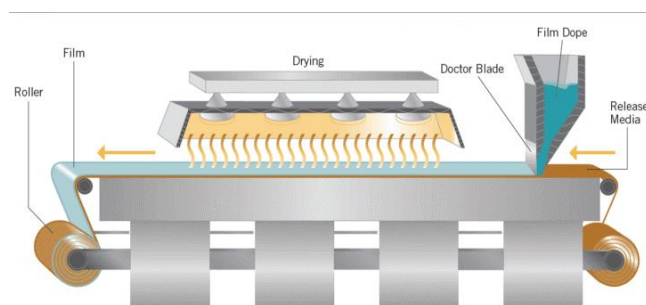


Figure 2. Solvent casting method (Ghodake et al., 2013)

Semi-Solid Casting Method

The method involves preparing a solution of a hydrophilic film-creating polymer, which is then poured into a solution containing acid-insoluble polymers like cellulose acetate phthalate or cellulose acetate butyrate in a 1:4 ratio—the addition of an appropriate plasticizer results in the formation of a gel mass. This gel is molded into ribbons using heat-controlled drums, aiming for a film thickness of approximately 0.015-0.05 inches (Kriplani et

al., 2020). Due to its convenience of application, low processing cost, and straightforward preparation, solvent casting is the most broadly used technique for creating oral rapid-dissolving films. A heated magnetic stirrer is used to combine ingredients that dissolve in water. The medicines and other additives are added to this combination to produce a sticky solution. The solution using this approach is placed on a Petri dish, and the solvent is permissible to evaporate. Depending on the solvent system used, these are kept for 22 to 25 or 24 to 48 hours at room temperature or for a shorter period in an oven at 40 C to 50 C. Films of a diameter of 15-20 mm and a thickness of 0.2-0.3 mm are created when the solvent evaporates and are carefully removed from the Petri dishes (Ozakar and Ozakar, 2021).

Hot Melt Extrusion Method

Primarily utilized for the creation of granules, tablets with sustained action, and transdermal or mucosal drug delivery systems, this method includes mainly mixing the drug with transporters in a solid system (Fig. 3). The blend is then molten using an extruder equipped with heaters, and the molten material is ultimately shaped into films through the use of dies (Muhammed et al., 2023).

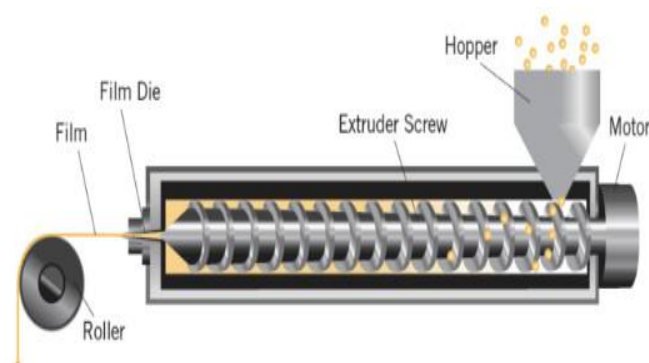


Figure 3. Hot melt extrusion technique (Muhammed et al., 2023)

Solid Dispersion Method

This technique uses amorphous hydrophilic polymers to assist the dispersion of one or more medicines in a solid form within an inactive carrier to make a solution, and the medicine is first dissolved in a suitable solvent (Guo et al., 2022). Then, without removing the liquid solvent, this solution is added to the melt of an appropriate polymer, such as polyethylene glycol, that has reached a temperature under 70 C. Finally, the solid dispersions are formed into films using dies (Singh et al., 2020).

Rolling Method

Primarily, a pre-mix is arranged by combining film, creating polymers, a polar solvent, and other excipients excluding the drug. The necessary quantity of the drug is then added to this pre-mix. The active ingredient is mixed with the pre-mix to attain an unchanging matrix. This combination is fed into the roller, where a film is shaped and passed away by an upkeep roller (Fig. 4). The wetted films are subsequently dehydrated using measured bottom drying, and the resulting films are cut into their favorite shape and size (Maskare et al., 2023).

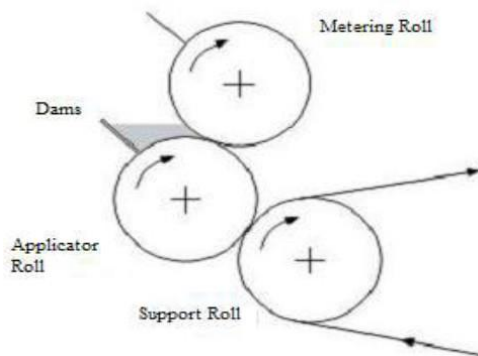


Figure 4. Rolling method (Muhammed et al., 2023)

Characterization of Oral Disintegrating Films

Numerous measurements and analyses are done as part of the characterization investigations of the oral fast-dissolving films created. These include the following: thickness, content uniformity, flavor, dissolving rate dispersion, release kinetics, degree of transparency, swelling ability, moisture absorption, flexibility (elongation), pH determination, folding ability, weight variability, scanning electron microscope (SEM), X-ray powder diffraction (XRD), Fourier transform infrared spectroscopy (FT-IR), and differential scanning calorimetry (DSC) analyses and measurements. Because the disintegration and solvation processes in oral disintegrating films happen quickly, it is challenging to discriminate between them. The disintegration time examination can be used as an alternative to the dissolution assessment, according to the United States Association of Pharmaceutical Scientists//International Pharmacy Federation. The rate of API release only depends on the extent of time the film takes to disintegrate if the drug is molecularly dissolved. In addition, if the active ingredients are dispersed in a specific form in the film matrix, the dissolving amount and disintegrating time examinations are suggested. The FDA and European Pharmacopoeia recommend a disintegration period of 30 seconds or less for ODFs; however, the former allows up to three minutes. Guidelines from the FDA and USP (American Pharmacopoeia) propose a 30 s or less time.

Since there is less than 2 mL of saliva in the mouth, these tests are typically advised for disintegration test in 2–7 ml of fluid in a small setting with conditions similar to those in the mouth. A chronometer can measure the disintegration time of orally disintegrating films when applied to the liquid's surface in a petri dish. To simulate tongue movement in the mouth, the petri dish can be shaken constantly in the interim. This approach is straightforward and convenient to use. If not, it causes problems and is highly challenging to automate the procedure (Wasilewska & Winnicka, 2019). Using dissolving test equipment, the taste-masking capabilities of ODF can be evaluated in vitro. The safest method is in vivo testing on volunteers; however, this raises ethical concerns. Before the experiment, volunteers were given four standard materials, and their sensory sensitivity thresholds were measured for various flavors. Quinine, sucrose, sodium chloride, and tartaric acid are weighted. After that, they apply a film specimen with the exact medication dosage to their

tongue for 30 seconds, followed by a quantity of pure drug. The volunteers then rinse their lips with water after spitting. They are then put through a taste evaluation scoring system ranging from 0 to 3. 0 is tasteless, and 1 is quite bitter (Wasilewska & Winnicka, 2019).

Evaluation of Oral Disintegrating Films

Mechanical Properties

The thickness and correctness of medicine dosage in the film are indicated by its thickness. Measurement is carried out using a micrometer screw gauge or standardized digital Vernier calipers at five dissimilar planned sites, and the mean value is considered to determine the last thickness, ideally falling within the range of 5-200 μm (Wasilewska & Winnicka, 2019).

Dryness/Tack Test

During the film drying process, tack- a measure of how firmly the strip sticks to a fixture like a piece of paper forced into contact is evaluated. Numerous stages are identified, such as dust-free, set-to-touch, tack-free, dry-hard, dry-to-touch, dry-through (dry-to-handle), dry-to-recoat, and dry print-free. Numerous tools are accessible for conducting this test (Muhammed et al., 2023)

Tensile Strength

This property measures the valuable pressure to a point on the film at which the strip sampling breaks down. A film with good tensile strength is the favorite, and the load letdown, the weight at which the film breaks, is measured. Tensile strength is then determined by the applied weight at rupture separated by the cross-sectional part of the strip (Rathore et al., 2022).

Percent Elongation

When pressure is helpful in the film, it undergoes stretching, known as strain. Strain is the film's distortion separated by its unique measurement and is directly influenced by the added plasticizer. The percentage elongation of the film rises as the amount of plasticizer increases (Rathore et al., 2022).

Young's Modulus

These characteristics, which measure the proportion of usable stress over the strain in the elastic distortion area, determine how robust the strip is. Hard and stiff films have high Young's modulus and tensile strength (Irfan et al., 2016).

Tear Resistance

This property measures the extreme resistance to tear the film, with a low load rate of 51 mm/helpful min. The measurement part is Newton or pounds-force (Irfan et al., 2016).

Folding Endurance

Indicating the breakability of the film, folding endurance is measured manually by the number of times the film can be folded without breaking or showing any visible cracks (Rao et al., 2013).

Organoleptic Test

As the oral system disintegrates in the mouth, exhibiting acceptable organoleptic characteristics such as color, flavor, and taste is essential. For optimal appeal, oral thin films intended for children should have an attractive and uniform color. The flavors incorporated in the preparation should offer pleasant odors and effectively cover the taste of the polymer, medicine, and other additives. Taste holds significant importance in patient acceptance, and specialized taste panels and the electronic tongue method based on the principle of potentiometric titration are employed for the physical evaluation (Rathore et al., 2022).

Surface pH Test

The superficial pH of the film can potentially irritate the oral mucosa, requiring a thorough inspection. Ideally, the superficial pH must be neutral, close to 7, and can be assessed using a combined pH electrode. The film is moistened with water, and the pH is determined by taking the conductor in connection with the film, with readings taken on at least six films. The mean \pm SD determines the final value of the surface pH. Another method involves preparing a 1.5%w/v agar gel, placing the films on it, and measuring the superficial pH-consuming pH paper. When placed on the film, the color change in the pH paper provides the value of the surface pH (Rao et al., 2013).

Contact Angle

The contact angle test provides insights into the oral film's moistening performance, disintegration, and dissolution. Shown at room temperature with double-distilled water, a dry film is selected, and a droplet of double-distilled water is located on its exterior. Digital images of the water droplet are captured within 10 seconds of deposition, and analysis is performed using Image J 1.28v software (NIH, USA) to control the angle (Darshan & Sudheer, 2023).

Transparency

Utilizing a UV spectrophotometer, the transparency of the film is determined by introducing the film on the interior side of the spectrophotometer and analyzing it at 600 nm (Rao et al., 2013).

Assay/Drug Content Uniformity

Conducted by employing a standard assay method from any recognized pharmacopeia for the specific drug, the assay or drug content consistency is resolute by approximating the drug content in separate films. The acceptable range for content uniformity is set at 85-115%. (PR & Sudheer, 2023).

Permeation Studies

Permeability is investigated using a Modified Franz Diffusion Cell with buccal mucosa. This cell comprises the giver and receptor compartments separated by mucosa. The mucosa size should match that of the receptor section head. The receptor section is full of buffer (pH 6.8) and sustained at $37 \pm 0^\circ\text{C}$, while the donor section contains 1 ml of simulated saliva fluid (pH 6.8). A magnetic bead stirrer at 50 rpm is used to maintain thermodynamics. The film,

moistened with simulated saliva, is in contact with the mucosal surface. Samples are withdrawn at specific intervals, and the fraction of drug-infused is determined using an appropriate analytical method (Darshan & Sudheer, 2023).

Scanning Electron Microscopy

The ODFs' color, homogeneity, transparency, fragrance, and texture are assessed viscerally and visually. It's critical to evaluate them, particularly regarding taste and flavor characteristics. Scanning electron microscopy is used to examine the superficial morphology of the film, particularly among various additives and medications. A film sample is collected, put in the sample holder, and viewed at a magnification $\times 1000$. Different photomicrographs are taken using a tungsten filament as the electron source (Singh et al., 2018).

In Vitro Disintegration Test

The time taken for the film to break or disintegrate upon contact with water or saliva is known as the in vitro disintegration time (Agnihotri et al., 2020). This test is performed by insertion the film into a phosphate buffer. The United States Pharmacopeia disintegration device can also be employed to study the disintegration time, with the ideal range set between 5-30 seconds (Singh et al., 2018).

In-Vitro Dissolution Test

The dissolution test measures the quantity of drug material entering the solution per unit of time under homogenous temperature, solvent concentration, and the liquid/solid interface. A typical basket or paddle device described in pharmacopeias can be used for dissolution testing. However, when using a paddle-type dissolution device, conducting dissolution studies for oral films can be challenging due to their potential to float over the dissolution medium. The choice of dissolution media depends on sink conditions and the maximum dose of the drug. For the duration of dissolution studies, the medium temperature should be kept at 37 ± 0.5 °C, and the rotation per minute (rpm) should be set at 50 (Singh et al., 2018).

Stability Investigations

The primary objective of stability analysis for the making formulation is to ascertain its overall stability. This process is instrumental in assessing the impact of humidity and temperature on the drug's stability, which is essential for appropriate storage. Primarily, the drug formulation is encased in butter paper, tracked by an additional layer of aluminum foil wrapping. Subsequently, the wrapped formulation is placed in an aluminum pouch and heat-sealed. The recommended storage conditions involve maintaining the formulation at $45^{\circ}\text{C} / 75\%$ RH for 3 months. Throughout the stability study duration, triplicate samples are collected at intervals of 0, 1, and 3 months, and the films undergo assessment for any physical alterations and changes in medicine content (Auda et al., 2018).

Moisture Absorption Capacity

This test is carried out in a highly humid atmosphere to maintain the physical stability of the films. Following individual sample weighing, the samples are put in desiccators with an

aluminum chloride solution and let to soak in moisture for three days. After that, the films are weighed, and the succeeding formula determines their percentage moisture absorption capacity (Mushtaque ET AL., 2020).

$$\% \text{ Moisture absorption capacities} = (\text{Initial Weight} - \text{Final Weight}) / \text{Initial Weight} \times 100$$

Conclusion

Oral disintegrating film has great potential as a medication delivery strategy since it provides benefits such as simpler administration and better patient compliance. The prospects for oral disintegrating films are defined by ongoing advancements in formulation techniques, expanding uses, and incorporating new technologies. Enhanced formulation methods, such as the use of numerous polymers, excipients, and additives, as well as the investigation of cutting-edge manufacturing processes like hot melt extrusion, inkjet printing, and electrospinning, are some of the upcoming breakthroughs in oral disintegrating films. Research is also being done on incorporating nanotechnology into oral disintegrating films, emphasizing nanostructured films and nano-carriers to improve drug solubility, stability, and permeability. It is predicted that combination therapy within oral disintegrating films will allow for the sequential or simultaneous delivery of various medications, resulting in individualized treatment.

Furthermore, oral disintegrating films could include regulated and targeted drug delivery methods that enable site-specific drug release by focusing on ligands or stimuli-responsive systems. The future of quickly disintegrating films appears bright, with continued research and development aimed at enhancing formulation methods, adding new technologies, and extending apps. These developments may improve patient outcomes by increasing patient compliance, tailored therapy, and the effectiveness of medication distribution.

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