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Review Article

MOUTH DISSOLVING FILM: AN APPROACH TO NOVEL DRUG DELIVERY SYSTEM-A REVIEW

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ABSTRACT

Mouth Dissolving Films (MDF) or Oral Thin Films (OTFs), offer a convenient way of dosing medications, not only to special inhabitants groups with swallowing difficulties such as Pediatrics and Geriatrics, but also to the general population. Fast dissolving drug delivery have been developed as an alternative to conventional dosage form as an oral means of drug delivery in case of chronic conditions. Present days fast dissolving films are preferred over conventional tablets and capsules for masking the taste of bitter drugs to increase the patient compliance. Mouth Dissolving Films consist of a very thin oral strip which dissolves in less than one minute when placed on the tongue. Dissolvable oral thin films are in the market since past few years in the form of breath strips and are widely accepted by consumers for delivering vitamins, vaccines and other drug products. Mouth Dissolving Films are the novel dosage forms that disintegrate and dissolve within the oral cavity. Intra-oral absorption permits rapid onset of action and helps by-pass first-pass effects, thereby reducing the unit dose required to produce desired therapeutic effect.

Keywords :-Fast Dissolving Oral Film, Oral Thin Films, Oral cavity.

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INTRODUCTION

Oral route is most common and mostly applicable route of drug administration. Recent advances and developments in the technology have presented viable dosage alternatives from oral route for pediatrics, geriatric, bedridden, nauseous or noncompliant patients. Various bioadhesive mucosal dosage forms have been urbanized which includes adhesive tablets, gels, ointments, patches and more recently the use of polymeric films for buccal delivery, also known as mouth dissolving films [1]. Mouth dissolving films, a new drug delivery system for the oral delivery of the drugs, was developed based on the technology of the transdermal drug delivery system. The delivery system consists of a very thin oral strip, which is simply placed on the patient's tongue or any oral mucosal tissue, instantly wet by saliva the film rapidly hydrates and adheres onto the site of application. It then rapidly disintegrates and dissolves to release the medication for oromucosal absorption or with formula modifications, will maintain the quick-dissolving aspects allow for gastrointestinal absorption to be achieved when swallowed. In contrast to other existing, rapid dissolving dosage forms, which consist of liophylisates, the rapid films can be produced with a manufacturing process that is competitive with the manufacturing costs of conventional tablets [2]. Pharmaceutical companies and consumers alike have embraced oral thin films (OTFs) as a practical and accepted alternative to traditional OTC medicine forms such as liquids, tablets, and capsules. OTFs offer fast,

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accurate dosing in a safe, efficacious format that is convenient and portable, without the need for water or measuring devices [3]. 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 [4,5].

Composition of the system

Buccal dissolving film is a thin film with an area of 5- 20 cm2 containing an active ingredient. The immediate dissolution, in water or saliva respectively, is reached through a special matrix from water-soluble polymers. Drugs can be incorporated up to a single dose of 15mg. formulation considerations (plasticizers etc.) have been reported as important factors affecting mechanical properties of the films, such as shifting shifting the glass transition temperature to lower temperature [2]. A typical composition contains the following

Drug 1-25%
Water soluble polymer 40-50%
Plasticizers 0-20%
Fillers, sweetener, colours, flavours, saliva stimulating agents etc. 0-40%

Drugs

Several class of drugs can be formulated as mouth dissolving films including antiulcer (e.g. omeprazole), antiasthamatics (salbutamol sulphate), antitussives, expectorants, antihistaminics, NSAID'S (e.g.paracetamol, meloxicam, valdecoxib) [6,7,8,9].

Water soluble polymers

Water-soluble polymers are used as film formers. The use of film forming polymers in dissolvable films has attracted considerable attention in medical and nutraceutical application. The water-soluble polymers achieve rapid disintegration, good mouthfeel and mechanical properties to the films. The disintegration rate of the polymers is decreased by increasing the molecular weight of polymer film bases. Some of the water soluble polymers used as film former are HPMC E-3 and K-3, Methyl cellulose A-3, A-6 and A-15, Pullulan, carboxymethylcellulosecekol 30, Polyvinylpyrollidone PVP K-90, Pectin, Gelatin, Sodium Alginate, Hdroxypropylcellulose, Polyvinyl alcohol, Maltodextrins and Eudragit RD10 [8,9,10,11,12].Polymerized resin is a novel film forming polymer [13].

Plasticizers

Formulation considerations (plasticizer, etc.) have been reported as important factors affecting mechanical properties of films. The mechanical properties such as tensile strength and elongation to the films have also been improved by the addition of plasticizers. Variation in their concentration may affect these properties. The commonly used plasticizers are glycerol, di-butylpthallate, and polyethylene glycols etc [10].

Surfactants

Surfactants are used as solublising or wetting or dispersing agent so that the film is getting dissolved within seconds and release active agent immediately. Some of the commonly used are sodium lauryl sulfate, benzalkonium chloride, bezthonium chloride, tweens etc. One of the most important surfactant is polaxamer 407 that is used as solubilizing, wetting and dispersing agent [14].

Flavour

Any flavor can be added, such as intense mints, sour fruit flavors or sweet confectionery flavors [15].

Colour

A full range of colors is available, including FD&C colors, EU Colours, Natural Colours and custom Pantone-matched colours [15]. Some saliva stimulating agents may also be added to enhance the disintegration and to get rapid release. Some of these agents are citric acid, tartaric acid, malic acid, ascorbic acid and succinic acid [16].

Sweetening agents

Sweeteners have become the important part of pharmaceutical products intended to be disintegrated or dissolved in the oral cavity. The classical source of sweetener is sucrose, dextrose, fructose, glucose, liquid glucose and isomaltose. The sweetness of fructose is perceived rapidly in the mouth as compared to sucrose and dextrose. Fructose is sweeter than sorbitol and mannitol and thus used widely as a sweetener. Polyhydric alcohols such as sorbitol, mannitol, and isomalt can be used in combination as they additionally provide good mouth-feel and cooling sensation. Polyhydric alcohols are less carcinogenic and do not have bitter after taste which is a vital aspect in formulating oral preparations. The artificial sweeteners have gained more popularity in pharmaceutical preparations. Saccharin, cyclamate and aspartame are the first generation of the artificial sweeteners followed by acesulfame-K, sucralose, alitame and neotame which fall under the second generation artificial sweeteners. Acesulfame-K and sucralose havemore than 200 and 600 time sweetness. Neotame and alitame have more than 2000 and 8000time sweetening power as compared to sucrose. Rebiana which is a herbal sweetener, derived from plant *Stevia rebaudiana* (South American plant) has more than 200 -300 time sweetness [17].

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

Citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid [18] are the few examples of salivary stimulants, citric acid being the most preferred amongst them.

Characterization of fast dissolving oral films

Drug-excipients interaction studies

Assessment of possible incompatibilities between an active drug substance and different excipients plays an important part of the formulation stage during the development of solid dosage form. Fourier Transformer Infra Red Spectrum (FTIR), Differential scanning calorimeter (DSC), thin layer chromatography and X Ray Diffraction (X-RD) can be used to assess possible drug excipient interaction. DSC allows the fast evaluation of possible incompatibilities, because it shows changes in appearance, shift of melting endotherms and exotherms, and variation in the corresponding enthalipies of the reaction [19].

Thickness

Thickness test can be carried out using an electronic micrometer [20]. The thickness of the film sample should be measured at five locations (center and four corners), and the mean thickness is calculated. Samples with air bubbles, nicks or tears and having mean thickness variation of greater than 5% are excluded from analysis.

Folding endurance

To determine folding endurance, a strip of film is cut and repeatedly folded at the same place till it broke. The number of times the film could be folded at the same place without breaking gives the value of folding endurance.

Swelling index

The studies for swelling index of the film are conducted in stimulated salivary fluid. The film sample is weighed and placed in a preweighed stainless steel wire sieve. The mesh containing the film is submerged into 50 ml of stimulated salivary medium contained in a mortar. Increase in weight of the film is determined at each interval until a constant weight is observed. The degree of swelling is calculated using the formula:

SI = wt – wo / wo (1)

Where SI is the swelling index,
wt is the weight of the film at time "t", and
wo is the weight of film at t = 0

Uniformity of drug content

This parameter can be determined by dissolving known weight of film by homogenization in 100 ml of stimulated saliva of pH 6.8 for 30 min with continuous shaking.

Tensile strength

The tensile strength (psi) is the property of the film that requires a load to cause load deformation failure of film. It was evaluated this mechanical property by using Instron Universal Testing Instrument (model F. 4026), Instron Ltd., Japan, NITK, Surathkal) with a 5-kg load cell. Film strips in special dimension and free from air bubbles or physical imperfections were held between two clamps positioned at a distance of 3 cm. During measurement, the strips were pulled by the top clamp at a rate of 100 mm/min; the force and elongation were measured when the film broke. Results from film samples, which broke at and not between the clamps, were not included in the calculations. Measurements were run in triplicate for each film. Tensile strength is also defined as the maximum stress applied to a point at which the film specimen breaks and can be computed from the applied load at rupture as a mean of three measurements and cross sectional area of fractured film from the following equation [21].

Tensile strength (N/mm2) = breaking force (N) / cross sectional area of sample (mm2)

Percent elongation

The percent elongation is measured when the film snaps as sufficient force applied so as to exceed the elastic limit. Percentage elongation can be obtained by following equation:

Elongation at break (%) =increase in length at breaking point (mm) / original length (mm) X100%.

Palatability test

Palatability study is conducted on the basis of taste, after bitterness and physical appearance. All the batches are rated A, B and C grades as per the criteria. When the formulation scores at least one A grade, formulation is considered as average. When the formulation scores two A grade then it would be considered as good and the one with all three A grade it would be the very good formulation [19].

Grades: A= very good, B= good, C=poor.

Disintegration test

Disintegrating time is defined as the time (second) at which a film breaks when brought into the contact with water or saliva. The disintegration time is the time when a film starts to break or disintegrate. Thickness and mass play a role in determining the dissolvable films physical properties [19]. Disintegration test is done by Disintegration apparatus.

Dissolution test

Dissolution is defined as the amount of drug substance that goes into the solution per unit time under standardized conditions of liquid/solid interface, temperature and solvent concentration. *Invitro* release

studies are carried out in modified USP XXIII apparatus (paddle over disk) [22].

Permeation studies

Permeation studies are carried using the modified Franz diffusion cell by using porcine buccal mucosa. The mucosa is mounted between the donor and receptor compartment of Franz diffusion cell. The receptor compartment is filled with buffer and maintained at 37 °C ± 0.2 °C and the hydrodynamics were maintained by stirring with a magnetic bead at 50 rpm. One previously weighed film is placed in intimate contact with the mucosal surface of the membrane that should be previously moistened with a few drops of simulated saliva. The donor compartment is filled with 1 ml of simulated saliva of pH 6.8. Samples are withdrawn at suitable interval, replacing the same amount with the fresh medium. The percentage of drug permeated is determined by measuring the absorbance by selected analytical method.

Stability study

Stability study of fast dissolving films is carried out for all the batches according to ICH guidelines. After predetermined time intervals, the films are evaluated for the drug content, disintegration time and physical appearance.

Packaging

In the pharmaceutical industry it is vital that the package selected adequately preserve the
integrity of the product. Expensive packaging, specific processing, and special care are required during manufacturing and storage to protect the dosage of other fast dissolving dosage forms. A variety of packaging options are available for fast dissolving films. 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 raid films on each side. Every dose can be taken out individually. The material selected must have the following characteristics:

1. They must protect the preparation from environmental conditions.
2. They must be FDA approved.
3. They must meet applicable tamper-resistant requirement
4. They must be non-toxic.
5. They must not be reactive with the product.
6. They must not impart to the product tastes or odors [23].

Foil, paper or plastic pouches

The flexible pouch is a packaging concept capable of providing not only a package that is temper- resistance, but also by the proper selection of material, a package with a high degree of environmental protection. A flexible pouch is usually formed during the product filling operation by either vertical or horizontal forming, filling, or sealing equipment. The pouches can be single pouches or aluminum pouches.

Single pouch and Aluminum pouch

Soluble film drug delivery pouch is a peelable pouch for“quick dissolve” soluble films with high barrier properties. The pouch is transparent for product display. Using a 2 structure combination allows for one side to be clear and the other to use a cost-effective foil lamination. The foil lamination has essentially zero transmission of both gas and moisture. The package provides a flexible thin film alternative for nutriceutical and pharmaceutical applications. The single dose pouch provides both product and dosage protection. Aluminum pouch is the most commonly used pouch.

Blister card with multiple units

The blister container consists of two components: the blister, which is the formed cavity that holds the product, and the lid stock, which is the material that seals to the blister. The blister package is formed by heat – softening a sheet of thermoplastic resin and vaccum-drawing the softened sheet of plastic into a contoured mold. After cooling the sheet is released from the mold and proceeds to the filling station of the packaging machine. The semi –rigid blister previously formed is filled with the product and lidded with the heat sealable backing material. The film selection should be based upon the degree of protection required. Generally the lid stock is made of aluminum foil. The material used to form the cavity is typically a plastic, which can be designed to protect the dosage form from moisture [23].

Applications of fast dissolving buccal films

Vaccines

Fast dissolving buccal films film can be delivered in the form of vaccine which is stable at room temperature so it is quickly dissolved in mouth and in saliva. Rotavirus vaccine prepared in United states is a room temperature stable fast-dissolving buccal film delivery system for vaccines that will make vaccinations almost as simple as freshening your breath. This delivery system exhibits many advantages which include: improved patient compliance, improved bioavailability, reduction in the costs associated with storage and distribution, handling and administration.

Controlled and Sustained release film

Sustained release buccal film is applicable in hospital preparations and various polymers like chitin and chitosan derivatives are used as excipients. They contribute to expansion of application, decrease toxicity, wound dressings, oral mucoadhesive and water-resisting adhesive by virtue of their release characteristics and adhesion [24].

Taste masking is an essential requirement for fast dissolving tablets for commercial success. Fast dissolving buccal films dissolve or disintegrate in patient's mouth, thus releasing the active ingredients which come in contact with the taste buds and hence this property becomes critical for the patient compliance. In taste masking, drugs with unacceptable bitter taste can be microencapsulated into pH sensitive acrylic polymers by solvent evaporation and solvent extraction techniques. These polymers microspheres showed efficient taste masking and complete dissolution in a short period [25].

Table 1. Marketed Product of Mouth Dissolving Films

Product categories	Ingredients	Indication/application
Biofilm Energy boosters Detoxification strip	Caffeine, green tea extract and guarana Green tea extract which is high in polyphenols and rich in anti-oxidants.	The product maintains the energy levels. Wound healing, regulating body temperature, blood sugar and promoting a healthy digestion
Male vitality strip	Maca root extract and Siberian ginseng extract, herbs which enhance libido, Cinnamint flavor.	Aphrodisiac
Appetite suppressant	fucusvesiculous and guarana extract, garciniacambogia	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	Mouth freshener
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 chemotherapyand radiation-induced nausea and vomitingand prevention of postoperative nausea andvomiting.
DonezepilRapidfilm®	Donepezil Hydrochloride 5 mg and 10 mg.	Treatment of mild to moderately severe dementia of the Alzheimer's type.
Paladin Labs (Bioenvelop) Smoking cessation	Nicotine	To reduce the smoking habit
Multivitamin for kids and adults	B6, B12, C; D3 for kids, D3 for adults	Multi vitamin supplement,
Teeth whitening	-	Lifestyle improvement product
Food supplements	Benzocaine, Caffeine, Melatonin, Menthol Omega, Hoodia, Protein,Vinpocetine	Nutraceuticals
Minerals	Chromium	Mineral supplements
Natural products InnozenInc	Ginseng, Guarana	Aphrodisiac, Appetite reducer
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
Chloraseptic® Kids Sore Throat Relief Strips	Benzocaine 2 mg & menthol, grape flavor, BHT, corn starch, erythritol, FD & C Blue 1, FD & C Red 40, hydroxypropyl methylcellulose, malic acid, menthol, monoammoniumglycyrrhizinate, polyethylene oxide, sucralose	Occasional minor irritation, pain, sore throat and sore mouth
Suppress™ Cough strips with Dextromethorphan	Dextromethorphan hydrobromide 2.5 mg, Asulfame potassium, FD&C Blue 1, glycerin, menthol, natural and artificial flavors, pectin,	Temporarily suppresses coughs due to minor throat and bronchial irritation associated with cold or inhaled irritants.

	peppermint oil, sucralose, sugar, wate	
Suppress™ Cough strips with menthol	Artificial flavors, ascorbic acid, aspartame, asulfame potassium, carrageenan, diglycerides, fatty acid ester, FD&C yellow 5 (tartrazine), glycerin, menthol, mono glycerides, pectin, sodium alginate, sorbitanmonolaurate, sorbitol, spices, starch, water	Temporarily suppresses coughs due to minor throat and bronchial irritation associated with cold or inhaled irritants.
Hughes Medical Corporation Methylcobalamin	1 mg	Peripheral neuropathy, Diabetic neuropathy
Dextromethorphan	2.5 mg - 5.5 mg -15 mg	Anti-tussive agent used to prevent cough.
Folic Acid	1 mg - 5 mg	Required for formation of healthy red blood cells and used in anemia.
Loratidine	10 mg- 20 mg	Allergy
Caffeine	2.5 mg	CNS stimulant
Diphenhydramine HCl Novartis Pharmaceuticals	2.5 mg - 5 mg	Antihistaminic
Night Time Triaminic Thin Strips® Cold & Cough	Diphenhydramine HCl 12.5 mg, Phenylephrine HCl 5 mg, acetone, FD&C blue #1, FD&C red #40, flavors, hypromellose, maltodextrin, mannitol, polyethylene glycol, polypropylene glycol, purified water, sodium polystyrenesulfonate, sucralose, titanium dioxide.	Antihistamine/cough suppressant,Nasal decongestant. It temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold.
Triaminic Thin Strips® Long Acting Cough	Dextromethorphan 5.5 mg (equivalent to 7.5 mg Dextromethorphan HBr), acetone, alcohol, dibasic sodium phosphate, FD&C red #40, flavors, hydroxypropyl cellulose, hypromellose, isopropyl alcohol, maltodextrin, microcrystalline cellulose, polacrilin, polyethylene glycol, pregelatinized starch, propylene glycol, purified water, sodium phosphate, sorbitol, sucralose, titanium dioxide.	It temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold.
Triaminic Thin Strips® Cough & Runny Nose	Diphenhydramine HCl 12.5 mg, acetone, alcohol, FD&C blue #1, FD&C red #40, flavors, hydroxypropyl cellulose, hypromellose, isopropyl alcohol, maltodextrin,microcrystalline cellulose, polyethylene glycol, pregelatinized starch, propylene glycol, purified water, sodium polystyrene sulfonate, sorbitol, sucralose, titanium dioxide	It reduces cough due to minor throat and bronchial irritation as may occur with a cold. It relieves itchy, watery eyes due to hay fever.
Day Time Triaminic Thin Strips® Cold & Cough	Dextromethorphan 3.67 mg (equivalent to 5 mg Dextromethorphan HBr), Phenylephrine HCl 2.5 mg, acetone, alcohol, FD&C blue #1, FD&C red #40, flavors, hypromellose, isopropyl alcohol, microcrystalline cellulose, polacrilin, polyethylene glycol, propylene glycol, purified water, sodium polystyrene sulfonate, sucralose, titanium dioxide	It is used as nasal decongestant
Triaminic Thin Strips® Cold with Stuffy Nose	Phenylephrine HCl 2.5 mg, acetone, alcohol, FD&C blue #1, FD&C red #40, flavors, hypromellose, isopropyl alcohol,maltodextrin,microcrystalline cellulose,	It temporarily relieves nasal and sinus congestion as may occur with a cold

	polyethylene glycol, propylene glycol, purified water, sodium polystyrene sulfonate, sucralose and titanium dioxide	
Theraflu® Daytime Thin Strips	Dextromethorphan 14.8 mg (equivalent to 20 mg Dextromethorphan HBr), Phenylephrine HCl 10 mg, acetone, alcohol, FD&C red #40, flavors, Hypromellose, mannitol, polyethylene glycol, polystyrene sulfonate, polacrilin and sucralose	It reduces cough due to minor throat and bronchial irritation as may occur with a cold.
Theraflu® Nighttime Thin Strips	Diphenhydramine HCl 25 mg, Phenylephrine HCl 10 mg, acetone, alcohol, FD&C blue #1, flavors, Hypromellose, mannitol, polyethylene glycol, polystyrene sulfonate, polacrilin and sucralose	It is used for nasal congestion, runny nose, sneezing, itchy nose and throat etc.
Theraflu® Thin Strips®–Multi Symptom	Diphenhydramine HCl 25 mg, acetone, alcohol, FD&C red #40, flavors, Hypromellose, hydroxyl propyl cellulose, maltodextrin, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, polystyrene sulfonate, sorbitol and sucralose. Titanium dioxide.	It temporarily relieves nasal and sinus congestion as may occur with a cold.
Pfizer Inc Listerine® pocketpaks®	Available in cool mint®, Fresh Citrus, Cinnamon, and fresh burst®. Pullulan is used as a film forming polymer.	These strips dissolve instantly and kill 99 percent; of bad breath germs.
Prestige Brands Little cold sore throat Strip	Ascorbic acid, pectin	Cold/allergy
Chloraseptic relief strip Bio Delivery Sciences International	Benzocaine, menthol	Sore throat [26]

CONCLUSION

Mouth Dissolving Films are most important and valuable formulation for the pediatrics and geriatric patients. In case of pediatric patients the stomach and intestine does not fully develop for the complete absorption of the drug (eg. tablets and capsules), so a difficulty arises and toxicity occurs. But in the case of geriatric patients the stomach and intestine does not perform well absorption of the drugs like tablets and capsules. So the fast dissolving oral film is the best formulation for such type of patients. This review shows the composition, characterization and evaluation of MDFs. Marketed products are reviewed in this review article.

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Nil

CONFLICT OF INTEREST

No interest

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