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REVIEW ARTICLE

Advancement of Novel Oral Dissolving Film: An Overview

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ABSTRACT
This review discusses mouth-dissolving films as a potential dose form for elderly and pediatric patients. These films dissolve quickly in the mouth without water, making them adaptable and patient-friendly. They are suitable for medications with low bioavailability and high metabolism. Mouth dissolving films can be made using various techniques, including solvent casting due to its excellent physical properties and consistency. The study assesses the chemical and physical properties of mouth dissolving films and provides an overview of formulation considerations, preparation procedures, and assessment criteria for oral dissolving films. These films are a potential dosage form for administering medications to these patients.
Keywords*: Oral dissolving film, Buccal film, Improved patient compliances, Standard composition, Method of preparation, Evaluation*

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INTRODUCTION

Oral drug delivery is commonly acknowledged as a handy, economical, and preferred drug administration approach. Fast-disintegrating drug delivery systems are a crucial advancement in pharmaceutical science, offering many advantages over traditional drug delivery systems. These methods for delivering drugs can be administered orally, topically, buccally, sublingually, or by a combination of these methods. This review examines oral thin films from a contemporary standpoint. It sheds light on the industry's rising worldwide market share as a result of developing research fields and technical breakthroughs [1].

One such innovative strategy to boost consumer adoption is oral fast dissolving film (OFDF), which dissolves quickly and can be self-administered without the need for water or chewing. The film is the perfect intraoral fast-dissolving medication administration solution because it meets unmet market needs, is simple to handle and administer, keeps packaging straightforward and convenient, reduces bad taste, and is easy to produce. The film is positioned on the tongue's floor or top. It quickly releases the active ingredient for local and/or systemic absorption while remaining at the application location. The creation of a fast-dissolving film also offers a chance to expand the market for a variety of medications, including cardiovascular and neuroleptic medications, analgesics, antihistamines, and antiasthmatics drugs for erectile dysfunction [2].

Plasticizers, film-forming polymers (polymeric matrices), and an active pharmaceutical ingredient (API) are the usual components of ODFs. Functional excipients for flavoring, coloring, saliva stimulation, and sweetening are also added to satisfy particular requirements. Polymeric matrices can be used to create drug release platforms.[3] In essence, ODFs are a polymeric matrix whose composition can be altered by varying the kind, quantity, or grade of polymers to produce the required product characteristics, including disintegration, drug loading, and mechanical qualities. ODF formulations can contain both natural and synthetic polymers, and effective drug delivery platforms can be designed by modifying the matrix composition.[4] Plasticizers can improve the flexibility and decrease the brittleness of ODF strips. By reducing the glass transition temperature of the polymers, they significantly enhance the film-forming properties.[5] The compatibility of polymers and plasticizers should be considered prior to selecting themsince this may vary depending on the kind of solvent used during the film casting procedure. To

facilitate the rapid release of API and the dissolution of ODFs in a matter of seconds, surfactants are used as solubilizing, wetting, or dispersing agents.[6]

POSSIBLE ADVANTAGES OF ODFs

- Rapid breakdown and disintegration in the oral cavity are facilitated by their large surface area.
- Its flexibility and decreased fragility make it simpler for customers to handle, carry, and store.
- Simplicity in administering to mentally ill, incapacitated, or uncooperative patients.
- Accuracy in dosage administration.
- A pleasant mouthfeel.
- Provides water nil therapy.
- Improves bioavailability, absorption, and action speed.
- Boosts patient compliance.
- Extends product life cycle.
- Provides good stability.

Advantages of ODFs Over Fast Disintegrating Tablets:

- Offer a greater disintegration surface area
- Uses less costly materials for processing and packaging
- No loss of friability
- Less excipients are needed; the procedure takes less time; it is more elegant and cost-effective; No chance of choking exists.

Property/sub type	Flash release wafer	Mucoadhesive melt-away wafer	Mucoadhesive sustained release wafer
Area (cm2)	2-8	2-7	2-4
Thickness (mm)	20-70	50-500	50-250
Structure	Single layer	Single or multilayer system	Multi-layer system
Excipients	Soluble, highly hydrophilic polymers	Soluble, hydrophilic polymers	Low/non-soluble polymers
Drug phase	Solid solution	Solid solution or suspended drug particles	Suspension or solid solution
Application	Tongue (upper palate)	Gingival or buccal region	Gingival, (another region in the oral cavity)
Dissolution	Maximum 60 sec	Disintegration in few minutes, forming gel	Maximum 8-10 hrs
Site of action	Systemic or local	Systemic or local	Systemic or local

Table:1 Different properties of oral dissolving film

Limitations:

- Incorporating high doses is not possible.
- It is not possible to use excessively bitter medications.
- One of the major technological challenges is dose consistency.
- Oral bioavailability should be good for oral films.
- This method is not suitable for administering medications that cause irritation to the oral mucosa.
- They need the things to be packaged specifically. security and stability.

Oral films possess the following special qualities:

- They are ultrathin.
- They are available in various sizes and shapes.
- Have excellent mucoadhesion.

Applications

- Suitable for both local action and the treatment of the central nervous system disorder, pain, allergies, and trouble sleeping.
- They can be used topically as antimicrobials or analgesics to treat wounds.
- They can be used to make isolation barriers to separate several reagents so that a timed reaction with a diagnostic device can occur, or they can be loaded with sensitive reagents to allow controlled release when exposed to biological fluids.
- low bioavailable drugs can have their bioavailability increased by using oral films.[8]

The following characteristics are appropriate for an ODF medication candidate:

- The integrating APIs should have a modest dosage of up to 40 mg.
- Low molecular weight medications are preferred
- They should taste well
- They ought to partially unite at the buccal cavity's pH.
- They should be stable and soluble in both water and saliva
- The oral mucosal tissue should be permeable to them.

Formulation of ODFs

The following excipients should be included in a standard formulation of oral dissolving films:

- Drug 25 %
- water-soluble polymers 40 - 50 %
- Plasticizers 0 - 20 %
- Fillers, color, flavors etc. 0 - 40 % [9]

Oral film composition:

- Active pharmaceutical ingredient
- Plasticizer
- Film forming polymers
- Super disintegrants
- Sweetening agent
- Surfactants
- Saliva stimulating agent
- Flavoring agent
- Colouring agent

ACTIVE COMPOUNDS IN PHARMACEUTICALS

Approximately 1-30% w/w of the oral film composition is made up of the active therapeutic component. Since it is difficult to combine a large quantity of medication into a fast-dissolving oral film, low-dose active pharmaceutical ingredients are used. The market for thin oral films is mostly composed of minerals, vitamins, and supplements. Numerous API types can be successfully integrated with oral strip technology. API can be milled, micronized, or injected as particles or nanocrystals, depending on the desired ultimate release profile. Before adding API to the formulation of oral films, the bitter taste of drugs must be covered up. Other methods of enhancing flavor include obscuration, which is the process of mixing and co-processing bitter testing API with excipients that have a lovely, pleasant taste.[9]

Film formers

These give the dose form a platform. The physicochemical characteristics of the film can be altered based on the type of film former used. The resulting film needs to be sufficiently durable to prevent any damage while handling or transit. The kind of polymers and their quantity in the formulation mostly determine the film's resilience. The majority of film-forming materials are aqueous polymers.[10] Some widely used film formers are hydroxyl propyl methylcellulose (HPMC) of different grades, hydroxypropyl cellulose (HPC), polyvinyl alcohol (PVA), polyvinylpyrrolidone (PVP), sodium alginate, sodium carboxy methyl cellulose (sodium CMC) and polyethylene glycol, and pullunan.[11]

Plasticizers

In order to increase the flexibility of mouth dissolving film, plasticizers are added in its composition to lower the film's glass transition temperature. The mechanical characteristics of the film may be impacted by improper usage of plasticizers. PEG 400, glycerol, propylene glycol, acetyl citrate castor oil, and others are examples of plasticizers that are often used.[12]

Sweetening Agents

When making mouth dissolving films, sweetening compounds are used to mask the taste of some harsh medications and create a pleasing mouthfeel. The most often used sweetening agents are glucose29, mannitol, sorbitol, sucrose, maltose, neotame, aspartame, and fructose. Compared to sucrose, aspartame and neotame are sweeter. Sucralose and acesulfame-K have sweetening properties that are more than 2000 and 8000 times more, respectively, than sucrose. The South African Plant Stevia rebaudiana is used to make Rebiana, a herbal sweetener that is more than 200–300 times sweeter than artificial sweeteners. However, these sweeteners have an aftertaste effect, which can be lessened by combining or blending natural and synthetic sweeteners. Synergism and better formulation could arise from the addition of sweeteners.[13]

Surfactant
Surfactants are employed as dispersing, wetting, or solubilizing agents to disintegrate films in a matter of seconds and release active agents instantly. Among the often-utilized ones are tweens, sodium lauryl sulfate, benzalkonium chloride, bezthonium chloride, and others. The solubilizing, wetting, and dispersion substance polaxamer 407 is one of the most significant surfactants.[14]

Saliva stimulating agents
Acids including citric, malic, lactic, ascorbic, and tartaric acids—of which citric acid is the most frequently utilized—that are frequently employed in food preparation can also be used as salivary stimulants. The fast-dissolving strip formulations will dissolve more quickly because to the introduction of saliva stimulating chemicals, which boost saliva production. These agents vary from 2 to 6%w/w of the strip weight and can be used either alone or in combination.[15]

Colouring agents
Pigments such as Titanium dioxide or FD & C approved colouring agent are incorporated (not exceeding concentration of 1% w/w) in solution

Flavoring agent
Type of drug that will be utilized in the formulation determines the flavor selection. What decides whether a person can identify the oral disintegrating/dissolving formulation is the flavor quality that is detected in the first few seconds after the product is consumed and that persists for at least ten minutes following consumption. The kind and strength of the flavor determine how much is needed to cover it up. 10%w/w of the flavoring ingredient is used in the formulation.[16]

Methods of Preparation of ODF
Following methods which can be used for preparation of fast dissolving film such as:

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

Solvent casting method [17, 18 Fig 1]
Advantages

- Great uniformity of thickness & great clarity than extrusion.
- Films have fine gloss & freedom from defect such a die lines.
- Films have more flexibility & better physical properties.
- **Disadvantages**
- The polymer must be soluble in a volatile solvent or water
- The stable solution with reasonable minimum solid content & viscosity should be formed.

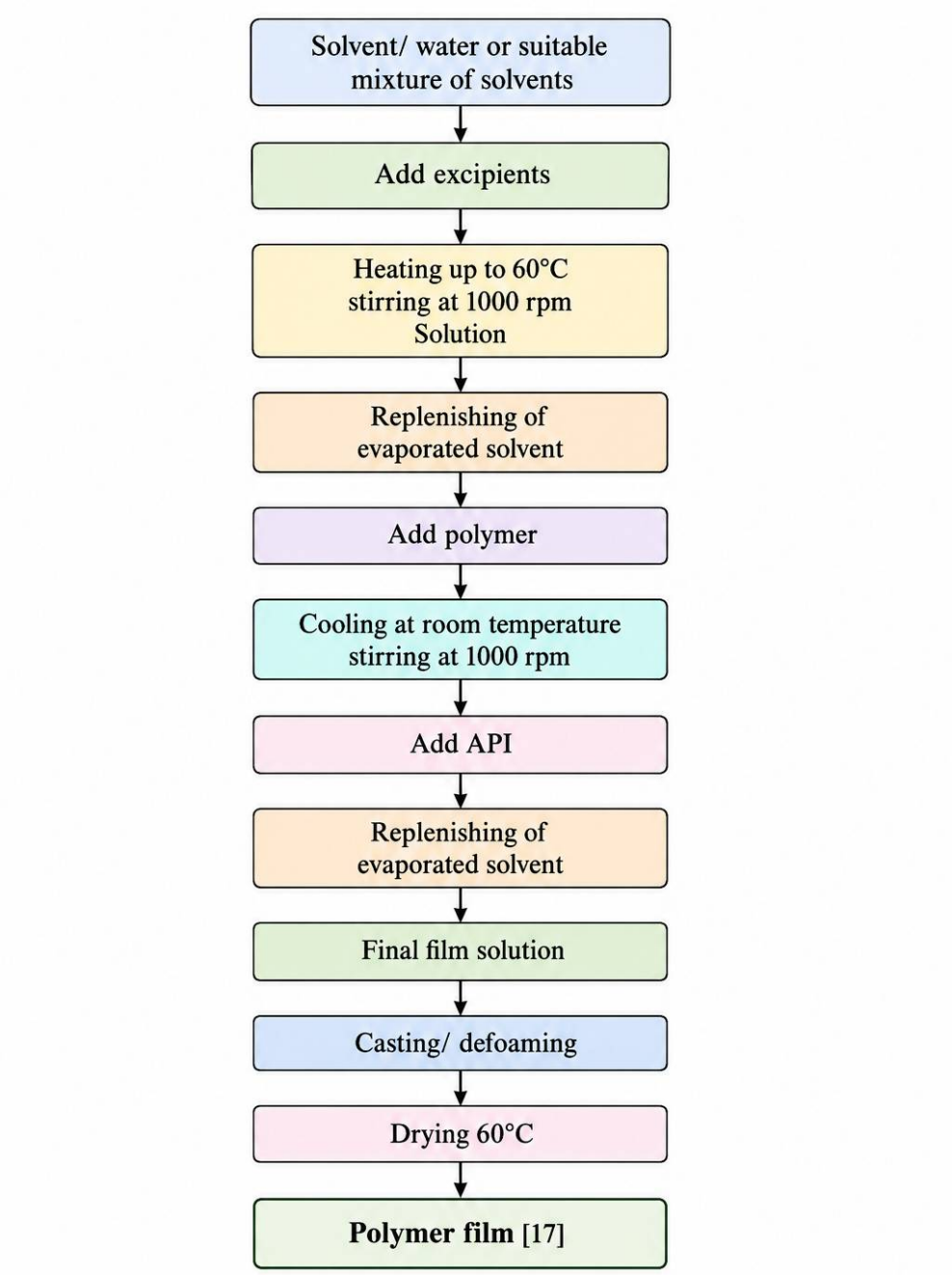

Figure 1. Solvent casting method [18]

Semisolid casting method

A solution of a hydrophilic film-forming polymer is prepared and then added in a 1:4 ratio to a solution of acid-insoluble polymers, such as cellulose acetate phthalate or cellulose acetate butyrate; the addition of a suitable plasticizer causes a gel mass to form. Using heat-controlled drums, this gel is molded into ribbons with a target film thickness of roughly 0.015 to 0.05 inches .

Hot-Melt Extrusion

A common technique for creating granules, sustained-release tablets, and transdermal and transmucosal drug delivery systems is hot melt extrusion. Film processing is the process of utilizing heat to form a polymer into a film. filled the hopper with the drug carrier mixture, which the extruder then transported, combined, and melted. After that, the die-shaped melt takes on the required film shape.[19]

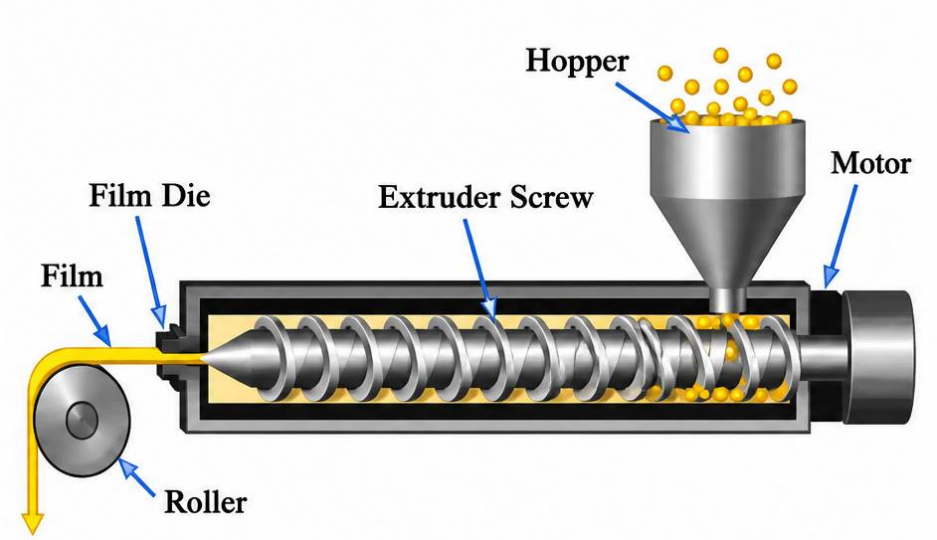

Figure:2 Hot-Melt Extrusion [20]

Solid dispersion Extrusion

This process involves dissolving the medication in an appropriate liquid solvent first, and then adding the solution to a PEG melt that is below 70C. The chosen drug or solvent might not dissolve in PEG melt, and the solvent may have an impact on the polymorphic form of the drug that precipitates in solid dispersion**.**

Rolling Method

The film is made by pre-mixing an active, preparing the additives, and then forming the film. Make the pre-mix using a polar solvent, film-forming polymer, and other materials, excluding a drug. Pour the premix into the master batch feed tank. A first metering pump and control valve supply it to the first and second mixers, or both. Next, add the required quantity of medication to the mixer of your choice. To make a uniform matrix, combine the medication with the pre-mix from the master batch.After a specified quantity of uniform is measured by second metering, the matrix is subsequently delivered to the pan by pumps. Finally, the support roller is used to remove the film that has been formed on the substrate. After that, the wet film will be left to dry. Using bottom drying.[21]

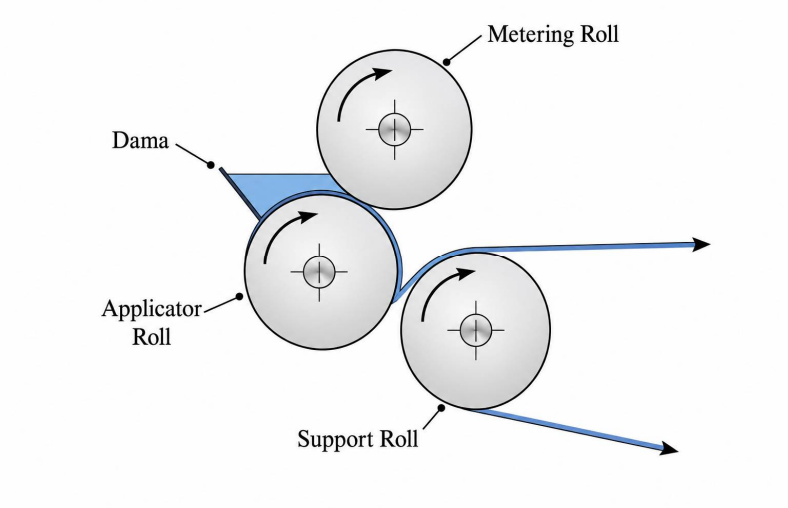

Figure:3 Rolling method

Evaluation of ODFs

Thickness and hardness

The test is conducted using accepted practices. Three randomly chosen tablets' hardness from each formulation is ascertained by positioning each tablet diagonally between the tablet hardness tester's two plungers (using the nozzle) and exerting pressure until the tablet fully splits into two pieces, at which point the scale's reading is recorded. Using a vernier caliper (Pico India), the thickness of three randomly chosen tablets from each formulation is measured in millimeters. The average values are computed. [22]

Tensile strength

This is the maximum stress that a film specimen can withstand before breaking. It is calculated by dividing the cross-section area of the film by the load at rupture.

Film tensile strength = F max

Youngs modulus

It is use to estimate stiffness. It is found as balance applied stress to the strain in the region. it is determined by,

Youngs modulus = force of corresponding strain/cross sectional area.[23]

***In-vitro* disintegration studies**

In order to replicate the in-vitro and in-vivo settings, the disintegration time research was slightly altered. For the investigation, a stainless-steel wire mesh with 10 mL of distilled water was covered with film that had the proper size (3 x 2 cm) for dose administration. The in-vitro disintegration time was defined as the amount of time needed for the film to shatter and dissolve. Only 10 mL of medium was utilized because it is anticipated that the film may dissolve in the mouth when saliva is present.

***In-vitro* dissolution studies**

300 mL of simulated saliva was used for the in-vitro dissolving tests. The USP dissolving equipment XXIV (Electro lab, Mumbai, India) was used for the dissolution studies, which were conducted at 37 ± 0.5 °C and 50 rpm using the designated dissolution media. A stainless-steel wire mesh with a 700µm sieve aperture was used to hold each 3 x 2 cm2 film. After being put on the sieve, the film sample was immersed in dissolving media. Samples were extracted at intervals of 0, 15, 30, and 60 seconds, filtered through 0.45 µm Whatman filter paper, and then subjected to spectrophotometric analysis at 250 nm. After removing the samples, an equivalent volume of brand-new dissolving medium kept at the same temperature was added to preserve the volume. Using a standard calibration curve that had been previously acquired through experimentation, the absorbance readings were translated to concentration. For each batch, the dissolution testing investigations were carried out three times.[24]

Uniformity of drug content

A 3 × 2 cm2 film is cut and placed in a 30 mL solvent-filled volumetric flask. After an hour of shaking in a mechanical shaker, this is filtered to produce a homogenous solution. The medication is measured using spectroscopy following the proper dilution.[25]

pH value

To measure pH, dissolve one oral film in 10 milliliters of distilled water. The resulting solution's pH should be almost constant.[26]

Percentage Elongation: Strain is the term used to describe how a film sample stretches when tension is applied. In essence, strain is the film's deformation divided by its initial the sample's dimension. In general, the more plasticizer there is in the film, the longer the film gets.[27]

$$\% \text{ Elongation} = \frac{\text{Increase in length}}{\text{Original length}} \times 100$$

Weight Variations

Ten randomly chosen films are individually weighted in order to measure weight variation. There shouldn't be a big difference in average weight between controlled drums and the mean weight.[28]

Folding endurance

By folding a small bit of film over and over again (2 cm x 2 cm) in the same spot until it broke, the folding durability of the film was assessed. The folding endurance value was the number of timesthe film would not shatter if folded in the same position.[29]

Contact Angle Measurement

An optical contact angle meter measures the time-dependent contact angle. Numerous techniques, including the two tangential methods, a height-width ratio, circle fitting, and sessile drop fitting, are used to estimate the contact angle. Its forecast for oral film wetting behavior, breakdown, and disintegration [30]

Transparency

A UV spectrophotometer is used to measure a strip's transparency. This test is conducted to evaluate the formulation's visual appearance. Rectangular pieces of film are cut off and positioned within the photometer cell. The film's transmittance is calculated at a wavelength of 600 nm.

The following formula can be used to determine transparency:

Transparency = (log T600)/ b= -€c

T600 = transmittance at 600 nm, b = film thickness (mm), and c = concentration [31]

Stability Testing

According to ICH recommendations, oral strips are kept in a stability chamber at controlled temperatures of 25°C/60%RH and 40°C/75% for a period of 12 months in order to measure stability. Throughout the storage period, a number of assessment parameters are looked at, such as thickness, morphological traits, tensile strength, water content, and dissolving behavior. [32]

Table :2 A list of marketed goods that are available as ODFs

Product	Manufacturer	API	Use
Listerine	Pfizer	Cool mint	Mouth fresheners
Triaminic	Novartis	Dextromethorphan HBr	Cough suppressants
Suppress®	InnoZen®, Inc	Menthol	Cough suppressant
Chloraseptic	Prestige	Benzocaine menthol	Cough suppressants
Gas-X	Novartis	Simethicone	Anti flatuating
Theraflu	Novartis	Dextromethorphan HBr	Cough suppressants
Ondansetron ODF	Seto film	Ondansetron	Anti-emetic
Donepezil film	Labtec	Donepezil HCL	Alzheimer's disease
Klonopin wafer	Solvay pharmaceutical	clonazepam	Anti-anxiety

Table:3 Patents on fast dissolving oral films

Tittle	United state patent	Issued	inventors
Film comprising nitroglycerin	20100215774	Aug. 26,2010	Maibach, Todd
Fast disintegrating orally consumable films containing a taste masking agent	7,648,712	Jan.19,2010	Bess; William S (Edison, NJ), Kulkarni; Neema (Randolph, NJ), Ambike; Suhas H. (West hill, CA), RAMASAY; MICHALE p. (Ajax, CA)
Oral fast disintegrating film for erectile dysfunction bioactive agent	2009/0047330	Feb.19,2009	Ramesh, Bangalore
Disintegrable film for diagnostic devices	7,470,397	Dec.30,2008	William G. Meathrel, Nathan A. Meyer, Scott, D. Barnhart, Cathy M, Moritz, Andrew P. Full, Susan R. Newsom. Mary Robertson
Thin film strip	7,241,411	Jul.10,2007	Craig J. Berry, Walter Klauser
Flavored film	7,132,113	Nov.7, 2006	Horst G. Zerbe, Fadia Al-khalil
Fast disintegrating orally consumable film	7,025,983	Apr.11,2006	Sau hung spence Leung, Robert S. Leone, Lori D, Kumar, Neema Kulkarni, albert F, Sorg
Process for manufacturing thin film strip	6,824,829	Nov.30,2004	Craig J. Berry, Walter Klauser
Fast disintegrating film for oral administration of drug	2001/0208931	Oct.21,2004	David R. friend, Aaron W. Levine, Kerrie L. Ziegler, Emmanuel Manna
Method for producing film type dosage	6,800,329	Oct.5,2004	Michael Horstmann Wolfgang Laux, horst Dzekan, Katja Zinndorf

CONCLUSION

Drug formulation into many film genres has been more and more popular in recent years. Pharmaceutical companies, both new and old, are keeping an eye on this medication delivery method. Although they were first utilized commercially in over-the-counter drugs, ODFs are now also found in prescription drugs. The companies strive to create a broad variety of thin film formulations for oral, sublingual, ocular, buccal, and transdermal routes because of patient compliance (especially in children and the elderly). To address the shortcomings of existing dosage forms, it is therefore expected that these polymeric thin films would emerge as a competitive substitute for conventional dosage forms. Hygroscopic dosage is one of the disadvantages of mouth dissolving tablets (MDTs), despite their widespread use.ODFs can help with this, but they can also cause choking anxiety, grittiness in the mouth if not formed correctly, and stability issues. OTC medications are likely to be replaced by this drug delivery technology due to consumer preferences in the US, Japan, and Europe. Recently approved prescription ODFs have the potential to replace other oral dosage forms of the same drug. ODF's recent rise in popularity and success in the global market has made it significant due to consumer demand. Despite being in its early stages, ODF technology

has a bright future because of patient compliance and pharmaceutical acceptance. Thus, more investigation into this intriguing drug delivery system is required for the benefit of researchers and individuals in general.

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