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# A Short Review on "A Novel Approach in Fast Dissolving Film & their Evaluation Studies"

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## ABSTRACT

In case of chronic illnesses, fast-dissolving drug delivery systems were developed as an oral medication administration alternative to traditional dose forms. For masking the taste of unpleasant drugs and enhancing patient compliance, fast-dissolving films are now recommended over traditional tablets and capsules. Fast dissolving films consist of a very thin oral strip that dissolves in less than one minute when placed on the tongue. Customers have responded positively to dissolvable oral thin films in the form of breath strips, which have been on the market for a few years and are used to administer vitamins, vaccinesand other medicinal products. In fact, the review goes through the various production methods for film preparation. The current review summarizes the majority of recent patents on fast-dissolving films. A brief analysis of the several factors considered to analyse such films has been carried out. These fast-dissolving films are better to other oral traditional dose forms in terms of delivering drugs and attaining faster therapeutic blood levels in the case of chronic diseases.

**Key Words:** Dissolution, Disintegration, Fast dissolving film, Polymer, Surfactants, Types of films

## INTRODUCTION [1-4]

The oral route is the most common route of drug administration delivery until now because it has several benefits over other routes of drug administration. However, the oral drug delivery system still needs to be improved due to various drawbacks related to specific patient groups, such as geriatric, paediatric, and dysphasic patients who suffer from a variety of medical conditions and have difficulty speaking.To improve these drawbacks fast dissolving tablets ororally dissolving film immersed as alternative oral dosage forms. The FDT technology allows tablets to dissolve or disintegrate without the use of extra water in the mouth.The Food and Drug Administration [FDA] defines the FDT formulation as "a solid dosage form containing medicinal compounds that disintegrates fast, generally within seconds, when put on the tongue." Orally fast dissolving film is a novel drug delivery method for oral administration. It was produced using the technique of a transdermal patch.It consists a very thin oral strip which is placed on tongue or any oral mucosal tissue, immediately hydrates by soaking saliva, it adheres at the site of application then it fastly disintegrate and dissolve to releases drug into oral cavity.

### Special features of oral dissolving film[5,6]

1. A very thin film
2. Un-obstructive
3. Fast disintegration and dissolving
4. Excellent mucoadhesive
5. Should not leave residue in mouth
6. Give a pleasant mouth feel
7. Available in various size and shape
8. Quick release

## Ideal properties of fast dissolving films [7]

- It should have a pleasant flavour and a pleasant tongue feel.
- To resist post-manufacturing handling, it should be less friable and have excellent mechanical strength.
- The drug's stability and solubility in water and saliva should be good.
- It should leave the least amount of residue in the mouth.
- It should dissolve rapidly in the mouth, releasing the drug instantly.
- It should be compatible with the other ingredients.

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## Advantages [7,8]

1. Dosing convenience
2. Water is not Required
3. No fear of choking
4. Taste masking
5. Increased stability
6. Patient compliance has improved.
7. Rapid onset of action
8. Handling and transportation ease
9. Improved bioavailability for certain active pharmaceutical ingredient

## Disadvantages [9,10]

- As it's hygroscopic, it must be stored in a dry environment.
- It also shows the granule's fragile nature.
- They need specific packaging in order for the products to be stable and safe.
- A high dosage of drug cannot be incorporated into an oral film.
- Drugs that are unstable at the pH of the buccal cavity cannot be given.
- Oral route cannot be used to deliver drugs that irritate the mucosa.
- Only drug with a low dose requirement can be administered.
- Taste masking-most medicines have a bitter flavour, which requires the use of a taste masking agent.

## Applications of Oral Films in Drug Delivery [11]

- Oral mucosal transport via buccal, sublingual, and mucosal routes using OTFs might become the efficient delivery technique for therapies that need rapid absorption, such as those for pain, allergies, sleep problems, and central nervous system illnesses.
- Topical applications: Using dissolvable films to deliver active ingredients such as analgesics or antimicrobial agents for wound care and other applications may be possible.
- Gastro retentive dosage systems:Water-soluble and poorly soluble molecules of varying molecular weights are packed in a film format for dissolvable films, which are being evaluated in dosage forms. The films' dissolution might be triggered by the gastrointestinal tract's pH or enzyme secretions, and might be employed to treat gastrointestinal problems.
- Diagnostic devices: Dissolvable films can be loaded with sensitive reagents to allow controlled release when exposed to biological fluids, or they may be used to form isolation barriers for separating different reagents within a diagnostic device to permit a timed reaction.

## Classification of fast dissolving technology [12]

Fast dissolve technologies may be divided into three categories for ease of explanation.

- Lyophilized systems
- Compressed tablet-based systems
- Fast dissolving film

## Fast dissolving film [13-15]

Oral films are one of the most recent advancements in the development of oral disintegrating dosage forms. They are thin, elegant films made of edible water-soluble polymers that come in a variety of sizes and forms, such as square, rectangle, and disc. The stripes might be soft or hard, opaque or translucent. They are meant to disintegrate quickly on the tongue without the need of water. Fast dissolving films [FDFs] have a significant disintegration specific surface area. The films reduce the risk of choking, are easy to handle and administer, and keep a simple and conventional packaging that is simple to manufacture, solving the drawbacks of oral rapid dissolving tablets. Low drug loading capacity and limited taste masking options are two key drawbacks of these dosage forms. A thin film with a thickness of 1-10 mm and a surface area of 1-20 $cm^2$ of any shape is referred to as a fast-dissolving film. Drugs can be incorporated up to 15 mg in a single dosage. Due to a particular matrix consisting of water-soluble polymers, it dissolves rapidly in saliva and has a low tack for easy handling and application. The system's wet tack and muco-adhesiveness capabilities, on the other hand, are designed to attach the film to the application site when wet. Films are chosen for their flexibility and strength to aid in the manufacturing process, as well as processes such as rewinding, die cutting, and packaging. Fast disintegrating film is placed on the patient tongue are mucosal tissue, which gets instantly wetted by saliva. The film rapidly hydrates and sticks to the application site. It then disintegrates and dissolves rapidly, releasing the drug for oral mucosal absorption or stomach absorption when swallowed.

## Types of Oral Film [16]

The three types of oral films are differentiated from each other in following table.

| Property/ sub type | Flash release wafer | Mucoadhesive melt- away wafer | Mucoadhesive sustained release wafer |
|---|---|---|---|
| Area $[cm]^2$ | 2-8 | 2-7 | 2-4 |
| Thickness [mm] | 20-70 | 50-500 | 50-250 |
| Structure | Single layer | Single or multi-layer system | Multi-layer system |
| Excipients | Soluble, highly hydrophilic polymers | Soluble, hydrophilic polymers | Low/non-soluble polymers |

| | | | |
|---|---|---|---|
| Drug phase | Solid solution | Solid solution or suspended-drug particles | Suspension and/ or solid solution |
| Application | Tongue (upper palate) | Gingival or buccal Region | Gingival, (other region in the oral cavity) |
| Dissolution | Maximum 60 seconds | Disintegra-tioninafew-minutes, forming gel | Maximum 8-10 hours |
| Site of action | Systemic or local | Systemic or local | Systemic or local |

## Formulation of fast dissolving oral films [16]

The many types of excipients that are utilised in oral films are listed below chemically inert and approved excipients should be utilised in the formulation of oral films. Depending on the characteristics of the film forming substance, the development of dosage forms might bring a number of significant challenges.Foaming during film formation as a result of material heating or solvent evaporation, flaking during slitting, and cracking during cutting are all common issues.

## Active Pharmaceutical Ingredient [15,16]

The drug is incorporated in the film in concentrations ranging from 1 to 30% w/w. Fast-acting films can be used to administer a variety of drugs. Oral strips are thin, flexible films with a surface area of up to 8 $cm^2$ that dissolve in seconds, thus molecules with a high dose and low solubility are not recommended. Antihistamines, anti-diarrheal, antidepressants, vasodilators, anti-asthmatics, antiemetic, and other medications can be administered as fast dissolving oral films. Dimenhydrinate can also be used to mask the taste of ODFs. Common examples of drugs incorporated into ODFs are rizatriptan benzoate, salbutamol sulphate, rofecoxib, verapamil, ondansetron, dexamethasone, cetirizine, pilocarpine, tianeptine sodium, indomethacin, etc.

## Film forming polymer[17]

They impart the desired properties into the film, mainly hydrophilic polymers used in the preparation, as the film dissolves rapidly in the oral cavity. The type and amount of polymer employed, for example, pullulan, sodium alginate, pectin, hydroxy propyl cellulose, and hydroxy methyl cellulose, affect the film's toughness.

Film formers fall into the category of water-soluble polymers. In medical and nutraceutical applications, the use of film forming polymers in dissolvable films has gained a lot of attention. The water-soluble polymers enable the films to disintegrate rapidly, have a pleasant tongue feel, and have acceptable mechanical properties.

By increasing the molecular weight of polymer film bases, the rate of polymer disintegration is reduced. HPMC E-3 and K-3, Methyl cellulose A-3, A-6, and A-15, Pullulan, carboxymethylcellulose Cekol 30, Polyvinyl pyrrolidone PVP K-90, Pectin, Gelatine, Sodium Alginate, Hydroxy propyl cellulose, Polyvinyl alcohol, Maltodextrins, and Eudragit are just a few of the water-soluble polymers used as film formers.

## Plasticizer [18,19]

The plasticizer is an important component that increases the film's flexibility and minimises its brittleness.If the plasticizer is applied inappropriately, it might cause film cracking, fracturing, and peeling. The plasticizer should be added to the formulation in a 0-20 percent concentration range to affect the mechanical characteristics of the film, such as tensile strength and percent elongation.Plasticizers include PEG, glycerol, diethyl phthalate, triethyl citrate, and tributyl citrate.

## Surfactant [19]

Surfactants are used to solubilize poorly soluble drugs and also to solubilise or wet and disperse the film and release the active ingredients easily. Examples include poloxamer 407, sodium lauryl sulphate, benzalkonium chloride, benzethonium chloride, tweens and spans.

## Sweetening agent [20,21]

The mouth dissolving films need to have good taste for patient acceptance and compliance as the films are to be taken without water and they are not swallowed but are required to disintegrate and dissolve in the oral cavity.Sweeteners used include

(a) Natural water-soluble sweetener: xylose, ribose, glucose, sucrose, maltose, sativoside etc.
(b) Artificial water-soluble sweetener: sodium or calcium saccharin salts, acesulfame -K etc.c] Dipeptide based sweetener: aspartame

## Saliva stimulating agent [22]

These agents are used to increase saliva production in the mouth, which helps the mouth dissolving films dissolve faster. Examples includemalic acid, citric acid, tartaric acid, lactic acid and ascorbic acid. Citric acid is one of the most preferred ingredients.

## Flavouring agents[23,24]

These are added for patient acceptance and compliance. The flavours selectedare determined by the patients; age, the type of drug, and the taste of the drug tobe masked. Synthetic flavour oils, oleo resin, and extract produced from various section of plants such as fruits, leaves, and flowers can all be used as flavouring agent.One can

use a single flavour or a mixture of flavours. Essential oil or water-soluble extract of menthol, strong mints like sweet mint, spearmint, peppermint, wintergreen, clove,cinnamon, sour fruit flavours like orange, lemon, or sweet confectionary flavours like vanillin, chocolate, or fruit essences like apple,pineapple,cherry, and raspberry-can all be used as flavouring.

## Colouring agent [25]

Colours approved by FD &C are used for improving the appearance of film incase the drug is insoluble or for aesthetic appeal. Pigments like titanium dioxide can be used for colouring. The concentration of colouring agent should not exceed 1% w/w.

## Composition of oral thin film

### *Method of Manufacture of Mouth Dissolving Film*

1. Casting and drying
   A. Solvent casting
   B. Semisolid casting.
2. Freeze dried wafer
3. Extrusion
   A. Hot melt extrusion.
   B. Solid Dispersion Extrusion
   C. Rolling method.

## Solvent casting method[26]

This method is preferred for fast dissolving buccal films, in which the water-soluble ingredient is dissolved to form a clear viscous solution, and the drug, along with other excipient, is dissolved in a suitable solvent, then both solutions are mixed and stirred before being cast in a Petri plate and dried.

## Semisolid casting [27]

In this process, a solution of water-soluble film producing polymer is initially produced. The resulting solution is combined with an ammonium or sodium hydroxide-prepared solution of an acid insoluble polymer [e.g.,cellulose acetate butyrate, cellulose acetate phthalate]. The appropriate amount of plasticizer is applied, resulting in a gel mass. Finally, the gel mass is cast in the film or ribbon using heat-controlled drum. The film is between 0.015 and 0.05 inches thick. A 1:4 ratio of acid insoluble polymer to film-forming polymer should be used.

## Freeze dried wafer [28]

It's also known as Lyophilisation or Cryodesiccation because it involves dehydrating water and lowering surrounding pressure to allow water in a substance to sublime straight from the solid to the gaseous phase. Lyophilization produces extremely porous preparation with a high specific surface area that dissolve quickly and have increased absorption and bioavailability.

## Hot melt extrusion[29]

In this procedure, the API is combined with carrier, and a stable granular mass is produced and dried. So that the granules stay in the extruder for 3-4 minutes, the screw speed should be about 15 rpm. 80°C [zone 1], 115°C [zone 2], 100°C [zone 3], and 65°C [zone 4] are the recommended processing temperatures [zone 4]. The extrudate [T= 65°C] is squeezed into a cylindrical calendar to form a film. In this solvent-free method, low molecular weight and low viscosity polymers are chosen.

## Solid Dispersion Extrusion

Solid dispersion is prepared by immiscible component and drug. Finally, thesolid dispersion is shaped in to film by means of dies.

## Rolling method[30]

In this approach, a drug solution or suspension is made with rheological considerations in mind. As a solvent, water or a combination of water and alcohol is employed. The carrier is rolled with a drug-containing suspension or solution. The films are cured on rollers before being cut into the desired shapes and sizes.

## Evaluation parameters of fast dissolving films

### *Physical Appearance*

The mouth dissolving films checked visually for uniformity,clarity and tackiness.

### *Weight and thickness*

Cut the films into 2cm X 2cm squares and weigh them using an electric scale. The average weigh and standard deviation were obtained after three films were individually weighted. The thickness of the films was measured with a micrometre in three locations, with an average of three readings from three films and a standard deviation recorded.

## Surface pH[23]

The pH was determined by putting the electrode of a pH metre in contact with the surface after placing the film on a glass petri-plate and moistening it with 0.5ml of phosphate buffer. The standard deviation was calculated using an average of three measurements from three films.

## Drug content[31]

Each formulation must have three film units put in separate 100 ml volumetric flask, 100 ml of solvent added, and the flasks constantly swirled for 24 hours. The solution must be filtered, diluted properly, then measured at a particular wavelength in a UV spectrophotometer. As a final reading, the average of the drug content of three films must be used.

### Folding Endurance[31]

Using a sharp blade, cut three films of each composition to the required size. Folding endurance should be assessed by folding the film in the same spot over and over until it breaks. The value of folding endurance is determined by the number of time the film can be folded at the same location without breaking.

### Tensile Strength

Tensile strength is the maximum stress applied to a point at which the stripspecimen break. It is calculated by the formula,

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

### Disintegration Test[32]

The visual technique should be used to determine the *in-vitro* disintegration time of film strip. The film strip should be swirled every 10 seconds in a glass Petri dish with 10-25 ml of distilled water at 37°C. The moment at which the film begins to shatter or disintegrate was recorded as the disintegration time. The time it took for the disintegration to occur was measured.

### *In-vitro* dissolution studies

To assess drug release, simulated salivary fluid should be used as the dissolving media. The dissolution profile of rapid release films was measured in a beaker with 30 ml of simulated salivary fluid [pH 6.8] as a dissolving medium and kept at 37 0.5°C. At 100 rpm, the medium was agitated. At 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10-minute intervals, aliquots [5 ml] of the dissolving media were removed and replaced with fresh medium. At specified nm, samples were spectrophotometrically analysed. All of the samples were subjected to three trials, with the average value taken. At various time intervals, the percentage of the drug dissolved was recorded and plotted against time.

### Stability studies [33]

The fast-dissolving films' stability should be tested under a variety of environmental circumstances. For stability experiments, the film was wrapped in aluminium foil and kept for 90 days at 2-8°C [45 percent RH], 25-30°C [60 percent RH], and 45-50°C [75 percent RH] in a stability chamber. During the stability investigation, the patches were characterised for drug content and other characteristics.

## DISCUSSION

In this review article, we have discussed the detailed study on fast dissolving film & their unique features, Ideal properties, advantages, disadvantages, applications, types of films, formulations of fast dissolving oral films, active pharmaceutical ingredients used in the preparation of oral films, methods for the manufacturing of oral films & evaluation parameters of fast dissolving films.

## CONCLUSION

Recently As a dosage form for mouth fresheners, fast dissolving films have gained appeal. Meanwhile, pharmaceutical companies have noticed the technology's promise for delivering medical goods and have created many OTC items utilising it. The fast-dissolving thin film has received little attention in the literature, but it appears to be an appropriate dose form for usage in young children, particularly geriatric and paediatric patients. They combine the increased stability of a solid dosage form with the ease of use of a liquid dosage form. The availability of goods on the market is limited due to a lack of consistent technique for preparation and analysis.

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**Authors' Contribution:**

**Prajjwal Gupta:** His contribution to this review article is that he compiles the total study based on fast dissolving films & their parameters.

**Chaya Rani:** Her contribution to this review article is that she does the literature review on evaluation parameters of fast dissolving films.

**Kanishka Chauhan:** Her contribution to this review article is that she does the literature review on the introduction & classification of fast dissolving films.

**Harsh Sisodia:** His contribution to this review article is that he does the literature review on methods of preparation of oral films.

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