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An In-Depth Analysis of the Oral Film Medication Delivery Technique

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Abstract: *Orally dissolving films are a commonly used oral dose form because they release the active component in pharmaceuticals rapidly into the oral cavity upon contact with saliva. The benefits of quickly melting in the mouth to provide instant release and avoiding first pass metabolism make oral dissolving films a popular method of administration. The focus of the present research is on the fundamental knowledge of film formulation, the application of different polymers, and standard measurements of common film kinds. The current research presents a segment of the oral dissolving film market based on accumulated assessment techniques and marketed items.*

Keywords: Orodispersible Films, Fast Dissolving Films, Oral Thin Films, ODFs, Drug Delivery, Pharmaceutical

I. INTRODUCTION

Of all the dosing ways, the oral route is one of the most practical for administering medication. Elderly care is seen as a challenging condition at the same time as pediatric care. Another challenge when using the oral mode of administration is the amount of time it takes for the medicine to dissolve and release from the dosage form so that the therapeutic impact may be felt right away. In contrast, oral dissolving films show immediate release, excluding interaction with stomach contents, long time to release, and first pass metabolism. All other oral dosage forms, such as tablets, capsules, and pellets, travel to the gastrointestinal tract and undergo disintegration and dissolution to give pharmacological activity. Patients with dysphagia, those confined to bed, and those with Parkinson's disease may also benefit from oral dissolving films. By adding both natural and artificial excipients, the formulation may be made to release the medication more effectively, treating the patient's illness or problems.

These oral films have been referred to by a number of names, including buccal films, wafers, ophthalmic films, mucoadhesive films, oro-dispersible films (ODFs), oral soluble films, buccal films, and transmucosal films. It is a postage stamp-sized, very thin (50–150 microns thick) strip with a working specialist and many excipients made using transdermal patch technology.

ANATOMY OF ORAL CAVITY

grasp the environment created for medication delivery requires a grasp of the physiology and anatomy of the mouth cavity. The oral mucosa prevents first pass metabolism and permits direct medication entry into the systemic circulation. The oral cavity's epithelium and skin's are quite similar, with a few minor variations in keratinization and the lubricating and protecting mucus that covers the surface. The oral mucosa has a permeability that is 4–1000 times higher than the skin's. The oral cavity is separated into two areas: the tonsils, floor of the mouth, hard and soft palates, and the oral vestibule, which is surrounded by the lips and cheeks. For many years, oral drug delivery has been recognized as the most popular mode of administration out of all the routes investigated for the systemic distribution of medications via a variety of pharmaceutical products with varying dose forms.

APPLICATIONS OF ORAL FILMS IN DRUG DELIVERY

Oral medication administration by sublingual, mucosal, and buccal routes becomes the preferred method for treatments requiring quick absorption, such as those for pain, allergies, insomnia, and central nervous system diseases. When it

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comes to topical applications, oral films are perfect for delivering active components such as analgesics or antimicrobials for wound care and other uses. Film format is used for gastroretentive dose systems, water soluble and poorly soluble compounds with varying molecular weights (Barnhart and Sloboda, 2007a). Oral films are used to treat gastrointestinal diseases and may dissolve when the pH or enzymatic secretion of the GIT reaches a certain level. Oral films filled with sensitive reagent to enable regulated release when confronted with biological fluid are used in diagnostic equipment to separate various reagents and enable a timed reaction (2).

Advantages of Orally Dissolving Films (16)

- The drug enters the systemic circulation with reduced hepatic first pass effect.
- Site specific and local action.
- Availability of large surface area that leads to rapid disintegration and dissolution within oral cavity.
- Dose accuracy in comparison to syrup.

Disadvantages of orally dissolving films

- The disadvantage of orally dissolving film is that high dose cannot be incorporated into the strip.
- The dose should be between 1-30 mg.
- There remain a number of technical limitations with use of film strips; the thickness while casting the film.
- Glass Petri plates cannot be used for casting.

Ideal characteristics of a suitable drug candidate (17, 18)

- The drug should have good stability and solubility in water as well as saliva.
- It should be partially unionized at the pH of oral cavity.
- It should have ability to permeate the oral mucosal tissue.

Classification of fast dissolving technologies (18)

- Orally dissolve technologies can be divided in to three broad groups.[3]
- Lyophilized systems.
- Compressed tablet-based systems.
- OTF

Classification of fast dissolving technologies

Properties	Lyophilized system	Compressed tablet based system	Oral thin films
Composition	Solution or suspension of drug with excipients	Active pharmaceutical ingredient with superdis integrants	Hydrophilic polymers with drug and other excipients
Technology used	Lyophilization	Direct compression	Solvent casting, hot melt extrusion
Characteristics	High porosity which allow rapid water or saliva penetration and disintegration	Different levels of hardness and friability these result in varying disintegration and packaging needs	Large surface area leads to rapid disintegration
Packaging	Blister pack	High density polyethylene bottles	Blister cards with multiunits

Classification of orally dissolving films

- Flash releasing oral films
- Mucoadhesive Melt-away wafers
- Mucoadhesive sustained-release wafers

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S. No	Property/Sub/Type	Flash Release films	Mucoadhesive Melt - away wafer	Mucoadhesive sustained - release wafer
1	Area (cm2)	2-8	2-7	2-4
2	Thickness (µm)	20-70	50-500	50-250
3	Structure	Film, single layer	Single or multilayer system	Multi-layer system
4	Excipients	Soluble, highly hydrophillic polymers	Soluble, hydrophillic polymers	Low/Non-solid solution
5	Drug phase	Solid solution	Solid solution or suspended drug particles	Suspension and/or solid solution
6	Application	Tongue (upper palate)	Gingival or buccal region	Gingival, (other region in the oral cavity)
7	Dissolution	Maximum 60sec	Disintegration in a few mins, forming gel	Maximum 8-10 hrs

Ideal Properties of the Film Forming Polymers. (4)

- The polymer employed should be non-toxic, nonirritant and devoid of any leachable impurities.
- It should be tasteless.
- It should have good wetting and spreadability property.
- The polymer should exhibit sufficient peel, shear and tensile strengths.
- The polymer should be cheap and readily available.

List of some synthetic and natural polymers useful in film forming (8)

Natural polymer	Synthetic polymer
Starch	Hydroxy propyl methyl cellulose
Pectin	Poly vinyl pyrolidone (PVP)
gelatin	Polyvinyl alcohol (PVA)
Sodium alginate	Sodium Carboxy methyl cellulose
Maltodextrin	Poly ethylene oxide (PEO)
Pullulan	Kollicoat IR
Xanthan	Hydroxy propyl cellulose (HPC)
Polymerized rosin	Hydroxy ethyl cellulose (HEC)
Gum acacia	Methyl cellulose (MC)

SOME QUALITY PARAMETERS OF SOME DIFFERENT NATURAL POLYMERS

Pullulan

soluble in water. This non-ionic polysaccharide has good adhesion and film-forming abilities, is non-toxic, non-immunogenic, biodegradable, nonmutagenic, and noncarcinogenic properties. It is also compatible with blood. It works well as a binder and adhesive since it is spinnable and flexible. Pullulan may be processed into highly elastic films that are resistant to grease and oil.

Sodium Alginate

Almost completely insoluble in ether and ethanol; insoluble in acid and other organic solvents as well. It functions as a viscosity-increasing agent, tablet binder, tablet and capsule disintegrant, stabilizing agent, and suspending agent.

Rosin

The plasticizer-free solutions were used to make smooth, translucent, but brittle films. The presentation of film coating is significantly influenced by the addition of plasticizers, which results in increased elongation and flexibility of the films as well as lower Tg and tensile strength.

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STANDARD COMPOSITION OF FAST DISSOLVING FILMS (19)

Ingredients	Amount	Examples
Drug	5-30%w/w	Antiallergic, antiemetic, antiepileptic, antimigrant
Water soluble polymer 45%w/w	45%w/w	HPMC E3, E5 and E15 and K-3, Methyl cellulose A- 3, A-6 and A-15, Pullulan, carboxmethylcellulose cekol 30, polyvinylpyrollidone PVP K-90, pectin, gelatin, sodium, alginate, hdroxypropylcellulose, polyvinyl alcohol, maltodextrins
Plastisizers	0-20%w/w	Glycerol, dibutyl pthallate, polyethylene glycol, etc.,
Surfactants	q.s.	Sodium lauryl sulfate, benzalkonium chloride, Tween, etc.,
Sweetening	3-6%w/w	Saccharin, cyclamate, and aspartame
Saliva stimulating agents	2-6%w/w	Citric acid, malic acid, lactic acid, and ascorbic acid
Fillers, colors, flavors	q.s.	FD and C colors, US FDA approved flavors

APPROACHES USED FOR THE FORMULATION OF FAST DISSOLVING FILMS (20)

Conventional approaches

Solvent casting method
Hot-melt extrusion
Semisolid casting

Solvent casting method

The water soluble polymers in this approach are first dissolved in water at a speed of 1,000 rpm and heated to a maximum of 60°C. Each and every additional excipient, including coloring, flavoring, sweetening, and so forth, is dissolved individually. After that, the two solutions are well combined while being stirred at 1,000 rpm. The resulting solution is combined with the API that has been dissolved in an appropriate solvent. By using a vacuum, the trapped air is released. The resultant mixture is poured onto a film, given time to dry, and then sliced into the required size pieces.

Hot-melt extrusion

Carriers aid in the formation of the initial mass in the hot melt extrusion process. The medication is combined with carriers to create the first bulk, which is then dried and solidified. Next, granular material that has dried is added to the extruder. The temperature of the four zones on the extruder are 800°C (zone 1), 1150°C (zone 2), 1000°C (zone 3), and 650°C (zone 4). In order to process the granules within the extruder barrel for around 3–4 minutes and ensure that the mass is thoroughly melted, the extruder screw speed should be set at 15 rpm. To create a film, the extrudate (T = 650°C) is then forced into a cylindrical calendar. The use of hot melt extrusion has many advantages, such as fewer operating units, less product waste, the ability to scale up, anhydrous processing, no organic solvents, reduced temperature and residence time of the drug carrier mix, and improved content homogeneity.

Semi-solid casting

This approach is often used when a polymer that is acid insoluble is used as a film constituent. First, water is used to dissolve the water-soluble polymers. The resulting solution is mixed with the separately generated acid-insoluble polymer solution. The two answers are correctly combined. Following the mixing of the two solutions, the proper quantity of plasticizer is added to the resultant final solution in order to get the mass of the gel. Finally, using heat-controlled drums, the gel mass is cast onto the films or ribbons. The film should have a thickness of between 0.015 and 0.05". A 1:4 ratio should be maintained between the acid insoluble polymer and the film-forming polymer. Cellulose acetate butyrate and cellulose acetate phthalate are two examples of acid-insoluble polymers.

PATENTED APPROACHES

The following special product advantages are offered by XGel XGelTM film for pharmaceutical and healthcare products: The film is devoid of genetically modified organisms (GMOs), acceptable for religious reasons, and appropriate for vegetarians. Its non-animal origin and continuous production processes provide a competitive and cost-

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effective manufacturing platform. XGelTM film has the capacity to include active pharmacological compounds and may be taste-masked, colored, layered, and have enteric qualities. Any oral dose form may be encapsulated in the XGelTM film systems, which are soluble in both hot and cold water. A variety of distinct water soluble polymers that have been specially tailored for the desired use make up XGelTM film.

SOLULEAVES

A variety of oral delivery films with active chemicals, colors, and tastes may be made using this technique. When saliva comes into touch with SoluleavesTM films, the active chemicals and tastes are released fast. Because of this feature, edible films are a great way to deliver a wide variety of items that need to release quickly in the mouth. When it comes to pharmaceutical applications, this mode of administration is particularly helpful for young patients or the elderly who may have trouble swallowing regular pills or capsules. The distribution method may be used to nutritional product administration as well as the therapeutic areas of cough/cold, gastrointestinal, and pain. Additionally, SoluleavesTM films may be made to stick to mucous membranes and release the active component gradually over a 15-minute period.

WAFERTAB

The WafertabTM medicine administration technology combines pharmaceutical active ingredients into a filmstrip that may be eaten. When the strip comes into touch with saliva in the mouth, the mechanism offers a quick disintegration and release of active ingredients. You may flavor the WafertabTM filmstrip to get even better taste masking. The active component is carefully dosed and incorporated into the body of an XGelTM film that has already been made, protecting it from needless heat and moisture exposure and perhaps improving product durability. The WafertabTM method makes it possible to link together several films with various active ingredients, opening up a world of creative product design possibilities. WafertabTM is a versatile product that comes in several sizes and shapes, making it the perfect choice for patients who have trouble swallowing or for the administration of medications that need to release quickly.

TENSILE STRENGTH (18)

The greatest stress given to a strip specimen before it breaks is known as its tensile strength. It is computed using the following formula: applied load at rupture divided by strip cross-sectional area.

Tensile strength = Load at failure × 100/Strip thickness × Strip width

PERCENT ELONGATION [26]

Strain is the result of a film sample (2 x 2 cm2) being stretched under force. In essence, strain is the strip's distortion just before it breaks from tension. The Hounsfield Universal Testing Machine is used to measure it. Generally speaking, strip elongation rises with plasticizer concentration. The formula is used to compute it:

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

TEAR RESISTANCE

The resistance a film provides to a load or force applied to the film specimen is known as tear resistance. The primary applied load is at a very slow 51 mm/min. A Newton, or pounds-force, is used to measure tear resistance. Stated differently, it represents the highest force necessary to rip the specimen.

YOUNG'S MODULUS

Elastic modulus, also known as Young's modulus, is a measurement of a strip's stiffness. It may be shown as the following ratio of applied stress to strain in the elastic deformation region:

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

With little elongation, hard and brittle strips show a high Young's modulus and tensile strength.

FOLDING ENDURANCE

Folding endurance contributes to a film's brittleness. The film specimen (2 x 2 cm2) is repeatedly folded at the same location until it breaks or a visible fracture appears. This process is used to calculate the endurance value. The folding

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endurance value of a film is determined by counting the folds it can withstand without breaking or showing any visible cracks.

IN VITRO DISINTEGRATION TEST

The moment an oral film begins to disintegrate when it comes into contact with saliva or water is known as the disintegration period. A film that dissolves quickly should have a disintegration period of between five and thirty seconds. The disintegration apparatus from the United States Pharmacopoeia (USP) may be used to measure disintegration time. By submerging the film in 25 milliliters of water in a beaker, one may visually ascertain the disintegration time using an alternative approach. Gently shake the beaker, and record the moment the film begins to shatter or disintegrate.

IN VITRO DISSOLUTION STUDIES

The quantity of medication material dissolved in a solution per unit of time under typical temperatures, solvent concentrations, and liquid/solid interfaces is known as dissolution. For dissolving testing, any of the pharmacopoeia's conventional basket or paddle apparatuses may be utilized. The greatest dosage of API and the sink circumstances will largely determine which dissolving medium is used. It is recommended to keep the dissolving media at 37 ± 0.5°C and 50 rpm. One drawback of using the paddle equipment is that oral films tend to float on top of the dissolving media. A 700 µm-opening stainless steel wire mesh sieve is used to dip salbutamol rapid dissolving film into the dissolution solvent.

DRUG CONTENT UNIFORMITY

Any standard assay procedure specified for the specific API in any standard pharmacopoeia will determine this. By evaluating the API content in each individual strip, content consistency is ascertained. 85–115% is the maximum content homogeneity.

ORGANOLEPTIC TEST

A quick dissolving formulation should have the following required organoleptic qualities: taste, flavor, and color. Given that the formulation would dissolve in the mouth, it need to have appropriate organoleptic pleasant properties. A formulation's color helps patients take it, and when oral films are given to youngsters, they should also have a pleasing hue. Therefore, the formulation's hue should be consistent and appealing. Visual examination is one method of evaluating color. The smell is the other organoleptic feature. The taste that is included into the recipe should give it a pleasant scent. In order to hide the smell of the polymer, medicine, or any other excipient, flavoring agents should be used. Another crucial component that has to be considered is taste. Specialized human taste panels are employed to assess the flavor. There have also been reports of studies that use electronic tongue measurements to differentiate between different sweetness levels in taste masking formulations. Potentiometric titration method is the foundation upon which the electronic tongue technology operates. In this case, solid samples must first be dissolved in an appropriate solvent before analysis can begin on liquid samples. Using this approach, the E-tongue software measures and records the potentiometric difference between each sensor and a reference electrode when the electrodes and reference electrode are submerged in a beaker filled with a test solution for 120 seconds.

SURFACE PH TEST

A film's surface pH must be assessed since the fast-dissolving strip's pH might have negative effects on the oral mucosa. The film's surface pH should be 7 or very nearly neutral. A mixed pH electrode may be used for this. The pH of the oral film was determined by gently moistening the OS with water and placing an electrode on its surface. For each formulation, this investigation should be conducted on a minimum of six films so that the mean ± SD may be determined. Another technique to get the surface pH of a film involves placing it on 1.5%w/v agar gel, covering it with pH paper, and then measuring the change in color of the paper to find the film's surface pH.

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CONTACT ANGLE

The measurement of contact angle forecasts the oral film's wetting behavior, disintegration time, and dissolution. The goniometer (AB Lorentzen and Wettre, Germany) is used to conduct these measurements, which must be done at room temperature. Water that has been double-distilled should be used to calculate the contact angle. A droplet of doubly-distilled water is applied to the dried film's surface. Using a digital camera, pictures of the water droplets are captured within ten seconds after their deposition. The NIH, USA's imageJ 1.28v program may be used to analyze digital images in order to determine angles.

TRANSPARENCY

One may use a basic ultraviolet (UV) spectrophotometer to measure the transparency of oral film. Position the film specimen on the inside of the spectrophotometer cell. Film transparency is determined using the formula below:

Transparency = (log T600)/b = −€c

Where T600 represents the transmittance at 600 nm, b is the thickness of the film in millimeters, and c represents the concentration.

SCANNING ELECTRON MICROSCOPY

Electron microscopy may be used to examine the surface morphology of films between various excipients and drug scanning. After inserting the film sample into the sample holder, several types of photomicrographs may be taken at a magnification of ×1000 by employing tungsten filament as the electron source.

PERMEATION STUDIES

Permeation investigations must to be done even though the oral mucosa has a permeability that is 4-1000 times higher than that of the skin. Porcine buccal mucosa and a modified Franz diffusion cell may be used to investigate the permeability. There is a donor compartment and a receptor compartment in the Franz diffusion cell. Mucosa is positioned between the two compartments, and its dimensions should match those of the receptor compartment's head. The buffer-filled receptor compartment is kept at 37 ± 0.2°C, and a magnetic bead stirrer running at 50 rpm is used to preserve thermodynamics. The mucosal surface should be in touch with a film specimen that has been slightly wet with a few drops of artificial saliva. The donor compartment should hold one milliliter of pH 6.8 artificial saliva. Samples are taken out and replaced with an equal volume of fresh medium at certain intervals. Drug penetration may be calculated as a percentage using an appropriate analytical technique.

PERCENTAGE MOISTURE LOSS

In order to ascertain the percentage of moisture loss, sheets measuring 2 × 2 cm2 are precisely cut and weighed using an electronic scale. The films were stored in desiccators with fused anhydrous calcium chloride after they had been weighed. The films need to be stored in the desiccator for 72 hours. They are removed after 72 hours, weighed once again, and the method below is used to calculate the films' % moisture loss:

Percent moisture loss = (Initial weight - Final weight)/Initial weight × 100

The purpose of the investigations on % moisture loss is to ascertain the film's physical integrity and stability.Estimating the percentage yield of buccal patches One may compute the percentage yield of buccal patches using the following formula:

% yield = Mass of the buccal patches obtained/Total weight of drug and polymer × 100

Stability study

The guidelines set out by the International Conference on Harmonization (ICH) should be followed while conducting a stability study. The produced mixture was wrapped in a unique fashion. It was first wrapped with butter paper, and then covered with aluminum foil. The packaging was then put into an aluminum bag and heat-sealed. Formulations should be stored between 30°C and 60% relative humidity (RH) between 40°C and 75% RH. The films were assessed for drug content, disintegration time, and physical appearance observation after three months.

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Storage and packaging

Single pouches, blister cards with multiple units, multiple-unit dispensers, and continuous roll dispensers may all be used to package oral dissolving strips. Certain fast-dissolving film packaging techniques, such Labtec's Rapid card and Amcor Flexible's Core-peel, are patented. The fast card has three sides that can carry three films, and it is the same size as a credit card. Each dosage may be removed on its own.

II. CONCLUSION

The significance of oral dissolving films and its many benefits over other dosage forms are highlighted in this study. When the medication is applied on the tongue or cheeks, it facilitates its quick release into the mouth. Along with formulation techniques, it lists the fundamental roles played by the many natural and synthetic polymers used to create orally dissolving films. It provides details on how to conduct assessment exams. finally comes to a conclusion on how well people are using oral dissolving films to get instant relief from their illness or condition.

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