



# FAST DISSOLVING ORAL FILMS: A REVIEW

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## Abstract:

A large no of drugs can be formulated as mouth dissolving films, for example antihistamines, antiasthamatic drugs, and cardiovascular drugs for erectile dysfunction. Fast dissolving drug delivery system was discovered in 1970s. and these films have been alternative for the capsule, syrup, tablet. This system can be easily applied on the dysphagia, pediatric patient, geriatric patient, and brdridden patient. Its self-administration no water is required or chewing, patient compliance is increase. These films have greater advantages it passes the first pass effect and due to its directly reaches the concentration and produce good therapeutic effect. In this review it characterized by their selection of polymer for formulation, and the preparation methods for the oral films, and the last evaluation parameter.

**Keywords:** fast dissolving oral films, disintegration, geriatric, pediatric.

## 1. Introduction

The oral route of drug administration is one of the most convenient, cost-effective, and preferred routes of drug administration. However, some patients, particularly children and the elderly, have difficulty swallowing or chewing some oral solid dosage forms, such as tablets and hard gelatine capsules(1). This route is unaffected by first-pass metabolism, and as a result, degradation will not occur, making it a better option for dysphagic, paediatric, and geriatric patients. This is due to the sublingual route being more permeable than the buccal area. This route is effective, but it has some limitations in that it cannot deliver all molecules. Fast dissolving oral films are useful in patients such as paediatrics, geriatrics, bedridden patients, emetic patients, diarrhoea, and patients experiencing a sudden episode. Those who lead an active lifestyle are at risk of allergic reactions or coughing. It is also useful for local action, such as local anaesthesia for toothaches, oral ulcers, cold sores, or teething(2).



Figure no- 1 oral strip

Every pharmaceutical company wishes to develop a novel oral dosage form with increased bioavailability, rapid action, and minimal patient observation. As a result, they use superdisintegrant/s and hydrophilic components to create fast dissolving tablets. In the late 1970s, the first fast dissolving drug system was developed. Because of their greater flexibility and comfort, fast dissolving oral films [FDOFs] are the most advanced type of oral solid dosage form(3).

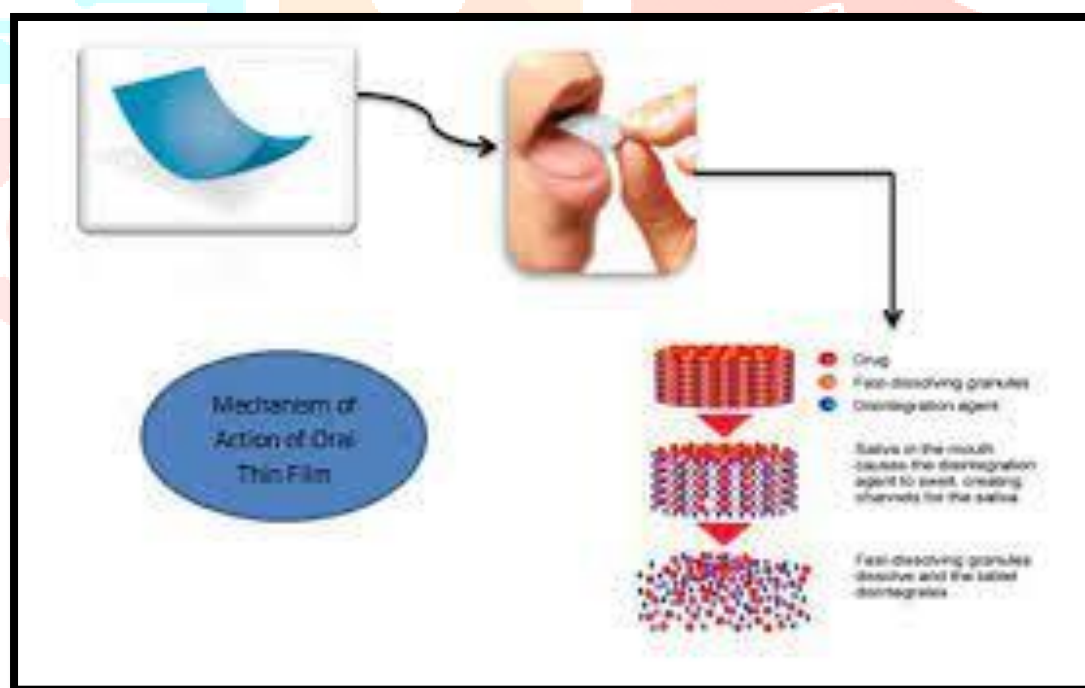


Fig. 2: rout of administration

It improves API effectiveness by dissolving within minutes in the oral cavity after contact with saliva without chewing and without the need for water for administration. It provides quick absorption and instant bioavailability of drug due to high blood flow and permeability of oral mucosa, which is 4-1000 times greater than that of skin. Oral fast dissolving film [OFDF] is one such novel method for increasing consumer acceptance through the consistency of rapid dissolution and self-administration without the use of water or chewing.(4) The film is an ideal intraoral fast-dissolving drug delivery system that meets the market's unmet needs, is simple to handle and administer, has simple and convenient packaging, eliminates unpleasant taste, and is simple to

manufacture. The film is placed on the tongue's top or bottom. It adheres to the application site and rapidly releases the active agent for local and/or systemic absorption. The outcome of a fast-dissolving film also provides an opportunity for market chain expansion, a wide range of drug [e.g., neuroleptics, cardiovascular drugs, anaesthetics, this dosage form may be appropriate for antihistamines, antiasthmatics, and erectile dysfunction medications. A large number of drugs can be developed as mouth-dissolving films. Creative products may improve the therapeutic possibilities in the following indication(1).

Paediatric (antitussives, expectorant, antihistamines)

Geriatric (antiepileptic, expectorants)

Gastrointestinal disease

Nausea (due to cytostatic therapy)

Pain (migraine) CNS (antiparkinsonism therapy)

### 1.1. Special features of oral film(5)(6)(7)

- Thin elegant film
- Available in variety of size and shapes
- Unobstructive
- Excellent mucoadhesion
- Fast disintegration
- Fast release

### 1.2. Ideal properties of oral films (8)(9)(10)

1. It should have a pleasant mouth gel and an acceptable taste.
2. It should be less friable and have a high mechanical strength to withstand the post- production handling.
3. The drug should be stable and soluble in water as well as in saliva.
4. It should leave little or no residue in mouth.
5. It should dissolve quickly enough to release the drug instantly in mouth.
6. It should be compatible with the other ingredient.

### 1.3. Advantages(10)(11)

1. Avoiding the risk of choking
2. Avoid first pass metabolism and provide quicker onset of action at lower doses.
3. Palatable
4. Good stability
5. No requirement of water
6. Large surface area provides rapid disintegration and dissolution in the oral cavity.
7. Ease of administration of film to the patients suffering from dysphagia, repeated emesis, motion sickness, and mental disorders
8. Dose precision.

### 1.4 Disadvantages(12)(13)

- High doses cannot be included into the film.
- Expensive packaging of the film.
- Drugs that cause mucosal irritation are not permitted be administered
- As it is fragile and must be protected from water
- It requires special packaging

### 2 limitation of oral fast dissolving films:

The FDOFs have several shortcomings in terms of dose uniformity from one strip to the next since it is difficult to maintain the same dose throughout all strips. The drug loading capability is another disadvantage because not all medications can be placed on the FDOFs due to certain limitations, one of which is the drug concentration/dose. Because the highest amount that may be loaded is 75 mg, not all medications can be loaded onto the film. Additionally, there are some limitations with regard to the packing of the strips, which necessitates some particular criteria because it is difficult to pack while also requiring that the pack not interact with the film(14)(12)(15).

### 3. Types of fast dissolving oral film:(16)(17)

There are three different subtypes

1. Flash release
2. Mucoadhesive melt release
3. Mucoadhesive Sustained release

Sub type	Flash release	Mucoadhesive melt release	Mucoadhesive sustained release
Area (cm <sup>2</sup> )	2-8	2-7	2-4
Thickness	20-7	50-500	50-250
Structure	Single layer	Single or multilayer system	Multilayer system
Excipients	Soluble, highly hydrophilic polymer	Soluble, hydrophilic polymer	Low and non-soluble polymer
Drug phase	Solid solution	Solid solution or drug particle	Suspension and /or solid solution
Application	Tongue (upper palate)	Gingival or buccal region	Gingival and other region of oral cavity
Dissolution	Maximum 60 seconds maximum 8-10hours	Disintegration in few minutes forming gel	Maximum 8-10hours
Site of action	Systemic or local	Systemic or local	Systemic or local

Table 1: fast dissolving oral film

#### 4. Classification of fast dissolving technology<sup>(5)(18)</sup>

For case description, fast dissolving technologies can be divided into three broad group.

##### I. Lyophilized system:

The technology behind these systems entails forming tablet-shaped units from a drug suspension or solution with other structural excipients using a mould or blister pack. In the pack or mould, the units or tablets are frozen and lyophilized. The resulting units are extremely porous, allowing for rapid water or saliva penetration and disintegration.

##### II. Compressed tablet- based system:

This system is made using standard tablet technology and excipients that are compressed directly. Tablet technologies vary in hardness and friability depending on the manufacturing method. When compared to a standard tablet, the speed of disintegration for fast dissolve tablets is achieved by formulating with either water soluble excipients superdisintegrant or effervescent components, allowing rapid penetration of water into the core of the tablet.

##### III. Thin film strips:

Oral films, also known as oral wafers, evolved from the confection and oral care markets in the form of breath strips over the last few years and became a novel and widely accepted form by consumers for delivering vitamins and personal care products. FDFs are now a proven and accepted technology for the systemic delivery of APIs in over-the-counter (OTC) medications, and they are in the early to mid-development stages for prescription drugs. This has been attributed to the consumer success of breath freshener products like Listerine Pocket Paks in the US consumer market. To create a 50-200 mm film, such systems employ a variety of hydrophilic polymers. The film is made in large sheets and then cut into individual dosages units for packaging in a pharmaceutically acceptable format

#### 5. Benefits of oral fast dissolving films

Films quickly disintegrate and dissolve in the oral cavity because they have a bigger surface area. Because OFDFs are adaptable and portable, they are simple to transport, handle by consumers, and store. It is appropriate for people with dysphagia, people who regimens, and those who feel queasy. The movie is helpful in situations requiring an ultra-rapid initiation of action, such as motion sickness, severe pain, allergy attacks, or coughing fits. Since the medication is taken in solid dosage form until it is ingested, it is stable for a long time. Therefore, it combines the stability benefits of solid dosage forms with the convenience benefits of liquid dosage forms<sup>(15)</sup>.

## 6. Comparison between oral films and oral disintegrating tablet:(19)(20)(18)

Fast dissolving films	Fast dissolving tablet
Greater dissolution due to large surface	Lesser dissolution due to less surface area
Better durable than oral disintegrating	Less durable as compared with oral films
More patient compliance	Less patient compliance than films
Low dose can be incorporated	High dose can be incorporated
No risk of choking	Fear of choking

Table 2: oral film and oral disintegrating tablet

## 7. Structural feature of oral mucosa:(21)

### Buccal mucosa structure:

The mouth cavity is around 100 cm in length overall. Out of this, the buccal surface, which is lined with an epithelium of around 0.5mm thickness, makes up about one third (Fig. 3). The oral epithelium's keratinized and non-keratinized areas differ from one another in terms of the lipid makeup of the cells. The non-keratinized epithelium has minimal, polar lipids, mostly cholesterol sulphate and glucosylceramides, as opposed to the keratinized epithelium, which has a majority of neutral lipids (such as ceramides). Numerous elastic dermal fibres in the buccal membrane act as another barrier to medication diffusion over the buccal membrane. A network of capillaries and arteries and reach the systemic circulation. The venous vascularization and lymphatic drainage practically run parallel(22).

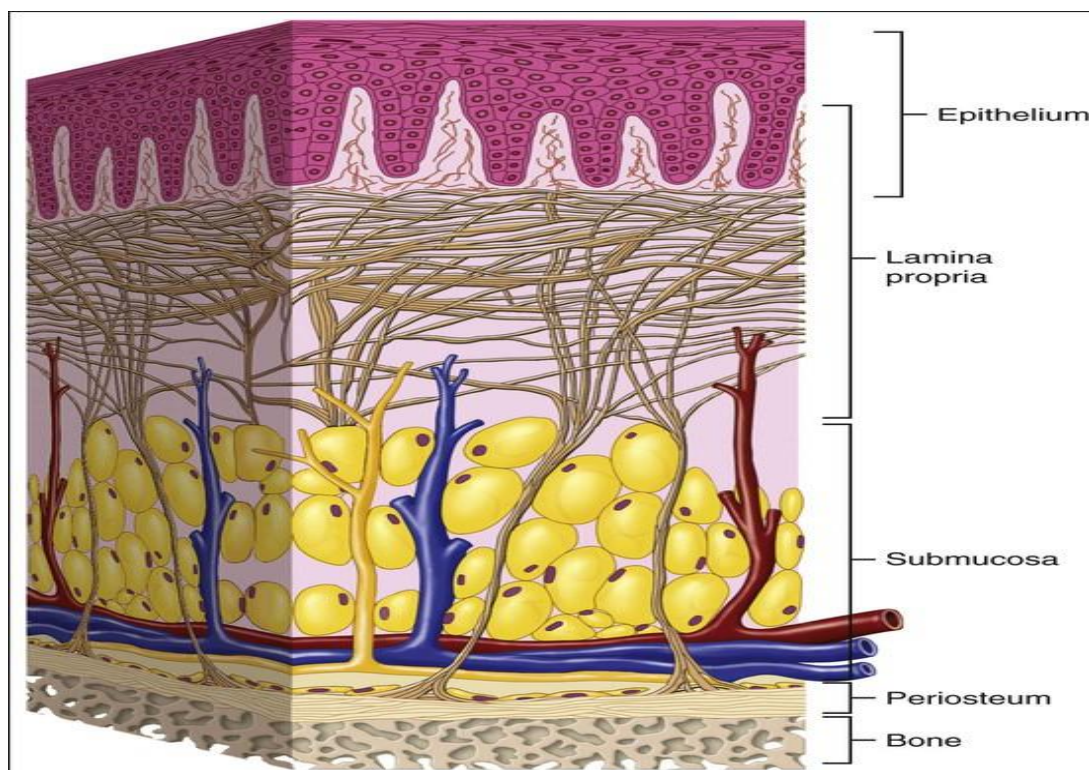


Fig. 3: buccal mucosa structure

### Permeability:

The oral mucosa has a relatively low degree of permeability, yet varies in different areas of the oral region, taking into account that the buccal membrane is thicker more porous than other oral regions. Its buccal Drug permeability and the effects of drugs are prevented by the mucosa. The factors are this barrier and buccal absorption. impacting the administration of drugs. According to estimates, the permeability of the buccal mucosa is 4–4000 times greater than the skin The mouth cavity is more permeable in the following order: buccal, then sublingual, in descending order, and the palate follows. This ranking is based on the relative thickness and keratinization level. A drug's permeability coefficient is used to assess the simplicity with which the medicine(23).

### 8. Standard composition of oral fast dissolving film:

Oral dissolving films are thin films with an area of 5-20cm that contain a drug. The drug can be loaded to a maximum of 30mg in a single dose. According to regulatory guidelines, all excipients used in the formulation must be generally recognised as safe and approved for use in oral pharmaceutical dosage form(24)(25)(26)(27).

A typical formulation contains the following ingredients.

1. Drug
2. Film forming polymer
3. plasticizer
4. Saliva stimulating agent
5. Sweetening agent
6. Flavouring agent
7. Surfactant
8. Colours, filler

### 8.1 Active pharmaceutical ingredient:

A typical film composition contains 1-25% w/w of the drug. Fast dissolving films can deliver a wide range of APIs. Small dose molecules are the most likely candidates for incorporation into OFDFs. With a dissolution time of less than 60 seconds, multivitamins up to 10% w/w of dry film weight were incorporated in the films. Micronized API is always beneficial for improving the texture of the film as well as for better dissolution and uniformity in the OFDFs. Many APIs that could be candidates for OFDF technology have a bitter taste. This renders the formulation unpalatable, particularly in paediatric preparations. As a result, before incorporating the API into the OFDF, the taste must be masked. Several methods can be used to improve palatability. because of the formulation Among the techniques used, the simplest involves mixing and co-processing bitter tasting API with pleasant tasting excipients. This is known as an obscuration technique(28).

Drug	Dose	Therapeutic action
Nicotine	2mg	Smoking cessation
Ondensteron	2.5mg	Anti emetic
Salbutamol	4mg	Anti histaminic
Omeprazole	10-20	Proton pump inhibitor
Cetirizine	5-10mg	Anti histaminic

Table 3: active pharmaceutical ingredient (APIs)

### 8.2 Film forming polymer

The polymer type is chosen based on the function required in the dosage form. Polymers can change the film stability in relation to all of these critical parameters. OFDFs can be prepared using a variety of polymers. Polymers can be used alone or in combination to improve the hydrophilicity, flexibility, mouth feel, and solubility of OFDFs. The stiffness of the film is determined by the type of polymer used in the formulation as well as the amount of polymer used. The polymer used should be non-toxic, non-irritant, and have good wetting and spreading properties. The polymer should be reasonably priced and widely available. Natural gums such as xanthan, guar, acacia, and tragacanth gums are water soluble polymers that may be used; other available polymers include cellulose or cellulose derivatives, hydroxyl propyl methyl cellulose (HPMC) with different grades such as HPMC E15, HPMC E5, HPMC K4M, HPMC K100, hydroxy ethyl cellulose, hydroxy propyl cellulose carboxy methyl cellulose Modified starches are also used in the preparation process. There are numerous polymers with various physical properties(29)(30).

The polymer employed in oral film should be

- Non-irritant and non-toxic
- Free of leachable impurities
- Water soluble and low in molecular weight



Natural polymer	Synthetic polymer
Pullulan	Hydroxy propyl methyl cellulose
Starch gelatine	Polyvinyl pyrrolidone
Pectine	Polyvinyl alcohol
Sodium alginate	Carboxy methyl cellulose
Xanthan	Hydroxy ethyl cellulose
Maltodextrin	Poly ethylene oxide
Polymerized rosin	kollicoat

Table 4: polymer

### 8.3 Plasticizers:(24)

Plasticizer is an essential component of the oral film formulation. It aids in the improvement of the strip's flexibility and decreases its brittleness. Plasticizers play an important role in improving strip properties by lowering the polymer's glass transition temperature. The plasticizer chosen will be determined by its compatibility with the polymer as well as the type of solvent used in film casting. The use of plasticizer improves the flow of polymer and increases the polymer's strength. Plasticizers that are commonly used include glycerol, propylene glycol, di-butylphthalate, and polyethylene glycols, among others. Incorrect plasticizer use can cause film splitting or cracking. The use of certain plasticizers may affect the rate of drug absorption. The permanent should be imparted to the strip by the plasticizer used. It should be noted that plasticizer properties are important in lowering the glass transition temperature of polymers to 40-60°C for non-aqueous solvent systems and below 75°C for aqueous systems. Plasticizers should be compatible with the drug as well as other excipients used in strip preparation. With hydroxyl-containing plasticizers such as PEG, propylene glycol, glycerol, and polyols, cellulosic hydrophilic polymers were easily plasticized. Glycerol is a better polyvinyl alcohol plasticizer than diethylene glycol, which can be used for both hypromellose and polyvinyl alcohol films.

### 8.4 Saliva stimulating agent:

The use of saliva stimulating agents is intended to increase the rate of saliva production, which will aid in the faster disintegration of the rapid dissolving strip formulations. In general, acids used in food preparation, such as citric acid, malic acid, lactic acid, ascorbic acid, and tartaric acid, can be used as salivary stimulants. These agents are used alone or in combinations ranging from 2 to 6% w/w of the strip's weight.

### 8.5 Sweetening agent:

Sweeteners have evolved into an essential component of formulations designed to be disintegrated or dissolved in the oral cavity. Natural and artificial sweeteners are both used in the formulation of fast dissolving films. Sweeteners are typically used in formulations at concentrations ranging from 3-6% w/w, either alone or in combination. Polyhydric alcohols such as sorbitol, mannitol, and isomalt can be combined to provide a good mouth-feel and cooling sensation. It should be noted, however, that the use of a paediatric population case. Both

natural food and pharmaceutical products Sweeteners, both natural and artificial, are used to improve the palatability of mouth dissolving formulations by being disintegrated or dissolved in the oral. Aspartame was used in the preparation of valdecoxib oral strips, and maltodextrin was used as a sweetening agent in the preparation of piroxicam oral strips.(31)(32)

Sr no	Sweetening agent	Example
1	Natural sweeteners	Xylose, ribose, glucose, galactose, fructose, dextrose, sucrose, maltose.
2	Artificial sweeteners	First generation- saccharin, cyclamate and aspartame Second generation – acesulfame, sucralose, alitame.

Table 5: sweetening agent

### 8.6 Flavouring agent:

OFDF formulations should contain up to 10% w/w flavours. An individual's acceptance of an oral disintegrating or dissolving formulation is largely determined by the initial flavour quality observed in the first few seconds after the product has been consumed, as well as the after taste of the formulation, which lasts for at least 10 minutes. The flavour chosen is determined by the type of drug to be included in the formulation. It was discovered that age has a significant impact on taste fondness. The elderly prefers mint or orange flavours, whereas the younger generation prefer fruit punch, raspberry, and so on. Flavouring agents can be chosen from a variety of synthetic flavour oils, oleo resins, and extracts derived from various parts of the plant. Plants with leaves, fruits, and flowers Flavours can be used alone or in combination. Flavour oils include peppermint oil, cinnamon oil, spearmint oil, and nutmeg oil, whereas fruity flavours include vanilla, cocoa, coffee, chocolate, and citrus. Fruit essences include apple, raspberry, cherry, and pineapple, to name a few.

Sr no	Flavouring agent	Example
1	Flavour oil	Peppermint oil, cinnamon oil, spearmint oil.
2	Fruity flavours	Coffee, cocoa, citrus, vanilla, chocolate.
3	Fruit essence type	Raspberry, cherry, pineapple, apple.

Table 6: flavouring agent

### 8.7 Surfactant:

Surfactants are used as a solubilizing, wetting, or dispersing agent, allowing the film to dissolve in seconds and release the active agent immediately. Sodium lauryl sulphate, benzalkonium chloride, bezthonium chloride, tweens, and other commonly used ingredients. One of the most important surfactants is polaxamer 407, which is used as a solubilizer, wetting agent, and dispersant(8).

### 8.8 Colouring agent:

There is a wide variety of colours available, including FD&C colours, EU colours, Natural colours, and custom Pantone-matched colours. Some saliva stimulating agents may be added to improve disintegration and speed up release. Citric acid, tartaric acid, malic acid, ascorbic acid, and succinic acid are some of these agents.

## 9.METHODS OF PREPARATION OF FILM:(33)

- ✚ Solvent casting method
- ✚ Semisolid casting method
- ✚ Hot melt extrusion method
- ✚ Rolling method
- ✚ Solid dispersion method

### 9.1 Solvent casting method:

Fast dissolving films are preferably formulated using the solvent casting method, in which the water-soluble ingredients are dissolved to form a clear viscous solution and the drug, along with other excipients, is dissolved in suitable solvent, then both solutions are mixed and finally casted in to the Petri plate and dried, which is then cut into pieces of the desired size. The API's properties are critical in selecting a suitable solvent. Water-soluble hydrocolloids used to make RDFs include hydroxyl propyl methyl cellulose (HPMC), hydroxyl propyl cellulose (HPC), pullulan, sodium alginate, pectin, carboxy methyl cellulose (CMC), and polyvinyl alcohol (PVA). Solvents used in the preparation of a solution or suspension should ideally come from the ICH Class 3 solvent list. Pouring the solution on an inert base necessitates the use of specialised equipment such as rollers. The required thickness of the film is determined by the clearance between the roller and the substrate. The final step, drying the film, removes the solvent and contributes to the final product. As an inert base for film casting, glass, plastic, or teflon plates are commonly used. Several issues can arise when manufacturing technology is transferred from the laboratory to the production scale. These issues may include casting the film, achieving uniform thickness of the film, and properly drying the sample. In the final step of drying, the proper type of dryer must be chosen. After the films have dried, the cutting, stripping, and splicing can begin. The packaging is finished. Films of appropriate size and shape can be cut. The most common film sizes are 3 x 2 cm<sup>2</sup> and 2 x 2 cm<sup>2</sup>. Figure depicts a flowchart of the solvent casting method(33).

**Advantages:(33)**

- Greater thickness uniformity and greater clarity than extrusion.
- Have gloss and defect-free films, such as die line film.
- Have greater flexibility and physical properties.

**Disadvantages:**

- The polymer must be water or volatile soluble
- It is necessary to create a stable solution with a reasonable minimum solid content and viscosity.

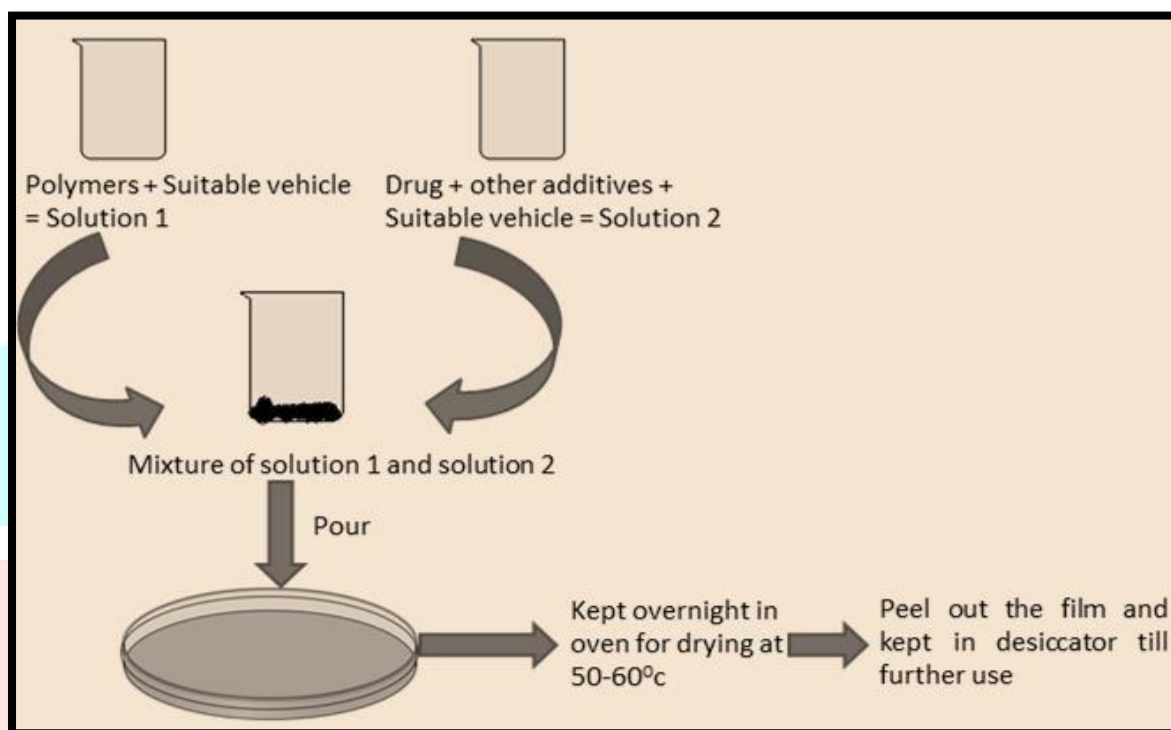


Fig.4: solvent casting method

**9.2 Semisolid casting method**

In this method, a solution of water-soluble film forming polymer is prepared and added to a solution of acid insoluble polymer (e.g., cellulose acetate phthalate, cellulose acetate butyrate) prepared in ammonium or sodium hydroxide. The appropriate amount of plasticizer should then be added to form a gel mass. Finally, using heat-controlled drums, the gel mass should be cast into the films or ribbons. The thickness of the formed film will be between 0.015 and 0.05 inches. In this method, the acid insoluble polymer to film forming polymer ratio must be 1:4.(31)(5)

**9.3 Hot melt extrusion method:**

In the hot melt extrusion method, as shown in Fig.9, the initial mass must be dried and obtained with carriers as the drug is mixed with carriers and obtained as solid mass, then the mass is introduced into an extruder divided into four zones with varying degrees of temperature, zone 1 at 800°C, zone 2 at 150°C, zone 3 at 1000°C, and zone 4 at 650°C. To process the granules inside the barrel of the extruder for 3-4 minutes, set the

extruder speed to 15 rpm. After being pressed into a cylindrical calendar, the film is obtained. Hot melt extrusion has many advantages, such as limited operation units. It reduces waste and eliminates the need for the Because of intense mixing and agitation, the use of solvent or water (anhydrous) results in uniform content.

#### Advantages:(14)

- A few units of operation.
- Improved content consistency.
- A non-hydrous procedures.

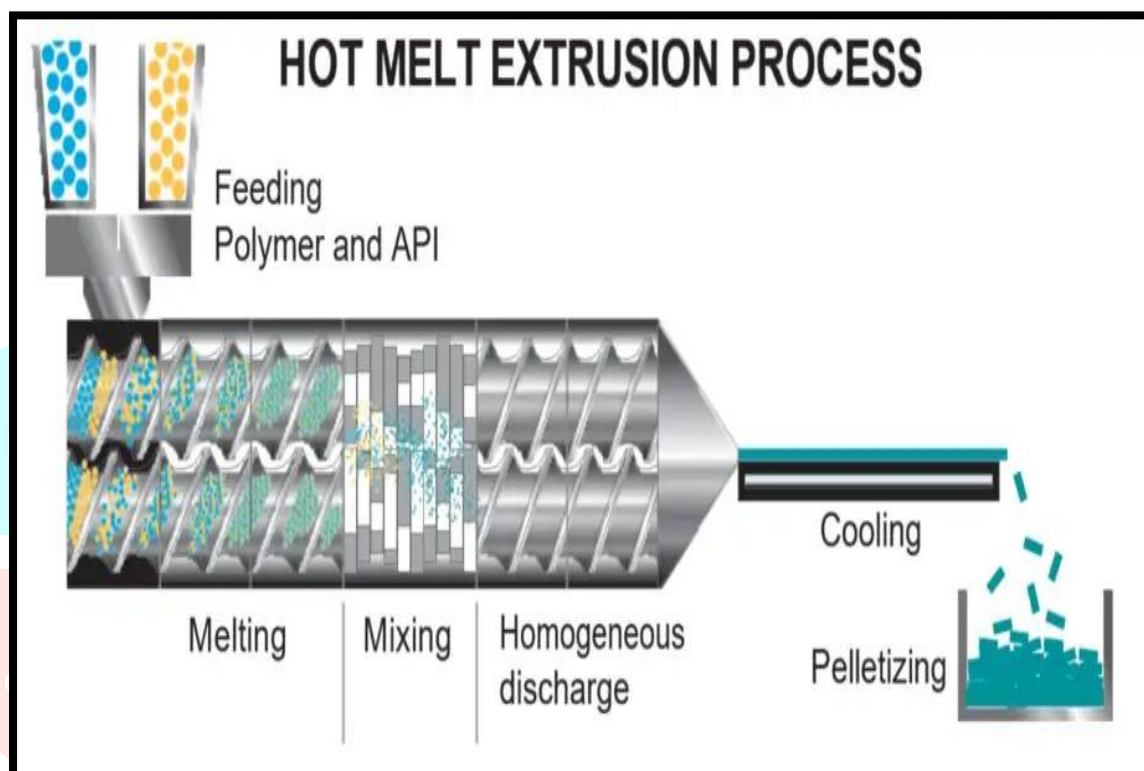


Fig. 5: hot melt extrusion method

#### 9.4 Rolling method:

A drug-containing solution or suspension is rolled on a carrier in the rolling method. The solvent is mostly water or a water-alcohol mixture. The film is dried on the rollers before being cut into the desired shapes and sizes. Using a high shear processor, other ingredients, including the active agent, are dissolved in a small amount of aqueous solvent. Hydrocolloids that dissolve in water to form a homogeneous viscous solution(6).

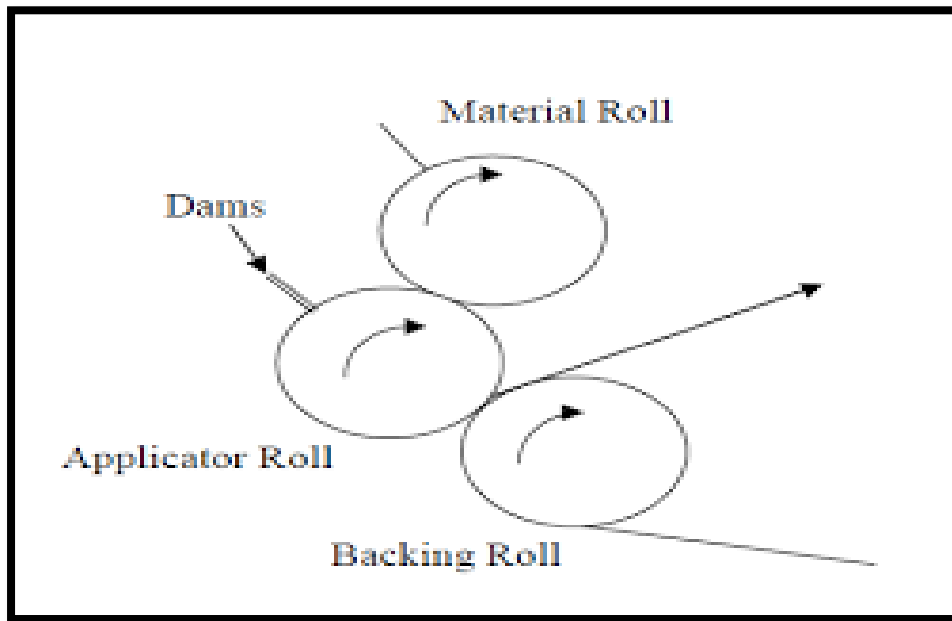
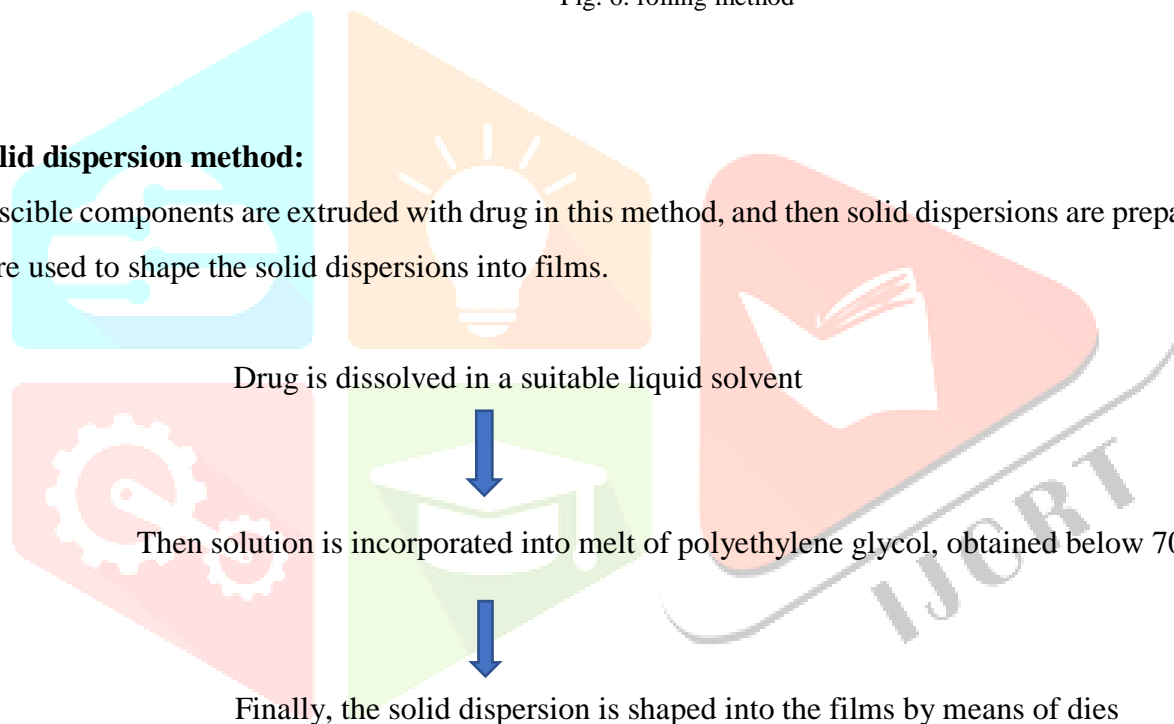


Fig. 6: rolling method

### 9.5 Solid dispersion method:

Immiscible components are extruded with drug in this method, and then solid dispersions are prepared. Finally, dies are used to shape the solid dispersions into films.



### 10. EVALUATION PARAMETER FOR ORAL FILMS:(13)(34)(3)

1. Morphology study
2. Weight variation
3. Thickness
4. Surface pH
5. Dissolution test
6. Disintegration time
7. Folding endurance

8. Tensile strength
9. Percent elongation
10. In vitro drug release
11. Swelling property
12. Storage and packaging

#### **10.1 Morphology study:**

Scanning electron microscopy (SEM) at a specific magnification is used to study the morphology of the oral strip. Examine the differences between the upper and lower sides of the films. It also aids in the determination of API distribution.

#### **10.2 Weight variations:**

Individual weighting of randomly selected weights is used to measure weight variation. The average weight should be similar to the average weighted 10 films.

#### **10.3 Thickness:**

The thickness of the film is measured using a micrometre screw gauge at five different points on the film, namely the centre and four corners, and the mean thickness is calculated. For thickness uniformity measurement, 5 films are chosen at random and thickness is measured at each formulation's location. The maximum variation in film thickness should be less than 5%, with means. Dis calculated.(35)

#### **10.4 Dissolution test:**

Dissolution testing in simulated saliva solution or pH 6.4 phosphate buffer can be done at 37.0±0.5°C using the standard basket or paddle apparatus described in any of the pharmacopoeias. At regular intervals, samples are taken and analysed with a UV-Visible spectrophotometer.

#### **10.4 Surface Ph:**

The surface pH of the films was determined in order to investigate the possibility of any side effects in vivo by placing the film on the surface of 1.5% w/v agar gel, followed by placing pH paper (pH range 1-11) on the films. The change in colour of pH paper was observed and reported.

#### **10.5 Disintegration time:**

Disintegration of orally fast dissolving films necessitates the use of a USP disintegration apparatus. The CDER guidance disintegration time limit of 30 seconds or less for orally disintegrating tablets can be applied to fast dissolving oral films. The disintegrating time varies depending on the formulation, but it typically ranges from 5 to 30 seconds. However, there is no official guidance for oral fast disintegrating films(36).

**10.6 Folding endurance:**

Folding endurance was determined by folding the film repeatedly in the same position until it broke. The folding endurance value is the number of times the films can be folded without breaking(34).

**10.7 Tensile strength:**

Tensile strength is the maximum stress that can be applied to a film specimen before it breaks. This test is used to determine the mechanical strength of the films. It can be calculated by dividing the applied load at cleavage by the film cross-sectional area, as shown in the equation below: Tensile strength = (load at failure / strip thickness / strip width)(37)

**10.8 Percent elongation:**

When stress is applied to a film sample, it stretches, which is known as strain. Strain is defined as the deformation of a film divided by its original dimension. Percentage elongation=length increase 100/original length.

**10.9 In vitro drug release:**

Dissolution studies on films are conducted using standard official basket or paddle apparatus. Sink conditions should be maintained during dissolution. Occasionally, while performing this process, film floats over the medium, making it difficult to perform the test properly. Because this problem is more likely to occur with the paddle method, the basket apparatus is generally preferred. The media used are 6.8 pH phosphate buffer (300ml) and 0.1 N HCl (900ml). The temperature is kept at 37 0.5 °C, and the rotation speed is usually set to 50 rpm. Dissolved drug samples are collected at predetermined intervals and analysed using a UV spectrophotometer.

**10.10 Swelling property:**

Each film sample is weighed and placed in a stainless-steel wire mesh that has been preweighed. The mesh with the film sample is then immersed in 15ml medium (simulated saliva solution) in a plastic container. The weight of the film was increased at predetermined time intervals until a constant weight was observed.

$$\text{Swelling degree} = (W_t - W_0) / W_0$$

**10.11 Storage and packaging:**

Drug manufacturers benefit from product flexibility during the converting and packaging stages. As needed for the application, the rolled film can be die-cut into any shape or size, or slit into narrower rolls. Converters may choose to print information directly onto the film unit doses before packaging for branding purposes and to comply with industry regulations. Among the criteria that may be considered are the unit-dose packaging, barcode labelling, and content in instructions for use, child-resistant seals, and senior-friendly packaging are all required(38).



**11. List of oral film available in the market:(39)(16)**

Sr no.	Product	Manufactured by
1	Dextromethorphan HBr (cough suppressant) diphenhydramine citrate (cough and cold)	MonoSolRx
2	Donepezil rapid dissolving film, ondansetron rapid dissolving film.	Labtech pharma
3	Diphenhydramine HCL fast dissolving film, folic acid 1mg fast dissolving film, caffeine fast dissolving films	Hughes medical corporation
4	Altoid cinnamon strips, cool shock peppermint strips, benzocaine films,	Dow chemical company
5	Listerine pocket paks breath freshening strips	Pfizer's warner- lambert consumer healthcare division
6	Energy strips- caffeine 20mg, acetyl salicylic acid (ASA) ondansetron HCL, Dexamethason,	ODF technologies Inc.
7	Caffeine films	Dow chemical company
8	Triaminic thin strips	Novartis pharmaceutical
9	Methylcobalamin fast dissolving film	Hughes medical corporation
10	Diphenhydramine hydrochloride film	monosolRX
11	Life- saving rotavirus vaccine to infants	Johns Hopkins undergraduate biomedical engineering student
12	Suppress	InnoZen, inc
13	Chloraseptic	prestige
14	Gas-X	Novartis
15	Klonopin wafer	Solvay pharmaceutical
16	Sudafed PE	Wolters Kluwer health Inc

Table no-7

**Conclusion:**

Fast dissolving oral film is most acceptable and accurate oral dosage form which bypass the hepatic system and show more therapeutic response. The pharmaceutical companies prefer this dosage form due to both patient compliance (especially paediatric and geriatric) as well as industrial acceptability. Oral films can replace the over-the-counter (OTC) drugs, generic and name brand is a good tool for product life cycle management for

This technology is a good tool for product life cycle management for increasing the patent life of existing products.

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