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Oral Fast Dissolving Films: A Detailed Review

AkshayK. Jadhav[1], Dr. PratimaS. Shinde [2], Tejaswini A. Ahire[3], SiddhiD. Abhang[4]

[1]*Department of Pharmaceutics, Siddhant College of Pharmacy, Sudumbre, Pune Affiliated Savitribai Phule Pune University, Maharashtra, India.*
[2]*Department of Pharmaceutics, Siddhant College of Pharmacy, Sudumbre, Pune, Affiliated Savitribai Phule Pune University, Maharashtra, India.*
[3]*Department of Pharmaceutics, Siddhant College of Pharmacy, Sudumbre, Pune, Affiliated Savitribai Phule Pune University, Maharashtra, India.*
[4]*Department of Pharmaceutics, Siddhant College of Pharmacy, Sudumbre, Pune, Affiliated Savitribai Phule Pune University, Maharashtra, India.*

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ABSTRACT
By virtue of its quick breakdown and ability to be administered without the use of water or chewing, oral fast dissolving film (OFDF) is one such unique strategy to boost consumer acceptance. The intraoral fast-dissolving drug delivery technique using the film is perfect. There are a lot of medications that designed as mouth-dispersing films, such as erectile dysfunction medications, analgesics, antihistamines, cardiovascular medicines, and analgesics. There are numerous methods for making oral films in the buccal cavity. One of the parts of the mouth is the buccal cavity, which has a mucosal layer that quickly distributes and absorbs the body. The preparation techniques for oral films, the choice of polymer for formulation, technologies, assessment criteria, and finally applications are all covered in this review.
Keywords: Fast dissolving drug delivery system, Composition of Film, Manufacturing method, Recent advancement

I. INTRODUCTION:

A new kind of drug delivery technology called quick dissolving/disintegrating film is used for oral medication administration.

Drugs that combine the benefits of standard tablet and liquid formulations and were developed in the late 1970s as an alternative to tablets, capsules, syrups, and other formulations for pediatric and geriatric patients who have trouble swallowing typical solid dose forms.

FDDS is simple to use and improves patient compliance in individuals who are elderly, young, intellectually challenged, queasy, and recalcitrant.

This administration technology uses solid dosage forms that dissolve in the mouth in a matter of seconds without the need for liquid.

Liquid formulations are often preferred by younger children since they are easier for them to ingest [1,]. Recent advances in oral delivery techniques have improved patient compliance while addressing the physicochemical and pharmacokinetic characteristics of drugs. Manufacturing tablets with computer-aided three-dimensional printing (3DP) and electrostatic drug deposition and coating are recent innovations. Fast-dissolving drug delivery techniques were consequently created in the late 1970s as an alternative to tablets, capsules, and syrups for young children and elderly patients who have difficulty ingesting traditional oral solid-dosage.[2]

Oral fast dissolving films have recently been developed as a result of research and development in the oral drug delivery segment. Previously, dosage forms included simple conventional tablets or capsules, modified release tablets or capsules, oral disintegrating tablets (ODTs), wafers, and more recently, simple conventional tablets or capsules (OFDFs).ge forms.[3]

Fast dissolving drug delivery system

For pediatric and elderly patients who have trouble swallowing traditional solid dose forms, fast dissolving drug delivery systems—also known as quick dissolving/disintegrating film—were developed in the late 1970s as an alternative to tablets, capsules, syrups, and other formulations.

The elderly, children, mentally retarded, nauseous, and uncooperative patients respond better to FDDS because it is simple to administer

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and improves patient compliance. This delivery technology uses solid dose forms that dissolve in the oral cavity in a couple of seconds without the use of water. A very thin oral strip serving as the delivery mechanism is simply placed on the patient's tongue or any other oral mucosal tissue, where it is immediately moistened by saliva. On the application location, the film hydrates quickly. The drug is subsequently quickly released and disintegrates, allowing for oro-mucosal absorption. Because of its portability, convenience of distribution, and precise dose, fast dissolving oral thin films are well-liked by both patients and careers. [4,5]

Anatomy of oral cavity

Anatomy of the mouth in order to comprehend the environment that is supplied for delivery, the structure and anatomy of the mouth cavity are researched drugs. The oral mucosa prevents first pass metabolism and permits direct medication entry into the systemic circulation. The epithelium of the oral cavity resembles the skin relatively closely, with a few minor exceptions in terms of keratinization and the protective and lubricating mucus that coats its surface. Oral mucosa is 4–1000 times more permeable than skin, on average.

The hard and soft palates, the floor of the mouth, and the tonsils make up the outer region of the oral cavity, which is split into two sections by the lips, cheeks, and oral vestibule. For decades, oral medication administration has been acknowledged as the most. [6]

By virtue of its quick breakdown and ability to be administered without the use of water or chewing, oral fast dissolving film (OFDF) is one such unique strategy to boost consumer acceptance. The film is a perfect intraoral fast-dissolving drug delivery method because it meets unmet needs in the market, is simple and convenient to handle and administer, lessens bad taste, and is easy to handle and administerand is simple to create. The tongue's top or bottom is where the film is placed. It quickly releases the active ingredient for local and/or systemic absorption while being maintained at the application location. The creation of a fast-dissolving film offers the chance to expand the line of medications available on the market,including neuroleptics, cardiovascular medications, analgesics, antihistamines, and antiasthmatics.[7]

Advantages of oral fast dissolving films

- Oral dissolving films can be used anytime, anywhere, and without water.
- Films offer quick dissolving and disintegrating in the oral cavity due to the larger surface area.
- The flexibility and portability of oral dissolving films make them convenient for storage, handling by consumers, and transportation.
- Suitability for elderly and young patients, those who have trouble swallowing, those who are mentally ill, those who are developmentally disabled, and those who are uncooperative, on limited liquid intake regimens, or who feel queasy.
- Used when an ultra-rapid commencement of action is needed, such as in cases of motion sickness, severe discomfort, allergic reactions, or coughing.
- Longer-lasting stability because the medicine stays in solid dose form until it is taken. It thereby combines the stability of a solid dose form with the bioavailability of a liquid dosage form.
- Drugs can be absorbed immediately and can enter the systemic circulation without first passing through first-pass hepatic metabolism because the oral or buccal mucosa is highly vascularized.
- This benefit can be used to create products that have better oral bioavailability of compounds that experience the first pass effect. The sublingual and buccal distribution of a medicine via thin film has the potential to improve the onset of action, lower the dose, and enhance the efficacy and safety profile of the medication.[8]

Disadvantages

- High doses cannot be incorporated.
- Dose uniformity is a technical challenge

Active pharmaceutical ingredient

❖ A typical film composition contains 1-25% of the drug by weight. Many APIs can be delivered by quickly disintegrating films. Small dose chemicals are the best choices for including in OFDFs. Multivitamins were added to films with a dissolving time of < 60 seconds up to 10% by weight of the dry film. Generally speaking, micronized API is advantageous since it will improve the texture of the film and improve dissolution and uniformity in the OFDFs. There is a bad aftertaste to many APIs that may be used with OFDF technology.

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❖ **Film forming polymer**

The final film utilized must unavoidably be water soluble because the principal function of all thin film oral dosage forms depends on their dissolution in the saliva of the oral cavity. A water-soluble thin film formulation requires excipients or polymers that are water soluble, have a low molecular weight, and have excellent film forming capabilities. The polymer used should not be poisonous, irritating, or contain any leachable contaminants.It should have good spreading and wetting properties.The polymer needs to have strong enough peel, shear, and tensile properties.The polymer should be easily accessible and reasonably priced. The literature suggests a wide variety of polymers for oral films, and different research teams have developed distinct materials. To enhance the hydrophilicity, flexibility, mouthfeel, and solubility properties of fast dissolving films, the polymers can be utilized singly or in combination.The kind of polymer used and how much is used in the formulation determine the stiffness of the strip. Due to the brittle nature of polyvinyl pyrrolidone films, copovidone is combined with the material to create flexible, quickly disintegrating films.

1. Hydroxypropyl Methylcellulose

The film-forming abilities and high acceptance of hydroxypropyl methylcellulose (HPMC) are well recognized.Because of their low viscosity, lower grades of HPMC like Methocel E3, E5, and E15 are frequently utilized for ODFs.HPMC grades were found to have Tg values of 160, 170, and 175 °C, respectively. The HPMC E series maximum pierce strength grew from E3 to E5 to E15 to E50 as the polymer's molecular weight increased.The various grades of HPMC had a significant impact on the in vitro disintegration time and in vitro dissolution profiles of the ODF, and it was determined that HPMC E3 LV was the best grade for the production of ODFs.[9]

2. Poly (Ethylene Oxide)

A nonionic, highly molecular-weighted, water-soluble polymer is called poly (ethylene oxide). Poly (ethylene oxide) (PEO) is a thermoplastic semicrystalline polymer with a glass transition temperature of -67 °C and a melting point that ranges from 60 °C to 75 °C. PEO films were discovered to be elastic with a low elastic modulus and an incredibly high % elongation due to their negative glass transition temperature (-67 °C) and chemical makeup.

It is offered for sale under the trade name POLYOX. Polyox N-80 is a polyox polymer that might be employed in the oral film. A 5% aqueous solution at 25 °C, Polyox N-80 has an estimated molecular weight of 200,000 and a viscosity of 65 to 115 mPa/s. Comparable to the commercially available Listerine films, Polyox N-80 has an in vivo disintegration time of 4 seconds and an in vivo dissolving time of 23 seconds.[10]

3. Hydroxypropyl Cellulose

Thermoplastic non-ionic cellulose (HPC) polymer is water soluble. It is cellulose poly (hydroxypropyl) ether that has been partly replaced. It is an amorphous polymer that softens depending on molecular weight between 100 and 150 degrees Celsius. Commercially accessible HPC comes in a variety of grades with various solution viscosities. As films made from polymers with very high glass transition temperatures are known to be rigid, cellulose (Tg = 500) is not a good choice for a film-forming polymer. Thus, it is suggested to use its synthetic counterparts, such as HPC and HPMC, which have Tg values that are comparably lower.[11]

4. Pullulan

Pullulan is a neutral, linear polysaccharide made up of 1,6-linked maltotriose residues that is water soluble. It is a fungus called Aureobasidium pullulans that produces the exopolysaccharide from starch. Pullulan can be used to create films that are highly water soluble, transparent, tasteless, odorless, colorless, have low permeability to oxygen and oil, and are heat sealable. They are the perfect material for edible films because of their qualities.

It has been demonstrated that pullulan dissolves after 48 seconds and disintegrates within 6 seconds in vivo.[12]

5. Pectin

Citrus and apple products contain pectin, a carbohydrate. Pectin’s are effective film formers with good drug-carrying capacity and are especially well-suited for low pH applications. The films' solubility varies on the polymer's molecular weight, but generally speaking, it dissolves slowly in the oral cavity. Pectin (X-939-04) films have been discovered to have in-vivo dissolving times of 141 and 15 seconds, respectively. Pectin's high inherent viscosity hinders the development of thin films with heavy active loadings. Pectin films have a reputation for leaving an unsettling aftertaste in the mouth as they dissolve. According to a

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research, pectin's inherent viscosity decreases from 4.9 dl/g to 2.5 dl/g as a result of degradation, making it more suited for usage in ODF.[13]

6. Gelatin

A complex collection of highly molecular-weighted water-soluble proteins makes up gelatin. Gelatin is transparent, brittle, in flakes or powder form, nearly flavorless, odorless, and slightly yellow in color. In aqueous solutions between 30-35°C, gelatin expands and absorbs 5–10 times its weight in water to create a gel.Gelatin is a natural protein derived from collagen and is used extensively in the culinary and pharmaceutical industries. Gelatin films offer a smooth tongue feel, disintegrate quickly, and make great flavor carriers. An in-vivo disintegration time of 8 seconds and an in-vivo dissolution time of 40 seconds have been discovered for gelatin films.[14]

❖ **Plasticizer**

A crucial component of the quickly dissolving films is plasticizer.

Plasticizer lessens the brittleness of the films and aids in improving the strip's flexibility. By lowering the polymer's glass transition temperature, it considerably enhances the film forming characteristics. The glass transition temperature of the polymers is significantly lowered by the chemical makeup of plasticizers and their concentration. The choice of plasticizer depends on how well it works with the polymer as well as the kind of solvent used in the casting of the film.

❖ **Sweetening agent**

Sweeteners now play a crucial role in formulations meant to dissolve or disintegrate in the oral cavity. Typically, sweeteners are used alone or in combination at concentrations ranging from 3 to 6%w/w. The creation of these quickly dissolving films involves the use of both natural and synthetic sweeteners. Polyhydric alcohols such as sorbitol, mannitol, and isomalt can be used in combination as they additionally provide good mouth- feel and cooling sensation. However, it should be emphasized that individuals on a diet or those who have diabetes must limit the use of natural sugars in such dishes. Artificial sweeteners have grown in popularity in culinary and pharmaceutical preparations as a result. The first generation of artificial sweeteners includes saccharin, cyclamate, and aspartame. The second generation includes acesulfame-K, sucralose, alitame, and neotame.

Sucralose and acesulfame-K contain 200 and 600 times the sweetness, respectively. Neotame and alitame have a sweetening capacity that is more than 2000 and 8000 times more than sucrose. In order to mask the bitter taste of fast-dissolving valdecoxib oral strips, aspartame was employed in their creation.[15]

❖ **Saliva stimulating agent**

The goal of utilizing saliva stimulating drugs is to speed up saliva production, which will help the rapid dissolving strip dissolve more quickly.

Broadly speaking, salivary stimulants can be made from acids that are used in meal preparation.For instance, tartaric acid, ascorbic acid, lactic acid, malic acid, and citric acid. Between 2 and 6% of the weight of the strips are employed with either one of these agents alone or in combination.

❖ **Flavorings agent**

In the OFDF formulations, flavors are added up to 10%w/w preferably. An individual's willingness to adopt an oral disintegrating or dissolving formulation depends in great part on. The sort of medicine to be included in the formulation will determine what flavor is chosen. It has been found that taste preferences are significantly influenced by age. Elderly people like flavors like mint or orange, whereas younger people prefer flavors like fruit punch, raspberry, etc. You can choose flavoring agents from artificial flavor oils, oleo resins, and extracts made from different plant components like leaves, fruits, and flowers. You can use flavors individually or in combination.

While vanilla, cocoa, coffee, chocolate, and citrus are examples of fruity flavors, flavor oils include cinnamon, nutmeg, spearmint, and coffee. A few examples of fruit essence are apples, raspberries, cherries, and pineapple.[16]

MANUFACTURING METHOD:

The following techniques are typically used to make fast-dissolving oral films:

1) Semisolid casting.
2) Rolling.
3) Solvent casting.
4) Solid dispersion extrusion.
5) Hot melt extrusion.

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1. Semisolid casting

In this approach, a water-soluble film-forming polymer solution is initially made. The resultant solution is then mixed with an ammonium or sodium hydroxide-prepared solution of an acid-insoluble polymer, such as cellulose acetate phthalate. The acid insoluble polymer: film forming polymer ratio should be 1:4. With the addition of a proper amount of plasticizer, a gel mass is formed. Finally, the gel mass is casted into the films or ribbons using heat-controlled drums.

2. Rolling

Water and water-alcohol mixtures are the most commonly employed solvents in this approach. The active substance and other components are dissolved in a tiny amount of aqueous solvent using a high shear processor. Hydrocolloids that dissolve in water produce a homogeneous viscous solution. The final step is to roll the drug-containing solution or suspension on a carrier. The finished product is then cut into the necessary shapes and sizes.[17]

3. Solvent Casting

This process involves dissolving the medication and other chemicals in a suitable solvent while also dissolving water-soluble polymers in water. The two solutions are then combined and agitated before being cast into a petri dish and dried.

4. Solid dispersion Extrusion

Extruding immiscible components with the medicine first creates the solid dispersion, which is subsequently molded into films using dies. This is dissolved in various solvents for use in technique drugs, and the resulting solution is melted PEG at a temperature of 70 °C. By using dies, solid dispersion is finally sliced into films. In this technique, the API-containing suspension or solution is rolled onto the carrier. Water alone or in combination with alcohol is the most common solvent. ODF is dried on rollers before being cut to the proper size and form.

5. Hot Melt Extrusion

It is a procedure where heat and pressure are used to melt polymers. SR-tablets and granules are mostly prepared using it. This approach departs from the conventional approach to ODF preparation. This movie was created using a heating method. After heating, ingredients are combined in a dry form before being removed in a molten condition. The resultant molten mass is utilized to cast film. The films are then trimmed and cooled. This method's primary flaw is that the high temperature renders the Active Ingredients inactive. The casting and drying steps are crucial in this process. Solvent casting emerged as a more improved procedure for the manufacturing of ODF, in relation to HME technology.[18]

Recent Manufacturing Technologies

1. XGel

Considering that this style of movie does not include animal products, vegans tend to favor it more. These substances have intestinal qualities and are used to disguise flavors, colors, and layers. Furthermore, API is included. As they can dissolve in water, they may be utilized to create any type of oral dosage form. It may be made in a variety of forms and dimensions. It is a great way of getting the drugs to people.

2. Soluleaves

For flavor-releasing ingredients like sweets, air fresheners, and vitamins, soluleaves are included. This technique is utilized in a wide range of ODF products to effectively and pleasantly transport the pharmaceutical active ingredient to the oral cavity. The API is promptly released when the film comes into contact with saliva since the soluleaves are designed to dissolve fast. Soluleaves are ideal for broad range release by oral ingestion because of this. Many pediatric and geriatric individuals who struggle with communication might benefit from this device.[19]

3. Wafer Tab

One of the several methods for loading a medication onto films for topical or oral delivery is the wafer tab. API chemicals are added to the films after casting. This method provides fast drug disintegration and release when the drug comes into touch with saliva in the system where the drug is in the form of an ingestible filmstrip. Wafer tab is also used to make food and enhance flavor. The medication is accruable weighted and put in the pre-made film to guard against heat and moisture and helps to increase product stability. Wafer tab facilitates more medication invention potential. Wafer tabs come in a variety of sizes and forms, and they aid in the fast release of medications as well as the people who have difficulty swallowing.

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EVALUATION TESTS

1) Morphology study

Scanning Electron Microscopy (SEM) is used to examine the morphology of the films at a certain magnification.

2) Organoleptic evaluation

To do this, specifically created equipment and invitro approaches involving taste sensors are being deployed. For high throughput taste testing of oral pharmaceutical formulations, several invitro taste evaluation tools are designed.

3) Thickness

At various sites, it may be measured with a micrometer screw gauge. The precision of the dosage in the strip is closely tied to the uniformity of the film's thickness, thus this must be determined.[20]

Mechanical Properties:

1. Tensile Strength

The greatest stress that may be applied to a spot before the strip specimen splits is known as the tensile strength. Formula is used to compute it.

Tensile strength = Load at Failure X 100 /Strip thickness X Strip Width

2. Tear Resistance

The force needed to start ripping is mostly measured using a very modest loading rate of 51 mm (2 in.)/min. The tear resistance value in newtons (or pounds force) is the maximal stress or force (that is often obtained around the beginning of tearing) required to tear the item.

3. Percentage Elongation

Strain is the stretching that occurs when tension is applied to a film (2×2 cm^2) sample. In essence, strain is the distortion of a film before it breaks under force. With the Houns Field Universal Testing Machine, it is measured. In general, strip elongation rises as plasticizer content does as well. [12]

% Elongation = Increase in length of film × 100/Initial length of film

4. Young's Modulus

The elastic modulus, also known as Young's modulus, is used to gauge a film's stiffness. In the zone of elastic deformation, it is expressed as the following ratio of applied stress to strain:

Young's modulus = Slope × 100/ film thickness × Cross head speed

With little elongation, hard and brittle films exhibit high tensile strength and Young's modulus.

5. Folding endurance

It imparts a film's brittleness. The film specimen (2 x 2 cm2) is repeatedly folded in the same spot to determine the endurance value until it breaks or a noticeable fracture is noticed. The computed folding endurance value is the number of folds that may be made without the film breaking or showing any visible cracks.[21]

6. Swelling property

To guarantee the swelling studies of films, simulated saliva solution is employed. A stainless-steel wire mesh with a predetermined weight is used to hold the film at its initial weight. The film holding the mesh is then submerged in a fake saliva solution. Until until there is no longer a rise in weight, the weight of the film continues to increase at constant pre-determined time intervals.

Degree of swelling =final weight-initial weight/initial weight

7. In vitro disintegration test

As an oral film comes into touch with saliva or water, it begins to shatter.

The time of disintegration should be in the range of 5 to 30 seconds for a fast-dissolving film. Disintegration time can be investigated using a USP (United States Pharmacopoeia) disintegration device. Another approach involves dipping the film in 25 ml of water in a beaker to visually assess the disintegration time. Gently shaking the beaker is required, and the moment the film begins to dissolve or degrade should be noticed.

8. In vitro dissolution studies

At standardized circumstances of liquid/solid interface, temperature, and solvent concentration, it is the quantity of drug ingredient that enters the solution per unit time. For dissolving testing, you can use the typical basket or paddle equipment mentioned in any of the pharmacopoeias. The sink conditions and greatest dosage of API will largely determine the choice of dissolving media. Dissolution media should be kept at 37°C with a 0.5°C temperature range and 50 rpm. One drawback of using the paddle device is that oral films have a propensity to float above the dissolving media.[22]

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9. Drug content uniformity

By calculating the API concentration in individual films using any standard assay method from the standard pharmacopoeia, one may assess the consistency of the content. 85 to 115% is the maximum content homogeneity.

10. Surface pH test

The oral mucosa may experience negative consequences from the fast-dissolving film's surface pH. The pH of the film's surface should be 7 or nearly neutral. In order to do this, a combination pH electrode can be utilized. OS was mildly moistened, and the pH was then determined by bringing the electrode into contact with the oral film's surface. In a different procedure, the films are first deposited on 1.5%w/v agar gel, followed by pH paper. The pH paper's color shift indicates the film's surface pH.

11. Contact angle

It computes the oral film's wetting behavior, disintegration time, and dissolution. At RT, these measures are made with the use of a goniometer. On top of the dried film, a drop of double-distilled water is applied. Within tens of seconds after deposition, images of water droplets are captured using a digital camera. Image J 1.28v program can analyze digital photos to determine the angle**.**

12. Transparency

It may be found using a basic ultraviolet (UV) spectrophotometer. The inside side of the spectrophotometer cell is where the film sample is put. The transparency of films is calculated as follows:

Transparency = (log T600)/b = €c

Where T600 is the transmittance at 600 nm and b is the film thickness (mm) and c is concentration.[23]

Recant Advancement

Bharti et al. [24]has formulated and characterized Fast Dissolving Oral Films containing Buspirone Hydrochloride Nanoparticles using Design of Experiment. The purpose of this work is to create fast-dissolving oral films (FDOFs) containing buspirone hydrochloride nanoparticles (BH). This formulation's design offers improved bioavailability and prolonged release action for the medication delivery mechanism. These drug delivery methods avoid the first pass metabolism and transfer the medication directly to the oral mucosa, increasing bioavailability. Films were created using a solvent casting technique, whereas nanoparticles (NPs) were created using the nanoprecipitation technique. Using central composite design, both formulations were improved.

Polymeric Nanoparticles were created using an altered nanoprecipitation technique. 80 mg of the medication buspirone hydrochloride and 1.5% w/v of the surfactant poloxamer 188 were dissolved over the course of 10 ml of double-distilled water (pH 6.2) with constant stirring. To get the clear aqueous solution of medication and surfactant, the procedure took 15 minutes. At room temperature, PLGA polymer (160 mg) was thoroughly mixed with 15 ml of acetone to dissolve it. The aqueous phase was then continuously stirred while the organic phase was added dropwise, creating a dispersion. Reduced pressure was used to evaporate the organic solvent.

Solvent casting was used to create the films. To 10 ml of a drug nanosuspension containing 80 mg BH, film formers HPMC E15 and PVA (1:1) (15% w/v of the total solution) were added. To create a dispersion, it was swirled for an hour at 400 rpm on the magnetic stirrer. The plasticizer propylene glycol 15%w/v of the total volume of solution was produced as an aqueous solution in 5ml of water. The polymeric dispersion, which included a nanosuspension of the medication, received the addition of the plasticizer solution. A total of 25ml of solution was produced in the end. The resulting mixture was placed in a petri dish with an internal diameter of 9.03 cm and heated to 60 °C for 24 hours. The dried film was taken out of the petri dish and divided into two pieces, each measuring 2 cm2. The aqueous solution of BH was used in place of the nanosuspension to create the reference film (film with the simple drug) in the exact same way.

FDOFs were assessed for their disintegration time, weight fluctuation, thickness, tensile strength, and surface pH. The findings showed that the nanoparticle-incorporated BH films exhibited excellent stability and physicomechanical 40 characteristics. They were discovered to be effective in causing a quick, sustained medication release activity.

Min Zhang et al. [25]has Prepared and evaluated Self- microemulsifying oral fast dissolving films of vitamin D3 for infants. In this work, self-microemulsifying oral fast dissolving films (SMEOFDF) containing vitamin D3 were created by combining the benefits of self-microemulsifying technology with oral rapid

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dissolving technology. Using the water titration method, the formulation of films was optimized, and the pseudoternary phase diagram of the microemulsion was created. The self-microemulsion of vitamin D3 was created as a thin film in which the liquid droplets were inserted.

After being redissolved in water, a microemulsion with a zeta potential of 16.1 mV and a particle size of 181.2 nm could form on its own. The first-order equation is a good fit for the release profile of vitamin D from SMEOFDF.

Haojie Shaet al. [26]has Formulated Pre-gelatinized cassava starch orally disintegrating films: Influence of β-Cyclodextrin. The study looked at the interactions between β-Cyclodextrin (-CD) and pre-gelatinized cassava starch (PCS) during the production of orally disintegrating films (ODFs). The ODFs' FTIR spectra, surfaces micromorphology, mechanical characteristics, thermal properties, and mechanical properties were all measured. Once β-CD was added to the film matrix, the moisture content, mechanical characteristics, and surface hydrophilicity of the ODFs were all enhanced. Due to the ODFs' increased thickness, the disintegration time was somewhat extended.

All samples of ODFs disintegrated in less than 60 seconds. Thermal characteristics, atomic force microscopy, and FTIR spectra revealed the following: The creation of a more comprehensive network structure and the uniform dispersion of PCS during stirring were both aided by β-CD. Nevertheless, too much β-CD prevented the accumulation of PCS chains. It aided in the establishment of a weakernetwork structure and the mono-dispersion of PCS molecules. The study will support the creation of a brand-new oral delivery platform for active compounds.

II. CONCLUSION

Recent global market growth in the success and acceptance of fast-acting oral films is proof of the need for potent, flavor-masking, "waterless" medicinal formulations. As a logical progression from fast dissolving drug delivery systems, fast dissolving oral films have distinct benefits over traditional dose forms and orally disintegrating tablets. Fast dissolving oral films have developed into user-friendly dose forms because of their significant usefulness in emergency situations such allergic reactions and high patient compliance. The reason why so many pharmaceutical companies are introducing this technology is because it allows for the production of these films using simple, straightforward tools and processes. Fast dissolving films provide future development potential that are both possible commercially and technologically.

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