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Review Article

A Modern Approach on Mouth Dissolving Drug Technology: Film-Based Oral Delivery

Ram Babu Sharma [1]*, Ankit Kumar [2], Anjali Dixit [3]

[1] Professor & Principal, Himalayan Institute of Pharmacy, Kala-Amb, Sirmour, Himachal Pradesh

[2] M. Pharm Scholar, Himalayan Institute of Pharmacy, Kala-Amb, Sirmour, Himachal Pradesh

[3] Associate Professor, Himalayan Institute of Pharmacy, Kala-Amb, Sirmour, Himachal Pradesh

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*For Correspondence:

Ram Babu Sharma, Professor & Principal, Himalayan Institute of Pharmacy, Kala-Amb, Sirmour, Himachal Pradesh

Abstract

Since oral drug delivery is convenient, affordable, and patient-compliant, it continues to be the most used method. However, taking medications can be difficult for both young and old, increasing the danger of choking. Since its introduction in the 1970s, buccal mucosal dosage forms and fast-dissolving drug delivery systems (FDDS) have improved in terms of usability and safety. Fast-dissolving oral films (OFDFs) are one of them that have become more well-liked due to their capacity to dissolve on the tongue rapidly without the need for water or chewing, enhancing self-administration. Improved bioavailability, decreased first-pass metabolism, quick onset of action, and compatibility with water-insoluble medications are just a few of the many benefits that OFDFs provide. They can be made using solvent casting, hot-melt extrusion, rolling, or solid dispersion extrusion procedures, and they can be prepared with polymers, plasticisers, surfactants, sweeteners, and flavor/color agents. Controlled or targeted release is provided by innovations such multilayered, mucoadhesive, and nanotechnological films (e.g., containing nanoparticles or cyclodextrin complexes). OFDFs appeal to a wide range of patients, including youngsters, migraineurs, and those with Parkinson's and Alzheimer's diseases. Strict quality, packaging, and labelling standards are guaranteed by regulatory guidelines issued by organisations like the FDA, CDSCO, and EMA. Film performance is assessed using characterisation techniques such as morphology, thickness, tensile strength, disintegration, moisture uptake, in vitro dissolution, and palatability. New technologies like as WafertabTM, SoluleavesTM, and FoamburstTM, customised and stimulus-responsive films, and environmentally friendly production techniques show great promise as the area develops. This review highlights OFDFs' expanding importance in patient-centric treatments by synthesising recent advancements and potential future approaches.

Keywords: Fast dissolving, Oral film, Drug delivery, regulatory agencies.

Introduction

One of the most popular methods is oral medication administration due to its higher patient compliance, ease of use, and lower cost. Older and younger patients find the oral route challenging since they have swallowing difficulties and fear choking. Research on patient convenience and compliance has led to safer and more sophisticated drug delivery methods. Drug delivery systems that dissolve quickly are one product that has recently gained popularity and public preference. This is due to the product's ability to dissolve or disintegrate quickly, allowing for self-administration without the need for chewing or water. In order to help patients who had trouble swallowing pills and capsules, especially those who were young or elderly, fast dissolving drug delivery devices were initially developed in the late 1970s.Recently, buccal medicine delivery has become more popular as a drug administration method. In addition to adhesive tablets, gels, ointments, patches, and, more recently, the use of polymeric films for buccal delivery—also referred to as mouth dissolving films1—bioadhesive mucosal dosage forms have been created[1].

Oral fast dissolving films (OFDFs) have become a novel solution to these problems. OFDFs are easy to deliver without water or chewing since they are thin, polymer-based films that dissolve rapidly on the tongue. Patient compliance is improved by this technology, especially for older patients taking several prescriptions and those suffering from diseases like schizophrenia, Parkinson's, and Alzheimer's. Paediatric patients benefit from OFDFs as well because they provide a simple and safe substitute for conventional forms. In contrast to immediate-release ODT, OTF is becoming more and more well-liked for its vibrant, powerful remedies. Healthcare providers are dealing with non-compliance when treating elderly and paediatric patients due to ODT. Although ODT is made to dissolve quickly in the mouth, some patients still worry about choking. However, by resolving swallowing difficulties, OTF

expression can increase patient compliance. Elderly people frequently take several prescriptions drugs each day. For individuals suffering from Alzheimer's, bipolar disorder, migraines, Parkinson's disease, and schizophrenia, the ease of taking lozenge forms is essential. OTF is the most often used lozenge form among all others because of its own benefits as well as the simplicity with which colourful medications (such as anaesthetics, antihistamines, anti-asthmatics, cardiovascular medications, neuroleptics, and erectile dysfunction medications) can be taken orally. The use of nanotechnology to improve the solubility and bioavailability of medications that are only weakly soluble in water is one recent development that has increased the capabilities of OFDF. For example, cyclodextrin inclusion complexes and nanonization are used to improve the rates at which BCS Class II drugs dissolve.[2-4]

Mucoadhesive compositions and multi-layered films also enable targeted distribution and controlled release, guaranteeing patient adherence and therapeutic effectiveness.[5,6]

When inserted in the mouth, oral thin films—a medication delivery method made up of thin, flexible sheets—usually dissolve or disintegrate rapidly, frequently in a matter of seconds. They can be used to administer a range of pharmaceuticals, including prescription and over-the-counter (OTC) medications, and are designed to be applied to the tongue or cheek. Although the oral film dosage form is referred to by a number of names, including thin strip, oral film, orally dissolving film, quick dissolve film, melt-away film, and wafer, the European Medicines Agency formally names it an orodispersible film (ODF), or soluble films as the U.S. Food and Drug Administration (U.S. FDA) more commonly calls them.

The European Pharmacopoeia (Ph. Eur.) defines ODFs as single or multilayered sheets made of suitable materials that are meant to dissolve quickly in the mouth. They quickly break down or dissolve in saliva to create a suspension or solution, which facilitates quick local effects or quick drug absorption and distribution into the circulation. Additionally, ODFs provide steady and quick drug release, which can increase some drugs' bioavailability. Because of its low enzymatic activity and extensive vascularization, the oral cavity may increase the bioavailability of medications with poor water solubility. For medications categorised as Class II and Class IV under the biopharmaceutical categorisation system (BCS), this path is beneficial.It can avoid the stomach's acid hydrolysis and the first stages of hepatic metabolism by quickly penetrating the oral cavity's mucosal lining. Strong drugs, particularly those intended for acute diseases, are especially well-suited for this channel because of its direct access to the jugular vein, oromucosal and pregastric absorption, and fast therapeutic impact. However, following consumption, some substances are only absorbed in the gastrointestinal system.[7]

Unique Characteristics of Mouth Dissolving Films[8]

1. A thin, tasteful movie
2. Ineffective
3. Available in a range of shapes and sizes
4. Quick breakdown
5. Quick release
6. Provide a pleasing oral sensation.
7. Have a taste that is acceptable.
8. Avoid leaving residues in the mouth.

Benefits

1. Superior clarity and thickness consistency compared to extrusion.

2. The films are free of flaws like die lines and have a beautiful sheen.

3. Films offer superior physical qualities and greater flexibility.

4. The on-set action is faster than with a tablet.

5. Its dosages did not require water during delivery.

6. There is no chance of choking.

7. Travelling is simple.

8. A wide surface area allows for rapid breakdown and dissolution in the oral cavity.

9. Ophthalmic thin films can be utilised to deliver drugs to the eye.

Disadvantages

1. Uniformity of dosage is a technological problem.

2. Naturally hygroscopic.

3. It is not possible to incorporate high doses.

Classification of Oral Films[9]

Oral films can be divided into three categories:

1. Flash release films
2. Mucoadhesive melt-away films
3. Mucoadhesive sustained-release films

Table 1 summarises the physical structure, appearance, composition, mode of application, properties, and site of action of each of these oral dissolving films.

Property/Sub Type	Flash release films	Mucoadhesive melt-away films	Mucoadhesive sustained release films
Area (cm2)	2-8	2-7	2-4
Thickness (µm)	20-7	50-500	50-250
Structure (Film)	Single layer	Single or multilayer system	Multilayer system
Excipients	Soluble, highly hydrophilic polymer Soluble,	hydrophilic polymer	Low/nonsoluble polymer
Drug phase	Solid solution	Solid solution or suspended drug particles	Suspension and/or solid solution
Application	Tongue	Gingival or buccal region	Gingival (other regions in oral cavity)
Dissolution	Minimum 60 sec Maximum 8-10 hrs.	Disintegration in few mins. forming gel	Maximum 8-10 hrs.
Site of action	Systemic or local	Systemic or local	Systemic or local

Composition of the Formulation[10]

1. **Drug (1-25%):** The medications chosen for oral films should be stable in water and saliva at low dosages. Micronised API is usually beneficial because it will enhance the film's texture and promote improved disintegration and homogeneity in oral fast-dissolving films. Anti-asthmatic (Salbutamol sulphate, Montelukast), antihistamine (Levocetirizine), antianginal (Verapamil), antiulcer (Omeprazole), antiemetic (Domperidone), expectorants, antitussives, and NSAIDs (Valdecoxib, Meloxicam, paracetamol) are among the classes of medications that can be made into mouth-dissolving films.
2. **Water Soluble Polymers (40-50%):** Polymers can be employed alone or in combination to provide the desired film characteristics. Water-soluble polymers are typically employed as film formers because they give the films mechanical qualities, a pleasing mouthfeel, and quick disintegration. The kind and quantity of polymer used in the formulation determine the film's strength. The disintegration rate of the polymer is reduced by raising the molecular weight of the polymer film basis. The following polymers are commonly used as film formers: pullulan, gelatine, sodium carboxy methyl cellulose, hydroxy propyl methyl cellulose E-3 and K-3, methyl cellulose A-3, A-6, and A-15, pectin, sodium alginate, hydroxyl propyl cellulose, and water-soluble grades of cellulose ethers, polyvinyl alcohol, polysaccharides, and polyvinylpyrrolidone K-90.
3. **Plasticizers (0-20%):** Plasticiser is used to make films more flexible and less brittle. By lowering the polymer's glass transition temperature, plasticiser improves mechanical qualities like tensile strength and elongation to the film. The kind of solvent used and how well it works with the polymer determine which plasticiser is best. Phthalate derivatives such as dimethyl, diethyl, and dibutyl phthalate, low molecular weight polyethylene glycols, castor oil, and citrate derivatives such as tributyl, triethyl, acetyl citrate, triacetin, and glycerol are a few of the often used plasticisers. When plasticiser is used improperly, the strip may bloom, split, peel, and shatter the film.
4. **Surfactants:** Surfactants are utilised as dispersing, wetting, or solubilising agents to disintegrate the film in a matter of seconds and release the active ingredient right away. Benzethonium chloride, sodium lauryl sulphate, tweens, poloxamer 407, benzalkonium chloride, and others are frequently used. Poloxamer 407 is the most widely utilised of these surfactants.
5. **Sweetening agents:** Pharmaceutical medications designed to dissolve or disintegrate in the oral cavity now frequently contain sweeteners. Dextrose, sucrose, fructose, glucose, isomaltose, and polyhydric alcohols are a few of the sweeteners that are frequently used.
6. **Salivary stimulating agents:** To speed up the disintegration of fast-dissolving strip formulations, salivary stimulating agents are utilised to boost the rate of saliva production. Citric acid, malic acid, lactic acid, ascorbic acid, and tartaric acid are a few examples of salivary stimulants. Of these, citric acid is the most favoured.
7. **Flavouring agents:** The type and strength of the flavour determine how much flavouring agent is needed to cover it up. Flavour oils (peppermint, cinnamon, and nutmeg) and fruity flavours (vanilla, cocoa, coffee, chocolate, and citrus) are frequently used. Oleo resins, synthetic taste oils, and extracts made from different plant components like fruits, flowers, etc. can also be used to choose flavours.

8. **Colouring agents:** FD&C dyes, natural dyes, pigments like titanium dioxide, and others are examples of common colouring agents.

Method of Preparation of Oral Film:

The Mouth dissolving film may be created using any one of the following procedures, alone or in combination: Solvent casting, Hot-melt extrusion, Semi-solid casting and Rolling strategies.

Solvent Casting:

Oral film is frequently developed using the solvent casting method, a widely used technology. This technique makes use of film-forming polymers, which have advantageous properties like improved drug release profiles, increased drug solubility, and a quick disintegration time. This specific approach makes it easier for the medicine and excipients to disperse uniformly by precisely dissolving water-soluble polymers in aqueous solutions. In order to help remove and settle any trapped air bubbles in the solution, the solution was then put through a degassing procedure in a controlled vacuum environment. After that, the bubble-free solution is transferred to a petri dish, where it is dispersed uniformly and left to dry.[11,12]

Hot-melt extrusion:

One of the most effective methods in the field of pharmaceutical manufacture is hot melt extrusion (HME). A mixture of a medication, polymer, and other excipients is extruded at high temperatures in this technique. Through this complex process, a homogenous mass is created, which is then cast onto a smooth surface to create films that are distinctly smooth. Achieving the required film qualities, such as thickness, homogeneity, and smoothness, depends heavily on the casting process. Excellent mechanical and physical properties make the films produced with the HME process appropriate for a range of medicinal applications.[12,13]

Rolling methods:

The prepared solution or suspension containing the drug and polymer must have particular rheological characteristics in order to guarantee optimal performance during the rolling process onto the drum. A smooth and even coating process might be facilitated by the solution or suspension's ability to stick to the drum. Aqueous solutions make up the majority of the solvent used in this experiment, with various amounts of alcohol added. In order to reach a condition of desiccation, the film goes through a drying process that is made possible by the rollers. A cutting process is then applied to the dried film, carefully dividing it into different sizes and shapes according to the required parameters.[13,14]

Solid dispersion extrusion:

In this specific approach, the medicinal ingredient and the immiscible polymer are both put through an extrusion process, which makes it easier to generate solid dispersions later on. The solid dispersions are shaped and moulded into a film-like structure during this process. The use of dies, which are specialised instruments made to give the solid dispersions a specified size and form, results in films with better physical qualities and drug delivery capabilities.[14,15]

Characterization Of Oral Film:

Oral film tested in a variety of evaluation procedures.[16,17,18,19,20,21]

Morphological studies:

The scientific community has long acknowledged the use of Scanning Electron Microscopy (SEM) as a potent investigative technique for the study and analysis of surface morphology. SEM allows researchers to acquire high-resolution images and comprehensive information about the composition, structural properties, and topographical aspects of different materials by using a concentrated electron beam to interact with the specimen's surface.

X-ray diffraction and Raman spectroscopy:

X-ray diffraction patterns and Raman spectra analysis techniques can be used to determine if unprocessed active pharmaceutical ingredients (APIs) integrated into films are crystalline or amorphous. These analytical techniques offer important insights into the molecular organisation and structural properties of the API samples. By using monochromatic light scattering, Raman spectroscopy can help identify and characterise the crystalline or amorphous nature of API samples by revealing details on their molecular makeup and vibrational modes.

Thickness measurements:

A Vernier calipermicrometer, a highly advanced measuring device, is used to precisely determine each film's thickness. This device is made especially to measure minuscule dimensions and distances, guaranteeing precise and trustworthy readings. The films' thickness is carefully measured at five different locations, including the middle section and the four corners. This thorough method ensures a thorough assessment of the film's thickness.

Tear resistance:

Plastic or ODF film's tear resistance is a complex characteristic that is closely related to its overall shatter resistance. The force used to initiate ripping is measured using a very low loading rate of 51 millimetres (2 inches) per minute. The greatest stress or force needed to cause tearing in a particular specimen is represented by the tear resistance value, which is measured in newtons.

Palatability study:

The sensory perception of flavour is the main focus of this investigation. Each batch receives an A, B, or C score based on the standards that have been provided. It is clear from the context that a "A" indicates outstanding performance, a "B" indicates a level of accomplishment that is satisfactory, and a "C" indicates a performance that is below average or unsatisfactory. A formulation is considered to be of adequate quality when it receives

two A grades, whereas a formulation of high quality is indicated by receiving three A grades.

Weight variation:

One square centimetre sample was used in this test, and it was drawn from five distinct and recognisable regions. Each film strip's weight is meticulously measured and recorded to provide exact and accurate measurements. A thorough grasp of the weight variations displayed by the film strips under investigation is made possible by this methodical procedure, which guarantees that any weight variations are appropriately recognised and recorded.

Transparency:

The degree of transparency that the films possess can be assessed using a main UV spectrophotometer. The film samples must first be cut into rectangles with a razor blade before they can be mounted on the spectrophotometer's interior. Determine the degree to which films permit the passage of light with a wavelength of 600 nm.

Determination of moisture uptake:

For a week, the films are exposed to a precisely regulated and controlled environment with particular relative humidity and temperature levels in order to assess their moisture absorption properties. A mathematical method that produces a percentage increase in weight is used to quantify and estimate the amount of moisture absorbed by the films.

Percent rise in weight = [(Experimental weight- Original weight)/ Original weight] x 100

Drug content determination:

Pharmacopoeias are authoritative sets of norms and suggestions for pharmaceutical ingredient quality control, guaranteeing that the selected test technique complies with strict legal and scientific requirements. Determine the identity, potency, and purity of the API by following these established protocols, ensuring the final drug product's quality and safety.

Content uniformity of drug:

A total of 20 films are analysed in this painstaking procedure, guaranteeing a thorough assessment of the batch-wide homogeneity of the API distribution. Strict requirements for content homogeneity must be followed in order to guarantee the quality and consistency of pharmaceutical products. In particular, it is advised that the content uniformity be between 85 and 115%, which includes a tolerable degree of fluctuation.

Tensile strength:

Tensile strength is measured using a device that consists of two clamps, one fixed at the top end and the other adjustable at the bottom. The 0.5 x 3 cm film sample is firmly clamped between the two clamps. Both ripping and elongation forces are calculated.

Contact angle measurement:

A very useful tool used in surface science and interfacial phenomena is a goniometer, which measures the contact angle that forms between a liquid droplet and a solid substrate precisely and correctly. To ensure that the entire area is evenly covered, distilled water is carefully dispensed onto the dry film's surface in a controlled amount during the experimental procedure. This procedure is carried out precisely, and it takes no more than ten seconds to finish. After that, high-resolution photos of the processed film are taken using a cutting-edge digital camera.

***In-vitro* disintegration time:**

In a controlled experimental environment, the length of in-vitro disintegration is quantitatively evaluated by visual inspection. The disintegration test is specifically carried out using a glass dish that has precisely 10 millilitres of pure water that has reached a temperature of 370C. For a precisely timed duration of 10 seconds, the sample film is swirled to start the procedure. In the context of film materials, the disintegration time is the amount of time needed for the film to fragment or disintegrate. This metric is a vital sign of the film's chemical and physical characteristics.

***In vitro* dissolution study:**

Drug release testing can be carried out using the paddle technique, a dissolving research tool that has been approved by the USP. The USP dissolving apparatus is kept at a steady temperature of 37°C while swirling at a rate of 50 revolutions per minute. Every movie is positioned on a clear glass slide. This is followed by soaking the slide in a 500mL container of phosphate buffer (pH 6.8). At intervals of 2, 4, 6, 8, and 10, the one millilitre aliquots are removed and replaced with an equivalent volume of dissolving media. Throughout the investigation, the sink conditions are kept constant. The absorbance is measured and the amount of drug release is calculated using a specific analytical tool.

Packaging

For the pharmaceutical industry, the package selection must sufficiently safeguard the integrity of the product. Special processing, expensive packaging, and extra care during production and storage are recommended to protect the dosage of other quickly dissolving dosage forms. 22 For branding purposes and in accordance with industry regulations, converters may choose to print information directly onto the film unit dose before to packing. Among the requirements that require particular attention are unit dose packaging, barcode labelling, usage instructions, child-resistant closures, and senior-friendly packaging.[23] The chosen material needs to fulfil the following requirements

- They must have received FDA approval.
- They have to protect the preparation from the weather.
- They must follow the applicable tamper-resistant standard.

- They cannot provide the product tastes or fragrances; they must not react with the material used to make films.

Novel Technologies Used for Preparation of Oral Dissolving Films:

1. **Wafertab™:** Active ingredients can be administered as ingestible filmstrips thanks to this patented drug delivery system. This delivery method incorporates a pre-measured dosage of medication into the body of a pre-made XgelTM film. This keeps the active substance stable and keeps it from being exposed to too much moisture and heat. Typically, they are designed to be applied topically or taken orally. The drug dissolves rapidly when it comes into contact with saliva.
2. **Soluleaves™:** This technology, which is frequently found in flavor-releasing products like mouth fresheners and vitamins, keeps the active ingredient in the oral cavity. These films break down rapidly when they come into touch with saliva, releasing the drug into the oral cavity right away. [24]
3. **Foamburst™:** One kind of foamed film is called a solulea. An inert gas is driven within during the film's creation, creating a honeycombed structure that facilitates rapid release and produces a unique mouthfeel that is comparable to melting in the mouth. [25]

Regulatory Guidelines for Oral Fast-Dissolving Films (OFDFS) In Different Regions

Regulations govern the production and distribution of oral fast-dissolving films, just like they do for other dosage forms.

Table 2 lists the various regulatory criteria. [26,27]

Region	Regulatory Authority	Key Guidelines and Regulations
India	Central Drugs Standard Control Organization (CDSCO)	Good Manufacturing Practices (GMP) at CDSCO Timetable M CDSCO's requirements for registration and marketing clearance Indian pharmaceutical product pharmacopoeia standards
Australia	Therapeutic Goods Administration (TGA)	Good Manufacturing Practice (GMP) regulations set forth by TGA The TGA's regulations for therapeutic goods registration TGA's regulations regarding alternative therapies
China	National Medical Products Administration (NMPA)	The Good Manufacturing Practice (GMP) rules set forth by the NMPA The NMPA's regulations for the approval and registration of drugs The technical criteria for pharmaceutical products issued by the NMPA
Brazil	National Health Surveillance Agency (ANVISA)	The Good Manufacturing Practices (GMP) standards set forth by ANVISA The rules set forth by ANVISA for drug approval and registration ANVISA's specifications for package inserts and labelling
South Africa	South African Health Products Regulatory Authority (SAHPRA)	The ANVISA-established Good Manufacturing Practices (GMP) guidelines The guidelines established by ANVISA for the registration and approval of drugs ANVISA's requirements for labelling and package inserts

Future prospective

Oral films have a bright future ahead of them, and more research is anticipated to help improve and streamline this medication delivery method. With the ability to customise medication distribution to meet the needs of each patient, the creation of customised oral films is a topic of special interest. It may be possible to improve patient outcomes by creating customised oral films that release medications at particular times or places within the mouth cavity. Another area of ongoing research is the application of nanotechnology to the formulation of oral films. To improve medication solubility and stability and offer sustained drug release, nanoparticles can be added to the oral film formulation. Another area of study is the creation of intelligent oral films that can react to environmental cues like temperature or pH variations. It may be possible to employ smart oral films for controlled drug release or targeted drug delivery. Lastly, a crucial topic for further study is the creation of durable oral film formulations. Oral films can be made more sustainable and have a smaller environmental impact by using biodegradable polymers and environmentally friendly production processes.

Conclusion

A promising and patient-friendly development in medication delivery, oral fast-dissolving films are especially suited for people who have trouble swallowing, including children, the elderly, and people with neurological impairments. OFDFs greatly improve medicine adherence by providing quick dissolving and absorption, doing away with the need for water or chewing. Wide drug compatibility and controlled-release profiles are made possible by their formulation versatility, which includes anything from flavourings and nanoparticles to polymer matrices and plasticisers. While maintaining medication stability, manufacturing processes include solvent casting, hot-melt extrusion,

and sophisticated 3D-printed extrusion enable scalable and repeatable production. By preserving dose accuracy, mechanical integrity, and sensory acceptability, characterisation techniques guarantee quality control and regulatory compliance. Innovative technologies including eco-friendly materials, stimuli-responsive systems, and customised films put OFDFs at the forefront of contemporary, sustainable, and customised drug administration. All things considered, OFDFs represent a synthesis of innovative formulation and patient-centered design, providing a flexible platform for both acute and long-term treatment. Realising their full therapeutic potential and meeting unmet needs in oral drug administration will require ongoing interdisciplinary research and adherence to regulatory norms.

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