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A REVIEW ON ORAL FAST DISSOLVING FILMS A NOVEL DRUG DELIVERY SYSTEM

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ABSTRACT

Oral route is most common and convenient route for the 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. In some cases, the oral solid dosage form may become difficult especially in swallowing (egs: motion sickness, sudden episode of allergic reaction, coughing, fear of choking, unavailability of water, and in different age group of patient and patients who suffer from dysphagia). To overcome these difficulties, fast dissolving drug delivery systems have been developed Fast dissolving oral delivery systems are solid dosage forms, which disintegrate or dissolve within 1 min when placed in the mouth without water or chewing. These thin sized film stripes are designed in such a manner for ease administration of drug when its placed on or under the tongue. There by the film enables the drug to deliver directly in to the blood stream either buccally or sublingually. Likewise, to improves the onset of action, lower the dosing and enhance the efficacy.

KEYWORDS

Dysphagia, Oral fast dissolving film, Sublingual and Buccal.

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INTRODUCTON

Fast dissolving drug-delivery systems were first developed in 1970s as an alternative to tablets, capsules, and syrups for pediatric and geriatric patients for experienced difficulties in swallowing traditional oral solid-dosage forms. OFDF is one of such novel approach to increase consumer acceptance by vitu of rapid dissolution, self-administration, easy to handle, convenient packaging, alleviates and pleasant taste. Oral fast dissolving film (OFDF) is also known as mouth dissolving film (MDF), oral strips, Oro-dispersive

films (ODF). This drug delivery system were developed based on the technology of transdermal patch. Generally, mouth dissolving films have the property to dissolve the drug within seconds by saliva when it simply placed on patients tongue or mucosal tissue and thereby passing the first pass hepatic metabolism, dissolved drug are dropped in to systematic circulation by a buccal mucosa. To achieve this, some of the criteria have to be maintained such as the polymers used in film preparation should be hydrophilic in nature. The drug should have a low loading dose with enhanced bioavailability¹⁻³.

Special features of oral thin films

- Thin elegant.
- Available in various size and shapes.
- Un-obstructive.
- Excellent mucoadhesion.
- Fast disintegration and rapid release⁴.

Ideal properties of fast dissolving films

- It should have an acceptable taste with pleasing mouth feel.
- It should be less friable and have good mechanical strength to withstand the post manufacturing handling.
- The drug should have good stability and solubility in water as well as in saliva.
- It should leave least or no residue in mouth.
- It should quickly dissolve to release drug instantaneously in mouth.
- It should be compatible with the other ingredients.

Advantages of fast dissolving films

- No risk of choking.
- Convenient dosing or accurate dosing.
- No need of water to swallow or chew.
- Rapid onset of action.
- Ease of handling and transportation.
- Improve bioavailability for certain therapeutic ingredient.
- Enhanced stability.
- Taste masking.

Disadvantages of fast dissolving films

- It is hygroscopic in nature so it must be kept in dry places.
- It also shows the fragile, granule property.
- They require special packing for the products stability and safety.
- High dose cannot be incorporated into the oral film⁵.

Drug delivery through the oral cavity can be subdivided as follows

Sublingual delivery

This is systemic delivery of drugs through the mucosal membranes lining the floor of the mouth (sublingual mucosa). Sublingual region shows higher drug permeability than buccal region. Drugs which require rapid onset of action are administered by this route e.g. Nitro-glycerine.

Buccal delivery

The drugs administration through mucosal membranes lining the cheeks and the area between gums, upper and lower lips to the systematic circulation.

Local delivery

Which is drug delivery in the oral cavity for the treatment of conditions of the oral cavity principally aphthous ulcers, fungal conditions, and periodontal disease etc.

Advantages of buccal drug delivery

The main advantages of buccal drug delivery are avoidance of pre systemic elimination within the GI tract. Moreover, that buccal mucosa has excellent accessibility and hence suitable for administration of retentive dosage forms. Also this will provide direct access to systemic circulation through the internal jugular vein by passes drugs from the hepatic first pass metabolism leading to higher bio availability. The buccal drug delivery provides low enzymatic activity, painless administration, easy drug withdrawal and versatility in designing as multi directional or unidirectional release systems for local or systemic action. Buccal mucosa has high patient acceptability compared to routes of drug administration other than oral. Drugs that show lesser bio availability when administered via oral route can be administered through buccal mucosa.

A drug which is not stable in the acidic environment (stomach) or in alkaline environment can be administered by this route. It has a facility to include permeation enhancer, enzyme inhibitor or pH modifier in the formulation.

Disadvantages of oral drug delivery system

Those drugs which are unstable at oral pH cannot be administered via oral route. Drugs with small dose requirement can only be administered. The Drugs which irritates the mucosa or having a bitter or unpleasant taste or an obnoxious odour cannot be administered by this route. Low permeability of buccal membrane specifically when compared to the sublingual membranes and has a smaller surface area¹³⁻¹⁴.

Current oral fast-dispersing dosage forms:

Although there are several technologies available, very few have reached to commercial. Table No.1 shows the classification of these technologies according to core manufacturing processes. Different methods have been employed in the formulation of oral fast-dispersing tablets, such as modified tableting systems, floss, or shear form formation by application of centrifugal force and controlled temperature, and freeze drying. Been used by some technology houses, branded companies and generic pharmaceutical companies, for in-house development of line extension and generic fast-dissolve dosage forms.

CLASSIFICATION OF FAST DISSOLVING TECHNOLOGY

For ease of description, fast-dissolve technologies can be divided in to three broad groups.

- i. Lyophilized systems,
- ii. Compressed tablet-based systems,
- iii. Thin film strips.

Lyophilized systems

This system has been by far the most successful among them in terms of sales value, sales volume and number of worldwide product approvals. The technology around these systems involves taking a suspension or solution of drug with other structural excipients and, through the use of a mould or blister pack, forming tablet-shaped units. The units or tablets are then frozen and lyophilized in the pack

or mould. The resulting units have a very high porosity, which allows rapid water or saliva penetration and very rapid disintegration. Dose-handling capability for these systems differs depending on whether the active ingredients are soluble or insoluble drugs, with the dose capability being slightly lower for the former than for some tablet based systems. The units are capable of incorporating a range of taste-masked materials and have more rapid disintegration than tablet-based systems.

Compressed tablet-based systems

System is produced using standard tablet technology by direct compression of excipients. Depending on the method of manufacture, the tablet technologies have different levels of hardness and friability. The speed of disintegration for fast-dissolve tablets compared with a standard tablet is achieved by formulating using water soluble excipients, or super-disintegrant or effervescent components, to allow rapid penetration of water into the core of the tablet. The one exception to this approach for tablets is biovails fuisz technology. It uses the proprietary shear form system to produce drug-loaded candy floss, which is then used for tableting with other excipients. These systems can theoretically accommodate relatively high doses of drug material, including taste-masked coated particles. The potential disadvantage is that they take longer to disintegrate than the thin-film or lyophilized dosage forms. The loose compression tablet approach has increasingly been used by some technology houses, branded companies and generic pharmaceutical companies, for in-house development of line extension and generic fast-dissolve dosage forms¹⁶.

Thin films (OTF)

Oral films, also called oral wafers in the related literature, are a group of flat films which are administered into the oral cavity. Although oral film systems, the third class, have been in existence for a number of years, they have recently become the new area of interest in fast-dissolve pharmaceutical drug delivery. Dissolvable oral thin films (OTFs) or oral strip (OS) evolved over the past few years from the confection and oral care markets in the form of

breath strips and became a novel and widely accepted form by consumers for delivering vitamins and personal care products. Companies with experience in the formulation of polymer coatings containing active pharmaceutical ingredients (APIs) for transdermal drug delivery capitalized on the opportunity to transition this technology to OTF formats. Today, OTFs are a proven and accepted technology for the systemic delivery of APIs for over-the-counter (OTC) medications and are in the early to mid-development stages for prescription drugs¹⁷.

Classification of oral film

There are three different sub types,

1. Flash release
2. Mucoadhesive melt-away films
3. Mucoadhesive sustained-release films

These three types of oral films are differentiated from each other in following table,

Oral films formulation components

Formulation of oral film involves the intricate application of aesthetic and performance characteristics such as taste masking, fast dissolving, physical appearance, mouth-feel etc. The excipients used in formulation of oral film are given below as per their categories. From the regulatory perspectives, all excipients used in the formulation of oral film should be generally regarded as safe (i.e. GRAS-listed) and should be approved for use in oral pharmaceutical dosage forms.

Films forming polymers

A variety of polymers are available for preparation of oral films. The polymers can be used alone or in combination to obtain the desired film properties. The film obtained should be tough enough so that there won't be any damage while handling or during transportation. The robustness of the strip depends on the type of polymer and the amount in the formulation¹⁹. On the other hand, fast dissolving. Films dosage form should have the property to disintegrate in seconds when placed in mouth and deliver the drug to the oral cavity instantaneously. Lists of polymers which are used in oral film are mentioned below,

As the film forming polymer (which forms the platform for the oral film) is the most essential and major component of the oral film, at least 45% w/w of polymer should generally be present based on the total weight of dry oral film²⁰. Of the various polymers available, pullulan, gelatin and hypromellose are most commonly used for preparation of oral film.

Plasticizers

Plasticizer is a vital ingredient of the oral film formulation. It helps to improve the flexibility of the strip and reduces the brittleness of the strip. Plasticizer plays important role to improve the properties of strip by lowering down the glass transition temperature of the polymer. The selection of plasticizer will depend upon its compatibility with the polymer and also the type of solvent employed in the casting of film.

Flow of polymer will get better with the use of plasticizer and enhances the strength of the polymer. Glycerol, propylene glycol, the commonly used plasticizers are glycerol, di-butylphthalate, and polyethylene glycols etc. Inappropriate use of plasticizer may lead to film splitting or cracking. Use of certain plasticizers may affect the drug absorption rate. The plasticizer used should impart the permanent to the strip.

It should be noted that the properties of plasticizer are important to decrease the glass transition temperature of polymer in the range of 40-60°C for non-aqueous solvent system and below 75°C for aqueous systems. Plasticizer should be compatible with drug as well as other excipients used for preparation of strip. Cellulosic hydrophilic polymers were easily plasticized with hydroxyl containing plasticizers like PEG, propylene glycol, glycerol and polyols. Glycerol acts as a better plasticizer for polyvinyl alcohol while diethylene glycol can be used for both hypromellose as well as polyvinyl alcohol films²¹⁻²⁸.

Choice of drug candidate²⁹

Suitable drug candidate for FDF should possess:

- No bitter taste.
- Stability in water and saliva.
- Dose should be low³².

Sweetening agent

Sweeteners have become the essential part of the formulation intended to be disintegrated or dissolved in the oral cavity. Both natural sweeteners as well as artificial sweeteners are used in the formulation of fast dissolving films. Generally sweeteners are used in the formulation in concentration of 3-6% w/w, either in combination. Polyhydric alcohols such as sorbitol, mannitol and isomalt can be used in combination as they additionally provide good mouth-feel and cooling sensation. However, it should be noted that the use of case of pediatric population. Natural food products as well as pharmaceutical products sweeteners as well as artificial sweeteners are used intended to be disintegrated or dissolved in the oral to improve the palatability of the mouth dissolving formulations^{30,31} aspartame was used for the preparation of oral strips of valdecoxib³² for the oral strip of piroxicam, maltodextrin was employed as sweetening agent³³.

Saliva stimulating agent

The rationale of 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. Generally, acids which are used in the preparation of food can be utilized as salivary stimulants, like citric acid, malic acid, lactic acid, ascorbic acid etc. These agents are used alone or in combination between 2 to 6% w/w of weight of the film. Sweeteners also act as saliva stimulating agent³⁴.

Flavouring agent

Selection of flavour is depending on which type of drug is to be incorporated in the formulation. The acceptance of the oral disintegrating/ dissolving formulation by an individual depend on the initial flavour quality which is observed in the first few seconds after the product has been consumed and the after taste of formulation lasts for at least 10 min. The amount of flavour required to mask the taste depend on the flavour type and its strength. Flavouring agent is used in the formulation in concentration of 10% w/w.

Colouring agent

FD and C approved colouring agent is incorporated in fast dissolving film. Generally colouring agent is not exceeding concentration a level of 1% w/w in fast dissolving film. Mainly titanium dioxide is used in the formulation³⁵.

Manufacturing methods

Various approaches to manufacturing of rapid dissolving film are classified as follow:

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

Evaluation of fast dissolving oral films

Organoleptic evaluations

Formulated films were evaluated for organoleptic evaluations like color, odor and taste.

Physical appearance and surface texture

Physical appearance was checked by visual inspection and surface texture was evaluated by touch or feel of the film.

Weight uniformity

The cast film was cut at different places and the weight of each film was checked with the help of an electronic balance and the average weight was calculated.

Folding endurance

Folding endurance was determined by repeatedly folding the film at the same position until it breaks. The number of times the films can be folded without breaking is termed as the folding endurance value.

Tensile strength

Tensile strength is the maximum stress applied to a point at which the film specimen breaks. This test is basically performed to measure the mechanical strength of the films. It can be calculated from applied load at cleavage divided by the film cross-sectional area given in the equation below:

Tensile strength = (load at failure / strip thickness × strip width) × 100

Percent elongation

When stress is applied, a film sample stretches, and this is referred to as a strain. Strain is basically the

deformation of film divided by the original dimension of the sample.

Percentage elongation = $\frac{\text{increase in length} \times 100}{\text{original length}}$

Thickness of films

The thickness of a film is determined by using a digital screw gauge at different decisive location (at least 5 locations). Therefore, it is essential to determine uniformity in the thickness of the film which is directly related to the accuracy of the dose in the film formulation.

Disintegration time

Disintegration of orally fast dissolving films requires USP disintegration apparatus. The disintegration time limit of 30 seconds or less for orally disintegrating tablets described in CDER guidance can be applied for the fast dissolving oral films. Disintegrating time will vary depending on the formulation but generally the disintegration ranges from 5 to 30 seconds. Although, no official guidance is available for oral fast disintegrating films.

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 films. The change in the colour of pH paper was observed and reported.

Drug content

The film can be tested for drug content uniformity by UV visible spectrophotometric method. Films of each formulation can be placed in different 100ml volumetric flask and can be dissolved using the pH buffer and volume was made up to 100ml. After 30 min, 5ml of sample can withdraw and transferred into a 10ml volumetric flask and the volume was made up to mark. The absorbance of resulting solution measured against blank in UV spectrophotometer. The percentage drug content was determined using the standard graph. The mean and standard deviation were calculated.

In-vitro drug release

Standard official basket or paddle apparatus is used for conducting dissolution studies on films. Sink conditions should be maintained during dissolution. Sometimes while performing this process, film floats over the medium making it difficult to perform the test properly. This problem is more likely to occur in case of paddle method thus the basket apparatus is mostly preferred. Media used are 6.8 pH phosphate buffer (300ml) and 0.1 N HCl (900ml). Temperature is maintained at 37 ± 0.5 °C and rotation speed of 50 rpm is usually adjusted. Samples of drug dissolved are collected at pre-determined intervals and are analyzed by using UV spectrophotometer³⁷⁻⁴⁰.

Storage and packaging

The converting and packaging stage also provides product flexibility to drug manufacturers. The rolled film can be die-cut into any shape or size or slit into narrower rolls as required for the application. For branding purposes and to meet industry regulations, converters may choose to print information directly onto the film unit doses before packaging. Criteria that may be taken into consideration include the need for unit-dose packaging, barcode labeling, and the content in instructions for use, child-resistant seals, and senior-friendly packaging⁴¹.

Table No.1: Current Oral fast-dispersing tablet technologies¹⁵

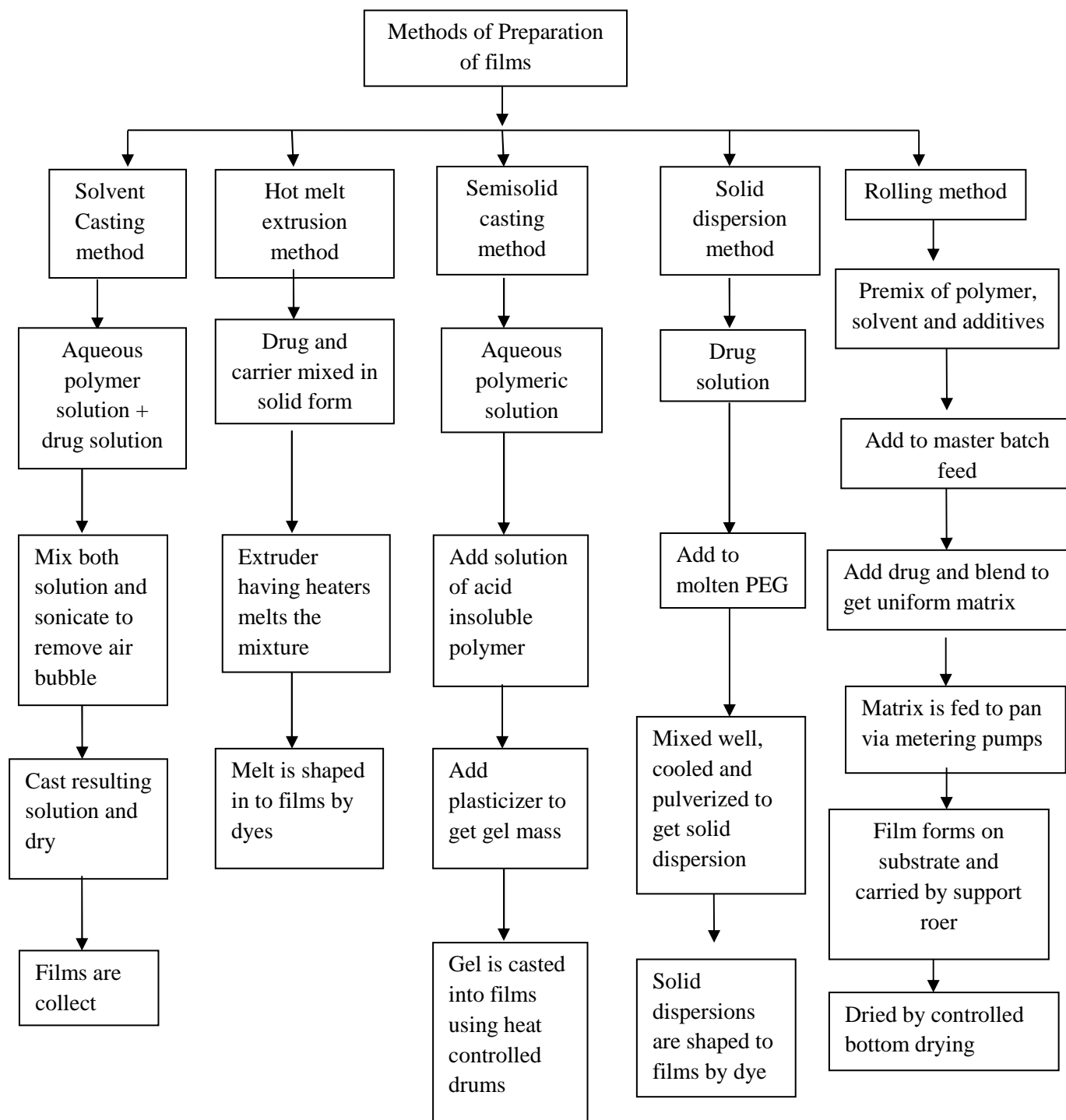
S.No	Technology	Company
I. Conventional tablet processes with modifications		
1	Wowtab ^{fi}	Yamanouchi pharma technologies, 1050 arastradero road, palo alto, ca, USA.
2	Orasolv ^{fi}	Cima labs, inc., 10000 valley hill road, eden prairies, mn, USA.
3	Efvdas ^{fi}	Elan corp., monkslandathlone, country westmeath, Ireland.
4	Flashtab ^{fi}	Prographarm, chaueauneuf-En-thymeraia, France
II. Freeze drying method		
5	Zydis ^{fi}	R.p. Scherer, frankland road, Swindon, UK
6	Lyoc ^{fi}	Farmalyoc, 5av charlesmarting, maisons-alfort, france
7	Quicksolv ^{fi}	Janssen pharmaceuticals, 1125 trenton-harbourton road, titusville, NJ, USA
III. Floss formation		
8	Flashdose ^{fi}	Fuisz technologies, 14555 avion at lakeside, chantilly, VA, USA.

Table No.2: Types of films and their properties¹⁸

S.No	Property/sub type	Flash release water	Mucoadhesive melt-away films	Mucoadhesive sustained release films
1	Area (cm ²)	2-8	2-7	2-4
2	Thickness(m)	20-70	50-500	50-250
3	Structure	Film: single layer	Single or multilayer system	Multi-layer system
4	Excipients	Soluble, highly hydrophilic polymers	Soluble, hydrophilic polymers	Low/non-soluble polymers
5	Drug phase	Solid solution	Solid solution or suspended drug particles	Suspension and/or solid solution
6	Application	Tongue(upper palate)	Gingival or buccal region	Gingival, (other region in the oral cavity)
7	Dissolution	Maximum 60 seconds	Disintegration in a few minutes, forming gel	Maximum 8-10 hours
8	Site of action	Systemic or local	Systemic or local	Systemic or local

S.No	Pullulan	Sodium carboxy methyl cellulose
1	Gelatin	Hydroxyl ethyl cellulose
2	Hydroxyl propyl methyl cellulose (hypromellose)	Xanthan gum
3	Polyvinyl pyrrolidone (pvp)	Locust bean gum
4	Modified starches	Guar gum
5	Polyvinyl alcohol	Carrageenan
6	Polyethylene oxide	Low viscosity grade HPC

Flow Chart for manufacturing of Fast Dissolving Film



CONCLUSION

Oral thin films are intended for application in the oral cavity and they are innovative and promising dosage form specially for use in pediatrics and geriatrics. They combine the greater stability of a solid dosage form and a good applicability of a liquid and thus bridges the gap between two ideas, incorporating positive elements from both solid and liquid dosage form into an elegant, stable and effective delivery vehicle. So they are of great importance during the emergency cases such as allergic reactions and asthmatic attacks whenever immediate onset of action is desired. Today, OTFS are a proven and accepted technology for the systemic delivery of AIPS for over-the-counter (OTC) medications and are in the early-to-mid-development stages for prescription drugs.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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