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CURRENT AND FUTURE ADVANCEMENT OF FAST DISSOLVING ORAL THIN FILM

Rumita Kumawat and Meenakshi Bharkatiya *

B. N. Institute of Pharmaceutical Sciences, B. N. University, Udaipur - 313001, Rajasthan, India.

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Correspondence to Author:
Meenakshi Bharkatiya

Associate Professor,
B. N. Institute of Pharmaceutical Sciences, B. N. University, Udaipur - 313001, Rajasthan, India.

E-mail: meenakshibharkatiya@gmail.com

ABSTRACT: The development of fast-dissolving oral thin films has recently followed the progression of dosage forms from straightforward ordinary tablets and capsules to modified release tablets and capsules, oral disintegrating tablets, and wafers. A hydrophilic polymer used in fast-dissolving oral thin films quickly hydrates or adheres when applied on the tongue or in buccal cavity. These films melt or disintegrate in a matter of seconds, releasing the active ingredient without need for drinking or chewing. A drug-containing thin film with surface area of 5 to 20 cm2 is called an oral dissolving film. The maximum single dose of the drugs that can be loaded is 30 mg. As opposed to tablets, several pharmaceutical companies are now producing oral thin films that dissolve quickly. Films combine the benefits of liquid dosage forms with those of tablets, such as exact dose and simple administration (easy swallowing, rapid bioavailability). At the same time, it gives a general overview of crucial formulation design factors that have an impact on thin films, such as thin film design, anatomical and physiological constraints, choice of the best manufacturing processes, characterization techniques, and the physicochemical properties of drugs and polymers. Fast-dissolving oral thin films can be used for a variety of purposes, including sublingual and gastro-retentive delivery systems in addition to buccal fast-dissolving systems. Future uses might involve employing laminated multilayer films to combine incompatible active medicinal components into a single product.

INTRODUCTION: The oral route of medication administration is one of the most practical, economical, and favoured drug delivery methods. However, certain patients, particularly those who are young or elderly, have trouble swallowing or digesting various oral solid dose forms, such as tablets and hard gelatin capsules. They are unable to consume these dose forms due to their fear of choking.

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Numerous fast dissolving drug delivery systems (FDDDS) were developed to address this issue [1]. Drug administration through the buccal cavity is crucial. By giving the medication via the buccal route, issues such high first pass metabolism and drug degradation in the gastrointestinal environment can be avoided [2].

The development of fast-dissolving oral thin films has recently followed the progression of dosage forms from straightforward ordinary tablets and capsules to modified release tablets and capsules, oral disintegrating tablets, and wafers. A hydrophilic polymer used in fast-dissolving oral thin films quickly hydrates or adheres when applied on the tongue or in the buccal cavity. These films melt or disintegrate in a matter of seconds,

releasing the active ingredient without the need for drinking or chewing [3]. Due to the mucosa's extensive blood supply, medications are quickly absorbed and instantly bioavailability. Bypassing first pass metabolism leads to immediate bioavailability. They are therefore often created for medications with high first pass metabolism in order to achieve higher bioavailability. Despite being in its infancy, oral thin- film technology has a promising future because of patient compliance [4].

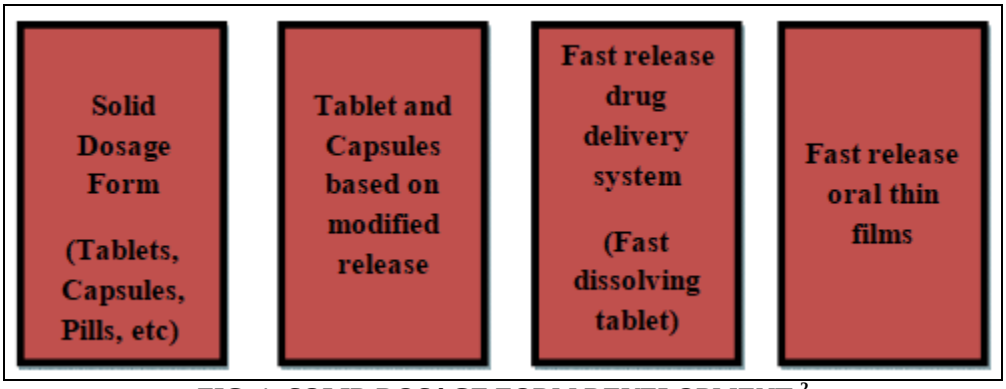

FIG. 1: SOLID DOSAGE FORM DEVELOPMENT [2]

Fast dissolving drug delivery systems are one such example that has recently begun to acquire popularity and acceptability with more customer choice due to its quick disintegration or dissolve and self-administration even without water or chewing. Fast dissolving medication delivery systems were originally developed in the late 1970s to help paediatric and elderly patients who had trouble swallowing tablets and capsules. Recent years have seen a rise in the importance of buccal medication delivery [5]. The use of polymeric films for buccal distribution, also known as mouth dissolving films, and other bio adhesive mucosal dosage forms, such as sticky tablets, gels, ointments, patches, and more recently, mouth dissolving films, have all been created. RDFs, or rapidly dissolving films, were first marketed as breath fresheners and personal care items like soap strips and dental care strips. Materials like strip-forming polymers, plasticizers, active pharmaceutical ingredients, sweeteners, saliva-stimulating agents, flavouring agents, colouring agents, stabilising and thickening agents, permeation enhancers, and superdisintegrants are used in the formulation of fast-dissolving buccal films. According to regulatory considerations, every excipient utilised in the creation of fast-dissolving films should be authorised for use in pharmaceutical dosage forms for oral administration [6-8].

Need for Formulating the Oral Thin Film: Children, the elderly, people who are bedridden, people who are emetic, and those who have CNS illnesses have trouble swallowing or digesting solid dose forms. Many of these individuals refuse to take solid dose forms because they are afraid of choking. Choking fears are common, even with ODTs, which can be dangerous. ODTs can be replaced by a fast- dissolving oral thin film drug delivery device. OTFs are immediately salivated upon placement on the tongue's tip or base. Because of this, OTFs quickly hydrate before dissolving or disintegrating to release the drug for local or systemic absorption. ODTs are brittle and might crack when being handled or transported. Consequently, quick dissolving oral thin film drug delivery devices are being created [9-11].

Features of Oral Thin Film [10]:

- Film should be thin and elegant.
- Available in various size and shapes.
- It should adhere to the oral cavity easily.
- Should processes fast disintegration without water.
- It should taste good.
- Drugs should be very moisture resistant and penetrate the oral mucosa.
- It should have appropriate tension resistance.
- It should be ionized in the oral cavity pH.

Advantages of Oral Thin Film [11-16]:

1. Convenient dosing.
2. No water needed.
3. No risk of chocking.
4. Taste masking.
5. Enhanced stability.
6. Improved patient compliance.
7. The drug enters the systemic circulation with reduced hepatic first pass effect.
8. Site specific and local action.
9. Availability of large surface area that leads to rapid disintegration and dissolution within oral cavity.
10. Bypasses the gastrointestinal tract and thus increasing bioavailability.
11. It provides more accurate dosage when compared to liquid dosage forms.
12. No need to measure, which is an important disadvantage in liquid dosage forms.

Disadvantages of Oral Thin Film [17-22]:

- Drugs with high dose cannot be incorporated into the film.
- Drugs which causes irritation to the mucosa cannot be administered.
- As it is fragile and must be protected from water, it requires special packaging.
- Dose uniformity is difficult to maintain.
- Only those active pharmaceutical ingredients having small dose can be incorporated.
- Since OTFs dissolve quickly, dose termination is impossible.
- OTFs are not official in any pharmacopoeia.

Types of Oral Thin Film [4]:
There are three types of Oral Thin Film:

1. Flash Release.
2. Mucoadhesive Melt Release.
3. Mucoadhesive Sustained Release.

Standard Composition of Oral Fast Dissolving Film: A drug-containing thin film with a surface area of 5 to 20 cm2 is called an oral dissolving film. The maximum single dose of the medications that can be loaded is 30 mg. All excipients employed in the formulation must be licenced for use in oral pharmaceutical dosage forms and be generally recognised as safe (i.e., GRAS-listed) from a regulatory standpoint [24-27].

A typical formulation contains the following ingredients:

1. Drug.
2. Film forming polymers.
3. Plasticizers.
4. Saliva stimulating agent.
5. Sweetening agent.
6. Flavouring agent.
7. Surfactant.
8. Colors, Filler.

TABLE 1: STANDARD COMPOSITION OF OTF [11-18]

Sr. no.	Category	Composition
1	Drug API	1-30 %
2	Film forming polymers	45-55 %
3	Plasticizers	0-20 %
4	Saliva sweetening agents	1-6 %
5	Sweetening agents	4-6 %
6	Flavoring agents	Q. S
7	Surfactant	Q. S
8	Colors and Filler	Q. S

Ideal Characteristics of APIs to be Incorporated into Fast Dissolving Oral Thin Films:

1. Low dose.
2. Palatability.
3. Small molecular weight.
4. Solubility and stability in saliva.

Some of suitable candidates for incorporation into thin film formulation are given in **Table 2.**

TABLE 2: SUITABLE DRUG CANDIDATE FOR OTF [1-8]

Sr. no.	Drug Candidate	BCS Class	Medicated Indications
1.	Glipizide	II	Anti-diabetic
2.	Donepizil	II	Anti-Alzheimer
3.	Famotidine	III	Antacid
4.	Ondansetron	II	Anti-emetic
5.	Loperamide	II	Anti-diarrheal
6.	Carvedilol	II	β-blocker
7.	Mirtazapine	II	Anti-depressant
8.	Indomethacin	II	NSAIDs
9.	Loratadine	II	Anti-histaminic

Film-forming Polymers used in OTFs: The choice of polymers, which relies on the quantity of films employed, is one of the most crucial and significant factors in the effective manufacture of oral films. A minimum of 45% polymer by weight must be present in the dry film, but 60%-65% polymer by weight is preferred to attain the desirable characteristics. To produce the necessary film qualities, polymers can be used alone or in combination. The film-forming polymers used must be water-soluble since OTFs are quickly dissolved and disseminated in the oral cavity. Additionally, the resulting films must be strong and damage-free throughout storage and transportation.

Properties of an Ideal Polymer for OTFs are the following [25-28]:

- The polymer used must be nontoxic and non-irritating.
- There should not be impurities.
- It must have enough wetting and spreading properties.
- It must have sufficient stress and tensile strength.
- It should be accessible and not too expensive.
- The shelf life should be reasonable.

Superdisintegrants used in OTFs: When Superdisintegrant are added to OTF formulations, the combined effects of swelling and water absorption result in fast disintegration. Due to their high water absorption, Superdisintegrant provide absorption and swelling, which speeds up disintegration and breakdown. Strong saliva contact is crucial for breakdown [2].

TABLE 3: ROLES OF POLYMER USED IN ORAL THIN FILM [1-5]

Sr. no.	Category	Composition	Examples
1	Film Forming Polymer	45-55 %	Carbohydrates, proteins, and cellulose derivatives, HPMC E3, E5 and E15 and K-3, Methyl cellulose A-3, A-6 and A-15, Pullulan, carboxmethylcellulose cekol 30, polyvinylpyrollidone PVP K-90, pectin, gelatin, sodium, alginate, hdroxypropylcellulose, polyvinyl alcohol, maltodextrins
2	Plasticizers	0-20 %	Glycerin, PEG-400, 300, propylene glycol, malic acid, sorbitol, castor oil, triethyl citrate, tributyl citrate, and triacetin, etc.
3	Saliva Stimulant	1-6 %	Ascorbic acid, citric acid, lactic acid, tartaric acid, and malic acid
4	Sweeteners	4-6 %	Saccharin, cyclamate, and aspartame, Natural (sucrose, mannitol, sorbitol, dextrose, glucose, liquid glucose, fructose, and isomaltose, etc.), synthetic (aspartame, saccharin, sucralose, acesulfame-K, cyclamate, alitam, and neotame, etc.)
5	Superdistintegrants	0-8 %	Sodium starch glycollate, crosspovidone, and polacrilin potassium
6	Flavouring agent	Q. S	Peppermint, cinnamon, clove, lemon, orange, vanilla, and chocolate,etc
7	Surfactants	Q. S	Sodium lauryl sulfate, benzalkonium chloride, Tween, , polysorbate, and poloxamer 407,
8	Colouring agents	Q. S	Titanium oxide, silicon dioxide, and zinc dioxide,

Formulation Techniques for Preparation of Oral Thin Film:

Conventional Approaches:

1. Solvent casting method.
2. Hot-melt extrusion.

3. Semisolid casting.
4. Solid dispersion extrusion.
5. Rolling.

Solvent Casting Method: The water-soluble polymers are first dissolved in water at 1,000 rpm while being heated to 60°C in this process. The remaining excipients- colors, flavourings, sweeteners, etc. are all dissolved separately. The resulting solutions are then fully combined while being stirred at 1,000 rpm. The API that has been dissolved in a suitable solvent is added to the resulting solution. A vacuum is used to extract the trapped air. The finished mixture is poured into a film and allowed to dry before being cut into the required number of pieces.

Hot-melt Extrusion: The initial mass is created using carriers in the hot melt extrusion process. The medication is combined with carriers to create initial mass, which is then dried after obtaining a solid mass. The extruder is then fed with dry, granular material. In order to process the granules inside the extruder barrel for around 3–4 minutes so that mass is adequately melted, the extruder screw speed should be set at 15 rpm. The resultant extrudate is then compressed into a cylindrical calendar to produce a film [28-30].

Semi-solid Casting: When using acid insoluble polymer as a film constituent, this approach is often recommended. In this initial step, water is used to dissolve the water-soluble polymers. The resulting solution is incorporated into the separately created acid-insoluble polymer solution. The two solutions have been suitably blended. After combining the two solutions, the resultant final solution is given a proper dosage of plasticizer to create gel mass. Finally, using heat-controlled drums, the gel mass is cast onto the films or ribbons. The ideal film thickness is between 0.015 and 0.05. The ratio of film-forming polymer to acid-insoluble polymer should be 1:4.

Solid Dispersion Extrusion: To enable loading of the medication, the method incorporates solid drug dispersion integrated in melted polymer solution. To create a solid dispersion, the medication is dissolved in a suitable liquid solvent and the resulting solution is added to a melt of a suitable polymer that may be generated at temperatures below 70°C. Finally, using dyes, they produced solid dispersions that were then formed into films.

Rolling Method: In the rolling process, the film-forming polymer solution and the drug solution are fully combined before the resulting solution or suspension is sent through a roller. Specific rheological considerations should be made for the solution or suspension. The film is cut into the necessary shapes and sizes after being cured on rollers [29-33].

Evaluation Parameters:

Organoleptic Test: Color, flavour, and taste are the required organoleptic attributes for a fast-dissolving formulation. The formulation should have appropriate organoleptic pleasant properties since it will dissolve in the mouth. He helps patients accept a formulation, and when oral films are given to youngsters, they should have appealing colour. Therefore, the colour of the formulation should be consistent and appealing. Visual examination can be used to assess colour. The smell is another organoleptic characteristic. The flavour added to the recipe should give it a pleasing aroma. By using a flavouring ingredient, the smell of the polymer, medication, and any other excipient should be concealed.

Taste is another crucial element that has to be considered. Special human taste panels are utilised to assess the flavour. The ability to differentiate between different sweetness levels in taste-masking formulations has also been demonstrated in experiments utilising electronic tongue measurements.

Surface pH Test: Evaluation of the surface pH of the film is required because the rapid dissolving strip's surface pH might have negative effects on the oral mucosa. The pH of the film's surface should be 7 or nearly neutral. A mixed pH electrode can be used for this.

OTF was made slightly damp with water, and the pH was determined by placing an electrode across the surface of the oral film. At least six films of each formulation should be used in this investigation so that the mean and standard deviation (SD) can be determined [34-35].

Thickness: Micrometer screw gauges or calibrated digital Vernier Calipers are used to measure film thickness. The recommended range for film thickness is 5-200 m. It is crucial to determine uniformity in the thickness of the film since this is directly connected to the accuracy of the dose distribution in the film. The thickness should be assessed at five distinct points (four corners and one in the centre).

Dryness/Tack Test: There are a total of eight drying phases for films, including set-to-touch, dust-free, tack-free (surface dry), dry-to-touch, dry-hard, dry-through (dry to handle), dry-to-recoat, and dry print-free. Tack describes how firmly a strip sticks to an accessory (such as a sheet of paper) after being rubbed against it. There are other instruments available for this research.

Tensile Strength: The highest stress that may be applied to a strip specimen before it breaks is its tensile strength. As shown in the equation below, it is computed by dividing the applied load at rupture by the cross-sectional area of the strip:

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

Percent Elongation: Strain is the stretching that occurs when tension is applied to a film (2×2 cm^2) sample. In essence, strain is the distortion of a strip prior to its failure under stress. The Hounsfield universal testing machine is used to measure it. In general, strip elongation rises as plasticizer content does. It is determined using the formula [37]:

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

Tear Resistance: A film's ability to resist being torn when a weight or force is applied to the film specimen is referred to as tear resistance. The main applied load is 51 mm/min, which is quite low. Newton or pounds of force are used to measure tear resistance. In other terms, it is the amount of force needed to completely destroy the specimen.

Young's Modulus: Young's modulus or elastic modulus is the measure of stiffness of strip. It is represented as the ratio of applied stress over strain in the region of elastic deformation as follows:

Young's modulus = Slope × 100/Strip thickness × Cross head speed

Hard and brittle strips demonstrate a high tensile strength and Young's modulus with small elongation.

Folding Endurance: Film is become brittle by folding endurance. The procedure used to calculate endurance value is repeatedly folding the film specimens (2×2^2) at the same location until they break, or a noticeable fracture is noticed. The computed folding endurance value is the number of folds the film can endure without cracking or breaking [38].

Transparency: A straightforward ultraviolet (UV) spectrophotometer may be used to assess the transparency of oral film. The spectrophotometer cell's interior side is where the film specimen is put. Film transparency is determined using the following formula:

Transparency = (log T600)/b = −€c

Where T600 is the transmittance at 600 nm and b is the film thickness (mm) and c is concentration.

Scanning Electron Microscopy: Electron microscopy may be utilised to examine the surface morphology of the film between various excipients and drug scans. At a magnification of 1000, the film sample should be set up in a sample holder. Using tungsten filament as an electron source, different photomicrographs can be obtained.

***In-vitro* Disintegration Test:** When an oral film comes in touch with saliva or water, it begins to disintegrate at that point. The time of disintegration should be in the range of 5 to 30 seconds for a film that dissolves quickly. Disintegration time can be investigated using a USP (United States Pharmacopoeia) disintegration device. Another approach involves dipping the film in 25 ml of water in a beaker to visually assess the disintegration time. Gently shaking the beaker is required, and the moment the film begins to dissolve or degrade should be noticed.

***In-vitro* Dissolution Studies:** Under typical circumstances of the liquid/solid interface, temperature, and solvent concentration, dissolution is the quantity of drug ingredient that enters the solution per unit time. For dissolving testing, you can use the typical basket or paddle equipment

mentioned in any of the pharmacopoeias. The sink conditions and greatest dosage of API will largely determine the choice of dissolving media. Dissolution medium temperature should be kept at 37 0.5°C, and rpm should be kept at 50. The use of the paddle device has the drawback because oral films have a propensity to float above the dissolution media [39].

Drug Content Uniformity: Any standard assay technique specified for the specific API in any of the standard pharmacopoeia can be used to ascertain this. By measuring the API content in each individual strip, content consistency is assessed. 85 to 115% is the maximum content homogeneity.

Permeation Studies: Even though the oral mucosa has a permeability that is 4 1000 times larger than the skin's, permeation tests need to be done. Modified Franz diffusion cells and porcine buccal mucosa can be utilised to examine the permeability. There are donor and receptor compartments in a Franz diffusion cell. Mucosa is positioned between the two compartments, and it should have the same size as the head of the receptor compartment. The receptor compartment is filled with buffer and kept at 37 0.2°C while being stirred by magnetic beads at a speed of 50 rpm to maintain thermodynamics. Keep a film specimen in close contact with the mucosal surface after moistening it with a few drops of simulated saliva. One millilitre of simulated saliva with a pH of 6.8 should be placed in the donor compartment. At certain intervals, samples are removed and are replaced with an equal volume of new media. An appropriate analytical technique can be used to calculate the percentage of drug permeation [38].

Percentage Moisture Loss: Films with a surface area of 2 x 2 cm2 are carefully cut and weighed on an electronic balance to calculate the % moisture loss. The films were weighed and then stored in desiccators with fused anhydrous calcium chloride. The desiccator should be used to store the films for 72 hours. They are removed after 72 hours, weighed once more, and the formula is used to calculate the % moisture loss of the films:

Percent moisture loss = (Initial weight - Final weight)/Initial weight × 100

The percentage moisture loss studies are done to determine physical stability and integrity of the film.

Determination of % Yield of Buccal Patches: Percentage yield of buccal patches can be calculated by the following formula [39]:

% yield = Mass of the buccal patches obtained/Total weight of drug and polymer × 100

Stability Study: According to the International Conference on Harmonization's (ICH) recommendations, stability studies should be conducted. The produced formula was packaged in a unique manner. It was first wrapped in a butter paper, which was followed by an aluminium foil wrap.

The packaging was then put into an aluminium bag and heat sealed. Formulations should be stored between 30°C and 40°C with a relative humidity (RH) between 60% and 75%, respectively. The films were assessed for drug content, disintegration time, and physical appearance after three months [40].

Packaging and Storage: The fast-dissolving dosage forms must be protected throughout production and storage using expensive packaging, specialised processing, and particular care. Single packing must be used. The most popular type of packaging is an aluminium bag. The Rapid card, a unique and patented packaging solution created by APR-Labtec, is specifically made for the Rapid films.

Three films may be stored on each side of the Rapid card, which is the same size as a credit card. Each dosage may be removed separately [41-44].

Market Formulated Product of OTF:

TABLE 4: LIST OF MARKETED PRODUCTS [45-50]

Sr. no.	Brand Name	Type of Formulation	Application
1.	Zolmitriptan Rapidfilm	Zolmitriptan ODF	Migraine
2.	Setofilm	Ondansetron ODF	Nausea

3.	KP106	D-amphetamine ODF	ADHD
4.	Onsolis	Fentanyl buccal soluble films	Breakthrough pain (cancer)
5.	Rapidfilm	Ondansetron and Donepizil ODF	Nausea and psychosis
6.	Triaminic Thin Strips	Phenylephrine and diphenhydramine ODF	Cough and Cold
7.	Suboxone	Buprenorphine and naloxone (sublingual films)	Opoid dependence
8.	Gas-X Thin Strips	Simethicone (sublingual films)	Bloating and gas
9.	Sudafed PE dissolved strips	Phenylephrine ODF	Cough and Cold

Applications of OTF in Drug Delivery Systems: For treatments requiring quick drug absorption, such as those used to treat pain, allergies, sleep disorders, and diseases of the central nervous system, oral mucosal administration via sublingual, buccal, and mucosal channels with the use of oral thin film may become the preferred delivery technique.

Topical Applications: In order to distribute active chemicals, such as analgesics or antibiotics, in the context of wound care and other applications, the use of dissolvable films may be practical [50-51].

Gastro Retentive Delivery System: Dissolvable films are being studied as a dosage form for molecules of diverse molecular weights that are both weakly and completely soluble in water. The gastrointestinal tract's (GIT) pH or enzyme secretion may cause a film to dissolve, which may be employed to treat gastrointestinal disorders [52].

Diagnostic Devices: Dissolvable films can be filled with sensitive reagents to permit controlled release when exposed to biological fluids or to make isolation barriers for separating numerous reagents to enable a timed response inside a diagnostic device [53-54].

CONCLUSION: As opposed to tablets, several pharmaceutical companies are now producing oral thin films that dissolve quickly. Films combine the benefits of liquid dosage forms with those of tablets, such as exact dose and simple administration (easy swallowing, rapid bioavailability). OTFs are new, innovative drug delivery methods that are crucial in emergency circumstances when quick action is necessary. They fill a demand by enabling children, the elderly, and the general public to discreetly take their prescriptions whenever and wherever they are needed. This technology offers a solid foundation for the creation of patent-compliant items and for extending the patent protection of currently available products. Fast-dissolving oral thin films can be used for a variety of purposes, including sublingual and gastro-retentive delivery systems in addition to buccal fast-dissolving systems. Future uses might involve employing laminated multilayer films to combine incompatible active medicinal components into a single product. The incompatible active medicinal components may be separated by an inactive film layer. Thin films can include active medicinal components with high transmucosal flux rates for gradual dissolution into buccal or sublingual areas. It is also possible to integrate medications coated with controlled release polymers. This technology is being studied extensively and there is wide scope for further research in this field.

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