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FAST DISSOLVING FILMS: AN INNOVATIVE APPROACH TO ORAL DRUG DELIVERY

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Abstract:
Fast dissolving films is a novel approach that are rapidly gaining interest for the patients having difficulties in swallowing or chewing of solid dosage forms such as tablets or capsules. Fast-dissolving drug-delivery systems were first developed in the late 1970s for pediatric and geriatric patients who experience difficulties in swallowing traditional oral solid dosage forms. These films may deliver the drug in a systemically manner through sublingual or buccal route and also used for local action. The present review reflects the information regarding the ideal characteristics, method of preparation and evaluation tests employed for fast dissolving oral films. However, for future growth point of view these films sector is well-positioned. It shows that the value of overall oral thin films market will be grow significantly.

Keywords: *Introduction, ideal characteristics, method of preparation, evaluation parameters and marketed products of fast dissolving films.*

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INTRODUCTION:

Fast dissolving films is a novel approach that are rapidly gaining interest for the patients having difficulties in swallowing or chewing of solid dosage forms such as tablets or capsules. [1]

The oral route is most preferred route of drug administration for systemic effect, despite of tremendous advancement in drug delivery system. Due to its ease of administration, avoidance of pain and various advantages over other routes is mostly used. [2, 3]

A film or strip may composed of a water-soluble polymer that allows it to quickly hydrate, adhere, and dissolve when placed on the tongue or in the oral cavity to provide rapid local or systemic drug delivery. [4]

ADVANTAGES

Improve patient compliance.
Un-obstructive (no risk of chocking).
Accurate or convenient dosing.
Provides controlled release that facilitates rate and extent of absorption of drugs.
Applicable for the delivery of the drugs that shows high risk of degradation in GIT.
Enhance the disintegration/dissolution of drug molecule.
Provides rapid drug release as well as rapid onset of drug action.
Easy to handle and transport.
No need of water to swallow.
Enhanced the stability of drug.
Ease of administration.
Improves the bioavailability of drug molecules.
Due to low dose, low side effect. [5, 6]

DISADVANTAGES

These films are difficult to pack because its packing requires special equipments.
These films are not suitable for those drugs which can irritate and are unstable at buccal pH.
Oral films are used only for small dose of drug administration.
These are hygroscopic in nature. So, requires longer preservation.
In many cases the restriction of eating and drinking is done after consumption of oral film.
Method for preparation is not so easy. [7, 8, 9]

IDEAL CHARACTERISTICS OF FILMS

Fast dissolving oral films should have pleasant taste.
Drug should be stable to moisture overtime and soluble in saliva.
These films should exhibit suitable tensile strength and gives excellent mucoadhesion.
Films should not stick to the packing material and fingers.
These should be ionized at pH of oral cavity.
Films should be able to permeate the oral mucosal tissue.
Fast dissolving films are available in various size and shapes.
These films should have quick onset of action.
Only small and moderate molecular weight drugs are preferable.
Widely used for drugs that should have high first pass metabolism.[10,11]

Table1: Comparison between oral dissolving films and oral disintegrating tablets [11]

Orally Dissolving Films	Oral Disintegrating Tablets
It is a film	It is a tablet
These films may shows greater dissolution due to larger surface area	These shows lesser dissolution due to less surface area
Shows better durability than oral disintegrating tablets	Shows less durability as compared with oral films
Shows more patient compliance	Shows less patient compliance than films
Only low dose can only be incorporated	High dose can be incorporated
No risk of chocking	It has a fear of chocking

METHOD OF PREPARATION OF FAST DISSOLVING ORAL FILMS

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

1. Solvent casting method

Water soluble polymers are dissolved in water

↓

Drug and other excipients are dissolved into suitable solvent

↓

Then mix both the solutions and stirred well

↓

Degassed under vacuum

↓

Finally, casted into Petri plate

↓

Dry in oven at 40-50°C

↓

Cut into the pieces of desired size. [12]

2. Semisolid casting method

A solution of water soluble film forming polymer is prepared

↓

Add it to the solution of acid insoluble polymer, prepared in ammonium or sodium hydroxide like cellulose acetate phthalate, cellulose acetate butyrate

↓

Add suitable amount of plasticizer to obtain a gel mass

↓

Gel mass is casted into film or ribbon by using heat controlled drums

↓

Then degassed it under vacuum

↓

Coat the bubble free solution on non-treated casting film

↓

Coated film is dried in aeration drying oven

Cut into desired shape and size [13, 14]

3. Hot melt extrusion method

Mix the drug with carriers in solid form

Then introduced the dried granular material into the extruder

Set the screw speed at 15 rpm in order to process the granules inside the barrel of the extruder for approximately 3–4 min.

The processing temperatures should be 80°C (zone 1), 115°C (zone 2), 100°C (zone 3) and 65°C (zone 4).

To obtain a film, pressed the extrudate into a cylindrical calendar.

Benefits of hot melt extrusion

- Fewer operation units
- Better content uniformity
- An anhydrous process[15,16]

4. Solid dispersion extrusion

Dissolve the immiscible drug in a suitable solvent

Then incorporating the above solution into melted polyethylene glycol: below 70°C

Solid dispersion are prepared

Finally dispersions are shaped into the films by means of dies. [17]

5. Rolling method

In rolling method, a solution containing drug is rolled onto a carrier

Water is mainly used as solvent and mixture of water and alcohol

The film is dried onto the rollers

Then cut in to desired shapes and sizes. [18, 19]

EVALUATION PARAMETERS

1. Thickness

The thickness of films can be measured by micrometer screw gauge at different locations. It directly related to the accuracy of dose in the strip.

2. Mechanical properties

A mechanical property includes tensile strength, tear resistance and percentage elongation are calculated below:

- **Tensile strength**

Maximum stress applied to a point at which the strip specimen breaks is called tensile strength. It is calculated by formula:

Tensile strength = Load at Failure * 100 / Strip thickness * Strip Width

- **Tear resistance**

It is the maximum stress or force (that is generally found near the onset of tearing) necessary to tear the specimen is called a stear resistance value in newtons (or pounds- force).

- **Percentage elongation**

It is calculated by formula

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

3. Folding endurance

It can be determined by folding the films of uniform cross sectional area and at uniform thickness at the same place repeatedly until it breaks. [20]

4. Swelling property

Weighed the film and placed in a previously weighed stainless steel wire mesh. Then submerged it into 15ml medium (simulated saliva solution) in a plastic container. Increase in the weight of the film is determined at preset time interval until a constant weight is observed.

$$\text{Degree of swelling} = W_t - W_0 / W_0$$

Where,

W_t is weight of film at time t

W_0 is weight of film at time zero [21]

5. Disintegration time

It is determined visually by placing the film in a glass dish of 25ml distilled water with swirling every 10 sec. The disintegration time is the time at which the film starts to break or disintegrates. The disintegration time for fast dissolving films is 5–30sec. [22]

6. Dissolution test

It can be performed in simulated saliva solution or pH 6.4 phosphate buffer using the standard basket or paddle apparatus as described in any of the pharmacopoeia at 37±0.5°C. Samples are withdrawn at regular time intervals and analyzed by UV-Visible spectrophotometer. [23, 24].

TABLE 2: MARKETED FAST DISSOLVING ORAL FILMS [25]

Product	Manufactured by	Indication
Caffeine films	Dow chemical company	CNS stimulant
Dextromethorphan fast dissolving films	Hughes medical corporation	Anti- tussive agent
Ondansetron Rapidfilms®	Labtec Pharma	Postoperative nausea and vomiting
Methylcobalamin fast Dissolving films	Hughes medical corporation	Peripheral neuropathy, Diabetic neuropathy
Chloraseptic® Relief stripsTM	Innozen Inc	Minor irritation, pain and sore throat.
Folic acid fast Dissolving films	Huges Medical Corporation	Anaemia
Triaminic Thin Strips®	Novartis Pharmaceuticals	Nasal decongestant
Diphenhydramine Hydrochloride films	MonoSolRX	Antihistaminic

CONCLUSION:

From above, this can be concluded that fast dissolving oral films have proved to be an innovative approach for all groups of population or patients with problem of swallowing. Whenever rapid onset of action is required like incase of asthmatic attack, cardiac heart failure and in epilepsy fast dissolving oral films have proved to be beneficial. These films are used as a tool to increase the life cycle of the existing product by getting patent of same product as fast dissolving oral films. So this technology is growing in fast pace challenging most of the pharmaceutical companies to develop oral films for a wide range of active pharmaceutical ingredients. A lot of research work is going on and will be started in near future on fast dissolving oral film. However, for future growth point of view these films sector is well-positioned. It shows that the value of overall oral thin films market will be grow significantly.

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