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A Brife Review on Mouthdissolving Film

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ABSTRACT:-
Mouth Dissolving Film is the solid oral drug delivery system, in which water soluble polymer is involved to disintegrate film into mouth fastly. Mouth dissolving film keep into mouth it rapidly disintegrates into mouth and absorbed via mouth and directly reach into systemic circulation via avoiding first pass metabolism. Basically those drugs irritate to gastro intestinal tract, suffering from first pass metabolism, having less dose and shows sufficient water solubility are eligible for preparation of mouth dissolving film. To make mouth dissolving film mostly anti-inflammatory, antiemetic, anti-allergic, antihypertensive and anti-epileptic drugs areconsidered. In this article we have given drug eligibility criteria for making film, Formulation aspect, advantages, method of preparation and Evaluation parameters for mouth dissolving film. Briefly explained studies on drug alongwith polymer{1}

INTRODUCTION:-

The phrase "orodispersible" refers to dose forms that disperse or dissolve in the oral cavity, or mouth. According to monograph1, the ideal time for orodispersible tablets to dissolve should be no longer than 3 minutes. Oral administration, which receives the majority of patient complaints, provides additional benefits for patients with dysphagia (difficulty swallowing), geriatric and paediatric patients, as well as those receiving anticancer therapy. They come in tablet and mouth-dissolving film dosage forms that, when placed in the mouth, instantly release the medicine with a quick onset of action.

Orodispersible films are thin polymeric rectangular strips that dissolve or disintegrate virtually instantly when placed on the tongue. Various terminology, such as wafer, oral film, thin strip, orally dissolving film, flash release wafer, quick dissolve film, and melt-away film, can be found in the literature. 2-5.

ODFs have just been added to the European Pharmacopoeia's monograph on "oromucosal preparations." However, no requirements governing the duration of disintegration have yet been established.

An ideal ODF should have sufficient flexibility, elasticity, softness, resistance to breaking, quick disintegration, and conformity with taste. All of these factors must be taken into consideration while developing a formulation and following the necessary standard procedures.

The orodispersible films can be characterised and evaluated using a variety of methodologies that draw on everything from physical and mechanical characteristics to in vitro disintegration to in vivo drug release in humans. This review describes several in vitro and in vivo techniques used by the pharmaceutical industry, government agencies, and researchers studying drug delivery to describe the mechanical and physical characteristics of ODF.(5)

- **HISTORY OF MOUTH DISSOLVING FILM:-**

History of Fast Dissolving Oral Films was first familiarized by North America in 1970(4). At that period, the oral films were introduced as mouth fresheners and personnel care merchandises. Pfizer was the founder designer of fast dissolving films who entitled it as Listerine pocket packs and it was used as a breath freshener. However, European markets and United States promptly framed fast dissolving filmsAt this moment there are 15 companies which are formulating oral fast dissolving films by ever-changing from formulation of tablet dosage form. The report ascertains that Lab tec GmbH, APR settled a unique technology for the formulation of oral fast dissolving films. In the preceding few years, oral strips get admiration in the breath freshening by rapidly dissolves to discharge minty flavour. Pharmaceutical companies are now making these oral strips as over the counter and prescription pharmaceuticals.{3}

- **IDEAL PROPERTIES:-**

The ideal requirements for ODF are summarized below.

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- ODF should be thin and flexible, but stable to guarantee a robust manufacturing and packaging process and ease of handling and administration.
- The films should be transportable, not tacky and keep a plane form without rolling up.
- Ease of administration for patients who are mentally ill disabled and uncooperative.
- They should provide an acceptable taste and a pleasant mouth-feel.
- Require no water.
- Disintegration time should be as short as possible.
- They should exhibit low sensitivity to environmental conditions such as temperature and humidity.
- They should have ability to provide advantages of liquid medication in the form of solid preparation.
- Size of a unit FDF should not be too large that it will affect the patient's compliance.
- Surface of the FDF should be smooth and uniform.
- They should remain physically and chemically stable throughout its shelf life.
- Cost effective and ease of commercial production.

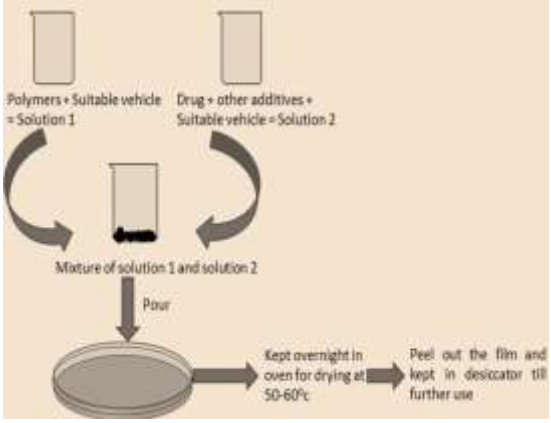
- **SPICIEAL FEATUREAS:-**
- Thin elegant film
- Unconstructive
- Available in various size and shape
- Fast disintegration
- Rapid release
- Give a pleasant mouth feel
- Should not leave residue in mouth(4)

- **MANUFACTURING METHODS:-**

1) Solvent casting method
2) Hot melt extrusion method
3) Semi solid casting method
4) Rolling method

1)SOLVENT CASTING METHOD:-

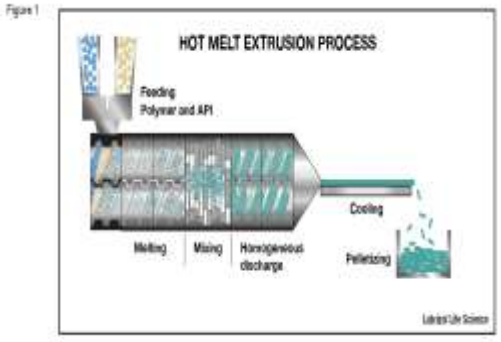
Polymers that are water soluble are dissolved to create a homogeneous solution. Drugs and other water-soluble components are given a little amount of water to dissolve in. With constant stirring, the two solutions are combined. Vacuum is used to release air bubbles that have become trapped. The produced solution is thrown onto an untreated surface. Cut into bits and subjected to drying11. Figure: 1 (from Particle Science) provides information on the solvent casting process.(5)



2) HOT MELT EXTRUSION METHOD:-

With this technique, polymer is heated and shaped into a film. First, a hopper is filled with the medication and polymer mixture, which the extruder then conveys, mixes, and melts. A die moulds the melt into the desired shape. This approach uses a low temperature and quick.

The drug polymer combination had a residence time of about two minutes. This process doesn't utilise organic solvents and it can run continuously with little product waste. This technique effectively controls operating parameters. (4)



- SEMI SOLID CASTING METHOD:-

Polymers that are soluble in water are dissolved to create a homogeneous solution. Drugs and other water-soluble components are given a little amount of water so they can dissolve in it. Continuous stirring is used to combine the two solutions. Vacuum is used to release air bubbles that have become trapped. Onto an untreated surface, you throw the generated solution. Separated pieces are dried(5)

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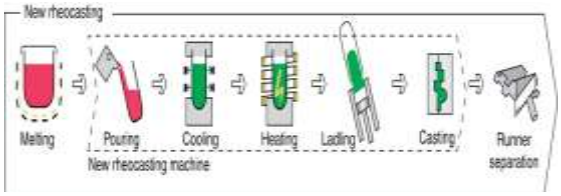
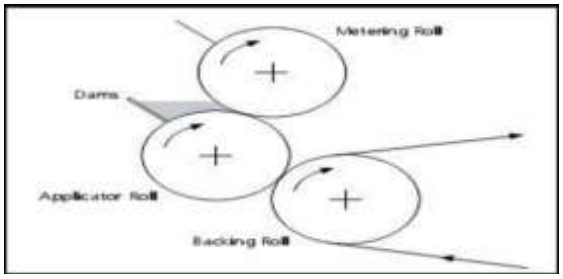


- ROLLING METHOD:-

To make a homogenous solution, water-soluble polymers are dissolved. A small amount of water is provided to drugs and other water-soluble components so they can dissolve in it. The two solutions are blended by constant stirring. In order to free trapped air bubbles, vacuum is utilised. You pour the produced solution onto an untreated surface. Pieces are separated and dried.(5)



- **ADVANTAGES OF MOUTH DISSOLVING FILM**:-
- Effective in conditions that call for a rapid initiation of action, such as motion sickness, allergic reaction, asthma or a cough
- Has several uses in pharmaceuticals, Rx Prescriptions, OTC drugs, and dietary supplements for treating pain, cough/cold, gastro-esophageal reflux illness, erectile dysfunction, sleep problems, etc.
- Since no water is needed for administration, it is appropriate for travel
- A number of medications are absorbed from the mouth, throat, and oesophagus as saliva travels into the stomach, increasing the bioavailability of such medications.
- By providing a high surface area and dissolving quickly, it may provide increased bioavailability for medications that are poorly water soluble.
- After administration, leaves little to no residue in the mouth. Has the capacity to offer liquid medicinal benefits in the form of a solid formulation.
- Compatible with already-in-use processing and packaging equipment
- Reasonably priced
- Provides more precise dosage than liquids
- Gives off good chemical stability
- Does not require measuring, which is a crucial flaw with liquids
- Offers product differentiation and market expansion
- Can be created and released in 12–16 months, resulting in a shorter product development lifecycle.(6)

- **DISADVANTAGES OF MOUTH DISSOLVING FILM:-**
- Technically, dose uniformity is difficult.
- High doses cannot be included since they are hygroscopic,
- they need particular packaging for the products' stability and safety.(8)

- **FORMULATION OF MOUTH DISSOLVING FILM:-**
- API:-choosing an API for the film's composition very important task due to medication loading capacity is pretty little into the movie. As a result, up to 40 mg API fill the film with. Drugs shouldn't aggravate people, bitter. Most frequently, the medication that causes first pass metabolism and gastric discomfort are compatible for the creation of films. Drugs should have enough Water permeability and solubility indicate membership from BCS Class 1 Substances.(9)

- FILM FORMING POLYMER:-mainly used water soluble polymer making of the film. Polymer concentration is important. essential part in the creation of the picture. If In that scenario, the polymer content is higher. take extra time for the aim of disintegration. Ultimately More film thickness is also possible. percentage of Polymer also contributes to the durability of folding Low focus during a movie results in the bare folding toughness leading to very readily film breaking strength when film is folded. Pullulan, gelatine, guar gum, and xanthan gum are examples of natural polymers. Hydrogenated propyl methyl cellulose (HPMC), modified starches, PVPK30, PVA, and other synthetic polymers are examples.E3/E5/E6/E15 HPMC.(9)

- SALIVA STIMULATING AGENT:-

These are the agent which responsible for the production of saliva. When we keep film into

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the mouth so for the dissolution purpose we need saliva therefore adding of the saliva stimulating agent into the formulation. If more amount of the saliva in the mouth then film dissolve easily and very less time. The basically used saliva stimulating agent include Citric acid, tartaric acid, ascorbic acid ,lactic acid and malic acid.(9)

- PLASTICIZER:-

Plasticizer plays an important role in to give flexibility to film. For the formulation purpose flexibility, tensile strength, elongation is very necessary so with adding of plasticizer we can get all this properties in the film. Concentration of plasticizer also impact on the film formulation like more amount of plasticizer in the film leads to turbidity to the film. Commonly used plasticizer include Tween 80, PEG-400.(9)

- COLOURING AGENT:-

Colouring agentcolour to the film. In some the cases some problem observed like bubble entrapment and transparency do not maintain so in such kind of cases we can add colouring agent. Most commonly used colouring agent include FDC approved natural colouring agents and natural juice(9)

- SWEETNER:-

To provide the formulation a sweetening effect, sweetener is added to the recipe.
Some medications have an extremely bitter taste, thus we add sweetness in those cases. The sweeteners Sodium Saccharin, Mannitol, Aspartame, and Neotame are the most widely used.(9)

- FLAV0UR:-

To disguise the unpleasant or bitter taste of an included medicine, flavours are required. The degree of flavour is dependent on its character and power. You can use any US-FDA-approved flavour, such as sweet, sour, or mint flavour. One study confirmed that a sucralose, liquorice, and mint flavour combination effectively hides the bitter taste of diclofenac sodium. To differentiate between the effects of various taste-masking chemicals, electronic tongues are used. (3)w

- **Evaluation Of Mouth Dissolving Film:-**
- Organoleptic properties:-

An organoleptic featuresare evaluated based on colour, odour, and taste.(1)

- Physical appearance and surface texture:-

Body shape was examined optically, and smoothness on the outside was assessed through touch or the film's reactivity.(1)

- Thickness:-

Body shape was evaluated optically, and smoothness on the exterior was determined by touch or the reactivity of the film.(1)

- Weight variation:-

It is necessary to ensure uniformity in the film's thickness since drug content uniformity is directly related to drug thickness. It was measured using a vernier calliper or micrometre screw gauge at three dissimilar locations on the film, and the mediocre of the film was taken.(1)

- Tensile strength:-

It is nothing but the maximum stress applied to the point at which the strip specimen disrupts.(1)

$$Tensilestrength = \frac{Loadatfailure \times 100}{Stripthickness \times Stripwidth}$$

- Percent elongation:-

A strip model expands as stress is applied, and this is related to a strain. A strain is eventually the strip's distortion divided by the sample's original dimension.

$$Percentelongation = (L - L0) \times 100 / L0$$

L0 was the starting length, while L was the final length.
In general, the strip's elongation gets better as the plasticizer content rises.(1)

- Folding endurance:-

It is established by repeatedly folding the strip at the same spot until the strip becomes disrupted. The number of folds without a break is considered the folding endurance value.(1)

- Surface pH:-

The films were allowed to swell in a safe petri dish with 1 cc of distilled water for 30 minutes at room temperature. To determine the surface pH, solution was positioned beneath the digital pH metre.(1)

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- Disintegration time:-

It expands knowledge of the film's disintegration physiognomies. The required film size was placed in a beaker with 25 ml of pH 6.8 simulated salivary secretions. In vitro disintegration time is the amount of time it takes for a film to break up and liquefy into a fluid.(1).

- In vitro dissolution studies:-

This training for all the film shipments took place over the course of five minutes, and each film was placed with the help of forceps in a 50 ml glass beaker with 30 ml of simulated salivary fluid at a pH of 6.8 and 30 ml of a buffer solution. The magnetic stirrer was rotated at 50 rpm while the dissolution media was kept at 30 ℃ 0.5 ℃. The sample (5 ml) was removed after 15, 30, 1, 2, 3, 4, and 5 minutes and replaced with freshly prepared simulated salivary fluid with a pH of 6.8. Using a UV-visible spectrophotometer, the models were examined for the drug emitted.(1)

- Drug content:-

The UV-visible spectrophotometer can observe it. Every consignment's films were kept in a unique 100 ml volumetric flask that could be used to liquefy them using a pH buffer. 5 ml of the sample were taken out and transferred to a 10 ml volumetric flask, where 10 ml of bulk was added. In a UV spectrophotometer, the absorbance of the resulting solution is measured in contrast to a blank sample. Using the conventional graph, it was possible to calculate the drug content percentage. The average and variances were calculated deliberately.(1)

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