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A Review on Recent Advances in Mouth Dissolving Film

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ABSTRACT: As the Mouth dissolving film is the most preferable oral solid dosage form because of its flexibility and easy, comfort in administration. These films are disintegrates and dissolve within a moment when placed in mouth without taking water or chewing. Mouth dissolving films helps to allows the medication to bypass the first pass metabolism so bioavailability of medication may be improved, also improve onset of action lower the dosing and eliminate the fear of chocking. In the Formulation of mouth dissolving film involves both the visual and performance characteristics as plasticized hydrocolloids, active pharmaceutical ingredient taste masking agents are being laminated by solvent casting and semisolid casting method. Solvent casting method is that the most preferred method over other methods because it offers great uniformity of thickness and films prepared having fine glossy look and better physical properties. Mouth dissolving films are evaluated for its various parameters like thickness, property like folding endurance, disintegration and dissolution time.
This review gives a thought about formulation techniques, evaluation parameters, overview on packaging and a few available marketed products of mouth dissolving films.
KEYWORDS: Mouth dissolving film, techniques, fast disintegration, oral dosage form.

I. INTRODUCTION

The mouth dissolving film (MDF) can be used for delivering a drug systemically to achieve the therapeutic or pharmacological effect. MDF formulations have improved systemic bioavailability as it escapes first pass effect [1,2]. Drug(s) which is to be delivered systemically, oral mucosa may be a discerning site. This may flow from to existence large area of the film which facilitates better absorption, pain avoidance also film can easily be swallowed without aqua [3]. Oral route of drug administration is a most preferred route due to its ease of administration, non-invasiveness, adaptability, patient compliance and acceptability. Regarding oral route of drug administration, many substitutes have continuously been presented by using recent novel technologies for paediatrics, geriatrics, nauseous and non-compliance patients. These systems were developed in late 1970 to function an alternate to standard dosage forms, as an example , fast disintegrating tablets and capsules for geriatrics and paediatric patients having difficulty in swallowing conventional dosage forms. A typical ODF is usually equal to the size of a postage stamp [4] . In market place, the introduction of ODT was strongly. New developments in technology have offered alternatives for oral dosage forms [5].
Orodispersible dosage forms have further advantages in patients who suffering from dysphasia (difficulty in swallowing), geriatric, and paediatric and also patients who undertaking anticancer therapy. Some available formulations like tablet, mouth dissolving films which are when placed in mouth they releases drug instantaneously with rapid onset of action [6,8] .

Table 1: Relationship between Mouth Dissolving Film and Orally Disintegrating Tablet

Mouth Dissolving Film	OrallyDisintegrating Tablet
Greater durable than ODT	A lesser durable as compared with MDF
Larger surface area gives better dissolution as this is thin film	Lesser dissolution due to less surface area as this is tablet
Suitable for drugs which need low dose	High dose can be incorporated
Patient compliance for film is more	Patient compliance is less than films

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Table 2: General composition of Mouth Dissolving Film

Ingredients	Concentration percentage
API (drug)	01–25
Plasticizer	00–20
Flavoring agents	02–10
Sweetening agents	03–06
Hydrophilic polymer/film former	40–50
Saliva stimulating agent	02–06
Color	01
Surface active agent	Quantity sufficient

The administration of Mouth Dissolving Films has numerous advantages and some of them are as follows[9]:

1. Easy transportation.
2. Ease of swallowing for geriatrics and pediatrics.
3. Convenient and accurate dosing. iv. No need of water for administration.
4. Convenient for dysphasic patients having difficulty in swallowing tablets and capsules.
5. Rapid onset of action with increased bioavailability due to bypassing hepatic first pass effect and stability.

Special features of mouth dissolving films [10]

1. Thin elegant film
2. Unconstructive
3. Available in various size and shapes
4. Fast disintegration 5. Rapid release
6. Give a pleasant mouth feel.
7. Have an acceptable taste.
8. Should not leave residues in mouth.

Advantages [11,14]:

1. It can be taken without water
2. It disintegrate/dissolve quickly in mouth
3. Flexible and light in weight
4. It is appropriate to all age group
5. Appropriate for patients who are ill or uncooperative
6. Films remain stable for longer time as it is a solid dosage form until its administration
7. The drug absorbed directly from film formulation into the blood, so it avoids undergoing first-pass hepatic metabolism which seen in conventional dosage forms
8. Rapid disintegration of film gives quick onset of action; thus, it enriches safety and efficacy profile of active pharmaceutical ingredient (API)
9. Pain-free self-administration is possible

Disadvantages

1. Dose uniformity is a technical challenge.
2. Hygroscopic in nature.
3. High doses cannot be incorporated (<40 mg/4cm2 piece)
4. Require special packaging for products stability and safety.

Formulation Aspects For Mouth Dissolving Films:

Active Pharmaceutical Ingredient:

Various classes of drugs can be incorporated into ODFs e.g., anti-histamine, anti-diarrheal, anti-depressants, vasodilators, anti-asthmatic, anti-emetic, etc. Dimenhydrinate can also be incorporated into ODFs for taste masking. Common examples of drugs incorporated into ODFs are salbutamol sulfate, rizatriptan benzoate, verapamil ondansetron, dexamethasone, rofecoxib, cetirizine, pilocarpine, tianeptine sodium, indomethacin, etc.

Film Forming Polymer:

Water-soluble polymers are used as film formers as they provide quick disintegration, good mouth feel, and mechanical strength to the films. The robustness of the strip depends on the type of polymer and its amount in the formulations. A variety of polymers are available for preparation of films of which pullulan, gelatin and hypromellose are most commonly used. Examples of watersoluble polymers include: Pullulan, Gelatin, guar gum, xanthan gum, Hydroxyl propyl methyl cellulose (HPMC), Modified starches, PVPK30, PVA etc. HPMC E3/E5/E6/E15.

Ideal properties of the polymers used in the oral film[15]:

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1. Polymers should be nontoxic, non- irritant and non-bitter.
2. Polymers should be tasteless
3. It should be devoid of leachable impurities
4. It should be inexpensive and readily available
5. It should not be an obstacle in the disintegration time
6. It should have good wetting and spreadibility property
7. It should exhibit sufficient peel, shear and tensile strength
8. It should not cause secondary infection in the oral cavity and should have sufficient shelf life.

Plasticizer:

It avoids breakability of films. It should have compatibility with other ingredients. Some excipients are such as polyethylene glycol, phthalate, citrate derivatives, and castor oil [16]. The concentration of plasticizer usually ranges from 0% to 20% w/w. Common examples of plasticizers are PEG, glycerol, diethyl phthalate, triethyl citrate, tributyl citrate, etc[17]

Sweetening agents:

Artificial or natural sweetening agents are often utilized in MDFs. samples of some sweetening agents are sucrose, fructose, aspartame, sorbitol, acesulfame-K, and sucralose, etc [18]. Some suitable sweeteners include: (1) Water soluble natural sweetener: xylose, ribose, glucose, sucrose, maltose, stevioside etc. (2) Water soluble artificial sweetener: sodium or calcium saccharin salts, acesulfame-K etc. (3) Dipeptide based sweetener: aspartame.

Saliva stimulating agent :

These are useful to reinforce the saliva creation within the mouth that provides quick disintegration. The samples of used acids are like tartaric, lactic, malic, ascorbic, and citric [19] .

Surfactant:

Surfactants are used as solubilizing or wetting or dispersing agents as a result that the film gets dissolved within seconds and release active immediately. Surfactants also improve the solubility of poorly soluble drugs in fast dissolving buccal films. E.g.: Polaxamer 407, sodium lauryl sulfate, benzalkonium chloride, benzthonium chloride, tweens and spans etc.

Flavor:

Flavors are needed to mask the bitter or nauseating taste of incorporated drug. Amount of flavor depends upon its nature and strength. Any US-FDA approved flavor are often used like sweet, sour or mint flavor one among the research work verified that mint, licorice and sucralose mixture flavors appropriately mask the bitter taste of Voltaren . Electronic tongues are wont to discriminate the effect of varied taste masking agents (TMAs)

Colouring Agent:

Pigments like titanium oxide or FD&C approved coloring agents are incorporated (not exceeding concentration levels of 1%w/w) in oral strips when a number of the formulation ingredients or drugs are present in insoluble or suspension form [20] .

Methods utilized in Preparation of Mouth Dissolving Film

Anyone of the subsequent or a mixture of one or more methods is often followed for creating film formulation.

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

Solvent casting method:

Films are often prepared using this method, the ingredients which are water-soluble are taken inaccurate quantity and are mixed well in beaker to form a transparent solution. In other beaker containing suitable solvent add accurately weighed API and other ingredients. Then, both beakers containing formulation ingredients are mixed with stirring and eventually cast into the Petri plate then allow it to dry for a few period and cut the film into the acceptable size [21,22].

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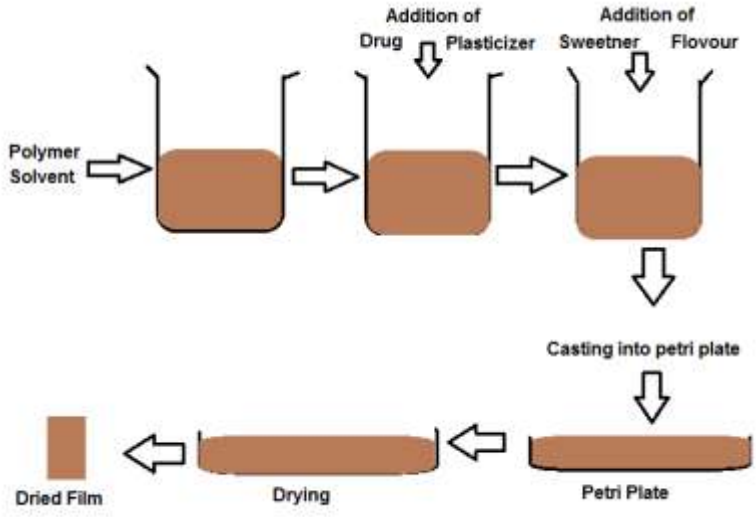

Figure 1: Solvent Casting Method

Hot Melt Extrusion:

Hot melt extrusion may be a technique during which a mix containing drug, polymer and excipients is extruded under heat to make a uniform mass which is then coasted to make smooth films. this is often a solvent free process; however, the processing of thermolabile substances may be a major drawback of this process thanks to the utilization of heat during extrusion [23].

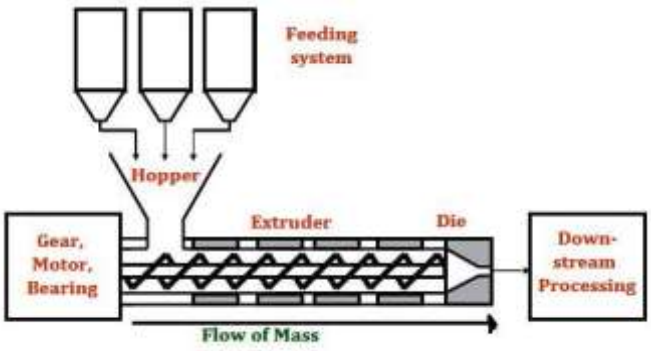

Figure 2: Hot Melt Extrusion

Semisolid casting method :

If films formulation contains some acid insoluble polymers, then this system is appropriate[24] . The samples of such polymers are cellulose ester butyrate cellulose ester phthalate. generally , film former and acid insol. polymer utilized in ratio of 04:01 [25,26].

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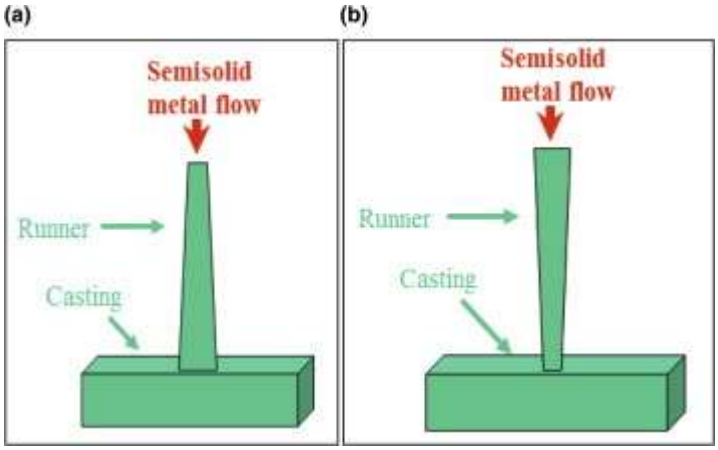

Figure3 : Solvent Casting Method

Solid dispersion extrusion:

When some immiscible substances are extruded with API during this methodology is followed. Solid dispersions are prepared, then these are designed into thin films using dies [27] .during this method extruder is employed for intense mixing of components. The components of the extruder are barrel, hopper, a kneading screw, heating jacket, and a die [28] . Generally physical mixture of both the carrier and drug is introduced into the hopper then skilled screw and eventually it's extruded from the die (figure 4). The advantage of the tactic is to urge various shapes and styles of the heated drug-matrix mixture into ophthalmic inserts, implants, or oral dosage form [29, 30] .

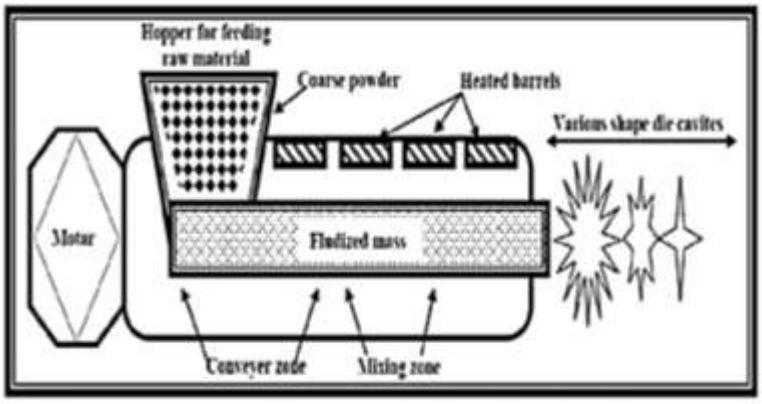

Figure 4 : Solid dispersion extrusion

Rolling Method[31, 32] :

Plot of rolling method is prepared solution should possess specific rheological properties for rolling onto the drum. Preparation of suspension of drug and polymer in water or alcohol Suspension is subjected to rollers Suspension is subjected to rollers evaporation of solvent.

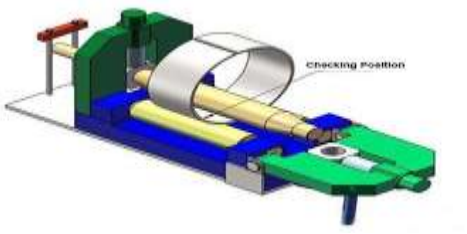

Figure 5 : Rolling Plate Method

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Packing and storage of mouth dissolving film

Blister card are often used as a packaging system for films. Single/unit packaging system is required. Widely used packaging- aluminum pouch, stored during a dry place [33] .

Figure 6: Packaging of film

Evaluation Parameters

Thickness test:

Thickness of a film is decided by using calibrated digital micrometer then subsequently mean average is calculated. Generally, three readings from all the batches are determined and average is calculated. Weight variation of a film is calculated in triplicate by cutting the film and determining weight of every film. Uniformity in thickness is vital to as certain because it is directly proportional to dose accuracy of the film[34] .

Tack test:

Tack is that the tenacity with which the film adheres to the accessory that has been pressed into contact with strip. This test also determines the dryness[35].

Tensile strength:

Tensile strength is defined as maximum stress applied at which the film breaks. Basically, this test is performed to measure the mechanical strength of films. It can be calculated from applied load at rupture divided by the strip cross-sectional area given in the equation below [36,37].

Tensile strength = Load at breakage/ Strip thickness × Strip Width

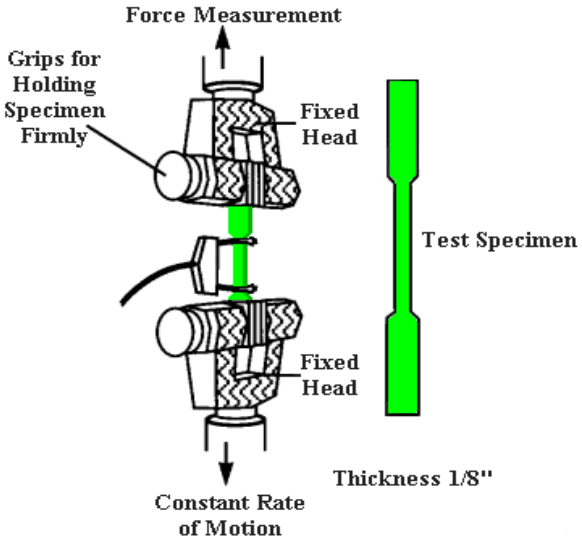

Figure7 : Tensile Strength Measurement Device

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Percentage elongation:
When the sample films are subjected to tensile stress, deformation of the films occurs leading to stretching or elongation of sample. it's performed to predict the ductility of polymers employing a texture analyzer.
it's calculated by formula:% Elongation = Increase in length ×100 / Original length

Folding endurance:
To determine folding endurance, some of film is cut and repeatedly folded at an equivalent point till it breaks. the amount of times the film might be folded at an equivalent point without breaking indicates the folding endurance value. Typical folding endurance for a film ranges between 100-150[38].

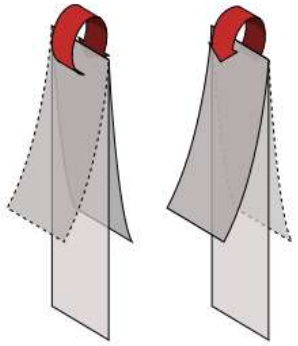

Figure 8: Double fold Film

Swelling property:
Simulated saliva solution is employed to see the swelling studies of films. Initial weight of film is decided and is placed in pre weighed chrome steel wire mesh. This mesh containing film is then dipped into simulated saliva solution. Increase within the weight of film is noted at constant pre-determined time intervals until no more increase in weight. Degree of swelling is decided by these parameters:
Degree of swelling = final weight (wt) – Initial weight (w0)/ Initial weight (w0)
Wt = weight of film at time interval t, w0 =weight of film at time 0.

Surface pH:
The pH value of a film is typically determined by putting the prepared film in Petri dish and subsequently film is formed wet by using water and noting pH by touching the film surface with a pH meter electrode. Determination of surface pH is significant as acidic or basic pH is susceptible to cause oral mucosal irritation [38].

Content uniformity:
Contents of a film are determined by standard assay method specified for individual drug in several pharmacopoeia. This test is performed on 20 samples using analytical techniques. The acceptance value of the test is a smaller amount than 15% in accordance with Japanese pharmacopoeia. consistent with USP27, the contents should range from 85% to 115% with the quality deviation of but or adequate to 6% Content uniformity is figured out for estimating drug contents in individual film [39,40].

Disintegration time:
Disintegration apparatus mentioned in official pharmacopoeias is employed for determining the disintegration time of a film. Normally, the disintegration time is that the function of composition of film because it varies with the formulation and usually ranges from 5 to 30 s. Mostly, the USP disintegration apparatus is employed for this test. There are not any official guidelines available for determining disintegration time of orally fast disintegrating films. There are two methods for determining disintegration time of film[41] .

Slide frame method:
A drop of water is poured onto the film clamped into slide frames placed on Petri dish . Time taken by the film to dissolves noted [42] .

Petri dish method:
A film is placed into 2 ml water taken in Petri dish . Time taken by the film to dissolve completely is taken into account because the disintegrating [43].

In-vitro dissolution test:
Standard official basket or paddle apparatus is employed for conducting dissolution studies on films. Sink conditions should be maintained during dissolution. Sometimes while

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performing this process, film floats over the medium making it difficult to perform the test properly. This problem is more likely to occur just in case of paddle method thus the basket apparatus is usually preferred. Media used are 6.8 pH phosphate buffer (300 ml) and 0.1 N HCl (900 ml). Temperature is maintained at 37 ± 0.5 C and rotation speed of fifty rpm is typically adjusted. Samples of drug dissolved are collected at pre-determined intervals and are analyzed by using UV-spectrophotometer. Despite its extensive use, dissolution test remains susceptible to noteworthy inaccuracy and tests disappointed [44, 45].

II. CONCLUSION:

The Mouth dissolving film formulations are one among the innovative approaches within the pharmacy field in future it's going to become one among the promising dosage forms for treatment of disease or disorders. These novel formulations have improved and better patient compliance also as acceptance, with enhanced safety and effectiveness than conventional formulations. Mouth dissolving film has numerous advantages and resulting in improved therapeutic response. at the present , these formulations are available just for the management of some diseases so reflecting their importance likely other diseases are often managed by making film formulations using suitable Active Pharmaceutical Ingredient.

Abbreviations :"Not Applicable"

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