Available online on 15.06.2021 at http://ajprd.com

Asian Journal of Pharmaceutical Research and Development

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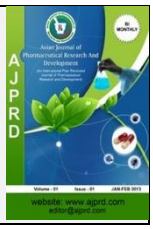

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Review Article

A Review on Fast Dissolving Oral Films

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A B S T R A C T

Oral route are the most convenient and common route of administration of drug because of the low cost of therapy and ease of administration lead to high levels of patient compliance as in the form of tablets and capsules. Generally In some cases, the oral solid dosage form may become difficult especially in swallowing. So to overcome these problems, fast dissolving drug delivery systems have been developed which disintegrate or dissolve within one minute when placed in the mouth without water or chewing. These are the formulations administered without water. These thin sized oral film stripes are designed in such a manner for the ease administration of drug when film is placed on or under the tongue. These film enables the drug to deliver directly in to the blood stream either through buccal or sublingually. Oral films improve the onset of action, lower the dosing and enhance the bioavailability.

Keywords: Oral dissolving films, Composition of oral films, Method of preparation, Drug release studies.

A R T I C L E I N F O: Received 26 Feb. 2021; Review Complete; 07 April 2021 Accepted; 19 May 2021 Available online 15 June. 2021

Cite this article as:

Karthik D.R, Keerthy H.S, Yadav RP, A Review on Fast Dissolving Oral Films, Asian Journal of Pharmaceutical Research and Development. 2021; 9(3):122-128. **DOI:** http://dx.doi.org/10.22270/ajprd.v9i3.969

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INTRODUCTION

Fast dissolving oral films were initially developed in 1970 to overcome swallowing difficulties as seen in capsules and tablets. Oral films are alternative to tablet and capsules. The main concept of oral films came from confectionary industry. Oral films are also known as oral strips, mouth dissolving film, oral dispersive films. Oral films is the most advanced form of oral solid dosage form due to more comfort and flexibility.[1] Oral films gives instant bioavailability and quick absorption of drugs due to permeability of oral mucosa. Oral films are useful in geriatrics, emetic patients, pediatric, diarrhea etc. it is also mainly useful as local anesthetic for oral ulcers, toothaches or cold sores. Oral films started gaining popularity and acceptance as new drug delivery system due to better patient compliance. These oral films have predominance over major drawbacks of rapid disintegrating tablets related to fear of friability, choking and can be utilized for schizophrenic and dysphasic patients.[2] These oral films are specialized in a way that the water is not required for the administration because oral films quickly fragments within a few seconds, discharging the drug in mouth. Oral films, at the point when placed on tongue, immediately hydrates by soaking saliva following disintegration and/or dissolution for discharging active pharmaceutical agent from the dosage form.[3] Generally the shelf life of oral film is two to three years mainly it depends on the API added to the film but films are more sensitive to environmental moisture. Salivary gland is present in the oral cavity which secretes saliva.[4]There are 3 salivary glands which are present in the oral cavity i.e. submandibular, parotid and sublingual glands. Saliva is mainly water which contains 1% inorganic and organic material. Saliva is a weak buffer and its pH ranges from 5.5-7. Saliva is relatively less viscous as compared to GI fluids. The total volume of saliva secreted from the salivary gland is 0.5-2 litres and it is the amount of saliva enough to hydrate oral mucosal dosage form.[5]

Advantages: [6-9]

1. There is no risk of chocking.
2. Oral films Provide good mouth feel.
3. Oral films are less fragile and more flexible so it can be easily transport handled and stored.
4. Oral films does not require water to swallow so it has better acceptability.

5. Oral cavity has large surface area which leads to rapid disintegration and dissolution of the oral dosage form.
6. Enhance Stability of the dosage form.
7. Oral dissolving films disintegrate immediately with in seconds when placed on tongue without the need of water.
8. Avoids first pass metabolism as it directly absorb from the buccal mucosa and enter into the systemic circulation, dose and side effects are reduced
9. Enhance the bioavailability of drug and fewer doses are required which improve the patient compliance.
10. Oral films are solid unit dosage form so it provide accurate dosing and great precision.

Limitations: [10-12]

High doses cannot be incorporated.
Excessive bitter drugs are not feasible.
Dose uniformity is a big technical challenge.
Oral films should have high oral bioavailability.
Drugs which irritate the oral mucosa cannot be administered by this route.
They require special packaging for the products Safety and stability.

Special features of oral films: [10-14]

Ultrathin oral films.
Available in various shape and size.
Available in various shape and size.
Mucoadhesion is excellent.

Applications: [12-15]

1. Oral films are administered for local action and also to manage pain, sleeping difficulty, allergies and CNS disorders.
2. Dissolvable films are feasible for topical application for wound care such as antimicrobial or analgesics.
3. Dissolvable films are loaded with sensitive reagents to allow controlled release when exposed to a biological fluids or to create isolation barriers for seperating multiple reagents to enable a timed reaction with a diagnostic device.
4. Oral films are applicable to enhance the bioavailability of poorly bioavailable drugs.

Composition of oral films:

- Active pharmaceutical ingredient
- Plasticizer
- Film forming polymers
- Super disintegrents
- Sweetening agent
- Surfactants
- Saliva stimulating agent
- Flavouring agent
- Colouring agent

Table No 1: Composition of oral films

Sl.No	Agents	Concentration
1	Drug	1-25%
2	Water soluble polymers	40-50%
3	Plasticizers	0-20%
4	Flavours, Colours, Fillers Etc.	0-40%

Active pharmaceutical ingredients[16]

The oral film composition contains 1-30% w/w of the active pharmaceutical ingredient. Use of low dose active pharmaceutical ingredients because high dose of drug are difficult to incorporate in fast dissolving oral film. The market for thin oral films is mainly for the minerals, vitamins and supplements. Different type of API can be incorporated successfully in the oral strip technology. API can be micronized, milled or loaded in the form of particles or nanocrystals depending upon the ultimate release profile desired. Bitter taste drugs is required to be masked before incorporating API in oral film formulation. Different techniques are used to enhance taste various method included are mixing and co-processing of bitter testing API with excipients with good pleasant taste called as obscuration technique.

List of few drugs that can be incorporated in fast dissolving films: [17-21]

Table 2: List of few drugs that can be incorporated in fast dissolving films

Sl. No.	Drug	Dose	Therapeutic action
1	Azatidine Maleate	1mg	Anti histaminic
2	Nicotine	2mg	Smoking cessation
3	Loperamide	2mg	Anti diarroheal
4	Ondensetron	2.5mg	Anti emetic
5	Triplodine hydrochloride	2.5mg	Anti histaminic
6	Zolmitritpan	2.5mg	Anti migraine
7	Salbutamol	4mg	Anti histaminic
8	Chlorpheniramine Maleate	4mg	Anti allergic
9	Cetrizine	5-10mg	Anti histaminic
10	Acrivastine	8mg	Anti histaminic
11	Loratidine	10mg	Anti histaminic
12	Omiprazole	10-20mg	Proton pump inhibitor
13	Famotidine	10mg	Antacid
14	Ketoprofen	12.5mg	Analgesic
15	Dicyclomine hydrochloride	25mg	Muscle relaxant
16	Diphenhydramine hydrochloride	25mg	Anti allergic
17	Sumatriptan succinate	35-70mg	Anti migraine

PLASTICIZER[22]

Plasticizer improves the flexibility a mechanical property of the film like tensile strength and elongation of the oral films and it decreases the brittleness of the film. Plasticizer are the important excipient in the oral film. Plasticizer significantly improves the strip properties by reducing the glass transition temperature of the polymer. A plasticizer

should be selected so that it should be compatible with the polymers, drug as well as with other excipients used in the oral film. Plasticizer can improve the flow and increases the strength of polymer. Film splitting, cracking and peeling take place by the use of inappropriate plasticizer. Plasticizers are used in the concentration of 0–20%w/w of dry polymer weight. Different plasticizers used in the preparation of the oral films are polyethylene glycol, Glycerol, propylene glycol, dimethyl, dibutyl phthalate, diethyl phthalate, tributyl phosphate, triethyl citrate, acetyl citrate, castor oil and triacetin.

FILM FORMING POLYMERS [23]

Polymers play an important role in the formation of film. Hydrophilic polymers are mainly used in the preparation so that film can be easily dissolve rapidly in the oral cavity and drug is delivered to the systemic circulation via dissolution when it comes in contact with the saliva in the buccal cavity. Film forming polymers can be used alone or in combination in a film to get the desired film properties. Robustness of film depends on the amount and type of polymer in the formulation. Both synthetic and natural polymers are used in the oral cavity. Natural polymers are effective, safe and avoid side effect so they are more preferred than synthetic polymers. The water soluble polymers result in good mouth feel, rapid disintegration and mechanical properties to the film.

List of few polymers: [24]

Table 3: List of few polymers

Natural polymer	Synthetic polymer
Starch	Hydroxy propyl methyl cellulose
Pectin	Poly vinyl pyrolidone (PVP)
gelatin	Polyvinyl alcohol (PVA)
Sodium alginate	Sodium Carboxy methyl cellulose
Maltodextrin	Poly ethylene oxide (PEO)
Pullulan	Kollicoat IR
Xanthan	Hydroxy propyl cellulose (HPC)
Polymerized rosin	Hydroxy ethyl cellulose (HEC)
Gum acacia	Methyl cellulose (MC)

SWEETNING AGENTS:[25,26]

Sweeteners have become the most important part of the formulation intended to be dissolved or disintegrated in the oral cavity. Both artificial sweeteners and natural sweeteners are used in the formulation of fast dissolving films. Sweeteners are used in the formulation in concentration of 3-6%w/w, either in combination. Polyhydric alcohols such as mannitol, sorbitol and isomalt can be used in combination as they additionally provide cooling sensation and good mouth-feel. However, it should be noted that the use of case of paediatric population. Natural sweeteners used are glucose, ribose, xylose, sucrose, maltose, steviosides, dextrose, fructose and isomalt. Fructose is sweeter than sorbitol and mannitiol and thus widely used as a sweetener. Artificial sweeteners used in oral films are aspartame, sodium or calcium saccharine salts, cyclamates salts, Acesulfame potassium etc.

SALIVA STIMULATING AGENTS:[27]

These saliva stimulating agents are used to increase the secretion of saliva so that the oral film can be easily dissolved and disintegrate faster in the oral cavity. Employing saliva stimulating agents is to increase the rate of production of saliva that would aid in the faster disintegration of the rapid dissolving film formulations. The acids which are used in the preparation of food are generally used as saliva stimulators. These agents are used alone or in combination between 3-6%w/w of the oral strip. Malic acid, citric acid, lactic acid, tartaric acid and ascorbic acid are the saliva stimulating agent mainly used in oral film formulation. Citric acid is the most preferred among them. The stimulation of salivation can be measured be comparing the amount of stimulated flow and resting flow at equal time under same condition.

FLAVOURING AGENTS:[28]

Flavouring agent are the ingredients which are added to impart flavour to the formulation. Selection of flavour mainly depends on which type of drug is to be incorporated in the formulation. The acceptance of the oral dissolving/disintegrating formulation by an individual mainly depend on the initial flavour quality which is observed in the first few seconds after the product has been consumed and after the taste of formulation lasts for at least 10 min. The amount of flavour to be added to mask the taste mainly depend on the flavour strength and its type. Flavouring agent is used in concentration of 10%w/w in the formulation.US-FDA approved flavour can be added to the formulation according to the choice of the individuals of different age groups. The flavours liking changes with the age as geriatric population like mint or orange flavour and young generation like strawberry, fruit, raspberry flavour. Flavouring agent must be compatible with the drug and also other ingredients. Flavouring agent can be extracted from different part of the plant like fruit, leaves, flower, fruit, seeds and bark.

COLOURING AGENTS:[29, 30]

FD and C approved colouring agent is incorporated in fast dissolving film. Colouring agent is used in concentration a level of 1%w/w in fast dissolving film. Titanium dioxide is the most used colouring agent in the formulation.

METHOD OF PREPARATION

Oral fast dissolving film can be prepared by five Methods:

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

Semisolid casting: [31]

This technique is mainly preferred in the preparation of oral rapid dissolving film when acid insoluble polymers are used. Water soluble film forming polymer solutions are prepared. The solution is added to the acid insoluble polymer solution. The appropriate amount of plasticizer is added so that a gel mass is formed. The gel mass formed is then casted into the ribbons or films by using heat controlled drums. Acid insoluble polymers used to prepare films include: cellulose acetate butyrate, cellulose acetate phthalate. Film forming polymer and acid insoluble polymer are used in the ratio of 4:1. The film thickness is about 0.015-0.05 inches.

Solvent casting: [32]

This is the one of the most preferred manufacturing method for quick dissolving film. First water-soluble ingredients are mixed in this process to form a viscous solution of water. API and the remaining ingredients are dissolved in smaller Solution quantity and combined with bulk by using the Elevated Shear Processor. The vacuum is used to eliminate the entrapped air. The solution formed is then cast as a film and pour the solution in a glass mould and allow. The solution dried in oven for 45-50°C, which is then cut in to the desired size.

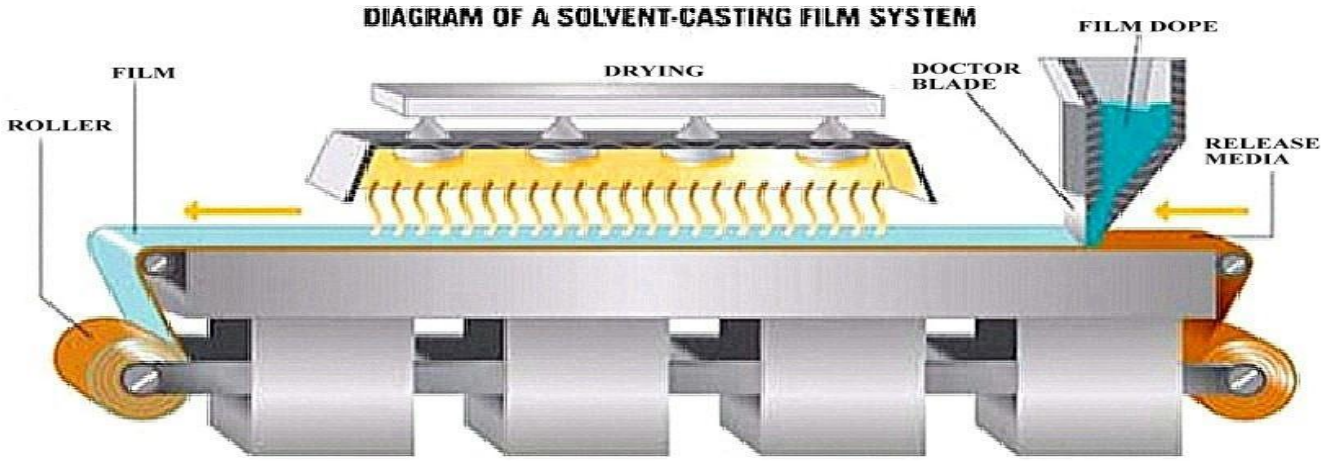

Figure 2: Solvent casting

Hot melt extrusion: [33]

The polymers which are having low molecular weight and low viscosity are preferred in this method. Active pharmaceutical ingredient is mixed with the carrier in the solid form so that it leads to the formation of granular material. These granules are then dried and placed into the extruder. The screw speed should be around 15rpm so that the granules reside for approximately 3-4min inside the extruder. The temperatures for processing should be 80 °C (zone1), 115 °C (zone 2), 100 °C (zone 3) and 65 °C (zone 4). The extrudate (T= 65 ° C) is then pressed to obtain a film in a cylindrical calendar.

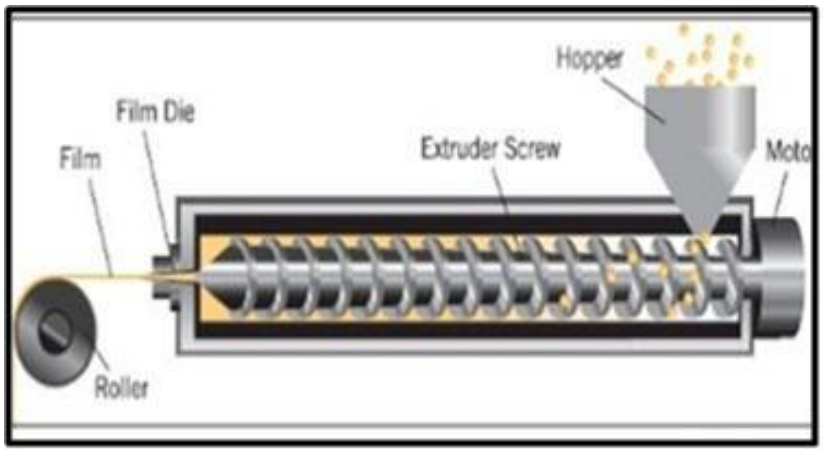

Figure 3: Hot melt extrusion

Solid dispersion technique: [34]

The definition of solid dispersions relates to the dispersion of one or more active ingredients in a solid State in the presence of hydrophilic amorphous polymers. In a suitable liquid solvent drug is dissolved. Later the solution is incorporated into the polyethylene melt. Glycol, which can be obtained below 70◦ C finally the solid dispersion are formed into the films by means of dies.

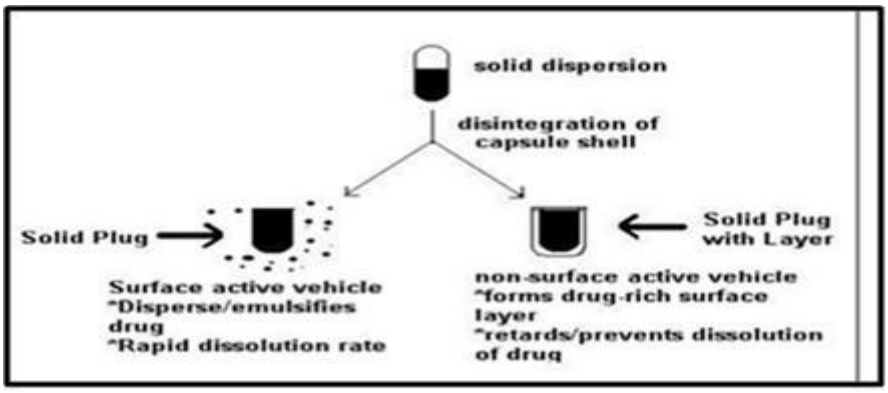

Figure 4: Solid dispersion technique

Rolling method:[35]

The film is prepared by preparation of addition, pre-mix of an active and subsequent formation of a film in this method. Prepare the pre-mix with polar solvent, film forming polymer and other additives except a drug Add pre mix to master batch feed tank. Fed it via a 1st metering pump and control valve to either or both of the 1st and 2nd mixer. Then add required quantity of drug to the desired mixer. Blend the medication with the pre-mix of the master batch to give a matrix that is uniform. Then a specific quantity of uniform through second metering, the matrix is then fed to the pan with pumps. Finally, the film is formed on the substrate, and carried away through the roller of support. Then the wet film will be dried Using bottom drying.

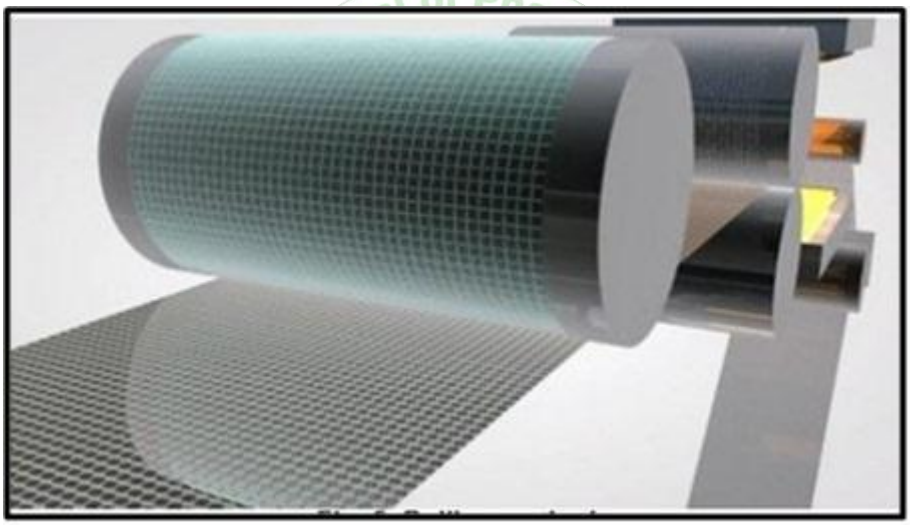

Figure 5: Rolling method

EVALUATION OF FILMS:[36-40]

a) Weight variation
b) Thickness
c) Tensile strength
d) Percent elongation
e) Folding endurance
f) Young's modulus
g) Transparency
h) Swelling property
i) Tear resistance
j) Content uniformity
k) Disintegration time
l) Dissolution test

a) Weight variation:

Weight variation is studied by weighing individually 10 randomly selected oral films and by calculating the average weight of the oral films.

b) Thickness:

Since film thickness is directly concerned with thickness, Uniformity of drug content, so it is necessary to Check for uniformity in the film's thickness. It could be measured by a screw gauge or digital vernier calipers at various strategic locations.

c) Tensile strength:

It is the utmost pressure, applied to the point at which the strip is applied to a film Breaks of specimens. It is calculated by the load applied to the rupture divided by the area of the cross section of the strip.

d) Percent elongation:

When stress is put into effect, a sample of the film stretches and this is called strain. Strain is essentially film deformation split by the sample's original dimension. As the plasticizer content increases, film elongation increases.

Percent elongation= L100/L0

L = Increase in length of film

L0 = Initial length of film

e) Folding endurance:

Folding endurance is determined by repeated film folding at the same spot until the filling breaks. The number of occasions without breaking, the film is folded and calculated as value of folding endurance.

f) Young's module:

Young's elastic or modulus, modulus is the metric of film stiffness. It is the proportion of applied stress over strain is represented in the region of elastic deformation.

g) Transparency:

The film transparency can be determined using simple UV spectrophotometer. The film samples are cut into rectangles and placed on the internal side of the spectrophotometer cell. The determine transmittance of films at 600 nm.

h) Swelling property:

Film swelling experiments are performed by Using simulated saliva solution. Each sample film is weighed and put into a pre-weighed wire of stainless steel Mesh, which is then immersed in a medium of 15ml in a Container of plastic. The increase in the film's weight was determined at a pre-set time interval up to a constant weight was observed. Parameters are used for calculating degree of swelling index.

$\alpha = (wt - wo)/wo$

wt = weight of film at time t

wo = weight of film at time zero.

i) Tear resistance:

The maximum force or stress (which is usually found near the beginning of the tearing process) It is recorded as the force required to tear the film Value of resistance in Newton (or pounds -force).

j) Content uniformity:

This has been determined by any standard method of assay defined in any of the standard pharmacopoeia for a particular API. The uniformity of content is determined by estimating the Individual strip API content. Content uniformity limit is 85%-115%.

k) Disintegration time:

US disintegration apparatus is required for disintegration of fast dissolving oral films. The time limit for disintegration of oral film should be 30 seconds or less. Orally disintegrating tablet described in Centre for Drug Evaluation and Research (CDER) guidance can be applied to fast dissolving oral films. Time for disintegration varies depending on the formulation but typically the disintegration time ranges from 5 to 30 seconds. There is no official guidelines available for rapid disintegrating oral films.

l) Dissolution test:

Standard paddle or basket apparatus are used for performing dissolution testing described in any of the pharmacopoeia. The dissolution medium will be selected as per the highest dose of the API and sink conditions. So many times the dissolution test can be challenging due to tendency of the strip to float when the paddle apparatus is employed onto the dissolution medium.

CONCLUSION

Fast dissolving oral films has gained popularity as dosage form and is most accurate and acceptable oral dosage form which bypass the hepatic system and show more therapeutic response. They combine the good applicability of liquid and the greater stability of a solid dosage form. The pharmaceutical companies prefer this dosage form due to both patient compliance (especially geriatric and pediatric) as well as industrial acceptability. Oral films can replace the over-the counter drug, brand and generic name from market due to consumer preference and lower cost. This technology is a best tool for product life cycle management for enhancing the patent life of existing products. OFDFs are also having great potential of delivering the medicinal agent locally as well as systemically and have several advantages over the fast disintegrating tablets and even over many dosage forms. This explains the extensive research on this technology actively going on this. Therefore this technology is rapidly growing in fast pace challenging for the pharmaceutical companies using various active pharmaceutical ingredients to develop oral dissolving films.

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