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ORAL DISPERSIBLE FILMS: AN OVERVIEW OF FORMULATION, EVALUATION AND RECENT TRENDS

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ABSTRACT
Oral dispersible Films (ODFs) are drug delivery systems that are produced using a variety of techniques for both small-scale pharmacies and personalized medications on a large scale. ODFs and the processes used to fabricate them have some drawbacks. In order to address these problems and discover novel formulations for a variety of APIs that might make their job profitable for them as well as useful for patients, numerous pharmaceutical corporations and academic research institutions worldwide collaborate. This review paper's objective is to offer details on ODF formulation, manufacture, and characterization. ODFs are innovative dosage forms that break down and dissolve in the mouth. Intra-oral absorption lowers the unit dose required to provide the intended therapeutic effect by facilitating rapid action and preventing first-pass effects. These thin, flexible films provide a potential therapeutic approach in the realm of pharmacological intervention since they are made to rapidly dissolve when they come into touch with saliva. The film is made using a variety of materials, including plasticizers, medications, and organoleptic compounds. The film's regular structure and efficacy depend on these components. To increase the flexibility and durability of film materials, for instance, plasticizers are substances that are added. They work by lowering the tension between polymer chains, which makes the film more elastic and resilient to breaking or cracking. Conversely, medications are integrated into the film's structure to achieve certain therapeutic objectives. In addition to examining the crucial elements involved in the packaging process, this study aims to give a thorough overview of the basic ideas and procedures that control the creation and assessment of film.

KEYWORDS: Buccal cavity, polymeric film, oral dispersible film, new drug delivery, and solvent extraction technique.

INTRODUCTION
Solid oral medication forms that are frequently utilized are tablets and capsules. However, some individuals find it difficult or even impossible to take these dosage forms on a daily basis. Some individuals have dysphagia, a fear of choking, or difficulty swallowing. Patients with Parkinson's disease, Alzheimer's disease, elderly, pediatric, or mentally ill patients, as well as those recovering from anesthesia, may encounter these issues.[1-5] Patients with swallowing difficulties, such as those with dysphagia or choking fear, may find it difficult to take the medication orally, which will impede therapy. Although liquid formulations (suspensions, emulsions, and syrups) are easy to swallow, they have a number of drawbacks, including the possibility of microbial contamination, higher taste masking costs, the need for costly storage conditions, the formulation's chemical instability, bulkiness, and related transportation expenses.[6-8]

In addition to these well-known oral formulations, oral dispersible films (ODF) are a novel and developing oral medication formulation that is currently the focus of increased study and attention due to its special qualities.[9] Depending on the underlying manufacturing method, active pharmaceutical ingredients (API) can be

loaded or incorporated into ODF, which is essentially made up of one or more layers of polymers that form a thin film of varying diameters.[10-12]

Additionally, these ODF can be scaled differently to meet the unique demands of the intended patient population, which includes elderly people and newborns, for whom oral medication administration is frequently more difficult.[13-15] Following ingestion, ODF rapidly dissolves in the oral cavity upon coming into contact with saliva, releasing the prepared API. This makes it possible to give medications orally to patients for whom an oral drug formulation would not seem like the best option, such as those who have trouble swallowing.[16] Furthermore, recent advancements have shown that new manufacturing and compounding techniques provide the opportunity to build patient-specific drug formulations that are customized to meet the demands of each unique patient, hence expanding the potential of ODF.[17-19]

Advantages

1. Beneficial dosage.
2. Water is not needed.
3. No chance of choking
4. Concealed flavor.
5. Focused on maintaining consistency.
6. There is less hepatic first pass impact when the drug enters the basic flow.
7. Local and site-specific activity.
8. The large surface area's accessibility causes rapid crumbling and disintegration within the oral cavity.
9. Accuracy of dosage in relation to syrup.[20-22]

Disadvantages

1. The polymer should dissolve in water or an unexpected solvent.
2. It is necessary to produce a stable arrangement with a sensible least robust material and thickness.
3. It must be feasible to develop a uniform film and present it with projection assistance.
4. There are still a number of specific limitations when using film strips, such as the thickness of the film when projecting it. Casting cannot be done on glass Petri dishes.
5. Another technical problem with these dosage formulations is dose homogeneity.
6. Packing films is challenging and calls for specialized equipment.[23-25]

Ideal characteristics

1. ODFs should dissolve quickly in the mouth in a matter of seconds, allowing for a rapid commencement of action without the need for water.
2. To guarantee patient comfort and compliance, they should taste well, feel good in the mouth, and leave little to no residue.
3. The films must possess mechanical strength, flexibility, non-stickiness, and the ability to endure handling, packaging, and administration without sustaining any harm.
4. Accurate dosing and a consistent therapeutic effect depend on uniform thickness, weight, and medication content.
5. ODFs must be resistant to moisture absorption and stable under a variety of environmental circumstances, such as temperature and humidity.
6. They should be simple and affordable to produce using common methods like hot-melt extrusion or solvent casting.
7. The medication release profile should guarantee adequate bioavailability and fit the intended therapeutic application, whether it is immediate or modified.
8. ODFs should be easy to administer, portable, and appropriate for certain patient populations, such as children, the elderly, and people who have trouble swallowing.[26,27]

Composition of ODFs

- Drug (Active pharmaceutical Ingredients)
- Film forming agent
- Plasticizer
- Saliva stimulating agent
- Sweetening agent
- Flavoring agent
- Surfactant
- Colour, Filler[28,29]

Methods of preparation

1. Solvent Casting Method
2. Rolling Method
3. Hot Melt Extrusion
4. Solid Dispersion Extrusion

1. Solvent Casting Method

Practically speaking, solvent casting is the method of choice because it is simple to make film and has low processing costs. The most often used solvents are ethanol and water. When selecting a solvent casting procedure, the API's properties are crucial. The physical properties of API and its compatibility with other excipients and solvents should be taken into account while using this approach. It is necessary to thoroughly investigate the characteristics of API, such as polymorphism and temperature sensitivity.[30,31]

Film-forming polymers, API, plasticizer, and other excipients are dissolved or dispersed by the solvent. After that, a magnetic stirrer is used to thoroughly mix the polymer solution for the whole night. The homogeneity is dependent on the removal of trapped air bubbles prior to casting.[32,33] Films were allowed to dry when casting was finished, ideally using convection or a hot air oven. Films are carefully peeled off or removed and cut into the proper sizes and shapes after they have adequately dried. In an industrial setting, the films are sometimes rolled (called "roll stock") and stored until a later time before being cut. Cutting and packing the films after preparation is the best way to maintain their integrity and stability. Thin film packaging materials are

made to have sufficient mechanical strength to protect the film from moisture and temperature fluctuations.[34,35] The film produced via solvent-casting offers several advantages, such as improved physical properties, easy and inexpensive manufacture, and consistent thickness. Because the solvent is removed at low temperatures, the solvent casting method is the best way to design the API in ODFs that are sensitive to light and heat.[36]

One of the limitations of solvent casting is that it only works with polymers that dissolve in the solvent used to make the polymer solution. Another factor that needs to be watched for human use is the necessity of using organic solvents. Organic solvent systems pose a major threat to human health. Because of this, numerous nations have passed stringent legislation governing the use of organic solvents.[37]

2. Rolling Method

The produced solution or suspension comprising the medicine and polymer must have certain rheological characteristics in order to guarantee optimal performance throughout the rolling process onto the drum.[38,39]

The medicinepolymer solution must have proper rheological properties for effective drum rolling. Good adhesion of the suspension helps achieve a smooth and uniform coating on the drum. Water-based solutions are mainly used as solvents in the experiment. Different quantities of alcohol are added to modify the solution properties. Rollers help dry the coated film by removing moisture and creating a desiccated film. Finally, the dried film is cut into specific sizes and shapes according to requirements.

3. Hot Melt Extrusion

When it comes to pharmaceutical production processes, hot melt extrusion (HME) is a very effective method. It entails extruding a combination at high temperatures that includes a medication, polymer, and other excipients. This complex process creates a uniform bulk, which is then cast onto a flat surface to create films that are obviously smooth. To achieve the desired film qualities, such as thickness, homogeneity, and smoothness, the casting stage is essential. The films produced using the HME process have outstanding mechanical and physical properties that make them appropriate for a range of medicinal uses.[40,41]

4. Solid Dispersion Extrusion

This technology facilitates the creation of solid dispersions by subjecting the immiscible polymer to an extrusion process alongside the medicinal ingredient. The solid dispersions are shaped and molded into a structure resembling a film during this procedure. The resulting films have improved drug delivery characteristics and improved physical qualities thanks to the use of dies, which are specialized instruments made to give the solid dispersions a specified shape and size.[42,43]

Evaluation and Characterization

Because API particles come into direct contact with taste receptors, the flavor and palatability of ODFs are important factors to take into account. Multisensory taste detectors with pattern recognition systems, or "electronic tongues," have recently been employed in specialized panels for taste assessment and seem to be suitable alternatives for formulation pre-testing. The most reliable test is the one conducted in vivo on human subjects, but it is also the most ethically questionable. The study is carried out by first rinsing the mouth with distilled water, then putting the necessary ODFs to the tongue and holding it there for 30 seconds. After spitting out the contents of the mouth, the mouth was rinsed with distilled water once again.[44-49]

A) Tensile Strength

The maximum force and pressure that an ODF can sustain before breaking is known as its tensile strength. A TA. XT2 texture analyzer or a tensiometer are two tools that can be used to measure this. In a tensiometer, the total weight applied to the string to fracture the film is used to determine the tensile strength of the film. A 5 kg load cell on the A TA.XT2 is used to measure the prepared film's tensile strength. After that, the films are placed between two clamps that are three centimeters apart. The force was measured when the film broke while the top clamp pulled the strip at a speed of 2 mm per second. MPa is used to express the tensile strength. Tensile strength is typically measured at 1.80±0.20 Mpa. The formula is used to determine tensile strength.[50,51] Tensile strength is calculated as follows: load at failure × 100/film thickness × film width

B) Thickness

To determine whether the dose in the film is correct, the film thickness is assessed. A micrometer screw gauge can be used to measure the thickness in at least five carefully chosen locations. The mean values were noted after the film thicknesses were measured from the centers and four sides. Uniformity in film thickness is essential for guaranteeing drug dose precision. Film thickness should be between 50 and 1000 micrometers.[52-54]

C) Percent elongation

One kind of deformation is elongation. When a material breaks, it is a testament to its tenacity. It determines the film's end-use handling characteristics. The percentage of elongation can be measured with a texture analyzer. Although it is easy to calculate as the difference between the film's initial length and its altered length upon breakage, the percentage elongation describes the stretching capacity of a film prior to its breakdown. 322.4±63.3% is the standard value. It can be calculated using the following mathematical expression.[55,56]

% elongation = film length increase **x** 100/film initial length

D) Young's Modulus

A graph between the stress-strain curves with slopes that represent young's moduli can be used to determine the degree of film elasticity or stiffness. This number can be used to describe a film's resistance to deformation. Slope elevation increases tensile modulus, and vice versa. Young's modulus values will be greater for films that are harder and more brittle. 0.30 ±0.07 mpa is the typical value. The following equation (57-59) can be used to represent the results as the ratio of applied stress to strain. Young's modulus is equal to slope × 100/film thickness × speed.

E) Folding Endurance (FE)

Repeatedly folding the film at the same location at a 180-degree angle until the film breaks is an indirect method of testing flexibility. There is a direct correlation between the mechanical strength of films and their FE. In proportion to the FE value, the mechanical strength will rise, and vice versa. Because it affects mechanical strength, the amount of plasticizer used in the film formulation affects the FE value. To improve accuracy, tests should be conducted three more times. Films are considered ideal if their FE value is 300 or more. The usual range is 100–150.[60,61]

F) Content Uniformity

The standard assay method described in the corresponding pharmacopoeias is used to assess the content uniformity. The content uniformity of formulations can also be ascertained. Spread the ODF (1 cm^2) in 100 ml of the buffer solution to start the test. Take two milliliter portions of the solution and dilute it with up to ten milliliters of buffer. A UV-visible spectrophotometer was then used to check the diluted sample float above, adjusting the absorbance according to the active ingredient. The absorbance value helps determine drug content homogeneity and estimate the amount of medication in the film. The range of content homogeneity is 85%–115%.[62,63]

G) Disintegration Time

A disintegration apparatus is used to measure the disintegration time. The formulation and composition of the film determine the disintegration time, which typically falls between five and thirty seconds. The USP disintegration device is frequently used in this test. A wire mesh made of stainless steel is used to hold the film. The device has salivary fluid that is pH-simulated. The amount of time it takes for a film to shatter and disintegrate is calculated.[64]

H) Dissolution Test in vitro

Standardized, approved basket or paddle equipment was used for the ODFs is dissolving test. Sink conditions should be maintained during the dissolution test. When the film floats over the medium during the dissolution test, it will be difficult. In these situations, the paddle strategy is recommended. The temperature is maintained at 37.5 degrees Celsius for the dissolution test. The samples are gathered at various intervals and analyzed with a UV spectrophotometer.[65,66]

I) Moisture content

The quantity of moisture in a film affects its mechanical strength, adhesive properties, and friability, making it potentially important. Elevation in the moisture level is caused by a number of variables, including the hygroscopic properties of API, polymers, manufacturing methods, and the solvent system utilized to dissolve the polymeric mixture. A number of methods, including the Karl Fisher titration and the weighing method, are frequently used to determine the moisture content of film. The films are first weighed and then exposed to temperatures between 100 and 120 degrees Celsius. This process is repeated until the films reach a consistent weight. After the sample has dried fully, its weight is determined. The ideal range is between three and six percent. The formula for determining the moisture content percentage.[67,68] A smooth and consistent coating process might be facilitated by the suspension or solution's ability to stick to the drum. Aqueous solutions are the main solvent used in this experiment, with different amounts of alcohol added. The rollers aid in the drying process, which removes moisture from the film to produce a desiccation condition. The desiccated film is then put through a cutting process that carefully divides it into different sizes and forms in accordance with the required parameters.[38,39]

Packaging and Storage of ODF

Because ODF film disintegrates quickly during production and storage, expensive packaging materials were needed. Most people agree that aluminum pouches are the most common type of packaging. APR-Labtec developed the quick card packaging technique especially for ODF films. The Food and Drug Administration (FDA) must approve the packing material. The system needs to be extremely resistant to manipulation or illegal access. Packaging materials must not contain any leach substances that could harm ODF film.[69] The ODF film was packaged using the materials listed below.

a. **Paper foil and plastic pouches:** The lightweight pouch demonstrates a significant level of environmental awareness and tamper resistance. During the product filling process, technology is used to create a condensed bag.
b. **Single pouch and aluminum pouch:** It's commonly known that aluminum is the most common type of pouch used to package ODF film. This bag can protect medicinal products in ODF film from the elements.
c. **Blister card containing several units:** The blister packing was made of thermoplastic resin. It is a great substance that keeps moisture from penetrating ODF film.
d. **Barrier films:** The use of high barrier films becomes essential because certain medicine formulations are sensitive to moisture. A variety of materials, including polypropylene film and

polychlorotrifluoroethylene, can be used to successfully provide moisture safety. Polypropylene may show resistance to stress-induced fracture under certain circumstances.[70,71]

e. **ODF Film's Stability Study:** The stability of oral dispersible film can be successfully maintained under certain controlled environmental conditions, according to the International Council on Harmonization's (ICH) criteria. These circumstances include 25°C with a relative humidity of 60% and 40°C with a relative humidity of 75%. For a whole year, the stability of the film was tested in a stability chamber. Film samples were taken at regular intervals of three, six, nine, and twelve months in order to assess standard parameters.[72,73]

Future Scope

Future advancements in oral dispersible films are expected to focus on the development of patient-specific and personalized drug delivery systems with improved palatability, stability, and therapeutic effectiveness. Emerging technologies such as 3D printing, inkjet printing, nanotechnology-based formulations, and continuous manufacturing techniques may provide better dose precision and enhanced patient compliance. In addition, the application of advanced taste masking approaches and electronic tongue systems can improve the acceptability of bitter drugs, particularly for pediatric and geriatric populations. Further research on novel polymers, multilayer films, and modified drug release systems may expand the therapeutic applications of ODFs in modern pharmaceutical drug delivery.

CONCLUSION

Oral dispersible films (ODFs) are emerging as a highly precise, palatable, and patient-friendly oral drug delivery system that improves therapeutic effectiveness by enabling rapid absorption and bypassing first-pass metabolism. They are especially beneficial for pediatric, geriatric, and dysphagic patients. ODFs offer improved safety, efficacy, and patient compliance compared to conventional dosage forms, and their formulation can be tailored based on drug properties and production scale. Despite some formulation challenges, optimization techniques are helping overcome these limitations. Overall, ODF technology represents a promising future in drug delivery systems with strong potential to enhance oral therapy and patient acceptance.

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