

Recent trends in oral medicine delivery system : A Review

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Abstract

In the recent most useful route of drug delivery system is the oral route in all types of patient. Mouth dissolving strips is the type of drug delivery system which when placed in the oral cavity disintegrates or dissolves within few seconds without intake of water. The advantages of mouth dissolving strips are the administration to pediatric and geriatric patient. This technology has been used for local action, rapid release products. These films have a potential to deliver the drug systemically through intragastric, sublingual or buccal route of and also been used for local action. The mouth dissolving strips are available in various administration shapes, size and thickness. Many companies are utilizing transdermal drug delivery technology to develop thin film formats. This article is an overview of mouth dissolving strips encompassing materials used in mouth dissolving strips, manufacturing process, application, commercial technologies and future business prospects of this technology.

Key words: Strips; Mouth Dissolving Strips; Rapid Release

Introduction

Fast dissolving drug delivery system came into existence in the late 1970's as an alternative to tablets' capsule and syrups for pediatric and geriatric patients who has difficulties in swallowing traditional oral solid dosage form. These systems consists of the solid dosage form that disintegrate and dissolve quickly in the oral cavity without the administration of water.[1]

The oral route is the most acceptable from patient compliance aspects. Many pharmaceutical firms have directed their research activity in re-formulating existing drugs into new dosage forms. Research and development in the oral drug delivery segment has led to transition of dosage forms from simple conventional tablets or capsules to modified release tablets or capsules to fast dissolving tablet and in the recent development of mouth dissolving strips are available for the oral drug delivery system as shown in Figure 1. A number of molecules can be incorporated into this delivery system. They may include cough/cold remedies (anti-tussive, expectorant), sore throat, and erectile dysfunction drugs, anti-histaminic, anti-asthmatics, gastrointestinal disorders, nausea, pain and CNS (e.g. anti-Parkinson disease). Other applications comprise caffeine strips, snoring aid, multivitamins, sleeping aid etc.

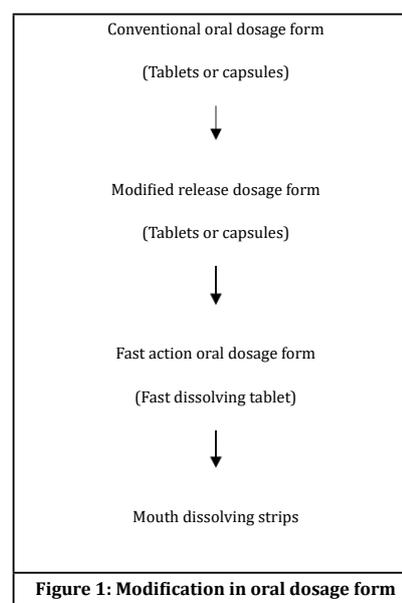


Figure 1: Modification in oral dosage form

An ideal buccoadhesive system is the one that adhere to the site of attachment for a few hours, releases the drug in a controlled

fashion, facilitates the rate and extent of drug absorption, does not cause any irritation or inconvenience to the patient, does not interfere with the normal functions such as talking, drinking etc. and that provides unidirectional drug release towards the mucosa. The mass about the proper way to administer the provides like giving instructions "do not swallow" or "do not chew" [2].

It was developed on the basis of technology of the transdermal patch. The delivery system of very thin oral strips, which is simply placed on the patient's tongue or any oral mucosal tissue, instantly wet by saliva the film rapidly hydrates and adheres to the site of application [3]. The epithelia of oral cavity are also composed of an intercellular ground substance called as mucus which basically consists of proteins and carbohydrates. It maintains hydrated condition of the oral cavity, provides adequate lubrication, concentrates protective molecules such as secretory immune globulins, and reduces the attachment of microorganisms. The negatively charged mucin contains sulfhydryl groups and silico acid residues that are responsible for mucoadhesion phenomena [4]. Total turnover rate Of the total whole saliva (output from the major and minor salivary gland) at normal physiological conditions has a flow rate of 1-2 ml/min [5]. A strips or film can be as a dosage form that employs a water-dissolving polymer (generally a hydrocolloid, which may be a bio adhesive polymer), which allows the dosage form to quickly hydrate, adhere, and dissolve when placed on the tongue or in the oral cavity (i.e., buccal, palatal, gingival, lingual, or sublingual, etc.) to provide rapid local or systemic drug delivery [6].

Developing formulations for children has been a challenging task. Amongst other factors, palatability of formulations of pediatric oral medications is one of the most significant factors influencing compliance to therapeutic regimens [7].

Characteristics of Mouth Dissolving Strips

- ✓ Do not require water to swallow and should dissolve or disintegrate in the mouth within a few seconds.
- ✓ Compatible with taste masking and other excipients.
- ✓ They possess pleasant mouth feel.
- ✓ Leave minimal or no residue in the mouth after oral administration.
- ✓ They can withstand the rigors of the manufacturing process and post
- ✓ Manufacturing handling [8].
- ✓ Processing and packaging of strips or films can be done at low costs prices.
- ✓ The strips are thin effective film and available in various size and shapes.
- ✓ The strips have also UN obstructive, excellent mucoadhesion.
- ✓ Due to presence of larger surface in mouth they have Fast integration of formulation and Rapid release of drug [9].

- ✓ Reduction in side effects associated with the molecule [10].
- ✓ Ease of swallowing and no need of water have led to better acceptability amongst the dysphasic patients.
- ✓ Oral films are flexible and thus less fragile As compared to Oral Dispersible Tablet Hence, there is ease of transportation
- ✓ During consumer handling and storage [11].

Choice of Drug candidate for Mouth Dissolving Strips

- ✓ The drug should have pleasant taste.
- ✓ The drugs to be incorporated have low dose upto 40mg.
- ✓ The drug have smaller and moderate molecular weight [1].
- ✓ The drug should be partially unionized at the pH of oral cavity.
- ✓ It should have the ability to permeate oral mucosal tissue [8].

Advantages of Mouth Dissolving Strips

- ✓ Oral dissolving films can be administered without water, anywhere, any time.
- ✓ Due to the presence of larger surface area, film provides rapid disintegrating and dissolution in the oral cavity.
- ✓ Oral dissolving films are flexible and portable in nature so they provide ease in transportation, during consumer handling and storage.
- ✓ Suitability for geriatric and pediatric patients, who experience difficulties in swallowing mentally ill, the developmentally disable and the patients who are un-cooperative, or are on reduced liquid intake plans or are nauseated [12].
- ✓ Beneficial in cases such as motion sickness, acute pain, sudden episodes of allergic attack or coughing, where an ultra-rapid onset of action required.
- ✓ Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability [13].
- ✓ As compared liquid formulations, precision in the administered dose is ensured from each strips of the film.
- ✓ 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. This advantage can be exploited in preparing products with improved oral bioavailability of molecules that undergo first pass effect.
- ✓ The sublingual and buccal delivery of a drug via thin film has the potential to improve the onset of action, lower the dosing, and enhance the efficacy and safety profile of the medicaments.

- ✓ Provide new business opportunity like product differentiation, product promotion, and patent extension.
- ✓ The oral film administered sublingually and buccally, delivers the drug with high potential to improve the onset of action, lower the dose, and enhance the efficacy and safety profile of the medicament [14].

Disadvantages of Mouth Dissolving Strips

- ✓ Oral disintegrating films have limitations in terms of the amount of drug that can be incorporated in each unit dose.
- ✓ Expensive packaging.
- ✓ Dose uniformity is a technical challenge.
- ✓ Water insoluble drug cannot incorporate or taste masking is required.

Biopharmaceutical Consideration of Mouth Dissolving Strips

When designing a new dosage form, before the formulation some biopharmaceutical factors need to be considered. Fast disintegrating oral films quickly disintegrate, facilitating the drug from the mouth, pharynx and esophagus through the oral mucosa. Factors like age, nature of the oral cavity, and blood flow to oral cavity should be considered. Distribution of drug depends on tissue permeability, perfusion rate; binding of drug to tissue, drug interaction etc. The duration and intensity of action depends on the rate of drug removal from the body or site of action [15].

Mechanism of Drug Release in Mouth Dissolving Strips

The drug release mechanism in mouth dissolving strips formulation delivery system includes simply strips placed on a patient's tongue or any or mucosal tissue. After placing it the film dissolves within seconds, promoting first pass metabolism as compared to tablet and other immediate release oral solid dosage forms, and may increase the bioavailability of drug. Due to presence of saliva in mouth and presence of hydrophilic polymer and other excipients, the film rapidly hydrates and to release the medication for or mucosal absorption [16].

Classification of Mouth Dissolving Strips

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

Lyophilized System

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 [17].

Compressed tablet based systems

This system is produced using standard tablet technology by direct compression of excipient. Depending on the method of manufacture, the tablet technologies have different levels of hardness and friability [17].

Oral Thin Films

Oral films are a group of flat films which are administered into the oral cavity. Dissolvable oral thin films (OTFs) or oral strips (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 consumer for delivering vitamins and personal care products. Such systems use a variety of hydrophilic polymers to produce a 50-200mm film [17].

Structure of Oral Mucosa

The oral mucosa is composed of an outermost layer of stratified squamous epithelium (Figure-2). Below this lies a basement membrane, a lamina propria followed by the submucosa as the innermost layer. The epithelium is similar to stratified squamous epithelial cell found in the rest of the body in that it has a mitotically active basal cell layer, advancing through a number of differentiating intermediate layers to the superficial layers, where cells are shed from the surface of epithelium [18].

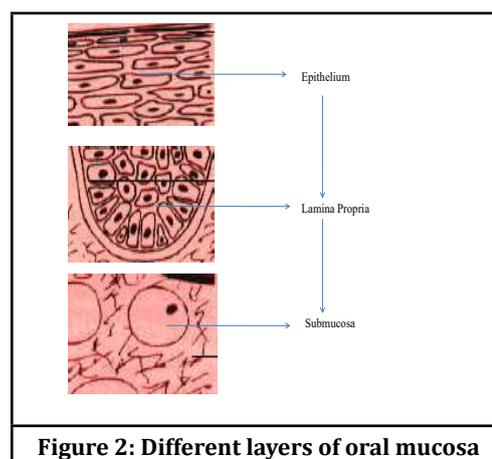


Figure 2: Different layers of oral mucosa

The turnover time for the buccal epithelium has been estimated at 5-6 days and this is probably representative of the oral mucosa as a whole. The oral mucosal thickness varies depending on the site: the buccal mucosa measures at 500-800µm, while the mucosal thickness of the hard and soft palates, the floor of the mouth, the ventral tongue and gingivae measure at about 100-200µm. The composition of the epithelium also varies depending on the site in the oral cavity. [19] The mucosae of the gingivae and hard plate are keratinized similar to the epidermis which contain ceramides and acylceramides (neutral lipids) which have been associated with the barrier function. The mucosa of the soft palate, the sublingual and the buccal regions, however, are not keratinized which are relatively impermeable to water and only have small amounts of ceramide. They also contain small amounts of neutral but polar lipids mainly cholesterol sulfate and glucosylceramides. The non-keratinized epithelia have been found to be considerably more permeable to water than keratinized epithelia [20].

Permeability

The oral mucosa in general is intermediate between that of the epidermis and intestinal mucosa in terms of permeability. It is estimated that the permeability of the buccal mucosa is 4-4000 times greater than that of the skin. There are considerable differences in permeability between different regions of the oral cavity because of the diverse structure and functions of the different oral mucosa. For the better absorption of active pharmaceutical ingredients in oral region permeation enhancers play an important role.[21] So if we want to absorb the drug mostly in mouth as drug released from formulation then there is the need of permeation enhancer some example of permeation enhancer given;

- Aprotinin
- 23-lauryl ether
- Azone
- Benzalkoniumchloride
- Cetylpyridiniumchloride
- Cyclodextrin
- Dextran sulfate
- Menthol
- Sodium taurodeoxycholate

Composition of Oromucosal Region

Oromucosal Cells are made up of proteins and carbohydrates. It is adhesive in nature and acts as a lubricant, allowing cells to move relative to one another with less friction [22]. The mucus is also believed to play a role in bio adhesion of mucoadhesive drug delivery systems. In other parts of the body mucus is synthesized and secreted by the goblet cells, however in the oral mucosa; mucus is secreted by the major and minor salivary glands of saliva. Up to 70% of the total mucin found in saliva is contributed by the minor salivary glands. Another feature of the oral cavity is the presence of saliva (digestive secretion) produced by three pairs of salivary glands (parotid, sub mandibular and sublingual glands). Saliva is mostly water with 1% organic and inorganic materials. The digestive enzyme present in saliva is salivary amylase, which breaks down starch molecules to shorter chains of glucose chemicals that are found in plasma [23]. The major determinant of the salivary composition is the flow rate which in turn depends upon three factors: the time of the day, the type of stimulus and the degree of stimulation. The salivary pH ranges from 5.5 to 7. The daily salivary volume is between 0.5 to 2 liters and it is this amount of fluid that is available to hydrate oral mucosal dosage forms. A main reason behind the selection of hydrophilic polymeric matrices as vehicles for oral trans-mucosal drug delivery system is this water rich environment of the oral cavity [24], (Figure-3).

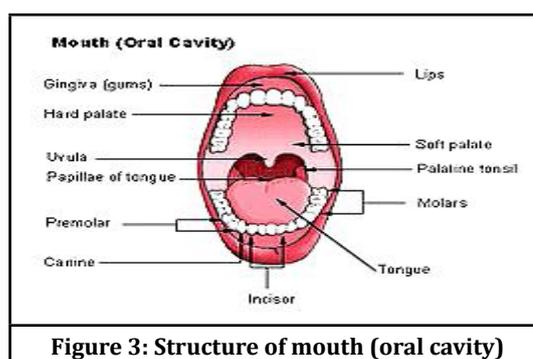


Figure 3: Structure of mouth (oral cavity)

Formulation Consideration

In the formulation of mouth dissolving strips dissolving strips excipients play an important role as follow;

- ✓ Active pharmaceutical ingredient
- ✓ Film forming polymers
- ✓ Plasticizer
- ✓ Saliva stimulating agent
- ✓ Sweetening agent
- ✓ Flavouring agent
- ✓ Coloring agent

Active Pharmaceutical Ingredient

A typical composition of the film contains 1-25%w/w of the drug. Variety of APIs can be delivered through fast dissolving films. Small molecules are the best candidates to be incorporated in the mouth dissolving strips. It is always useful to have micronized APIs which will improve the texture of the film and also for better dissolution and uniformity in the mouth dissolving strips [25]. Various methods can be used to improve palatability of the formulation. Among the techniques employed, the simplest method involves the mixing and co-processing of bitter tasting APIs with pleasurable taste. This is often termed as obscuration technique.[26]The bitter taste of paracetamol was masked with the use of lipidic excipients like hard fat and lecithin[27]. Some of the examples of suitable drug molecule that can be incorporated in the mouth dissolving strips are listed in following table 1:

Table-1: List of some drug those are suitable for incorporation in strips delivery dosage forms		
Drug	Category	Dos
Famotidine	Antacid	10mg
Cetirizine	Antihistaminic	5-10mg
Ketoprofen	Antiinflammatory	12-25mg
Acrivastine	Antihistaminic	8mg
Loperamide	Antidiarrhoeal	2mg
Salbutamol	Anti asthmatic	4mg
Chlorohexidine	Antiseptic	12mg
Ondensteron	Anti emetic	2.5mg
Omeprazole	Proton pump inhibitor	10-20mg

Film Forming Polymer

A variety of polymers are available for preparation of oral strips. The polymers can be used alone or in combination to obtain the desired strips 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 strips depends on the type of polymer and the amount in the formulation the other hand, fast dissolving strips dosage form should have the property to disintegrate in seconds when placed in/mouth and deliver the drug to the oral cavity instantaneously. A list of polymers and their properties are given in As the strips forming polymer which forms the platform for the oral strips is most essential and major component of the oral strips, at least 45%w/w of polymer should generally be present based on the total weight of dry oral strips [28]. Of various polymers available, pullulan, gelatin and hypromellose are most commonly used for preparation of oral strips. Pullulan is a natural polymer obtained from non-animal origin and does not require chemical modification. It has low oxygen permeability and low water content which makes it most suitable for production of oral strips [29].

Plasticizer

Plasticizer is a vital ingredient of the oral strips formulation. It helps to improve the flexibility of the strips and reduces the brittleness of the strips. Plasticizer significantly improves the strips properties by reducing the glass transition temp of the polymer. The selection of the plasticizer will depend upon its compatibility with the polymer and also the type of solvent employed in the casting of strips. The flow of polymer will get better with the use of plasticizer and enhance the strength of the polymer [30]. Typically the plasticizer are used in the concentration of 0-20%w/w of dry polymer weight. However inappropriate use of plasticizer may lead to film cracking, splitting and peeling of strips. It is also reported that the use of certain plasticizers may also affect the absorption rate of the drug [31].

Saliva Stimulating Agent

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 strips formulations. Generally acids which are used in the preparation of food can be utilized as salivary stimulants. Citric acid, malic acid, lactic acid being the most preferred amongst them. These agents are used alone or in combination between 2 to 6%w/w of weight of the strips. Other oral strips ingredients such as sweeteners also act as salivary stimulants. Food grade sugars as well as synthetic sugars are useful salivary stimulants long with acidulate. Glucose, fructose, xylose, maltose, lactose are few examples of such sweeteners [32].

Sweetening Agent

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 [33]. Generally sweeteners are used in the concentration of 3 to 6%w/w either alone or in combination of natural sweeteners as well as artificial sweeteners are used to improve the palatability of the

mouth dissolving formulations. Suitable sweeteners include [34].

- Water soluble natural sweetener: xylose, ribose, glucose, sucrose, maltose, etc.
- Water soluble artificial sweetener: sodium or calcium saccharin salts, cyclamate salt etc.
- Di-peptide based sweetener: aspartame.

Flavoring Agent

These agents play significant role in the taste fondness. The selection of flavor is also dependent on the type of the drug to be incorporated in the formulation. Flavoring agent can be selected from synthetic flavor oils, oleoresins, extract derived from various parts of the plants like leaves, fruits and flowers. The amount of the flavors needed to mask the taste depends on the flavor type and its strength. Preferably up to 10%w/w flavors are added in the oral strips formulations. Cooling agent like monomethyl succinate can be added to improve the flavor strength and enhance the mouth feel effect of the product.

Coloring Agent

Pigment such as titanium dioxide or FDC approved coloring agents are incorporated (not exceeding concentration levels of 1%w/w) in oral strips when some of the formulation ingredients or drugs are present in insoluble or suspension form [36], (Table-2).

Composition	Concentration
Drug	1-40%
Water soluble polymer	1-45%
Plasticizers	0-20%
Sweetening agent	3-6%
Saliva stimulating agent	2-6%
Fillers, colors, flavors	0-30%

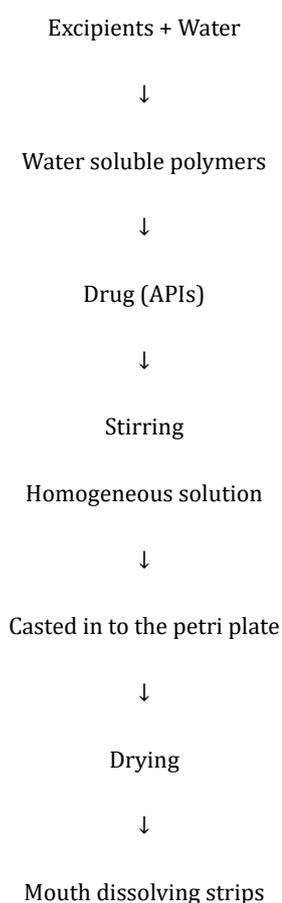
Methods of preparation

The following process can be used for manufacture the mouth dissolving strips:

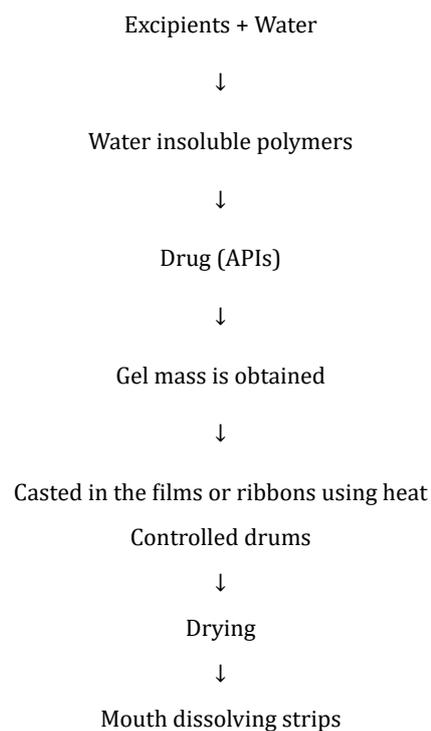
- ✓ Solvent Casting Method
- ✓ Semisolid Casting Method
- ✓ Solid Dispersion Extrusion Method
- ✓ Hot Melt Extrusion Method
- ✓ Rolling Method

Solvent Casting Method

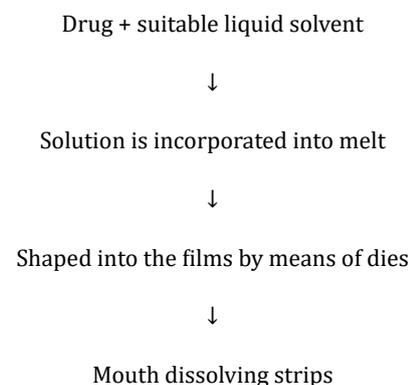
The mouth dissolving strips is preferably formulated using the solvent-casting method, whereby the water-soluble ingredients are dissolved to form a clear viscous solution. The API and other agents are dissolved in smaller amounts of the solution, and combined with the bulk. The mixture is then added 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 [37].

**Semisolid Casting Method**

In this method the gel mass is casted in to the films or ribbons using heat controlled drums. Gel mass is obtained by adding solution of film forming to a solution of acid insoluble polymer in ammonium or sodium hydroxide [38].

**Solid Dispersion Extrusion Method**

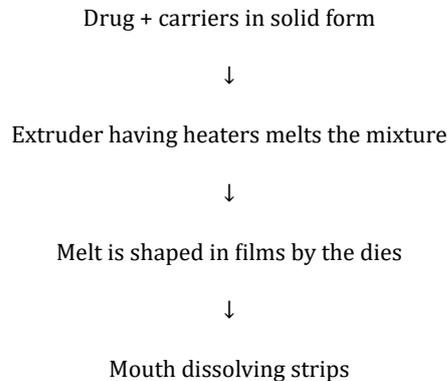
The term "solid dispersion" refers to the dispersion of one or more active ingredients in an inert carrier in a solid state in the presence of amorphous hydrophilic polymers and also using methods such as melt extrusion [39]. This involves a drug which is first dissolved in a suitable liquid solvent and then this solution is incorporated into the melt of suitable polymer, obtainable below 700C without removing the liquid solvent [40].



Hot Melt Extrusion Method:

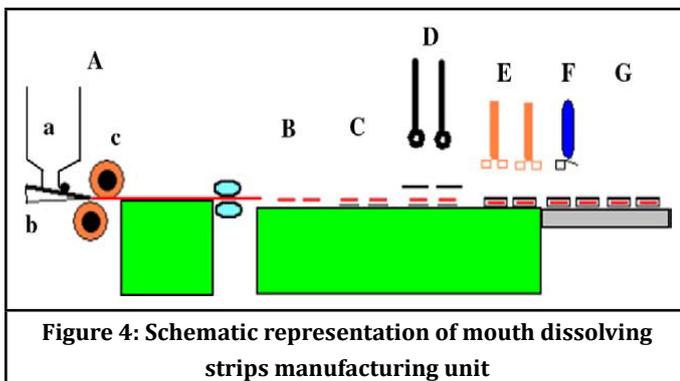
In hot melt extrusion method firstly the drug is mixed with carriers solid form. Then dried granular material is introduced into the extruder.

The extrudate (T=650C) then pressed into a cylindrical calendar in order to obtain a film [41].



Rolling Method

In rolling method a solution or suspension of drug with film forming polymer is prepared and subjected to the roller. The solution or suspension should have specific rheological consideration. The solvent is mainly water and mixture of water and alcohol. The film is dried on the rollers and cutter in to desired shapes and size [42], (Figure-4).



A – Formation of medicated film takes place.

a – Reservoir for the film forming material

b – Deaerator and film applicator

c – Rollers

B – The dried medicated film is slit and cut into little strips of desired size.

C – Strips are placed into lower packaging web.

D – Laser printer on upper packaging web

E – Sealing head seals the strips into single dose sachets.

F – Introduction of tear-notch/slit/cut off to sachets.

G -- Quality control conveyer to final packaging.

Evaluation Parameter

Quality Control Parameter

The quality control test for mouth dissolving strips is as follows

- ✓ Organoleptic test
- ✓ Thickness
- ✓ Dryness/ tack test
- ✓ Tear resistance
- ✓ Tensile strength
- ✓ Percent elongation
- ✓ Young's modulus
- ✓ Folding endurance
- ✓ Swelling test
- ✓ Surface pH test
- ✓ Disintegration test
- ✓ Assay
- ✓ In-vitro Dissolution test

Organoleptic test

In organoleptic test some general tests are carried out such as size, shape, taste of the product should possess the desired feature of sweetness and flavor which is acceptable to a large mass of population.

Color is a vital means of identification for many pharmaceutical products and is also usually important for consumer acceptance. The color of the product must be uniform within a dosage form, Odor is also be important for consumer acceptance of oral Dosage forms and can provide an indication of the quality of oral strips [43].

Thickness

The thickness of film can be measured by digital micrometer screw gauge or digital vernier at different planned locations. This is essential to ascertain to uniformity in the thickness of the film as this is directly related to the accuracy of dose distribution in the film. The thickness of film should be in range of the 5-200 micrometer. The thickness of the film can be adjusted depending upon the surface area and thickness of different areas in mouth [44].

Dryness/Tack test

Dryness is the property is to measure the water or used solvent content in the formulation. Tack is the tendency with which the film adheres to an accessory that has been pressed into contact with it.

accessory that has been pressed into container [45].

Tear resistance

Tear resistance of plastic film or sheeting is a complex function of its ultimate resistance to rupture. The maximum stress or force required to tear the specimen is recorded as the tear resistance value in Newton [46].

Tensile strength

Tensile strength is the maximum stress (applied at one point) required for a oral strips to breaks. It is calculated by the applied load at crack divided by the cross-sectional area of the strips as given in the equation below [47].

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

Percent Elongation

When stress is applied, a film sample stretches and this is referred to as strain. Strain is basically the deformation of film divided by original dimension of the sample. Generally elongation of film increases as the plasticizer content increases. The following formula helpful to determination of the percent elongation [48].

$$\text{Percent elongation} = \frac{\text{Increase in length of} \times 100 \text{ strips}}{\text{Initial length of strips}}$$

Young's modulus

Young's modulus or elastic modulus is the measure of stiffness of the strips. It is represented as the ratio of applied stress over strain in the region of elastic deformation as following formula [49].

$$\text{Young's modulus} = \frac{\text{Slope} \times 100}{\text{Strips thickness} \times \text{cross-head speed}}$$

Folding endurance

Folding endurance is determined by repeated folding of the film till the film breaks. The number of times the film is folded without breaking is computed as the folding endurance value [50].

Swelling test

Film swelling studies are conducted using a stimulated saliva solution. Each film sample is weighed and placed in a pre-weighed stainless steel wire mesh. The mesh containing film sample is submerged into a 15 ml medium in a plastic container. An increase in weight of the film was determined after 20 min weight of strips was observed. The degree of swelling was calculated using formula [51].

$$\alpha = \frac{wt - wo}{wo}$$

Where, wt= weight of film at time

wo = weight of film at time zero

Surface pH test

Surface pH of the film 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 color of pH paper was observed and reported [52].

Disintegration test

The disintegration time limit of 30s or less for orally disintegrating tablets described in CDER guidance can be applied to fast dissolving oral strips. Although, no official guidance is available for oral 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 sec [53].

Assay or Content Uniformity

The test for the content uniformity is carried out taking a sample film of size 1×1 cm² which is placed in a beaker containing 10 ml of suitable medium. The contents were stirred in a cyclomixer to dissolve the film which was transferred to a volumetric flask (10 minutes). The absorbance of the solution was measured against the corresponding blank solution at particular wavelength using a standard pharmacopoeia. Content uniformity is determined by estimating the API content in individual film.

In-vitro Dissolution test

Dissolution testing can be performed using the standard USP paddle over disc and basket or paddle apparatus described in any of the pharmacopoeia. The volume of the dissolution medium will essentially be selected as per the sink conditions and highest dose of the API. Many times the dissolution test can be difficult due to tendency of the film to float onto the dissolution medium when the paddle apparatus is employed. Another method to determine the drug release from the oral strips via conductivity [55].

Applications

The following some application of mouth dissolving strips in drug delivery

- ✓ In mouth dissolving strips formulation drug delivery via Buccal, sublingual and mucosal route.
- ✓ Mouth dissolving strips could become a better delivery method for therapies in which rapid absorption is desired.
- ✓ Mouth dissolving strips used to manage pain, allergies, sleep difficulties, and central nervous system disorders.
- ✓ Mouth dissolving strips used in topical applications for delivery of active agents such as analgesics or antimicrobial ingredients for wound care and other applications.
- ✓ Striss may be loaded with sensitive reagents to allow controlled release when exposed to a biological fluid

Marketed product:

Formulation	Key Attributes	Company
Zydis®	Freeze-Dried wafers	R P Scherer (cardinal)
Advatab®	Direct compression using external lubrication system	Eurand
Frosta®	Direct compression of granules	Akina
Pharm-abrust®	Direct compression of powder mixture	SPI Pharma
Advantol™ 200	Directly compressible excipient system	SPI pharma
WOWTAB®	High- and low - moldability saccharides	Yamanouchi Pharma
OraSolv®	Low compression force and an effervescent couple as a water soluble disintegrating agent	Cima Lab Inc.
DuraSolv®	Direct compression using water soluble excipients	Cima Lab Inc.

Conclusions

The mouth dissolving strips is a good tool for product life cycle management for increasing the patent life of existing molecules or products as compared to some of the complicated and expensive process (like lyophilization) used to manufacture. Mouth dissolving strips is relatively easy to fabricate; thus reducing the overall cost of the therapy. The application of mouth dissolving strips has not only been limited to buccal fast dissolving system, but also expands its horizon to other

Applications like gastroretentive, topical, implantable, sublingual delivery options. This delivery platform shows business potential promise for future in pharmaceuticals, nutraceuticals as well as cosmeceuticals. Mouth dissolving strips discovered excellent uniformity and stability of incorporated drug and rapidly disintegrated in water. All the population groups, particularly geriatric, and pediatric patients with the difficulty in swallowing.

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