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**RESEARCH ARTICLE**
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# ORALLY DISINTEGRATING FILMS: A NOVEL DRUG DELIVERY STRATEGY

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## Abstract
One of its most popular and usual techniques for administering drugs is still oral delivery. Traditional solid dose forms, such as pills and capsules, provide problems, particularly for elderly patients, children, and those who have trouble ingesting. Orally dissolving Film (ODFs) have become a unique and promising medication delivery method to get around these restrictions in recent years. ODFs are a great alternative for individuals whom struggle to consume traditional medications since they are flexible, thin, and quickly dissolving films that may be applied to the mouth or oral cavity with out the need of fluids. This review seeks to give an summary of oral dissolving films, containing information on their composition, production processes, and prospective medicinal uses.ODFs can be produced using methods including lyophilization process hot-melted extrusions, and cast in solvent, all of which are relatively straightforward procedures. These techniques guarantee accurate dosage and reproducible quality, solving significant issues with drug administration. It will also discuss the benefits and challenges of creating ODF, such as stiffness, scale-up production, and taste masking, as well as exactly how continuous technical advancements are addressing these problems. In conclusion but not the least, oral dissolving film are an innovative method of drug delivery which have an opportunity to revolutionise the pharmaceutical industry. Due to their ability to increase patient compliance and their ability to adapt in formulation and production, ODFs are positioned as a viable option for a variety of therapeutic applications.

## INTRODUCTION
Despite the significant developments in medication delivery technologies, capsules and tablets are still the most popular dosage forms (Samita Gauri, *et al*., 2012). However, they are now constrained by a variety of issues, such as elderly and children's concerns about swallowing and swelling (Subash Vijaya Kumar, *et al.*, 2010). The fast dissolving drug delivery system (FDDS) came into existence in late 1970 as an alternative to conventional pills, capsules, and syrups for old and young patients with dysphasia. Fast dissolving tablets are a type of solid dosage form that dissolve quickly and without liquid in the mouth (Arunachalam A, *et al*., 2010). Due to their fragility and brittleness, OFDF can occasionally be challenging to transport, store, and handle

because they are produced utilizing the pricy lyophilization process (V. Dinesh Kumar *et al.*, 2011). To address these issues, oral films, which have become very popular nowadays, were developed. The concept for oral films came from the confectionery industry (Alpesh R, *et al.*, 2010).The size of a postage stamp, oral films are a special type of ultrathin formulation combining excipients and active pharmaceutical components (Arun Arya *et al.,* 2010).
The effectiveness of API rises as it breaks down in the mouth. Oral films breakdown in a matter of a few seconds when coming into contact with saliva without the need for water (R.P. Dixit *et al.,* 2009).ODFs are helpful for elderly and children, as well as those who are having vomiting, bowel movements, allergies, cough fits, mental disorders, bedridden patients, etc. (Sheetal Malke *et al*. (2010). Oral films are also used to treat local effects, like local anesthesia for pain in the teeth, cold sores, and teething. Films can normally be stored for two to three years however they are particularly sensitive to moisture in the atmosphere (Malke M, *et al*., 2007).

**Fig-1:- Oral disintegrating film**

**Constraints of Oral Film:**
1. A high dose cannot be added.
2. Drug dosage should be minimal.
3. The oral bioavailability should be good.
4. The packing for oral films is pricey.

**Special Features of Oral Films:**
1. Extremely thin films.
2. Obtainable in a range of sizes and shapes.
3. Not a hindrance.
4. Quick release and dissolution.
5. Great mucoadhesion.

**General Advantages of ODFs:**
1. The oral cavity's vast surface area causes the oral dose form to dissolve and disintegrate quickly.
2. No chance of choking.
3. Because ODF are solid unit dose forms, they offer excellent accuracy and accurate dosing.
4. The bioavailability of the medicine is increased due to progastrin absorption, and fewer dosages are needed, which improves patient compliance.
5. Because ODFs do not require water to be swallowed, they are more well-tolerated by dysphagic patients (Kulkarni A S, *et al.*, 2011).
6. Give a s fragile satisfying mouthfeel.
7. Oral films can be handled and kept with ease because they are flexible and less than OFDFs.
8. Because it directly absorbs from the buccal mucosa and enters the systemic circulation, it avoids first pass metabolism, reducing the dose and adverse effects.

9. When placed on the tongue without water, fast-dissolving films dissolve instantly within seconds and release one or more API.
10. The dose form's stability is improved.

**Disadvantages of ODFs:**

1.It is not practical to use medications with bad tastes.
2.It is challenging to maintain dosage constancy.
3.Drugs that damage the oral mucosa cannot be administered by this method.
4.These ODFs cannot be given a higher dose.
5.Because of the hydrophilic nature and the need for specialized packaging, longer. preservation is problematic (Prabhu SC, *et al*., 2014).
6.It is not possible to deliver medications that are unstable at buccal pH.
7.Restrictions on consuming food and liquids for several hours following ODF consumption
8.Expensive methods are used in the production of these films as opposed to tablets that dissolve in the mouth.

**Ideal Characteristics of Drug For ODFs:**

1. Up to 40 mg of a modest dose should be used by the integrating API.
2. Drugs with a small molecular weight are desirable.
3. It must be able to penetrate the tissue of the oral mucosa.
4. The medication should taste well (R.P. Dixit, *et a*l., 2009).
5. It should be slightly united at the pH level of the oral cavity.
6. The medication should be sufficiently stable and soluble in both water and saliva.

**CHALLENGES IN FORMULATION DEVELOPMENT OF ODFs**

Technology improvements made it possible to obtain information on the pharmaceutical sector of oral film Products which at the time in 2007 had a market worth of around $500 million and projected to reach an estimated worth of 2 billion dollars in the next years. Since 2003, more than 80 distinct oral thin film medications are recently advertised in North America. Consumer demand was still quite low as compared to ODT. Marketing for over-the-counter drugs as well as films about nausea and vomiting can be found in the US market. Oral films are currently prescribed in the US, the European Union, and Japan. These approved films may be more effective than other accepted pharmacological dose forms.

The invention, production, and analysis on oral fast-dissolving or fast-disintegrating medications and films have resulted in a sizable body of literature. These concerns need to be addressed via more research on the subject in order to evaluate them and enhance the text as a whole. Patient adherence is significantly impacted by these problems. Therefore, whenever writing or marketing, they should come first. Below, we go into further detail regarding the difficulties in creating an oral visuals that dissolves quickly.


**Fig-2:- Challenges of ODFs.**

**Insolubility of Drug:**
In order to assert the appropriate amount of medication in the circulatory tract after oral administration, dissolution performs a critical role. Especially BCS type II medicines with poor solubility and elevated permeation, the difficulty of dissolution is a major barrier to composition into an oral film (Milko R, *et al*., 2017).

**Masking the Harsh and Unpleasant Taste of a Medicine**
To promote patient adherence for bitterness drugs utilized in fast-dissolving orally films, taste hiding appears to be necessary, especially in young and elderly patients. Odour is a key consideration in the case of an oral films that degrades quickly. Oral film must stay in touch with the inside of the mouth until fluid in the mouth totally destroys it. The bitterness of the unpleasant medications must be concealed for this. As a result, bitterness medicines employed in ODFs now require flavor concealment (Limbachiya M, *et al.*, 2012).

**Shortening the Film's Drying Time:**
The drying time of oral films is important for both their composition and the speed at which they undergo manufacturing in factories. Typically, steam ovens cannot be used to dry oral film of thermolabile medications. Oral film dries in this way at room temperature. However, drying takes more time—about a day.

**Dose Introduction in the Film:**
The amount of medication in an oral film preparation can be enhanced by expanding the container's surface area. To increase the volume of solution required for formulation, just the area should be raised while maintaining the thickness of the formulation solution. This will help to incorporate a high dose and shorten drying time (Yuvraj G, *et al*., 2013).

**Co-administration of Drugs:**
Making oral films while taking numerous medications is exceedingly difficult. This is known as co-management of pharmaceuticals. As a result, it might affect how quickly and how long the formulation dissolves (Yuvraj G, *et al*., 2013).

**Film Stability in Relation to Humidity and Temperature:**
A water-soluble polymer composition of around 45 percent causes up an oral films that dissolve quickly. In humid environments, film absorbs liquid and dissolve as an indication of the film's dissolution in water. Therefore, maintaining the homogeneity of the coating over moisture is a very difficult challenge (Gaisford S, *et al.*, 2009).

**Need of Special Packaging:**
In pharmaceuticals, it is crucial that the packaging properly preserves the drug's quality. Fast-dissolving films come in a range of packing configurations. The most popular type of packing is an aluminum pouch. The Fast Card is a patentable packing solution created by APR-Labtech for the Fast Films. Three quick films can be stored on both sides of the fast cards, which is exactly the same shape as credit cards. It is possible to consume each dose on its own. ( Gaisford S, et al., 2009)

**Dose Uniformity:** Film that must be produced in a container that must be cut into the desired region that contains the necessary dosage of medication. Therefore, it is a difficult task to achieve a homogeneous dosing for every films that cut into the appropriate Size.

## FORMULATION CONSIDERATION:

Most of the additives used in the development and use of oral films are deemed acceptable from the standpoint of regulation and need to be allowed for use in pharmaceutical oral dosage forms. 1985; Peppa's NA and others. Oral micro films can be as thin as 1 cm2 or as thick as twenty cm two (based on dosage and medication concentration). A list of the different compounds utilized in table 1.

**Table 1: Generalized Details of Different Ingredients of Oral Film**

| S. No | Ingredients | Concentration |
|---|---|---|
| 1. | Drug (API) | 1 -20% |
| 2. | Film forming polymer | 40-50% |
| 3. | Plasticizer | 0-20% |
| 4. | Saliva stimulating Agents | 2-6% |
| 5. | Sweetening agents | 3-6% |
| 6. | Flavouring agents | 1-10% |
| 7. | Colouring agents | 1% |

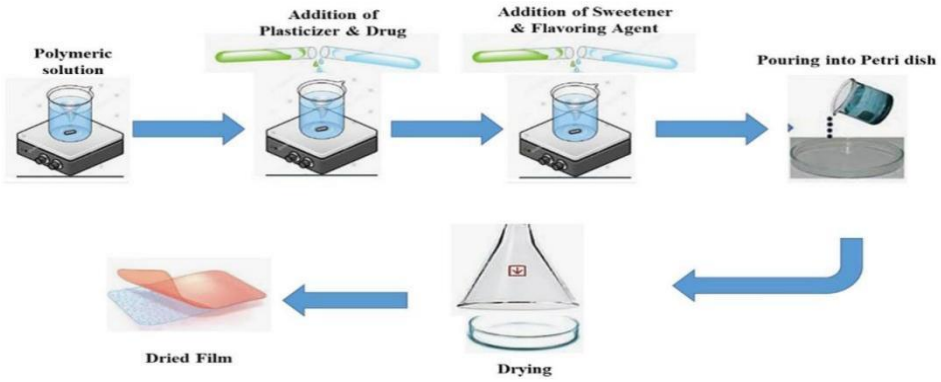


**Fig-3: - Formulation of ODFs**

## Drug (Pharmaceutical Active Ingredient):

Many different forms of API may be efficiently included using the oral strips method. Micronized APIs can enhance the appearance, uniformity and disintegration of these films. Multiple molecules could make up the distribution mechanism.2009, R.P. Dixit and others. Cyclodextrins or resins, which prevent API from interacting with saliva, may be used to mask the disagreeable smell of medications. Additionally, it addresses central nervous system (anti-Parkinson's ailment) medications, anxiety pills, CVS drugs, sore throat, GI problems, nausea, and painkillers.

## Polymers:

According to Dinesh Kumar et al. (2011), hydrophilic polymers are used in preparations to help them dissolve fast in the oral cavity and deliver the medicine to the system of circulation when they come into contact with saliva in the buccal cavity. Polymer substance can be used alone or in combination to produce the required film properties. The formulation's choice and amount of polymer has an impact on how durable the film is. (Kulkarni A. S., et al., 2010). Both synthetic and natural polymers are being used in the oral cavity. Natural polymers are effective, risk-free, and have no adverse side effects. As a result, natural polymers are preferred.

**Table2: Most commonly used natural and synthetic Polymers in ODFs.**

| Types of polymers | Examples |
|---|---|
| **Natural** | Pullulan, gelatin, polymerized rosin, sodium alginate pectin, starch, and sodium alginate pectin. |
| **Synthetic** | Polyvinyl alcohol, hydroxypropyl methyl cellulose, sodium carboxymethyl cellulose, polyvinyl pyrrolidone and hydroxy propyl cellulose. |

**Plasticizer:**
Combining plasticizers is a common practice to change the mechanical characteristics of materials, such as their rate of extension and shear strength. Plasticizers frequently increase an object's weight by 0% to 20%. Triethyl citrate & (PEG) Di phthalate are two compounds that can be used as plasticizing reagents. Make sure the plasticizer you choose for an ODF formulations is suitable with the polymers and solvents that will be used.

**Surfactants:**
Because it is important for films to break down and quickly disperse the drug they contain, surfactants must function as a spreading, soaking time, and disintegrating the substance. Sodium lauryl Sulphur the tween and benzalkonium chlorides are two of particularly used surfactants. Poloxamer 407 has a lot of advantages, which is why it's widely used (Siddiqui, *et a*l., 2011).

**Sweetening:**
The oral drugs are given in combination with sweets conceal the taste of the API. For the pediatrics grouping, where the inclusion of sweetness is particularly favorable, such a tasty aroma in the mixture is especially crucial. Oral disintegrating compositions can taste better when both synthetic and natural sweeteners are included. In preference to artificial sweeteners, natural sugars are used. Sucrose, dextrose, fructose, glucose, fluid sugar, & isomaltose constitute all organic sweeteners that belong to the family of saccharides. All synthetic sweeteners are, especially saccharine, cyclamate, an aspartame acesulfame K, neotame, and alitame (Ghodake P, *et al.*, 2013). Serve a vital purpose as a distributing, soaking, and solubilizing agent, enabling film to disintegrate quickly to disperse the contents they contain.

**Table 3: Examples of some commonly used sweetening agents in ODFs.**

| Sweetening agents | Examples |
|---|---|
| **Natural** | Glucose, fructose, dextrose, sucrose and isomaltose |
| **Synthetic** | Acesulfame-k, sucralose and neotame |

**Saliva Stimulating Agent:** Mixtures with compounds that increase salivation could be used to create substances that dissolve quickly. Maleic acids acid tartar, lactic acids, and vitamin C are some of the compounds that are widely used (Irfan M, *et al*., 2016).

**Flavoring Agent :**
Flavors are essential to mask the noxious or revolting taste of the newly introduced medicine. Any flavor that is US-FDA authorized and contains mint, sour, and pleasant flavors is appropriate (Bala R, *et al*., 2013). Using electronic tongues, the efficacy of different flavor masking agents is tested. According to a study, mixing the flavors of licorice, mint, and sucralose could provide a good approach to hide the unpleasant flavor of diclofenac sodium

**Coloring Agents:**
Color is produced by pigments. The most common use for titanium dioxide as a colorant is in ODFs and various medicinal products. There are many colors that can be used with titanium

dioxide, including FD and C, organic colors, and custom hues that are pantone-matched (Hulle N, et al., 2021).

## USUAL METHOD FOR FABRICATION OF ODFS:

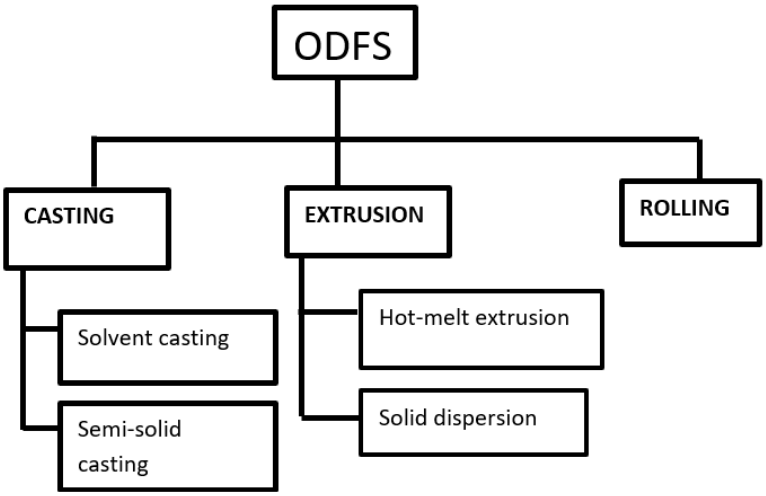


**Fig-4:- Conventional approaches for manufacturing ODFs.**

### Casting & Drying Method:

### Solvent Casting Method:

Casting was a quick and low-cost method of producing oral videos. Through this process, the ingredients and the film-forming polymers are blended uniformly in an appropriate solvent, such as fluid or ethanol as well. After carefully casting, the product is dried on culture plates or a dish made of Teflon, a transparent material, or other appropriate material. A roller-equipped piece of special machinery used in huge-scale manufacturing is used to apply the slurry to an inert foundation. Using a hoover, you can expel compressed air. In the final phase, air is forced into the films, and any remaining solvent is wiped away to produce the completed product. Prior to completing cutting it, stripping, and packaging, the films must cure ( R. Bala and co, *et al*., 2013).

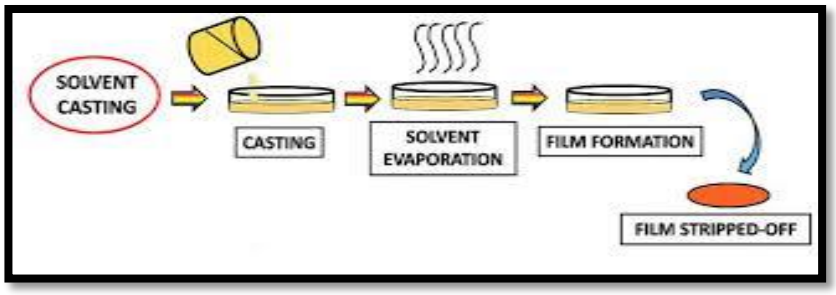


**Fig-5:- Description of solvent casting technique.**

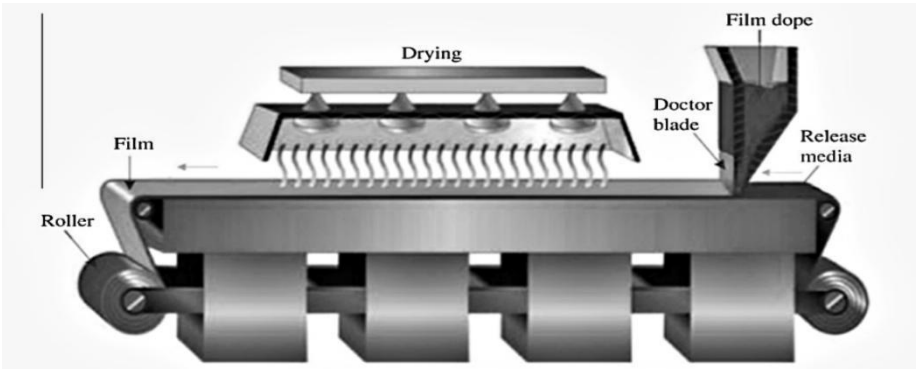


**Fig-6:- Solvent casting technique**

**Advantages**:
1. The solvent casting film developing technique is a tried-and-true approach.
2. A relative standard deviation (RSD) of 1.2% is imparted by an oral thin film.
3. This solvent casting approach is simple to use with heat-sensitive APIs (Yir-Erong B, *et al*., 2019).
4. Casting has excellent width and weight consistency, is inexpensive to produce, and is simple to assemble and operate.

**Disadvantages**:
1. Several nations have implemented legislation governing the intake of organic solvents because casting films may contain residues of a solvent, which are usually organic in nature and can be harmful to humans and the environment.
2. The scope of industrial production may be impacted by the large expenditure necessary to maximize manufacturing processes such as mixture rates, drying times, and film thickness.

**Semi-Solid Casting Method:**
The Solution is a combination of hydrophilic polymers that are inert to acids (Thakur et al., 2012). The proper quantity of plasticizer is then added to produce a semisolid material. The gel composition is then formed into film or ribbons using a drum with a thermostat. Film is produced using polymer materials that are impermeable to acid.

**Extrusion:**
**Hot Melt Extrusion:**
The medication, polymers, around excipient combination is blown out at a high temperature utilizing a method described as hot-melted extrusion procedures that yields a homogenous mass that is then shaped to make smooth films. Due to the high processing temperatures used in the thermolabile chemical procedure, this solvent-free method has a number of drawbacks (Fig. 7; Thakur, *et al*., 2012).

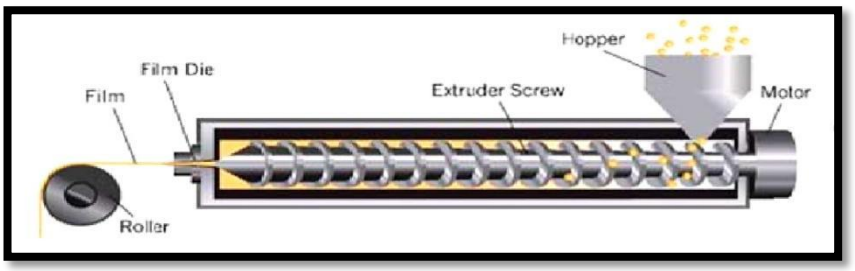


**Fig-7:- Film extrusion technique**

**Advantages:**
1. In comparison to traditional production methods, HME offers a variety of benefits to produce solid dosages suitable for the consumption orally.
2. Production of films and other formulations takes less time because there are fewer manufacturing processes.
3. Because organic solvents aren't used, it has also been demonstrated to be environmentally safe.

**Disadvantages**:
1. The main disadvantage of HME is the harmful effects of severe heat (thermal degradation) on APIs and other elements, specifically those that are thermolabile.
2. Since polymers rheology is crucial to the HME creation of films, the range of polymers that can be managed easily is constrained.
3. To avoid melting and evaporation during manufacturing, which would damage the uniformity,

texture, and strength of the finished film product, all HME constituents must be free of any liquids or other solvents.

**Solid Dispersion Extrusion:**
The dispersion of solids of hydrophilic vehicles has increased the rate of absorption and breakdown of hydrophobic drugs (Nikghabl L, *et al*., 2012). A suitable dispersion can be used to make solid particles without discarding its liquid solvent. One or more APIs must first be spread in a suitable solvent for a mixture with a solid extrusion approach before being added to polyols such as molten PEG (Agrawal AM, *et al*., 2013). Immiscible components are taken in this process, and they are then extruded with pharmaceuticals. The obtained solidified material distribution is then molded using dies into films.

**Rolling Method:**
The first step in this method is the creation of a topical solution or suspension that specifically addresses rheological issues (Panda, *et al.*, 2012). The majority of utilized solvents are fluid or a mixture of water and ethanol. The drug-containing liquid or solution is placed inside the folded-up carrier. Prior to being divided to size, films are dried on the rollers.

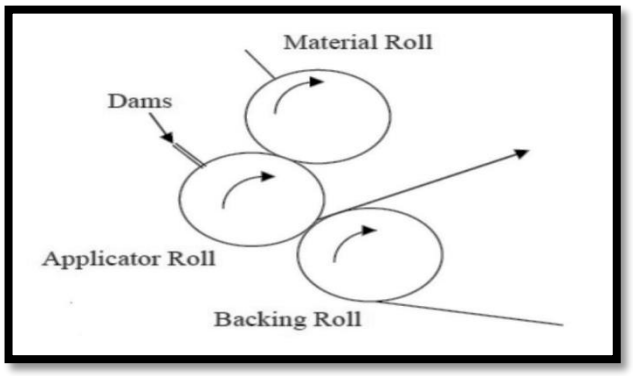


**Fig-8:- Plot of rolling**

**Spray Technique:**
A appropriate solvent is used to dissolve the drug ingredient, polymers, as well as other excipients to create a transparent solution. Then, this transparent solution is sprayed onto a suitable surface like Teflon sheet or glass polyethylene film from non-siliconized Kraft paper (panda, *et al*., 2012).

**TECHNOLOGIES FOR FDFs:**
These are 4 Patented technology they are :

**Wafer Tab:**
The therapeutic component, polymers, along with other excipients are disintegrating in an appropriate solvent to produce a solution that is clear. Following this, this clear solution is applied using a spray onto an appropriate surface, such as Teflon sheets or the glass polyethylene film made from Kraft paper that hasn't been siliconized (panda, *et al.*, 2012).

**XGEL:**
The XGel technology for films produced by Bio Progress transformed the product line and the manufacturing procedures. It is suitable for vegetarians, is accepted by religion, and is not made from animal products. This video might be colored, layers, taste-masked, have enteric properties, and integrate active pharmaceutical components. The XGELTM film procedures, which are dissolve both in cold and hot water, can include any form of oral administration (Ghosh.T, *et al.*, 2010).

**Foam Burst:**
By blowing air in the film as it has been created, this technique produces a film that has a honeycombed structure after it is finished. The spaces in the film may be occupied by gases, left empty, or filled with other materials to cause specific taste-burst properties or to convey active drugs. The delicate honeycomb structure of the capsules causes them to dissolve fast and give a melt-in-your-mouth sensation. The use of this technology to transport and release flavors is appealing to food and candy manufacturers (Siddiqui MD*, et al*., 2011).

**Soluleaves:**
Using this technique, a variety of films for oral delivery can be produced, including ones with scents, colors, and active ingredients. By using this technique, a film is produced that, when in touch with saliva, discharges its chemical constituents(Godake PP and colleagues, *et al.,* 2013), they are designed to adhere to mucosal membrane and release the medication gradually over the period of 15 minutes.

**CHARACTERIZATION AND EVALUATION:**
Characterization of films is accomplished via following tests:

**Organoleptic Evaluation:**
Specialized, controlled individual taste elements are used for this. This in-person tasting experiment involves individuals. ODFs are taste-tested in vitro using taste sensors as screening tools. In vitro approaches and technologies are adequate for high-throughput taste detection of such dosage formulations. The natural sweetness and taste-masking potency of taste-masking drugs are assessed using both in vivo and in vitro methods.

**Mechanical Properties:**

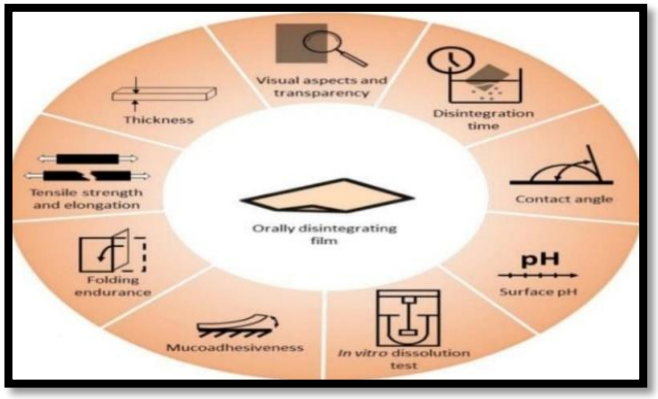


**Fig-9:- Mechanical properties.**

**Thickness Test:**
The width of a film can be determined utilizing a standardized digital micrometer, and its mean average is then calculated. The average of the three tests from each sample is typically calculated. The variation in weight of a film is calculated in triplicate by slicing it and weighing each piece separately. Because thickness consistency and the film's doses uniformity have a correlation, it is vital to confirm thickness uniformity.

**Dryness Test / Tack Test:**
This test measures a film's ability stay to a piece of paper sandwiched between two strips, according to Chaudhary et al. (2013). The word "tack" refers to how well two films adhere to one another when they are sandwiched between two distinct materials, such as papers. The process of drying for films goes through around eight stages: curing-to-touch, evaporates-to-recoat, dry challenging, set-to-touch, without dust, evaporates-through, tack-free, and dry print-free. These tests can be used to determine the degree of dehydration in both oral films and paint industry films.

With the use of recently developed technologies, assessment for the dehydration or tack is also possible (Bhyan, *et al*., 2011).

**Tensile Strength:**
A film's tensile strength is the highest stress at which it will snap. This test essentially evaluates the mechanical toughness of films. By multiplying the force exerted at breakage by the required strip's cross-sectional area, it can be calculated. In the equation below:

**Tensile strength ¼ ðload at failure=strip thickness- Strip widthÞ – 100**
**Percent Elongation:**
When strain, also known as stress, is applied to a film, it stretches. The strain is defined as the film's dimension divided by the film unit's initial/original dimension. A quantitative relationship exists between % elongation & the volume of a plasticizer utilized in the film composition. When the film contains more plasticizer, the strip frequently extends further. It is determined by the following formula:

**Percentage elongation ¼ ð change in length=initial length Þ- f**
**Folding Endurance:** Folding endurance is another manner to assess a film's mechanical attributes. It is discovered by folding a film repeatedly till it splits. The amount of the film's folded durability shows how many folds it can withstand without breaking. The tensile strength of the film is shown by a rise in folded durability value. Mechanically durability & films folding strength are closely connected. It is plainly obvious that the amount of plasticizer also indirectly affects the significance of folding endurance considering that the quantity of plasticizers impacts mechanical strength.

**Swelling Property:**
Simulated saliva is used to assess the swollen film investigations. After figuring out the starting weight of the film, a kind of stainless mesh of wire that was already pre-weighed is employed. The mesh bearing the film is then placed in a solution made to look like saliva. The mass of the film keeps on increasing at regular, planned intervals unless it has no longer a rise in weight. The following variables impact the swelling's intensity: 14 of the final weight in weight is the swelling intensity. Initial weight Wt equals the mass of the film at period 0; initial weight W0 equals the mass of the films at period t.

**Transparency:**
Transparency of a strip is assessed using a UV spectrophotometer. This test measures how aesthetically pleasing the formulation is. Film samples are cut out in the shape of rectangles and placed into a photometer cell. The film's transmittance at a wavelength near 600 nm is calculated. The formula for determining transparency is as follows:

**Transparency ¼ ðlog T600Þ=b ¼ €c**
T600 = transmittance at 600 nm,
b = film thickness (mm), And c = concentration.

**Content Uniformity:**
To ascertain the composition of a film, a standard assay process that is established for each unique medication in distinct pharmacopoeia is used. In this test, 20 samples are examined using analytical techniques. The examination's acceptable level is less than 15%, based on the Japanese Pharmacopoeia. As stated in USP27 (Chaudhary, *et al.,* 2013), the information contained within should range from 85% and 115%, with an acceptable deviation slightly more than or equal to 6%. Content uniformity is created to measure drug concentrations in specific films (Bhyan et al., 2011).

**Disintegration time:**
Utilizing dissolution apparatus that is listed in reputable pharmacopoeias, the duration of time it takes for a film to dissolve is computed. Depending on the formulation, the disintegration time frequently fluctuates and normally ranges from 5 to 30 seconds. The USP disintegrating equipment is commonly used for this test. There are no recognized guidelines for measuring the disintegration period of films that disintegrate quickly when taken orally (Bhyan, *et al.*, 2011). The timing of breakdown of the film can be determined in one of two ways:

**a. Slide frame method:** The slide frame is set on a culture plate with just a tiny bit of purified water applied to the film. It is stated how long the film will dissolve.

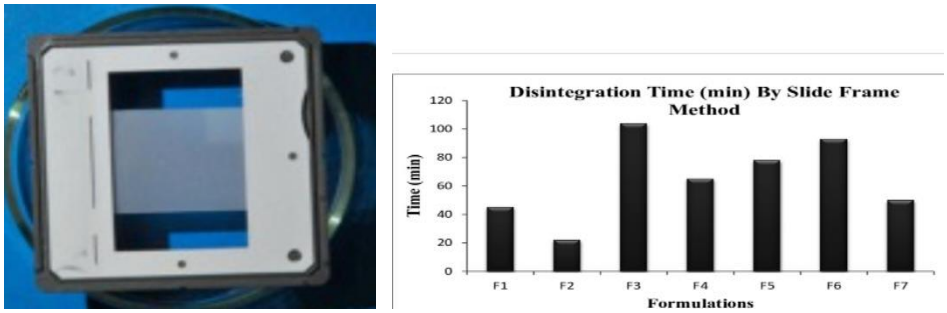


**Fig-10:- Slide frame method**

**b. Petri dish method:** A film is placed over a petri plate that contains 2 ml of the filtrated water (Patel, *et al*., 2014), the period of dissolution is the duration period of time necessary for the film to completely dissolve.

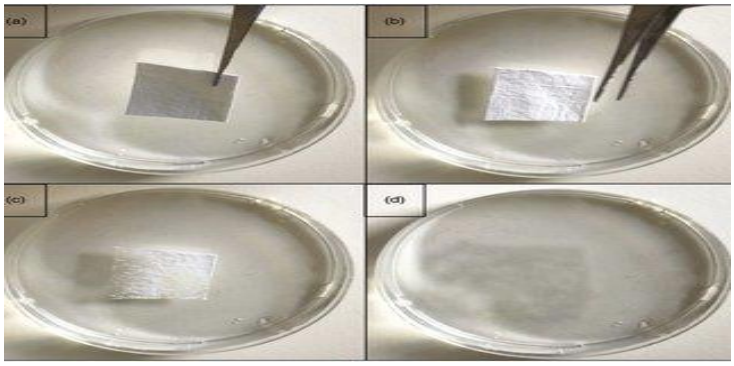

**Fig-11:- Petri dish method**

***In-vitro* Dissolution Test:** Studies on film dissolving are carried out with a basket or paddle that has been given the seal of approval. Sink conditions should be kept throughout dissolution. It can be difficult to perform the test accurately when film periodically floats over the medium. This problem is more likely The basket equipment is often preferred because the paddle technique is an option. The media consist of a phosphate buffer with a pH of 6.8 (300 ml) and 0.1 N a hydrogen chloride (900 ml). The temperature remains constant. In most cases, it is set to spin at 50 rpm and 37 0.5 °C. Samples of the medication are taken periodically, and they are analyzed with a UV spectrophotometer. Despite their widespread use, dissolution tests are nevertheless prone to significant inaccuracy and testing disappointment.

**Visual Inspection and Surface Morphology:**
color homogeneity, and transparency in a manufactured Oro dispersible film may all be assessed physically (Raju et al., 2011). It is possible to investigate the physical characteristics of surface using an electron scanning microscope. The outside is homogeneous and free of pores. Shows high-caliber movies.

**Surface pH:**
The produced film is frequently put in a culture dish and then kept moist in order to measure the pH value. Rubbing the film surface with fresh water and a pH monitor electrodes to measure the pH. A basic or acidic pH could damage the oral mucosa, hence measuring its surface pH is crucial (Patel et al., 2009).

**Moisture Uptake and Moisture Loss:**
The figure that determines a film's hygroscopicity is the amount of humidity lost. The standard approach is to first determine the film's after-Ward initial weights while putting it in a dehydrator for three days to determine this variable. Calcium carbonate is found in desiccators. The strips are removed after three days, and weight is measured again. The equation below is used to determine the loss of moisture (Yellanki et al., 2011). original mass1/4 final weight = 100 lesser than the initial weight % of moist loss by first slicing a bit of films with a dimension of 2 2 cm2, it is able to determine how much moisture the film absorbs. The strips of film are then maintained at ambient temperatures with an approximate moisture of 75% for 7 days. (Gorle, *et al*., 2009) moisture uptake is calculated as a percentage gain in weight of the strips.

**Percentage moisture loss ¼ initial weight final weight=initial weight- 100**


**Fig-13: - Mechanical properties**

**PACKAGING OF ODFs:**
In the pharmaceutical industry, it is essential that the chosen packaging offers sufficient safeguards to the quality of the medicine. Others readily disintegrating forms of dosage demand special processing, pricey packing, and extra care during production and storage (Brown D, *et al*., 2003).A few of the demands that need particular consideration are the requirement for tiny dose packing, barcodes packaging, the details of directions to use, child-resistant wrapping, & senior-friendly product.

**The Material selected must have the following Characteristics:**
1. They must have received FDA approval. They have to protect the process from the weather.
2. They must follow the pertinent tamper-resistant criterion.
3. They cannot interact negatively with the material used to create films.
4. They can't give the product any smells or odours.
5. They must not be toxic.

**Fig-14: - Packaging of ODFS.**

**Table-4: Comparison between fast-dissolving tablets and films**

| S.NO | CRITERIA | FAST DISSOLVING TABLETS | FAST DISSOLVING FILMS |
|---|---|---|---|
| 1. | FORM | It is a tablet. | It is a film. |
| 2. | THICKNESS | Thickness 0.015-0.5 inches. | Same size as of conventional tablet. |
| 3. | DISSOLUTION | Less dissolution due to less surface area. | Greater dissolution due to larger surface area. |
| 4. | DURABILITY | Less durable as compared with oral films. | Better durable than oral disintegrating tablets. |
| 5. | PATIENT COMPILANCES | Less patient compliances than films. | More patient compliance. |
| 6. | DOSE SIZE | Large dose can be incorporated. | Small dose can only be incorporated. |
| 7. | CHOCKING | Fear of chocking is present. | No risk of chocking. |

## APPLICATIONS OF ORAL DISINTEGRATING FILMS:

**Oral Mucosal Delivery:** Oral mucosal distribution via sublingual, buccal, and oral pathways with the help of oral thin films could end up being the most common delivery technique for medications that need quick the absorption of drugs like those utilized for treating pain, allergic reactions, insomnia, and issues with the central nervous system (N. Hulle and associates. *et al*.,(2002).

**Gastrorententive Delivery System:** Water-soluble films are being investigated for dosage forms that incorporate compounds having a range of weights of molecules that are soluble in water but insufficiently disintegrate in a film format. The digestive tracts pH or enzymatic secretion may cause the films to dissolve, which could be employed to treat digestive disorders (Ghodake P, *et al*., 2013).

**Diagnostic Devices:** Dissolvable films is filled with hypersensitive compounds to provide regulated discharges when coming into contact with biological solutions or used to construct separating barriers for separating distinct components to allow a specified response within a testing instrument( GodakeP, *et al*.,(2013)

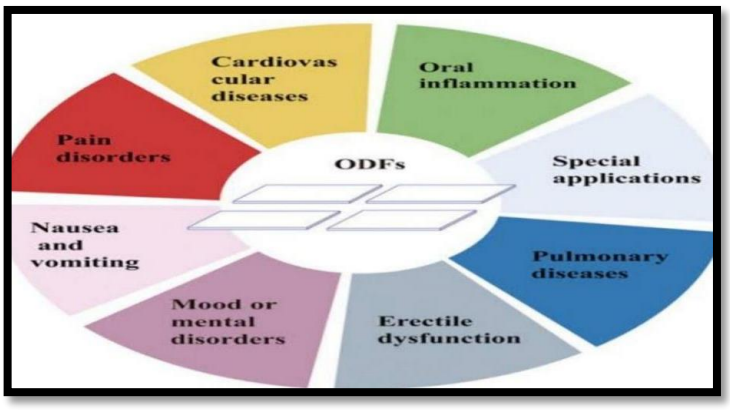


**Figure : 15.Therapeutic applications**

## CONCLUSION:

Simply said, oral dissolution films are now widely used and valuable on the international market due to the requirement to effectively mask flavor. The current investigation shows that one of the distinctive features in the pharmaceutical sector is the usage of sublingual rapidly- disintegrating films. These have greater compliance among patients, are safer and more effective than normal dose forms, and are more unlikely to lead to choking. Additionally, patients tolerate and accept them better. ODFs were created in part to address the problem of difficulty swallowing, which makes it difficult for patients to swallow conventional oral dose forms in the pediatric, elderly, and medical fields. ODFs are currently widely accessible, proving their usefulness. These drugs are used to treat ailments like high blood pressure, seasonal allergies, discomfort, and pH. Bypassing hepatic metabolism and satisfying the target population's desire for convenience in drug administration, the management of such a form of dosage without the requirement for water enhances therapeutic response.

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