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A REVIEW OF MOUTH DISSOLVING FILM

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ABSTRACT

Mouth dissolving film is the most advanced oral solid dosage form due to its flexibility and luxury in use. Mouth dissolving films are oral stable dosage forms that fall apart and dissolve within a minute while positioned in the mouth without taking water or chewing. This dosage form allows the medicine to pass through the primary bypass metabolism, so bioavailability of medication may be improved. The mouth dissolving film has the capability to improve the onset of action, lower the dosing and cast off the worry of chocking. Formulation of mouth dissolving films includes both the visible and overall performance traits as plasticized hydrocolloids. API flavor masking agents are being laminated with the aid of solvent casting and semisolid casting approaches. The solvent casting method is the preferred method over different strategies because it gives amazing uniformity of thickness and films organized having a satisfactory glossy look and better physical properties. Mouth dissolving movies are evaluated for their various parameters like thickness, physical assets like folding staying power, disintegration and dissolution time. This evaluates provides and concept about formula techniques, evaluation parameters, packaging, and a few to be advertised mouth dissolving films products.

KEYWORD: film, elegance, polymer, saliva, rolling, plasticizer.

INTRODUCTION

The oral path is the most preferred and patient-convenient means of drug management. Most of the medication is taken in the form of drugs and tablets by nearly all patients, including adult, paediatric, and geriatric sufferers. However, about 26–50% of patients find it tough to swallow tablets and tough gelatin pills. Oral dissolution film, a new drug delivery system for oral drug delivery, was developed based on transdermal patch technology.[1] The system consists of a very thin lip strip that is simply placed on the patient's tongue or orally mucous tissue, immediately moistened with saliva, the film quickly hydrating and adheres to the application site.[2] That then rapidly decomposes and dissolves to be released. Oromucosal absorption medication or formula the fast resolution aspect enables gastrointestinal absorption through consumption. A typical ODF is usually the size of a postage stamp. The ODT launch is very powerful with respect to advising patients about what is appropriate. Include instructions like "don't chew/do" or "don't swallow." But despite these instructions, incidents of chewing and swallowing are common. However, ODF freed the masses from these harmful programs. ODF administration is very much about the benefits, and some of them are as follows:

I. Ease of transportation.
II. Easy swallowing for geriatrics and pediatrics.
III. Convenient and accurate dosing.
IV. No water is required for administration.
V. Convenient for patients with dysphasia who have difficulty with it Swallow tablets and capsules. Rapid onset of action with increased bioavailability by passing the hepatic effect of first pass and stability.

SPECIAL FEATURES[3]

1. Elegant thin film
2. Not constructive
3. Available in various sizes and shapes
4. Fast decay
5. Quick Release
6. Give you a comfortable mouth feel.
7. Have an acceptable taste.
8. Do not leave residue in your mouth.

Figure 1: Special features of Mouth Dissolving Film.

ADVANTAGES[4]

- ✓ This film reduces the fear of choking in the throat.
- ✓ The film is easy to edit and manage.
- ✓ The film requires simple and convenient Packaging.
- ✓ This film covers the unpleasant taste and is easy to work with Manufacturer.
- ✓ This system allows children, parents and the general public to take their medicine directly where and when needed.
- ✓ The mouth dissolving effect is mainly due to this large surface of the foil.
- ✓ Strong, hard, soft, flexible and render able film does not require special packaging.
- ✓ Thin film and transferable to a Patient's purse and wallet.
- ✓ Films increase the stability of some

DISADVANTAGES

- ✓ I Dose uniformity is a challenging
- ✓ II Required special packaging

CONTENT OF MOUTH DISSOLVING FILM

Table 1: Percent Content in MDF.

Sr no	Content	Percent
1	Drug	1- 25%
2	Water soluble Polymer	40-50%
3	Plasticizer	0-20%
4	Filler, Colour, Flavour	0-40%

CONSTITUENTS OF ORAL FILM FORMULATION

MDF formulation is complex Aesthetic application and execution Features like taste cover, mouth dissolution, appearance, mouthfeel etc.

The excipients used in the MDF formulation are: Given below by category. For from a regulatory point of view, all excipients are used MDF words generally should be considered safe (i.e. on the GRAS list) and must be approved for use in oral pharmaceutical dosage forms.[5]

1. Film Formers

Various polymers are available for production from MDF. Polymers can be used alone or in combination to obtain the desired properties of the tape. So the resulting film must be strong enough so there will be no damage during handling or during transportation. Band strength depends on the type of polymer and the amount On the other hand, the mouth Dosage forms for patch reconstitution should be available. The property decays in seconds when placed in the mouth and releases the drug into the oral cavity.[1]

Table 2: polymer and their example use in the film.

Sr no	Polymer	Example
1	Natural polymer	Pullulan gum, locust gum Carrageenans gum, xanthan gum,
2	Synthetic polymer	Polyvinyl pyrrolidone (PVP), Sodium, Carboxy methyl cellulose, Gelatin, Hydroxyl propyl methyl cellulose, Methocel TM E3, E5, E15, E50 and K3, Polyethylene oxide, PolyoxTM N10, N80 and N750

2. Plasticizer

Generally, mechanical properties such as tensile strength and percent elongation are increased by adding a plasticizer to the word order. The plasticizer concentration usually varies from 0% to 20% w/w. Common examples of plasticizers are PEG, glycerin, diethyl phthalate, triethyl citrate, tributyl citrate, etc.[6]

3. Sweetening agent

Sweeteners have become an important part of the diet. Products and medicinal products intended for this purpose are crushed or dissolved in the oral cavity. Of course, artificial sweeteners and sweeteners are common and increase the taste of dissolution in the mouth. Some suitable sweeteners include:

- Natural water-soluble sweeteners: xylose, ribose, glucose, sucrose, maltose, stevioside, etc.
- Water soluble artificial sweetener: sodium or calcium Saccharin salt, acesulfame-K, etc
- Dipeptide-based sweetener: aspartame

4. Saliva Stimulating Agent

Salivary stimulants are usually acid stimulants that promote the production of saliva in the oral cavity and the collapse of the ODF. Some commonly used salivary stimulants are citric, malic, tartaric acid, ascorbic acid, and lactic acid.

5. Surfactant

Surfactants are used as solvents, humectants, or dispersants, causing the film to dissolve within seconds and immediately release the active ingredients. Surfactants also increase the solubility of poorly soluble substances. Drugs in the buccal film dissolve rapidly. For example: Polaxamer 407, Sodium Lauryl Sulfate, Benzalkonium Chloride, Benztonium Bleach, Tweens and Span, etc.

6. flavor

Fragrances are needed to cover bitterness or nausea. The taste of the drug is contained. The number of flavors depends on their nature and strength. One study found that all US FDA-approved flavours can be sweet, sour, or minty. The work confirms that a mixture of mint, licorice and sucralose. The taste is enough to cover the bitter taste of diclofenac Sodium. Electronic language is used for differentiation Effect of different Flavor Masking Agents (TMA).

7. **Coloring agent**

Pigments such as titanium dioxide, FD&C approved dye included (No Exceeds concentration level 1% w/w) in oral strip if some formulation ingredients or drugs are in insoluble or suspended form.

METHOD USE IN PREPERATION OF FILM

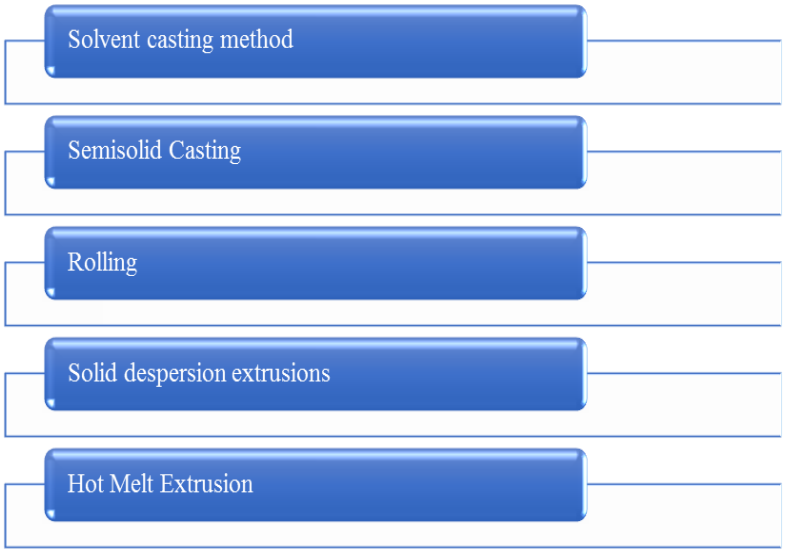

Figure 2: Methods Use in Preparation of MDF.

1. Solvent casting method
The solvent casting process involves a water-soluble polymer dissolved in water and medicine together with other excipients are dissolved in a suitable solvent, then both the solutions are mixed and stirred, and finally poured into a Petri dish and dried.

2. **Semisolid casting**
In the semi-solid casting process, the aqueous solution soluble film-forming polymers are produced. In the resulting solution is added to the acid solution of insoluble polymers (e.g. cellulose acetate phthalate, cellulose acetate butyrate), which is produced in ammonium or sodium hydroxide. Then a certain amount of plasticizer is added to obtain a gel mass. Finally, the gel mass is poured into the foil or a belt with a thermally controlled drum. Fatty the film is about 0.015-0.05 inches. The ratio of acid insoluble polymers to form polymer films must be.

3. Rolling method
In the rolling process, solutions or suspensions are obtained the drug is rolled into a carrier. The solvent is mainly water and a mixture of water and alcohol. The film is dry roll and cut according to the desired shape and size.

4. Solid dispersion extrusions
These process, immiscible components are extruded with active substance and then solid dispersion ready. Finally, a solid dispersion is formed Films with a matrix.

5. Hot Melt Extrusion
In the hot melt extrusion process, the drug is first mixed with a sturdy rope. Then an extruder heater melts the mixture. Finally, a melt is formed from the dying movies. Heat has certain advantages: melt extrusion, fewer work units. Anhydrous process with improved content uniformity.

TECHNOLOGIES
1. SOLULEAVE
This technology is used for a series of films for oral administration that can be activated with ingredients, color, and taste. SOLUBLEAVESTM films can be designed to disintegrate quickly when exposed to saliva, allowing the active ingredients to be released quickly and tasted. These characteristics make it an excellent shipping method for a wide range of products requiring rapid release in the mouth. For medicine, using this application method is very useful for paediatric or elderly patients who may have difficulty swallowing conventional tablets or capsules. The delivery system can be used for coughs and colds, gastrointestinal disorders, and pain therapy, as well as grocery delivery service. SOLUBLEAVES foil can also be designed to adhere to the mucosa membranes and for the slow release of active substances for more than 15 minutes.

2. FOAMBURST
This is a special version of SOLULEAVESTM Inert Gas Technology incorporated into the film during production. This causes film with a soluble honeycomb structure to quickly create a new feeling in the mouth. FOAMBURS arouses interest in food and confectionery producers as a mode of transportation and taste release.

EVALUATION PARAMETERS
1. Thickness Test
The film thickness is determined by a calibrated digital micrometer and then the average value is calculated. A total of three testimonials from everyone averaging is identified and average values are calculated. Weight film variation is counted three times by cutting films and determining the weight of each film. Homogeneity Thickness is important for safety and is directly proportional to film dose accuracy.[7]

2. Tack test
Beauty is persistence attached to film to the pressed accessory Tape. This test also determines dryness.

3. Tensile strength
Tensile strength is defined as the maximum applied stress at which the film is torn. Basically, this test is performed to measure the mechanical strength of the film. That can be calculated from the applied tensile load divided by the cross-sectional area of the strip and is given in the following equation.[8]
Tensile Strength = Breaking Load / Band Thickness × Strip width

4. Percent elongation
If the film sample is subjected to tensile stress, the foil deforms, resulting in stretching or stretching of the sample. This was carried out to predict polymer plasticity using a texture analyzer.[1] Calculated by the formula
% elongation = increase in length × 100 / original length

5. Folding endurance
To determine the flexural strength, parts of the film are repeatedly cut and folded in the same place until it breaks. How many times can the foil be folded? The same point without breaking indicates folding durability value. The typical foil fold thickness ranges between 100 and 150.[9]

6. Swelling properties
A simulated saliva solution is used. Check film source studies. The initial weight of the foil is determined and placed in a pre-weighed stainless steel wire network. This mesh sheet is then dipped in a simulated saliva solution. The weight gain of the film is from time to time at a predetermined constant interval. The degree of swelling is determined 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 time0

7. Surface PH

The pH of the film is usually determined by Place the prepared film in a petri dish, moisten it with distilled water, and record the pH. Touch the surface of the film with the pH metre electrode. Determining the pH of the surface is as important as the pH of an acid or base can cause irritation of the oral mucosa.

8. Content uniformity

Film contents are determined by standard analytical method specified for a single drug product in various pharmacopoeias. This test will be held on April 20 the sample uses analytical techniques. Acceptance value of Test score less than 15%, according to Japanese pharmacopoeia. According to USP27, content must be ranges from 85% to 115% with a smaller standard deviation greater than or equal to 6% content uniformity has been developed Assessing drug content in films alone.[5]

9. Disintegration time

The Disintegration is the official pharmacopoeia used for the determination of film disintegration. Usually resolution Time is a function of film composition as it varies with it formulation and usually varies between 5 and 30 seconds The USP decay apparatus was used for this test. There are no official guidelines for determination Disintegration time the film quickly disintegrates by mouth.[10]

2. Slide Frame Method

Pour a drop of distilled water on film mounted on a slide mount placed on a Petri dish. The time until the film dissolved was recorded.

3. Method of Petri dish

The film is placed in 2 ml of distilled water in a Petri dish. The time it takes the film to reveal a completely decomposing.

Dissolution Test in Vivo

Formal standard basket or paddle. This device is used to conduct dissolution research films. The condition of the sink must be considered during this time frame. Sometimes you film during this process, hovering above the center, making the test difficult. This problem is more likely to occur in the case of the rowing method, which is mostly basket equipment. Phosphate buffer pH 6.8 (300 mL) and 0.1N HCl (900 mL) were used as the media. Is maintained at 37 0.5 C and a speed of 50 rpm is set. Dissolved drug samples are collected at predetermined concentration intervals and analyzed by a UV spectrophotometer. Despite its widespread use, the dissolution test is still susceptible to inaccuracies and misguided testing.[11]

CONCLUSION

This rating shows that lips quickly destroy the film and is a new approach in the field of Pharmaceutical Science. You have increased acceptance and adherence in patients without the associated risk of shortness of breath with better safety and efficacy than conventional dosage forms. The basic idea behind it is that the words of the ODF must overcome the difficulties in taking conventional oral dosage forms at the pediatrician's, geriatric and psychiatric patients with Dysphagia. Now, ODFs are widely used for high blood pressure, hyperacidity, allergies, pain, etc., reflecting their importance. The main advantage of one of these dosage forms is its use without the use of water that meets the needs of the target group. Convenience in administering drugs together with bypass liver metabolism leads to an increased therapeutic response.

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