

**FAST DISSOLVING FILMS: A NOVEL APPROACH TO ORAL DRUG DELIVERY**Aggarwal Jyoti<sup>\*1</sup>, Singh Gurpreet<sup>1</sup>, Saini Seema<sup>1</sup>, Rana A.C<sup>2</sup><sup>1</sup>Rayat Institute of Pharmacy, Department of Pharmaceutics, Ropar. S. B. S Nagar-144533 (Punjab) India<sup>2</sup>Rayat Institute of Pharmacy, Department of Pharmacology, Ropar. S.B.S Nagar-144533 (Punjab) India

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\*E mail: [jyoti16881@gmail.com](mailto:jyoti16881@gmail.com)**ABSTRACT**

Amongst the plethora of avenues explored for rapid drug releasing products, oral strip technology (OST) is gaining much attention. Dissolvable oral thin films (OTFs) 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. Fast-dissolving oral films are solid dosage forms, which disintegrate or dissolve within 1 min when placed in the mouth without drinking water or chewing. These drug delivery systems allow the medication to bypass the first pass metabolism thereby making the medication more bioavailable. The sublingual and buccal delivery of a drug via thin film has the potential to improve the onset of action, lower the dosing and eliminate patient's fear of choking. Formulation of oral films involves the application of both aesthetic and performance characteristics such as plasticized hydrocolloids, active pharmaceutical ingredient, taste masking agent being laminated by solvent casting or hot melt extrusion. Solvent casting being the most preferred offers great uniformity of thickness and films have fine gloss and better physical properties. Oral strips are evaluated for various attributes such as thickness, folding endurance, disintegration and dissolution time. This review describes about the formulation methodology, evaluation parameters and the future aspects of oral fast dissolving films.

**Keywords-** Oral fast dissolving films, solvent casting, rapid disintegration

**INTRODUCTION**

Among the delivery routes, Oral route is the most preferred route for the delivery of the drugs till date due to ease of ingestion, pain avoidance and versatility (to accommodate various types of drug candidates)<sup>1,2</sup>. Also, solid oral delivery systems do not require sterile conditions and are, therefore, less expensive to manufacture, but oral drug delivery systems still need some advancements to be made because of their some drawbacks related to particular class of patients which includes geriatric, pediatric and dysphasic patients associated with many medical conditions as they have difficulty in swallowing or chewing solid dosage forms. Many pediatric and geriatric patients are unwilling to take solid preparations due to fear of choking. Even with fast dissolving tablets there is a fear of choking due to its tablet type appearance. One study showed that 26% of 1576 patients experienced difficulty in swallowing tablets. The most common complaint was tablet size, followed by surface form and taste. For the last two decades, there has been an enhanced demand for more patient-compliant dosage forms<sup>3</sup>. "Research and development in the oral drug delivery segment has led to transition of dosage forms from simple conventional tablets/capsules to modified release tablets/capsules to oral disintegrating tablet (ODT) to wafer to the recent development of oral strip (OS), a thin film that is prepared using hydrophilic polymers that rapidly dissolves on the tongue or buccal cavity". Fast-dissolving drug-delivery systems were first developed in the late 1970s as an alternative to tablets, capsules and syrups for pediatric and geriatric patients who experience difficulties swallowing traditional oral solid-dosage forms. The novel technology of oral fast-dispersing dosage forms is known as fast dissolve, rapid dissolve, rapid melt and quick disintegrating tablets. By definition, a solid dosage form typically the size of a postage stamp that dissolves or disintegrates quickly in the oral cavity resulting in solution or suspension without the need for the administration of water is known as an oral fast-dispersing dosage form. 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 drugs.

**Special Features Of Oral Thin Films<sup>4</sup>**

- Thin elegant film
- Available in various size and shapes
- Unobstructive

- Excellent mucoadhesion
  - Fast disintegration and Rapid release
- Ideal Characteristics Of A Suitable Drug Candidate**

- The drug should have pleasant taste.
- The drug to be incorporated should have low dose upto 40 mg.
- The drugs with smaller and moderate molecular weight are preferable.
- The drug should have good stability and solubility in water as well as in saliva.
- It should be partially unionized at the pH of oral cavity.
- It should have the ability to permeate oral mucosal tissue.

**Benefits Of Oral Thin Films**

- Larger surface area promotes rapid disintegration and dissolution in the oral cavity.
- Oral films are flexible and thus less fragile as compared to ODTs. Hence, there is ease of transportation and during consumer handling and storage.
- Precision in the administered dose.
- No risk of choking
- Good mouth feel
- Improved patient compliance
- Ease of swallowing and no need of water has led to better acceptability amongst the dysphagic patients<sup>5</sup>
- Dosage form can be consumed at any place and anytime as per convenience of the individual.
- The oral or buccal mucosa being highly vascularized, drugs can be absorbed directly and can enter the systemic circulation without undergoing first-pass hepatic metabolism<sup>6</sup>.
- Enhanced oral bioavailability of molecules that undergo first pass effect.
- Bypassing the first pass effect leads to reduction in the dose which can lead to reduction in side effects associated with the molecule.
- OTFs are typically the size of a postage stamp and disintegrate on a patient's tongue in a matter of seconds for the rapid release of one or more APIs<sup>7</sup>.

The mouth dissolving films has also a clear advantage over the Oral dissolving tablets (ODTs):

- ODTs are sometimes difficult to carry, store and handle (fragility and friability).
- Many ODTs are prepared by using the expensive lyophilisation process.

**Classification Of Fast Dissolve Technology**

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

- Lyophilized systems
- Compressed tablet-based systems
- Oral thin films.

**The lyophilized systems:** The technology around these systems involves taking a suspension or solution of drug with other structural excipients, 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.

**Compressed tablet-based systems:** This 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

**Classification Of Oral Films**

Three types of oral films are differentiated from each other in following table:-

**Types of wafers and their properties**

Property/SubType	Flash release wafer	Mucoadhesive melt-away wafer	Mucoadhesive sustained release wafer
Area (cm <sup>2</sup> )	2-8	2-7	2-4
Thickness (µm)	20-70	50-500	50-250
Structure	Film: single layer	Single or multilayer System	Multi layer system
Excipients	Soluble, highly hydrophilic polymers	Soluble, hydrophilic Polymers	Low/Non-soluble Polymers
Drug phase	Solid solution	Solid solution or suspended drug particles	Suspension and/or solid Solution
Application	Tongue(upper palate)	Gingival or buccal Region	Gingival, (other region in the oral cavity)
Dissolution	Maximum 60 seconds	Disintegration in a few minutes, forming gel	Maximum 8-10 hours
Site of action	Systemic or local	Systemic or local	Systemic or local

**Applications Of Oral Films In Drug Delivery**

- Oral mucosal delivery via Buccal, sublingual, and mucosal route by use of OTFs could become a preferential delivery method for therapies in which rapid absorption is desired, including those used to manage pain, allergies, sleep difficulties, and central nervous system disorders.
- **Topical applications:** The use of dissolvable films may be feasible in the delivery of active agents such as analgesics or antimicrobial ingredients for wound care and other applications
- **Gastro retentive dosage systems:** Dissolvable films are being considered in dosage forms for which water-soluble and poorly soluble molecules of various molecular weights are contained in a film format<sup>8</sup>. Dissolution of the films could be triggered by the pH or enzyme secretions of the gastrointestinal tract, and could potentially be used to treat gastrointestinal disorders.
- **Diagnostic devices:** Dissolvable films may be loaded with sensitive reagents to allow controlled release when exposed to a biological fluid or to create isolation barriers for separating multiple reagents to enable a timed reaction within a diagnostic device<sup>9</sup>.

**Oral Film Formulation Considerations**

Formulation of OS involves the intricate application of aesthetic and performance characteristics such as taste masking, fast dissolving,

disintegration for fast-dissolve tablets compared with a standard tablet is achieved by formulating it using water soluble excipients or super-disintegrant or effervescent components, to allow rapid penetration of water into the core of the tablet.

**Oral 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. 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. 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 drugs. This is largely as a result of the success of the consumer breath freshener products such as Listerine Pocket Packs in the US consumer market.

Such systems use a variety of hydrophilic polymers to produce a 50-200 mm film. This film can reportedly incorporate soluble, insoluble or taste-masked drug substances. The film is manufactured as a large sheet and then cut into individual dosage units for packaging in a range of pharmaceutically acceptable formats.

physical appearance, mouth-feel etc. From the regulatory perspectives, all excipients used in the formulation of OS should be Generally Regarded as Safe (i.e. GRAS-listed) and should be approved for use in oral pharmaceutical dosage forms.

A typical composition contains the following

Drug	1-25%
Water soluble polymer	0-40%
Plasticizers	0-20%
Fillers, colours, flavours etc.	0-40%

**Strip Forming Polymers**

The polymers in the formulation can be used alone or in combination to obtain the desired strip 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 its amount<sup>10</sup>. A variety of polymers are available for preparation of OS. On the other hand, fast dissolving strip dosage form should have the property to disintegrate in seconds when placed in mouth and deliver the drug to the oral cavity instantaneously Various polymers used in the formulation of oral strips are given in TABLE 1

Of the various polymers available, pullulan, gelatin and hypromellose are most commonly used for preparation of OS. At least 45%w/w of polymer should generally be present based on the total weight of dry OS<sup>11</sup>.

TABLE 1

Property	Hydroxy propyl methyl cellulose (Hypromellose)	Hydroxy propyl cellulose	Starch and modified starch	Pullulan	Gelatin	Carboxy methyl cellulose
<b>Synonym</b>	HPMC, Methocel, Metolose, Benecel	Hydroxyl propyl ether, hyplose, Klucel, Nisso HPC	Amido, amyllum, PharmGel, Fluftex W, Instant pure-Cote, Melogel	Pullulane, 1, 6 $\alpha$ linked maltotriose	Byco, cryogel, Instagel, Solugel	Akulell, Blanose, Aquasorb, CMC sodium
<b>Molecular weight</b>	10,000-1,500,000	50,000-1,250,000	50,000-1,60,000	8000-2,000,000	15,000-250,000	90,000-700,000
<b>Solubility</b>	Soluble in cold water, forming a viscous colloidal solution, insoluble in chloroform, ethanol	It is freely soluble in water below 38 °C forming a smooth, clear, colloidal solution.	Starch is insoluble in cold water and ethanol. It swells in water by about 5 to 10% at 37 °C	It is soluble in hot as well as cold water.	Soluble in glycerin, acid and alkali. Swells in water and softens. It is soluble in hot Water	It is easily dispersed in water to form a clear or colloidal solution.
<b>Film forming ability</b>	It has a film forming ability in 2–20%w/w concentrations	5%w/w solution is generally used for film coating.	Modified starches have a property to form quick dissolving films.	5–25%w/w solution forms flexible films	It has a very good film forming ability.	Carboxymethyl cellulose has good film forming property
<b>Viscosity</b>	Viscosity of various grades ranges from 3mPa s–100,000 mPa s	75 mPa s–6500 mPa s depending upon the polymer grade	2%w/v aqueous dispersion of Starch provides 13 mPa s Viscosity.	The viscosity (10%w/w, 30 °C) of pullulan was 100–180 mm <sup>2</sup>	4.3–4.7 mPa s for a 6.67%w/v Aqueous solution at 60 °C.	The 1%w/w aqueous solution has viscosities in the range of 5–13,000 mPa s.
<b>Melting point</b>	Browns at 190–200 °C. glass transition temperature is 170–180 °C	It softens at 130 °C; chars at 260–275 °C	It decomposes at 250 °C	107 °C	-	Browns at 227 °C and chars at 252 °C.

**Active pharmaceutical ingredient**

The OS technology has the potential for delivery of variety of APIs. A number of molecules can be incorporated into this delivery system. They may include cough/cold remedies (antitussives, expectorants), antianxiety drugs, cardiovascular agents, sore throat, erectile dysfunction drugs, antihistamines, antiasthmatics, gastrointestinal disorders, nausea, pain and CNS (e.g. anti-Parkinson’s disease). Other applications comprise caffeine strips, snoring aid, multivitamins, sleeping aid etc. However since the size of the dosage form has limitation, high dose molecules are difficult to be incorporated in OS. Generally 5%w/w to 30%w/w of active pharmaceutical ingredients can be incorporated in the OS<sup>12</sup>. It is always useful to have micronized API which will improve the texture of the film and also for better dissolution and uniformity in the OS<sup>13</sup>. Many APIs, which are potential candidates for OS technology, have bitter taste. This makes the formulation unpalatable especially for pediatric preparations. Thus before incorporating the API in the OS, the taste needs to be masked. Various methods can be used to improve the palatability of the formulation. Certain pathologies require instantaneous release of the medicament for prompt relief. For instance, in the case of migraine a rapid clinical effect is desired by the individual. Regiospecific delivery of the medicament would be required in the cases of sore throat, cough, allergy and other local oral manifestations. Some of the examples of suitable drug molecule that can be incorporated in the OS are listed in following table:

MOLECULE	THERAPEUTIC CATEGORY	DOSE
Chlorpheniramine maleate	Anti-allergic	4.0 mg
Zolmitriptan	Anti-migraine	2.5 mg
Cetirizine	Anti-histaminic	5.0-10.0 mg
Famotidine	Antacid	10.0 mg
Loperamide	Anti-diarrhoeal	2.0 mg
Ketoprofen	Analgesic	12.5 mg
Dicyclomine	Muscle relaxant	25.0 mg
Nicotine	Smoking cessation	1.0-15.0 mg
Omeprazole	Proton pump inhibitor	10.0-20.0 mg

**Plasticizers**

The selection of plasticizer will depend upon its compatibility with the polymer and also the type of solvent employed in the casting of strip. It helps to improve the flexibility of the strip and reduces the brittleness of the strip. Plasticizer significantly improves the strip properties by reducing the glass transition temperature of the polymer in the range of 40–60 °C for non aqueous solvent system and below 75 °C for aqueous systems<sup>14,15</sup>.

List of Plasticizers used in oral strip formulation

Glycerol	Propylene glycol
Low mol.wt polyethylene glycols	Phthalate derivatives like dimethyl, diethyl, dibutyl derivatives
Citrate derivatives like triacetin, acetyl citrate	Castor oil

Typically the plasticizers are used in the concentration of 0–20%w/w of dry polymer weight.

**Sweetening agents**

Sweeteners have become the important part of the food products as well as pharmaceutical products intended to be disintegrated or dissolved in the oral cavity. The sweet taste in formulation is more important in case of pediatric population<sup>16</sup>. Natural sweeteners as well as artificial sweeteners are used to improve the palatability of the mouth dissolving formulations. Suitable sweeteners include:

- (a) Water soluble natural sweetener: xylose, ribose, glucose, sucrose, maltose, stevioside etc.
- (b) Water soluble artificial sweetener: sodium or calcium saccharin salts, cyclamate salts, acesulfame-k etc.
- (c) Dipeptide based sweetener: aspartame
- (d) Protein based sweeteners: thaumatin I and II.

The sweetness of fructose is perceived rapidly in the mouth as compared to sucrose and dextrose. Generally sweeteners are used in the concentration of 3 to 6 %w/w either alone or in combination. The artificial sweetener is preferred over natural sugars because lower concentration is required and multiple uses don't result in dental caries in individuals<sup>17</sup>.

**Saliva stimulating agents**

The purpose of using saliva stimulating agents is to increase the rate of production of saliva that would aid in the faster disintegration of the rapid dissolving strip formulations. These agents are used alone or in combination between 2 to 6%w/w of weight of the strip<sup>18</sup>.

Generally acids which are used in the preparation of food can be utilized as salivary stimulants.

Citric acid	Ascorbic acid
Tartaric acid	Malic acid

**Flavoring agents**

Perception for the flavors changes from individual to individual depending upon the ethnicity and liking. It was observed that age plays a significant role in the taste fondness. The geriatric population likes mint or orange flavors while younger generation likes flavors like fruit punch, raspberry etc. The selection of flavor is also dependant on the type of drug to be incorporated in the formulation. The acceptance of the oral disintegrating or dissolving formulation by an individual by and large depends on the initial flavor quality which is observed in first few seconds after the product has been consumed and the after taste of the formulation which lasts for at least about 10 min<sup>19</sup>.

Synthetic flavor oils : - Peppermint oil, cinnamon oil, spearmint oil, oil of nutmeg

Fruity flavors : - vanilla, cocoa, coffee, chocolate and citrus

Fruit essence type : - Apple, raspberry, cherry, pineapple

The amount of flavor needed to mask the taste depends on the flavor type and its strength. Preferably up to 10% w/w flavors are added in the OS formulations.

**Cooling agents**

Cooling agents like monomethyl succinate can be added to improve the flavor strength and to enhance the mouth-feel effect of the product. Other cooling agents like WS3, WS23 and Utracoll II can also be used in conjunction with flavors<sup>20</sup>.

**Coloring agents**

Pigments such as titanium dioxide or FD&C approved coloring agents are incorporated (not exceeding concentration levels of 1%w/w) in OS when some of the formulation ingredients or drugs are present in insoluble or suspension form<sup>21,22</sup>.

**Stabilizing and thickening agents**

The stabilizing and thickening agents are employed to improve the viscosity and consistency of dispersion or solution of the strip preparation solution or suspension before casting. Natural gums like xanthan gum, locust bean gum, carragenan and cellulosic derivatives can be used in the concentration up to 5%w/w as thickening agents and stabilizing agents.

Other ingredients such as surfactants and emulsifying agents are also added in small amount to improve the strip properties.

**Surfactants<sup>23</sup>**

Surfactants are used as solubilising or wetting or dispersing agent so that the film is getting dissolved within seconds and release active agent. Some of the commonly used are sodium lauryl sulfate, benzalkonium chloride, benzthonium chloride, tweens etc. One of the most important surfactant is polaxamer 407 that is used as solubilizing, wetting and dispersing agent.

**Manufacturing And Formulation Of Oral Films**

One or combination of the following process can be used to manufacture the mouth dissolving films: -<sup>24</sup>

- i) Solvent casting
- ii) Semisolid casting
- iii) Hot melt extrusion
- iv) Solid dispersion extrusion
- v) Rolling

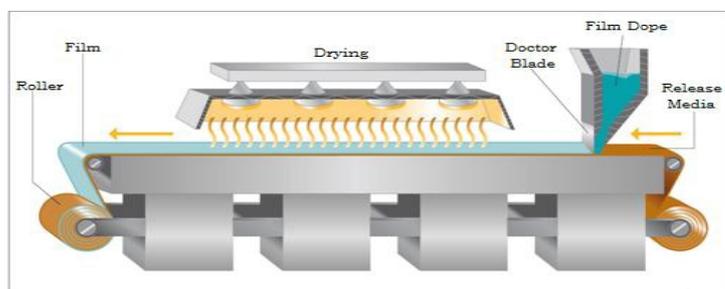
Generally the solvent casting method is employed for manufacture of strips.

**Solvent casting method**

The RDF is preferably formulated using the solvent-casting method, whereby the water-soluble ingredients are dissolved to form a clear viscous solution. The API and other agents are dissolved in smaller amounts of the solution, and combined with the bulk. This mixture is then added to the aqueous viscous solution. The entrapped air is removed by vacuum. The resulting solution is cast as a film and allowed to dry, which is then cut into pieces of the desired size.

Water-soluble hydrocolloids used to prepare RDFs include: hydroxyl propyl methyl cellulose (HPMC), hydroxyl propyl cellulose (HPC), pullulan, sodium alginate, pectin, carboxy methyl cellulose (CMC), polyvinyl alcohol (PVA). The selection of solvent essentially depends on the API to be incorporated into the strip. The physicochemical properties of the API like heat sensitivity, shear sensitivity, the polymorphic form of the API employed, compatibility of the API with solvent and other strip excipients are to be critically studied. The significant elements in this are liquid rheology, desired mass to be cast and content or dosage uniformity. Solvents used for the preparation of solution or suspension should ideally be selected from ICH Class 3 solvent list.





Solvent casting system

#### Advantages

- Great uniformity of thickness and great clarity than extrusion
- Film have fine gloss and freedom from defects such as die lines
- Film have more flexibility and better physical properties

#### Disadvantages

- The polymer must be soluble in a volatile solvent or water.
- A stable solution with a reasonable minimum solid content and viscosity should be formed.
- Formation of a homogeneous film and release from the casting support must be possible.

Multiple casting techniques may be selected on the basis of the fluid rheology, desired applied mass, and required dosage uniformity.

### QUALITY CONTROL TESTS FOR FAST DISSOLVING FILMS

#### Thickness

The thickness of strip can be measured by micrometer screw gauge at different strategic locations. This is essential to ascertain uniformity in the thickness of the film as this is directly related to the accuracy of dose in the strip.

#### Surface pH of film

Surface pH of the films was determined 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<sup>25,26</sup>.

#### Tensile strength

Tensile strength is the maximum stress applied to a point at which the strip specimen breaks<sup>27</sup>. It is calculated by the applied load at rupture divided by the cross-sectional area of the strip as given in the equation below:

$$\text{Tensile strength} = \frac{\text{Load at failure} \times 100}{\text{Strip thickness} \times \text{Strip width}}$$

#### Tear resistance

Tear resistance of plastic film or sheeting is a complex function of its ultimate resistance to rupture. Basically very low rate of loading 51 mm (2 in)/min is employed and is designed to measure the force to initiate tearing. The maximum stress or force (that is generally found near the onset of tearing) required to tear the specimen is recorded as the tear resistance value in Newtons (or pounds-force)<sup>28</sup>.

#### Folding endurance

Folding endurance is determined by repeated folding of the strip at the same place till the strip breaks. The number of times the film is folded without breaking is computed as the folding endurance value<sup>29</sup>.

#### Disintegration time

The disintegration time limit of 30 s or less for orally disintegrating tablets described in CDER guidance can be applied to fast dissolving oral strips<sup>30</sup>. Although, no official guidance is available for oral fast disintegrating films/strips, this may be used as a qualitative guideline for quality control test or at development stage. Pharmacopoeia disintegrating test apparatus may be used for this study. Typical disintegration time for strips is 5–30 s<sup>31</sup>.

#### Dissolution test

Dissolution testing can be performed using the standard basket or paddle apparatus described in any of the pharmacopoeia. The dissolution medium will essentially be selected as per the sink conditions and highest dose of the API<sup>32</sup>. Many times the dissolution test can be difficult due to tendency of the strip to float onto the dissolution medium when the paddle apparatus is employed.

#### Swelling property

Film swelling studies is conducted using simulated saliva solution. Each film sample is weighed and placed in a preweighed stainless steel wire mesh. The mesh containing film sample is submerged into 15ml medium in a plastic container. Increase in the weight of the film was determined at preset time interval until a constant weight was observed. The degree of swelling was calculated using parameters  $\alpha = \frac{wt - wo}{wo}$ , wt is weight of film at time t, and wo is weight of film at time zero.

#### Transparency

The transparency of the films can be determined using a simple UV spectrophotometer. Cut the film samples into rectangles and placed on the internal side of the spectrophotometer cell. The determine transmittance of films at 600 nm. The transparency of the films was calculated as follows:

$$\text{Transparency} = (\log T_{600})/b = -\epsilon c$$

Where  $T_{600}$  is the transmittance at 600 nm and b is the film thickness (mm) and c is concentration

#### Assay/drug content and content uniformity

This is determined by any standard assay method described for the particular API in any of the standard pharmacopoeia. Content uniformity is determined by estimating the API content in individual strip. Limit of content uniformity is 85–115%.

#### Organoleptic evaluation

Since the OS are intended to disintegrate rapidly or reside for more duration of time in the oral cavity, the product needs to have acceptable organoleptic palatable characteristics. The product should possess the desired features of sweetness and flavor which is acceptable to a large mass of population. For psychophysical evaluation of the product, special controlled human taste panels are used. In-vitro methods of utilizing taste sensors, specially designed apparatus and drug release by modified pharmacopoeial methods are being used for this purpose. These in-vitro taste assessment apparatus and methodologies are well suited for high throughput taste screening of oral pharmaceutical formulations<sup>33</sup>.

#### STORAGE AND PACKAGING

The converting and packaging stage also provides product flexibility to drug manufacturers. A variety of packaging options are available for fast dissolving films. The rolled film can be die-cut into any shape or size or slit into narrower rolls as required for the application. Single packaging is mandatory for films, which are pharmaceutical products; an aluminum pouch is the most commonly used packaging format. APR-Labtec has developed the Rapid card, a proprietary and patented packaging system, which is specially designed for the Rapid films. The rapid card has same size as a credit card and holds three rapid films on each side. Every dose can be taken out individually<sup>34</sup>. 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 packaging.

**MARKETED PRODUCTS OF ORAL STRIPS**

Product category	Ingredient/s	Indication/applications
Appetite suppressant	fucus vesiculosus and guarana extract, garcinia cambogia	These are top selling natural ingredients associated with weight loss. Cambogia helps to reduce the food intake by suppressing appetite
Vitamins and food supplements	Various vitamins, minerals and supplements	It is useful for the people who do not like to pop up the tablets or soluble supplements
Breath freshener strip, (Antibacterial strip)	Contain mint flavor and antibacterial agent, cetylpyridinium chloride	It is used as mouth freshener and to stop bad breath
Saliva promoting strips	Fruit acid extracts, range of flavors	It is used in the dry mouth as a side effect of the other medications.
Labtec GmbH Ondansetron Rapidfilm®	Ondansetron 4 mg and 8 mg.	It is used in the prevention of chemotherapy and radiation-induced nausea and vomiting and prevention of postoperative nausea and vomiting
Donepezil Rapidfilm®	Donepezil Hydrochloride 5 mg and 10 mg.	Treatment of mild to moderately severe dementia of the Alzheimer's type
Minerals	Chromium	Mineral supplements
Natural products	Ginseng, Guarana	Aphrodisiac, Appetite reducer
Innozen Inc Chloraseptic® Relief Strips™	Benzocaine 3 mg, BHT, corn starch, erythritol, FD&C Red 40, hydroxypropyl methylcellulose, malic acid, menthol, monoammonium glycyrrhizinate, cherry flavors, polyethylene oxide, sucralose	Occasional minor irritation, pain, sore throat and sore mouth
Loratidine	10 mg-20 mg	It is a non sedative antihistaminic agent used to treat the allergy

**CONCLUSION**

Oral thin films are intended for application in the oral cavity and they are innovative and promising dosage form especially for use in pediatrics and geriatrics. They combine the greater stability of a solid dosage form and the good applicability of a liquid and thus bridges the gap between two ideas, incorporating positive elements from both solid and liquid dosage forms 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 APIs for over-the-counter (OTC) medications and are in the early- to mid-development stages for prescription drugs.

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