

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

Orodispersible Films: The Future of Fast-Acting, Patient-Friendly Medication

Tanushri K. Patil a, Mr. Manoj M. Bari b

- ^a Department of Pharmaceutics, Shree Sureshdada Jain Institute of Pharmaceutical Education & Research, Jamner-424206, Maharashtra, India.
- b Department of Pharmaceutics, Shree Sureshdada Jain Institute of Pharmaceutical Education & Research, Jamner-424206, Maharashtra, India

ABSTRACT

Orodispersible films (ODFs) have become a viable oral medicine delivery method since they dissolve quickly in the mouth without the need for water. The design, categorization, assessment, and benefits of ODFs are examined in this review, with a focus on their suitability for pediatric, geriatric, and dysphagic patients. The unique features of ODFs such as improved bioavailability, ease of administration, and patient compliance make them a suitable alternative to conventional dosage forms. Various polymers, plasticizers, and excipients used in formulation are discussed along with methods like solvent casting, hot melt extrusion, and rolling. The paper also highlights evaluation parameters including disintegration time, mechanical properties, and drug content uniformity, along with novel technologies and packaging considerations. Despite certain limitations such as drug load capacity and taste masking, ODFs continue to gain traction as an innovative and effective platform in modern pharmaceutics.

Keywords: Oro-Dispersible Films, Film Forming Polymer, Method of Preparation, Solvent Casting, Evaluation, Packing.

Introduction

Numerous pharmaceutical research initiatives in the last few decades have sought to create novel dosage forms with the goal of enhancing quality of life by making medicine easier. Rapid Disintegrating Films, also known as Oral Disintegrating Films (ODFs), have garnered a lot of attention due to its ability to disintegrate rapidly in the mouth without the need for water. When the film enters the oral canal, saliva quickly penetrates it and dissolves it in a few seconds.

ODFs are helpful for patients having trouble swallowing conventional tablets, capsules, or syrups, such as young children, elderly people, bedridden people, or those with mental disabilities. They are also beneficial for those who lead active lives or who experience nausea, allergic reactions, or coughing. ODFs are also helpful for local oral actions, such treating toothaches, cold sores, ulcers, or teething.

Although helpful, traditional oral disintegrating tablets (ODTs) have disadvantages such as fragility, choking hazards, and swallowing anxiety, necessitating costly packaging. ODFs are easier to handle, transport, and store because they are less brittle and more flexible. In oral drug delivery, they signify a shift from tablets and capsules to wafers and, more recently, thin, dissolvable films.

Other names for these films include quick dissolving films (QDF), oral strips (OS), rapid disintegrating films (RDF), oro dissolving films, and fast mouth dissolving films (MDF).

A rapid disintegrating film or strip is a type of dosage form that uses a water-soluble polymer to hydrate saliva, stick to mucosa, and dissolve in a matter of seconds. When applied to the tongue or oral cavity, the drug dissolves and is released for oromucosal absorption. The thin membrane and numerous veins of the sublingual mucosa make it relatively porous. Its strong blood flow allows for quick medication absorption and immediate bioavailability.

For packaging in a variety of formats that are acceptable to pharmaceutical companies, the film is first produced as a large sheet and then cut into individual dosage units. (ref.1)



Fig. No.1: Oro-Dispersible Film

Anatomy and Physiology of Oral Cavity

Proteins and carbohydrates make up the mucus that the oral tissue epithelium's 40-50 cell layers produce. The gums, tongue, and base of the mouth all have mucosal thicknesses that range from 100 to 200 μm . The submucosal layer secretes a little gel-like fluid called mucus, which is made up of 90%-99% water, 1%-5% water-insoluble glycoprotein, and other substances such proteins, enzymes, electrolytes, and nucleic acids. On the other hand, lobules inside the salivary glands release saliva and parotid from the salivary duct near the sublingual canals and submandibular teeth. Small salivary glands are most commonly seen on the cheek and lip mucosa. In a minute, around 1-2 millilitres of saliva are released.

The mucus, water, the enzymes lysozyme and amylase, mineral salts, immunoglobulins, and blood clotting factors make up saliva. Saliva and mucin function as barriers for the oral mucosa as well. There are two distinct regions in the mucosal epithelial structure: the lipophilic space between cells and the lipophilic membrane of the stratified epithelium and the more hydrophilic region. In terms of substance permeability, the oral mucosa can withstand conditions that the intestinal mucosa and the epidermis cannot. There are two primary drug absorption pathways provided by the mucosal epithelium: the transcellular (intercellular) and paracellular (intercellular) pathways. While more hydrophilic molecules can enter the intercellular space due to their polarity, particles with a high partition coefficient can more easily pass through the lipophilic structure that makes up cell membranes. The drug's absorption depends on whether it is hydrophilic, hydrophobic, or amphiphilic. (ref.2)

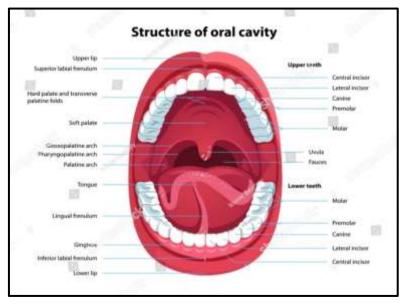


Fig.No. 2: Structure of Oral Cavity

Mechanism of Absorption from Oral Cavity

Buccal and sublingual mucosas are commonly used in the delivery of medications because of their superior properties compared to gingival and palate surfaces. The sublingual mucosa is thinner and has higher permeability efficiency than the buccal mucosa. Therefore, when prompt action is needed, the oral mucosa is a better site for administering medication. Because of frequent salivary washing and tongue movement, this position is not ideal for dose

form retention. A thin film made of hydrophilic polymers dissolves rapidly in the buccal cavity or under the tongue. After dissolving, the medication passes through the mouth mucosa and into the circulation. Through the epithelial barrier, the active ingredients reach the blood capillaries. They evade first-pass metabolism by entering the bloodstream and systemic circulation without first going via the liver or digestive tract. (ref.3)

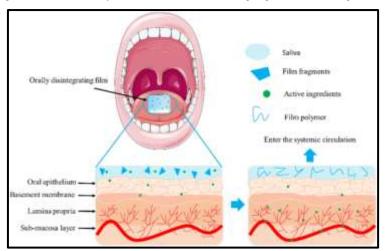


Fig.No. 3: Absorption from Oral Cavity

Factors Affecting Absorption

Solubility in salivary secretion:

The medicine must have both high lipid solubility and aqueous buccal fluid solubility; it must be biphasic in order to be absorbed.

• Assimilation into the oral mucosa:

Medication that adheres to the mouth mucosa has limited systemic access.

Saliva's pH and pKa:

The saliva's typical pH of 6.0 promotes the absorption of medications that stay unionized. Additionally, if the pKa is less than 10 for a base and larger than 2 for an acid, the medication will be absorbed via the mouth mucosa.

- Lipophilicity of the drug.
- A medication must have a little greater lipid solubility than that needed for GI absorption in order to be fully absorbed by the sublingual route, which is also required for passive permeation.
- Oral epithelium thickness:

The sublingual epithelium has a thickness of $100-200~\mu m$, which is smaller than the buccal thickness. Because the epithelium is thinner and the medication is submerged in a smaller volume of saliva, the absorption of medicines occurs more quickly. (ref.4)

Classification of ODFs

ODFs are often divided into three classes: type 1 based on dissolving, type 2 based on layering, and type 3 based on the API's characteristics.

• Type 1 ODFs:

There are three subtypes of Type 1 ODFs: slow, moderate, and rapid. Films with a thickness of around 50 to 150 mm that dissolve in 30 seconds are referred to as fast-dissolving ODFs; films that dissolve in 1 to 30 minutes are referred to as moderately dissolving ODFs; and slow-dissolving ODFs might take more than 30 minutes to dissolve. Slow/moderately dissolving films are used to create nicotine-based medications, whereas fast-dissolving films are employed in emergency situations. These films aid patients who have smoked tobacco frequently and grown addicted by reducing or eliminating cravings.

• Type 2 ODFs:

Type 2 ODFs are categorized based on how many layers they have. Monolayers, bilayers, and multilayers are all possible types of layers. An API, a film-forming polymer, and excipients make up monolayer oral films, whereas bilayer or double layer films have two layers: one for the API and another for taste masking or permeability enhancement.

• Type 3 ODFs:

Type 3 ODFs are further categorized based on the source of the API, which can be either natural (plant or animal) or synthetic (like sildenafil). Examples of these include ginger and turmeric. The other class of type 3 ODFs, such as vitamin D ODFs, are films made with minerals, vaccines, vitamins, or micronutrients. (ref.4, 5)

Special Features & Advantages of ODFs

- Quick start of action with enhanced bioavailability since it avoids the hepatic first-pass impact.
- Easy to use for children, elderly, and dysphasic individuals
- · Quick dissolving and disintegration in the oral cavity
- Lower dosage, improving the drug's safety and effectiveness profile with fewer adverse effects.
- Helpful in situations requiring an ultra-rapid commencement of action, such as motion sickness, acute pain, abrupt allergy reaction, asthmatic
 attack, and coughing.
- No water is needed for administration
- They are flexible and portable, making handling, transporting, and storing them simple
- · Ease of administration to mentally ill, disabled, uncooperative patients and patients who are on reduced liquid intake plans or are nauseated.
- Longer stability since the medication stays in solid dose form until it is taken.
- Accuracy in dose as compared to liquid formulations.
- Pleasant mouthfeel, leaving negligible or no residue in the mouth after administration.
- Non-invasive
- Site specific action & local action
- Minimal side effects (ref.4, 2, 6)

Disadvantages/Limitations of ODFs

- Drugs which irritate the oral mucosa cannot be administered by this route.
- Excessive bitter drugs are not feasible.
- Dose homogeneity is a technical difficulty.
- It can occasionally exhibit granular and brittle properties.
- Hygroscopic in nature, thus it needs to be stored in a dry environment,
- The product's stability and safety necessitate specific packaging
- Oral film cannot contain the high dosage.
- Preparation method is costly compared with oral dissolving tablets. (ref.2, 7, 8, 9, 10)

Ideal Drug Features to be Considered

- The therapeutic dosage of the medication shouldn't exceed 20 mg, and the pill should taste well.
- The medication should have a low molecular weight and tiny molecular size.
- The medication should be stable and soluble in both saliva and water.
- It ought to partially unite at the oral cavity's pH.
- The medication ought to be less sensitive to environmental factors.
- It must be able to penetrate the mucosal tissue of the mouth.
- Within a few seconds, it ought to dissolve or disintegrate in the mouth.
- The medication must work with flavor masking. (ref.2, 11)

Limitations in the Development of ODFs:

Some of the limitations in the development of oral films include:

• The drug's insoluble nature.

- The bitter and nauseating drug's taste is concealed.
- The film's integration of high doses.
- The film needs a lot of time to dry.
- The film's resistance to humidity and temperature changes.
- · Adequate mechanical power.
- Drug co-administration.
- Dosage uniformity.
- Particular packaging is required. (ref.7)

GENERAL COMPOSITION OF ORO-DISPERSIBLE FILM:

General composition of fast dissolving oral film: The oral film comprises of general ingredients in the following amount: (ref.12)

Table No. 1: General Composition of Oro-Dispersible Film

Sr. No.	Ingredients	Composition
1.	API	1-30%w/w
2.	Film Forming Polymer	40-50% w/w
3.	Plasticizers	0-20% w/w
4.	Saliva stimulant	2 to 6% w/w
5.	Sweetener	3 to 6 %w/w
6.	Flavor	q.s.
7.	Fillers, colors, flavors etc.	0-40%w/w

FORMULATION COMPONENTS OF ODF (ref.1, 13, 14)

- Active Pharmaceutical agents
- Film Forming Polymers
- Plasticizers
- Saliva Stimulating Agent
- Flavoring agents
- Sweetening agents
- Coloring agents
- Surfactants

1. Active Pharmaceutical agents:

An active pharmacological substance is any class of pharmaceutically active compounds that may be ingested orally or through the buccal mucosa. Antiepileptic, antianginal, antitussives, antiulcers, antiasthmatics, antihistaminic, and expectorants are a few of them. For the formulation to work, the pharmaceutical dosage should be in milligrams (less than 20 mg/day).

The ideal qualities of a drug to be selected are as follows:

- The medication should taste good.
- Generally speaking, the substance to be included should have a low dosage of less than 20 mg.
- It should be better to use medications with a moderate and lower molecular weight.

- The medication must be stable and soluble in both saliva and water.
- It ought to partially unite at the oral cavity's pH.
- It need to be able to penetrate the mucosal tissue of the mouth.

2. Film Forming Polymers:

The water-soluble polymers provide the films their mechanical qualities, pleasant mouthfeel, and quick disintegration. HPMC, carboxymethylcellulose, polyvinylpyrollidone PVP K-90, pectin, gelatin, sodium alginate, hydroxypropylcellulose, polyvinyl alcohol, maltodextrins, and eudragit-RD10 are a few examples of water-soluble polymers used as film formers. One new polymer that forms films is polymerized rosin.

3. Plasticizers:

Formulation issues significantly affect the mechanical characteristics of films. Additionally, the introduction of plasticizers has improved the mechanical properties of the films, including their elongation and tensile strength. These characteristics could be impacted by variations in their concentration. Among the most widely used plasticisers are polyethylene glycols, glycerol, and dibutylphthallate.

4. Saliva Stimulating Agent:

Increased salivation aids in the quick breakdown of fast-dissolving film compositions. Acids that are used to prepare meals as salivary stimulants should therefore be included in the formulations. The most popular salivary stimulant is citric acid, which is followed by tartaric acid, ascorbic acid, lactic acid, and malic acid.

5. Flavoring agents:

Synthetic flavour oils, oleo resins, and extracts made from different plant parts, such as leaves, fruits, and flowers, can all be used as flavouring agents. Flavours can be combined or used separately. Any taste can be added, including sour fruit flavours like lemon and orange, sweet confectionary flavours like vanillin and chocolate, fruit essences like apple, raspberry, cherry, and pineapple, and strong mints like peppermint, sweet mint, spearmint, wintergreen, cinnamon, clove, and water-soluble extracts of menthol. The type and strength of the flavour determine how much flavour is required to cover the taste.

6. Sweetener:

Sweeteners have emerged as a crucial component of pharmacological preparations meant to dissolve or disintegrate in the mouth. Sucrose, dextrose, fructose, glucose, liquid glucose, and iso-maltose are the traditional sources of sweeteners. Aspartame, cyclamate, and saccharin are the first artificial sweeteners.

7. Coloring agents:

The use of FD&C-approved coloring compounds is limited to concentrations of 1%; w/w in the manufacturing of orally fast dissolving films, e.g. Titanium dioxide.

8. Surfactants:

Surfactants are used in formulation as solubilizing, wetting, or dispersing agents. They cause the film to dissolve in a few seconds and release the active ingredient quickly. Some of the often used surfactants include PEG, sodium lauryl sulfate, and benzoalkonium chloride. Poloxamer 407 is one of the most important surfactants due to its solubilizing, wetting, and dispersing qualities.

METHODS OF PREPARATION OF ODF (ref.1, 15, 11, 16)

The following categories apply to different techniques for creating oral films:

1. Casting and Drying:

a) Solvent casting:

The solvent-extraction procedure, which involves dissolving water-soluble chemicals to create a transparent, viscous solution, is mostly used to manufacture the oral film. A tiny amount of solution is used to dissolve the active medicinal component and other agents, which are then combined with bulk. After that, this combination is put to an aqueous solution. After the trapped air has been removed, the resultant solution is cast as film, dried, and then cut into the appropriate-sized pieces. The most effective method for producing films with heat-sensitive active medicinal ingredients is solvent casting.

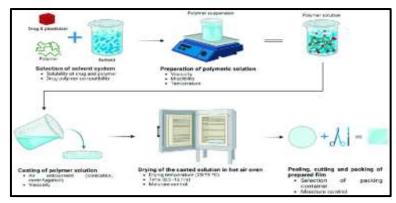


Fig. No. 4: Solvent Casting Method

b) Semi-solid casting

Water-insoluble polymers are employed in this process. An insoluble polymer solution is made with sodium hydroxide and ammonia. To create a gellike solution, the two solutions are combined with the proper quantity of plasticizer. Thin films or ribbons are created by applying this gel-like solution on thermoregulated drums. The ratio of the quantities of acid-insoluble polymer to the film-forming polymer is kept at 1:4. Cellulose acetate phthalate, cellulose acetate butyrate, and other acid insoluble polymers are examples.

2. Extrusion:

a) Hot Melt Extrusion

This technique is frequently used to prepare transdermal and transmucosal drug delivery systems, extended-release tablets, and granules. By using this procedure, films are processed by heating a polymer into a film rather than using the standard solvent casting method. Hot melt extrusion equipment includes an extruder, downstream ancillary equipment, and monitoring tools. The components of an extruder include a screw, die, screw-driving mechanism, heating/cooling device, and feeding hopper barrel. Film casting employs aqueous or organic solvents to create thin films for wound care and transdermal/transmucosal medication administration.

b) Solid Dispersion Extrusion

Amorphous hydrophilic polymers in their solid state are present when two or more active components are dispersed in an inert carrier. After dissolving the medication or API in an appropriate liquid solvent, the mixture is added to a PEG melt that is below 70°C. In melted PEG, the chosen medication or solvent could not be miscible. Then, solid dispersions are formed into films using dies.

3. Rolling method

In this procedure, the drug is rolled with solvents and a carrier. A film-forming polymer solution is made and run through a roller. There should be particular rheological considerations for the suspension or solution. Water and water-alcohol mixtures are the primary solvents employed in this process. API and other excipients are dissolved in a small amount of aqueous solvent by using a high shear processor. A smooth, viscous solution is created when water dissolves hydrocolloids. With the use of rollers, the resulting suspension or solution is used to create the film.

The second metering pump feeds a certain amount of solution into the pan. The film's thickness was determined by the metering roller. The support roller removes the film after it has finally developed on the substrate. Controlled bottom drying is used to dry the wet film. The resulting film is then cut into the appropriate sizes and shapes.

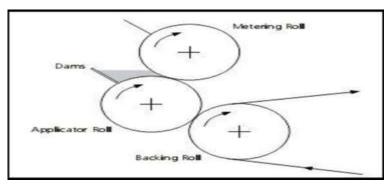


Fig. No. 5: Rolling method

NOVEL TECHNOLOGIES USED FOR PREPARATION OF ORAL DISSOLVING FILMs (ref.17)

- SoluleavesTM
- WaterTabTM
- Foam burstTM
- Rapid Film of
- Bio-erodible mucoadhesive (BEMA o")

Table No. 2: Proprietary Technology Platform for ODF

Proprietary Technology	Technological Platform
Soluleaves TM	Edible thin films with a variety of flavors, vitamins, and APIs are added for gradual release after adhering to the oral mucosa.
WaterTab TM	In order to limit heat and moisture exposure and to increase product stability, a technique was developed to load a precise dosage of API into the pre-assembled body of digestive strips. Orally or topically using it is an option.
Foam burst™	A unique patent for a foam film capsule with a honeycombed structure that delivers flavors for speedy dissolving and a satisfying mouthfeel was generated using Soluleaves technology.
Rapid Film °	According to a patent from Labtec GmBH, medications (up to 30 mg) can be included in water-soluble polymers rather than adhesives for rapid oral release.
Bio-erodible mucoadhesive (BEMA o")	The technique is designed for multiple, adherent bio-erodible coatings on the oral mucosa and disperses APIs from the backing layer in a single direction for an instant impact.

EVALUATION OF ORO-DISPERSIBLE FILM: (ref.18, 19, 20)

1. Organoleptic evaluation

As the film breaks down in the oral cavity, it should display the proper organoleptic characteristics, such as colour, flavour, and taste. An oral thin film should be uniform and have an appealing hue because it is administered to children. The formulation's flavours should cover the taste of the polymer, drug, and other excipients while also having a pleasing smell. Patients' sense of taste affects their acceptance. Specially made taste panels are used for the physical testing. Additionally, the potentiometric titration method-based electronic tongue approach is used.

2. Thickness

The precision of the film's dosage distribution is closely correlated with its thickness. The final thickness of the film is determined by taking measurements at five different important locations using a micrometer Screw gauge or calibrated digital Vernier calipers. The ideal range for the film's thickness is 0.05 to 0.1 mm.

3. Weight Variation

Weight variation of the oral film is evaluated by weighing the individual weight of any five films from the formulation on a digital balance accurately and then the average weight is calculated. The average weight of the strip is computed. A large number of weight variations indicate non-uniform drug content.

4. Surface pH

The film to be tested was put in a petri dish, soaked with 0.5 to 1 milliliter of distilled water, and then left for 30 seconds. After placing the pH meter's electrode on the formulation's surface and letting it settle for a minute, the pH was recorded. The surface pH should be close to neutral, generally in the range of 6.2 - 7.6. It should not be too acidic or alkaline to avoid irritation when the film dissolves in the mouth.

5. Folding Endurance

One important technique for assessing a film's mechanical properties is folding endurance. To ascertain it, the film was folded repeatedly in the same location until it broke. The folding endurance value was determined by counting the number of times ODF could be folded without breaking. The mechanical strength of the film increases with folding endurance. ODF should be able to fold more than 100 times and no more than 300 times.

6. Wetting Time

A circular single tissue paper was placed in the petridish. 6 ml of 1.1% w/v methylene blue solution added to the petridish. The film was then placed on the surface of tissue paper. The time required for the dye to appear on the surface of the film was noted as the wetting time of the film.

7. Uniformity Drug Content

The homogeneity of an oral film's content is determined in order to estimate API content in a single film. Any of the standard test procedures established in the standard pharmacopoeia for the drug can be used. It is determined by analysing the drug content of each film from formulation. The drug content of the material should be between 85 - 115 %.

8. Disintegration Time

The film was placed with tweezers in a glass beaker with 20 milliliters of distilled water to visually assess the in vitro disintegration time. When the movie begins to shatter or disintegrate, that is known as the disintegration period. The typical disintegration time for strips is 5-30 sec.

9. In-Vitro Dissolution Test

The release rate of API was determined using United States Pharmacopoeia (USP) dissolution testing apparatus type 2 (Paddle method). The dissolution test was performed using 900 ml of phosphate buffer pH 6.8 at 37 ± 0.5 °C and 50 rpm. In specified time intervals (0, 2, 4, 6, 8, 10 min) an aliquots of 5 ml samples of the solution were withdrawn from the dissolution apparatus with replacement of fresh fluid to dissolution medium. The samples were filtered through whatmann filter paper of 42 μ m. Using a UV Visible Spectrophotometer (Shimadzu-1800) The drug release was examined.

10. Percent Elongation

A film expands as stress is applied, and this is related to a strain. A strain is eventually the film's distortion divided by the sample's original dimension.

% Elongation = $(L - L_0) \times 100 / L_0$

L₀ was the starting length, while L was the final length.

In general, the strip's elongation gets better as the plasticizer content rises

11. Young's Modulus

The stiffness of the film is measured by its Young's modulus, which is the ratio of applied stress to strain in the area of elastic deformation.

12. Tear resistance

Its final resistance to rupture determines its complicated tear resistance. The tear resistance value, expressed as newtons [pounds force], is calculated by adjusting a meager rate to determine the force needed to tear the specimen.

13. Contact Angle

Contact angle measurements are made at room temperature using goniometry. The dried film was covered with a drop of double-distilled water. A digital camera was then used to capture the image of the water droplet.

14. Swelling Index

In a simulated saliva solution, the swelling property of the oral film is tested. The film sample is weighed before being put on the already weighted stainless steel wire mesh. The mesh is then placed in a container with 15 cc of media.

Swelling Index = $Wt - W_0/W_0$

Where, Wt is the weight of the strip at time t and W_0 is the weight of the strip at time zero.

15. Moisture Uptake

Determining the films' physical stability and integrity in high-humidity settings was the aim of this test. Through the use of a film that contained a standard solution of aluminium chloride, the humidity inside the desiccator was kept at 75% relative humidity. After three days, the films were collected and weighed to calculate the films' percentage moisture absorption.

 $\%\ Moisture\ uptake = (Final\ weight - Initial\ weight)/\ (Initial\ weight) \times 100$

16. Moisture Loss

The percentage of moisture loss in a film indicates its hygroscopicity. A common method for calculating this metric is to weigh the film first and then place it in a desiccator for three days. Calcium carbonate may be found in the desiccator. The films are removed after three days and weighed again. Moisture loss is calculated by using the formula below.

% Moisture loss = (Final weight – Initial weight)/ (Initial weight) ×100

17. Stability Studies

Stability studies were carried out as per ICH guidelines Q1A (R2). The aluminium packet with the optimized formulation was sealed. It was stored at accelerated ($40^{\circ}c \pm 2^{\circ}c$, 75% RH \pm 5% RH) conditions for a period of one month. Films were evaluated for various parameters like weight, folding endurance, disintegration time, drug content and % DR.

PACKAGING OF ODFs:

ODFs should not be stored unpacked because they are moisture-sensitive. ODFs are often individually packaged in pouches. It is necessary to use packaging materials that offer a moisture barrier. Unit weight variation could be measured off-line, and automatic systems could visually inspect as part of in-line in-process control. Both single-dose and multi-dose packaging are feasible, although single packets are recommended to prevent unintentional overdosing due to films adhering to one another. New possibilities for personalised medicine are presented by a roll dispenser with a continuous film that may be sliced into desired sizes on an individual basis, resulting in individual dosing.

Modern packaging technologies like Labtec GmbH's Rapidcard, which is the size of a credit card and has three films on each side, help to make the perfect take-out medication.

Packaging that is both kid-resistant and senior-friendly should be taken into account. To adhere to industry regulations, the necessary information can be printed directly into the film before packing. (ref.12)



Fig. No.6: Examples for Different Marketed Oro-Dispersible Films and Packaging Variants

CONCLUSION:

Orodispersible films (ODFs) are a major development in oral drug delivery systems, providing a quick, easy, and patient-friendly substitute for traditional dosage forms. Pediatric, elderly, and dysphagic patients benefit greatly from them because of their quick dissolution in the oral cavity without the need for water. The incorporation of suitable film-forming polymers, plasticizers, and excipients ensures desirable mechanical and physicochemical properties. Despite certain limitations such as drug loading capacity, taste masking challenges, and special packaging requirements, ongoing research and novel technologies continue to enhance the formulation, stability, and applicability of ODFs. With their potential for improved bioavailability, ease of administration, and high patient compliance, ODFs hold a promising future in the pharmaceutical landscape.

REFERENCES:

- 1. Rao, Y. M., & Jithan, A. V. (2016). Advances in drug delivery (Vol. III, 6th reprint, pp. 95-132). Pharmamed Press.
- 2. Badekar, R., Bodke, V., Tekade, B. W., & Phalak, S. D. (2024). An overview on oral thin films–Methodology, characterization and current approach. *International Journal of Pharmacy and Pharmaceutical Sciences*, 16(4), 1–10.
- 3. Kshirsagar, T., Jaiswal, N., Chavan, G., Zambre, K., Ramkrushna, S., & Deshmukh, D. (2021). Formulation & evaluation of fast dissolving oral film. *World Journal of Pharmaceutical Research*, 10(9), 503–561.
- **4.** Shetty, N., Kamath, K. K., Shripathy, D., & Shabaraya, A. R. (2024). Orodispersible films A review. *European Journal of Pharmaceutical and Medical Research*, 11(3).
- Salawi, A. (2022). An insight into preparatory methods and characterization of orodispersible film—A review. *Pharmaceuticals*, 15(844). https://doi.org/10.3390/ph15070844
- Dnyaneshwar, H. R., Wale, K. K., Sayyed, S. F., & Chaudhari, S. R. (2014). Orodispersible film dosage form: A review. World Journal of Pharmaceutical Research, 3(5), 1093–1111.

- 7. Tiwari, R. R., Umashankar, M. S., & Damodharan, N. (2018). Recent update on oral films: A bench to market potential. *International Journal of Applied Pharmaceutics*, 10(6), 27–33.
- 8. Himani, & Garg, R. (2018). Oral dissolving films: A review. Indo American Journal of Pharmaceutical Sciences, 5(10), 10315–10326.
- 9. Sevinç Özakar, R., & Özakar, E. (2021). Current overview of oral thin films. Turkish Journal of Pharmaceutical Sciences, 18(1), 111–121.
- 10. Raje, O., Khade, P., Bhosale, A., & Salunke, A. (2021). A review on fast dissolving oral films: Recent trend of drug delivery. *International Journal of Creative Research Thoughts*, 9(7), 336–350.
- 11. Sanap, D. P., Mhatre, U. S., & Sheth, R. R. (2022). Oral thin films: A multi-faceted drug delivery system. *International Journal of Pharmaceutical Sciences Review and Research*, 72(1), 90–99.
- 12. Hoffmann, E. M., Breitenbach, A., & Breitkreutz, J. (2011). Advances in orodispersible films for drug delivery. *Informa Healthcare*, 8(3), 299–316
- 13. Bhalse, P., Pagare, A., & Pawar, R. (2024). A review on mouth dissolving film. *International Journal of Pharmaceutical Sciences and Medicine*, 9(1), 82–93.
- 14. Kawale, K. A., Autade, N. B., Narhare, H. S., & Mhetrea, R. L. (2023). A review on fast-dissolving oral film. *Asian Journal of Pharmaceutical & Clinical Research*, 16(10), 7–17.
- 15. Mahboob, M. B. H., Riaz, T., Jamshaid, M., Bashir, I., & Zulfiqar, S. (2016). Oral films: A comprehensive review. *International Current Pharmaceutical Journal*, 5(12), 111–117.
- 16. Jaiswal, H. (2014). Oral strip technology: A review. Indian Journal of Pharmaceutical and Biological Research, 2(2), 130-143.
- 17. Patel, P., Prajapati, B. G., & Patel, D. (2023). Mouth dissolving film as a potential dosage form for paediatric usage. *Journal of Pharmaceutical and Biological Sciences*, 11(2), 133–141.
- **18.** Hemavathy, S., Sinha, P., Ubaidulla, U., & Rathnam, G. (2022). A detailed account on novel oral fast dissolving strips: Application and future prospects. *International Journal of Creative Research Thoughts*, *10*(4), 773–787.
- 19. Rodage, R. M., Sakhare, V. B., & Bhagat, B. V. (2023). A review on orodispersible film. World Journal of Pharmaceutical and Medical Research, 9(5), 115–120.
- 20. Karki, S., Kim, H., Na, S.-J., Shin, D., Jo, K., & Lee, J. (2016). Thin films as an emerging platform for drug delivery. *Asian Journal of Pharmaceutical Sciences*, 11, 559–574