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TOPIC: A REVIEW ON FAST DISSOLVING ORAL STRIP AUTHOR

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Abstract: Recently, fast dissolving films are gaining interest as an alternative of fast dissolving tablets. The films are designed to dissolve upon contact with a wet surface, such as the tongue, within a few seconds, meaning the consumer can take the product without need for additional liquid. This convenience provides both a marketing advantage and increased patient compliance. As the drug is directly absorbed into systemic circulation, degradation in gastrointestinal tract and first pass effect can be avoided. These points make this formulation most popular and acceptable among pediatric and geriatric patients and patients with fear of choking. Over-the-counter films for pain management and motion sickness are commercialized in the US markets. Many companies are utilizing transdermal drug delivery technology to develop thin film formats. In the present review, recent advancements regarding fast dissolving buccal film formulation and their evaluation parameters

Keywords: Mouth Dissolving Strip, Superdisintergrants, Taste Masking, Patented Technology

Introduction: An oral film delivery is emerging as an advanced alternative to the traditional oral method of drug administration. The oral film is a solid dosage form of drug administration that dissolves when administered. The oral film doesn't need to be chewed or taken with water. Oral films contain active drugs that are designed for oral administration, allowing the drug to bypass the first-pass metabolism in the liver which leads to an increase in drug bioavailability. Rapid or fast dissolving oral thin film is becoming an increasingly popular drug delivery system because of its wide and varied benefits.

The oral film dissolves in few seconds when comes in contact with saliva, it doesn't need water to swallow thus, it is considered best for children and elderly patients. Mouth dissolving films contain amorphous polymers which aid in the rapid dissolution of the drugs. Above points lead to improvement in patient compliance and inspire pharmaceutical manufacture to invest their money in switching from the former products in markets to FDFs. Some patients, especially geriatric and pediatric groups face difficulty in swallowing solid dosage forms and have the risk of choking. To comfort such patients, a variety of fast dissolving drug delivery modes have been developed. Fast dissolving drug delivery systems are generally manufactured by a variety of technologies, which are direct compression, wet granulation and freeze drying. Some make use of different disintegrating mechanisms, such as high levels of disintegrating or effervescent agents, which cause the dosages to disintegrate rapidly in the mouth. The oral route of administration still continues to be widely used

accepted route, contributing to 50 - 60% of total drug formulations because of ease of administration, self-medication, and pain avoidance as compared to parenteral mode.

Special Features Of Oral strip:

· 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 Strip:

· Larger surface area promotes rapid disintegration and dissolution in the oral cavity.

· Oral films are flexible and thus less fragile as compared toODTs. Hence, there is ease of transportation and during. consumer handling and storage.

· Precision in the administered dose.

· No risk of chocking.

· Good mouth feel.

· Improved patient compliance.

Table 1 : formulation of mouth dissolving film -

r. No.	articulars	ategory
.	icagrelor	API
.	PMC(Hydroxyl Propyl Methyl Cellulose)	olymer
.	extrin	iluent, Viscosity Enhancer
.	uar Gum	inder

.	Sugar	Sweeting Agent
.	Amaranth	Coloring Agent
.	Propylene Glycol	Anti Microbial Preservative
.	Citric acid (mg)	Saliva Stimulating agent
.	Water	Filling Agent
0.	Vanilla	Flavoring Agent

1. Active Pharmaceutical Ingredients :

5-30% w/w of active pharmaceutical ingredients are used for a standard composition of oral strips. Generally, small dose molecules are selected for oral strips. Micronization of APIs is very useful to improve the dissolution of the strip that will lead to fast absorption as well as the instant therapeutic action of the drug. Taste masking agents will be used for masking the itter taste of the drug. Highly lipophilic drugs should be preferred for oral strips. Different categories of drugs are used in the oral strips some of these are antiulcer (e.g. omeprazole) Antiemetic, Antiallergic,
antiasthmatics (salbutamol sulfate), antitussives, expectorants, antihistaminics, NSAIDS (e.g. paracetamol, meloxicam, valdecoxib).

2. . Water-soluble polymer :

The development of the film and the mechanical strengt of the film is strongly related to the selection and concentration of the polymers. These polymers can be used alone or in
combination with other polymers to increase the mechanical strength and modify the film property. 45% w/w of the concentration of the polymer is used to develop an oral strip. But it can be increased up to 60-65% w/w to attain the desired characteristics.15 A polymer that is used for formulation the thin strip should have the following properties .

Ideal properties of water-soluble polymers:

- **Nontoxic**
- **Nonirritant**
- **Should not affect the disintegration time of oral strip**
- **Should have a moderate half-life**
- **Should have good spreadability**

3. Plasticizers :

Plasticizers play an important role in the formulation of oral strips. By the addition of the plasticizers, the mechanical and tensile strength of the film will be improved. The selection of the plasticizer is dependent on the compatibility with the polymer used and type of solvent that employed. Commonly used plasticizers are polyethylene glycol, glycerol, low molecular weight polyethylene glycol, phthalate derivatives and citrate derivatives like tributyl, triethyl, acetyl
citrate and castor oil. 0-20% w/w concentration of plasticizer is commonly used that will help to prevent cracking, splitting and peeling of the strip.

4. Surfactan :

Surfactants are used to enhance the solubility and wetting property of the film that will provide quick dissolution and release the medicament within a minute, some of the commonly used surfactants are sodium lauryl sulfate, benzalkonium chloride, and a tween, etc. Poloxamer 407 is the most important surfactant used as solubilizing, wetting and dispersing agent.

5. Sweetening agent

Sweeteners have become one of the important ingredients in the pharmaceutical product to mask the bitter taste ofthe drug. Both natural and artificial sweeteners are used. Natural sweeteners like sucrose, dextrose, fructose, glucose, liquid glucose and isomaltose etc. and artificial sweeteners like monosaccharide's, disaccharides and polysaccharides such as galactose, glucose, mannose, fructose, xylose, ribose, dextrose, maltose, sucrose, sugar, sorbitol, xylitol, mannitol and soluble saccharin salts, saccharin, cyclamate salts, acesulfame-K, Aspartame, Neotame respectively.

Now day's popularity of artificial sweeteners in pharmaceutical formulation increasing day by day. Neotame and alitame have more than 2000 to 8000 times sweetening power than sucrose**.**

6. Saliva stimulating agent :

Saliva stimulating agents are helpful for rapid disintegration of the oral strips because they enhance the rate of production of saliva. Citric acid, malic acid, lactic acid, ascorbic acid, and tartaric acid are some of the examples of salivary stimulant. In the oral strip, 2-6% w/w concentration of salivary stimulant is used alone or in combination. Citric acid is one of the preferable stimulantsused in the oral strip.

7. Coloring and flavoring agents :

FDC approved natural coloring agents are commonly used. The concentration of the coloring agent should within the limit of 1% w/w.Flavoring agents are generally added to the formulation to give the flavor and make the formulation attractive towards pediatric patients. different flavor can be used such as essential oils or water-soluble extract of menthol, intense mint (peppermint,sweet mint.

Methods: APPROACHES USED FOR THE FORMULATION OF FAST DISSOLVING FILMS

Conventional approaches

- Solvent casting method
- Hot-melt extrusion
- Semisolid casting
- Solid dispersion extrusion
- Rolling. Solvent casting method

Solvent casting method: In this method firstly the water soluble polymers are dissolved in water at 1,000 rpm and can be heated up to 60°C. All the other excipients like colors, flavoring agent, sweetening agent, etc., are dissolved separately. Then both the solutions obtained are mixed thoroughly stirring at 1,000 rpm. The obtained solution is incorporated with the API dissolved in suitable solvent. The entrapped air is removed by vacuum. The resulting solution is cast as a film and

allowed to dry, which isthen cut into pieces of the desired size .

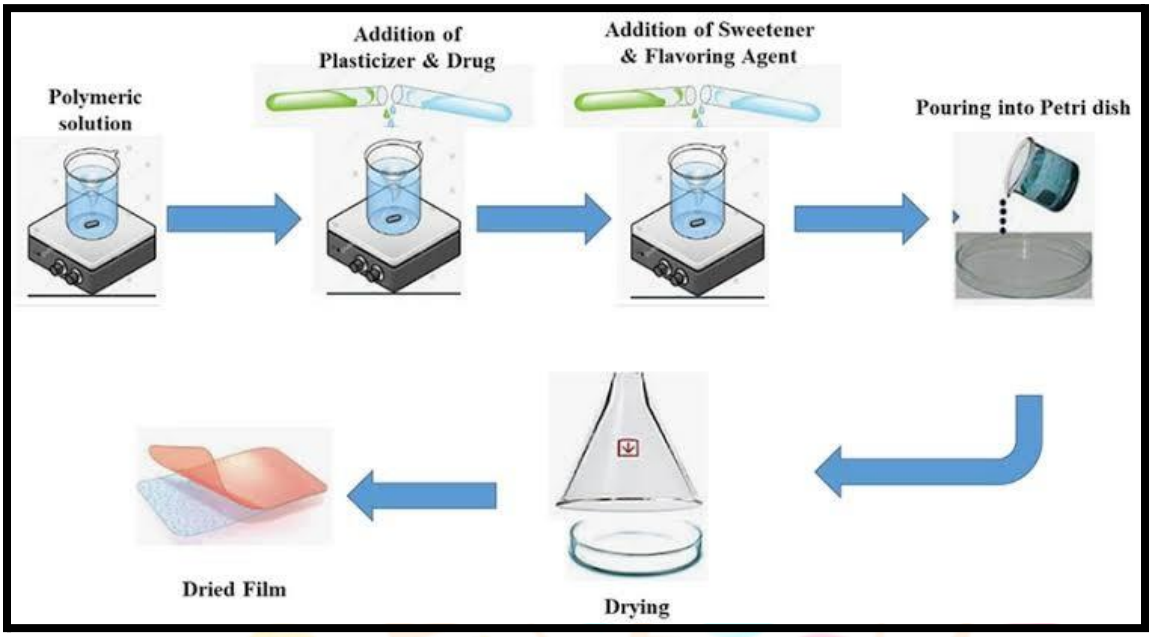


Fig 1 : solvent casting method.

1)Solvent / Water or suitable mixture of solvent2)Add excipients

3) Heating up to 60 degree solution and stirring at 1000 rpm

4) Replenishing of evaporated solvent

5) Cooling to room temperature and add polymer and add API

6) Replenishing of evaporated solvent

7) Casting / Defoaming and final film

Hot-melt extrusion: Hot-melt extrusion method is commonly used for the preparation ovariou dosages form in the pharmaceutical industry like sustained-release tablet, granules, transdermal and transmucosal drug delivery systems. 28 In this method, the drug and polymer are firstly blended in amixer for 10minutes and plasticizer is added slowly and in the presence of th

anti-sticking agent, the mixer is granulated. The prepared granules are dried overnight at room temperature and pass the dried granules in 250m sieve and standardize. The standardize granules are then poured into the extruder. The speed of the extruder is set to 15 rpm in order to process the granules inside the drum approximately less than 3mintues at 65 C and then pressed into a cylindrical calendar in order to obtain a strip with a thickness about 200m. for further testing, the strip is cut into the required size and shape and stored at 25 C.

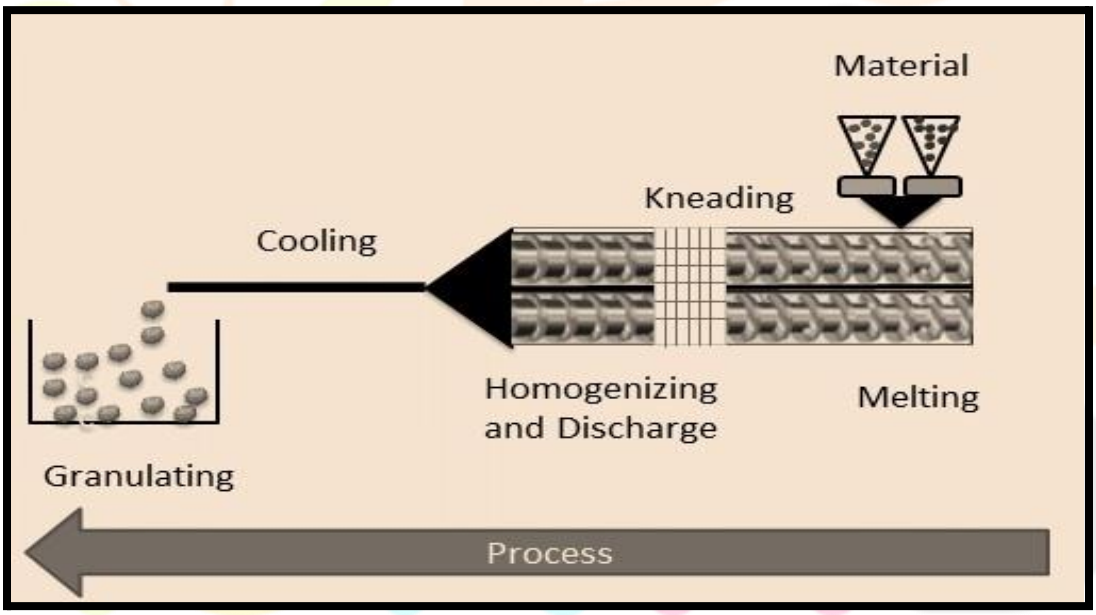
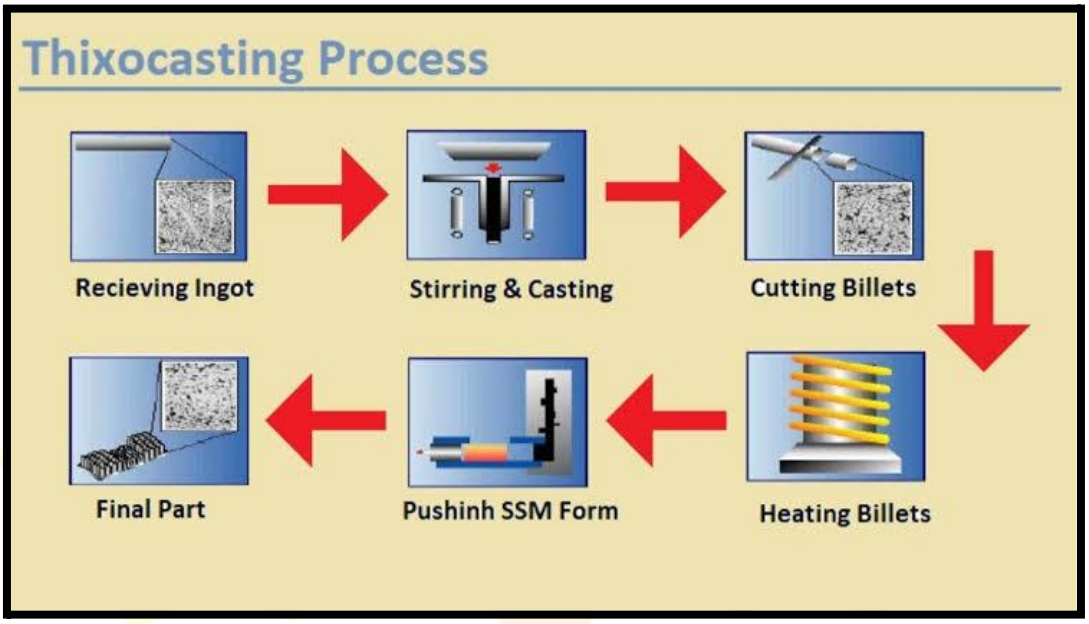


Fig 2 : hot melt extrusion.

Semi-solid casting: This method is mostly preferred when film ingredient involves acid insoluble polymer. In this firstly, the water soluble polymers are dissolved in water. The obtained solution is added to the acid insoluble polymer solution which is separately formed. Both the solutions are mixed properly. After mixing the two solutions, appropriate amount of plasticizer is added to the obtained final solution so that gel's mass can be obtained. At last, the gel mass is casted onto the films or ribbons using heat controlled drums. The thickness of the film should be about 0.015-0.05". The ratio of the acid insoluble polymer to film forming polymer should be 1:4. Examples of acid insoluble polymers are cellulose acetate phthalate and cellulose acetate butyrate.



Solid dispersion extrusion: Method involves the solid dispersion of drug incorporated in melted polymer solution so that drug can be loaded. The drug is dissolved in suitable liquid solvent and obtained solution is added to the melt of suitable polymer, obtainable below 70°C without removing the liquid solvent to obtain the solid dispersion. Finally the obtained solid dispersions are shaped into films by means of dyes.

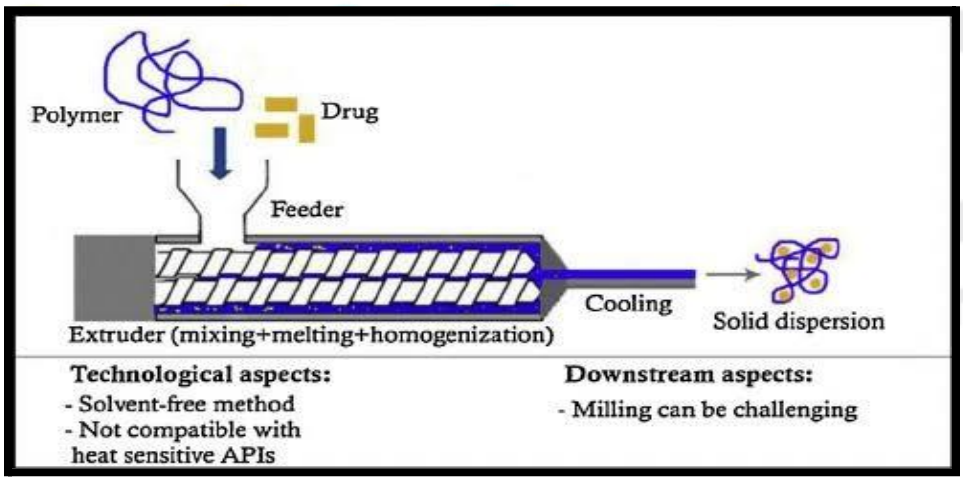
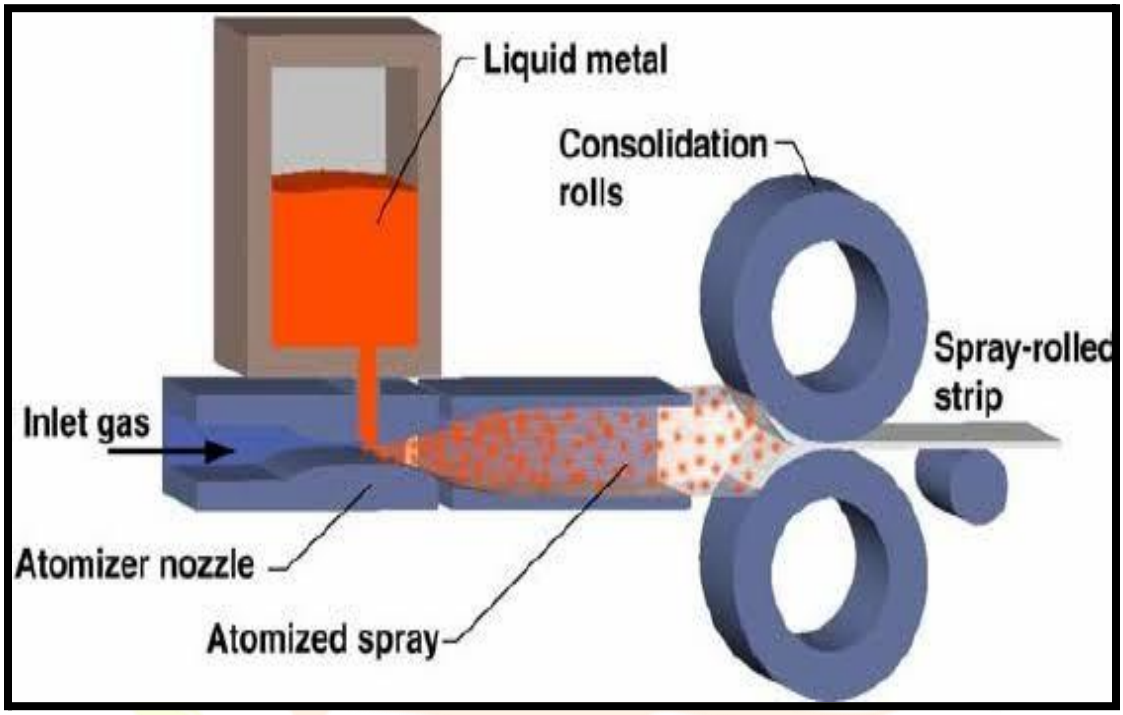


Fig 4 : solid dispersion extrusion

Rolling method: In rolling method, both the drug solution and film forming polymer solution are mixed thoroughly and the resultant solution or suspension is subjected to the roller. The solution or suspension should have specific rheological consideration. The film is dried on rollersand cut into desired shapes and sizes.



Evalution Test:

Thickness: The thickness of film is measured by micrometer screw gauge or calibrated digital Vernier Calipers. The thickness of film should be in range 5-200 µm.[21] The thickness should be evaluated at five different locations (four corners and one at center) and it is essential to ascertain uniformity in the thickness of film as this is directly related to accuracy of dose distribution in the film

Dryness/Tack test : In all there have been eight stages identified for film drying and these are set-to-touch, dust-free, tack-free (surface dry), dry-to touch, dry-hard, dry-through (dry-to-handle), dry-to-recoat, and dry print-free. Tack is the tenacity with which the strip adheres to an accessory (a piece of paper) that has been pressed into contact with strip. Instruments are also available for this study

Tensile strength: Tensile strength is the maximum stress applied to a point at which the strip specimen breaks. It is calculated by the applied load at rupture divided by the cross-sectional area of strip as given in the equation below: Tensile strength = Load at failure × 100/Strip thickness × Strip width Percent elongation When stress is applied on a film (2 × 2 cm2) sample it gets stretched, this is referred to strain. Strain is basically the deformation of strip before it gets broken due to stress. It is measured by using hounsfield universal testing machine.[23] Generally elongation of strip increases as the plasticizer content increases. It is calculated by the formula: % Elongation = Increase in length of strip × 100/Initial length of strip.

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Tear resistance: Tear resistance is the resistance which a film offers when some load or force is applied on the film

specimen. The load mainly applied is of very low rate 51 mm/min. The unit of tear resistance is Newton or pounds-force. In other words it is the maximum force required to tear the specimen.

Young's modulus: Young's modulus or elastic modulus is the measure of stiffness of strip.[25] It is represented as the ratio of applied stress over strain in the region of elastic deformation as follows: Young's modulus = Slope × 100/Strip thickness × Cross head Speed. Hard and brittle strips demonstrate a high tensile strength and Young's modulus with small elongation

Folding endurance : Folding endurance gives the brittleness of a film. The method followed to determine endurance value is that the film specimen (2 × 2 cm2) are repeatedly folded at the same place until it breaks or a visible crack is observed. The number of times the film is folded without breaking or without any visible crack is the calculated folding endurance value

In vitro disintegration test: Disintegration time is the time when an oral film starts breaking when brought in contact with water or saliva. For a fast dissolving film, the time of disintegration should be in range of 5-30 s. United State Pharmacopoeia (USP) disintegration apparatus can be used to study disintegration time.[27] In another method, the disintegration time can be visually determined by dipping the film in 25 ml water in a beaker. The beaker should be shaken gently and the time was noted when the film starts to breaks or disintegrates.[28]

In vitro dissolution studies : 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. The standard basket or paddle apparatus described in any of the pharmacopeia can be used for dissolution testing. The selection of dissolution medium will essentially depend as per the sink conditions and highest dose of API. The temperature of dissolution medium should be maintained at 37
± 0.5°C and rpm at 50. When the paddle apparatus is employed, it has a disadvantage that oral films have a tendency to float over the dissolution medium. Mashru et al.,[29] used stainless steel wire mesh with sieve opening of approximately 700 µm used to dip salbutamol fast dissolving film inside the dissolution medium.

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

Organoleptic test : The desired organoleptic properties a fast dissolving formulation should have are color, flavor, and taste. As the formulation will disintegrate in the oral cavity so it should provide acceptable organoleptic palatable characteristics. Color makes a formulation acceptable among the patients and moreover oral films should have attractive color as they are administered to children.
Hence, color of formulation should be uniform and attractive. Color can be evaluated by visual inspection. The other organoleptic property is the odor. The flavor used in the formulation should provide good odor to the formulation. The odor of the polymer, drug, and any other excipient should be masked with use of flavoring agent. Taste is also an important factor which has to be evaluated. To evaluate the taste, special human taste panels are used. Experiments using electronic tongue measurements have also been reported to distinguish between sweetness levels in taste masking formulation.[33] Electronic tongue technique works on the principle of potentiometric titration method. In this liquid samples can be analyzed directly, whereas solid samples need to be dissolved in a suitable solvent before analyzing. In this method, reference electrode and sensors are dipped in a beaker containing a test solution for 120 s and a potentiometric difference between each sensor and a reference electrode is measured and recorded by the E-tongue software.

Surface pH test: The surface pH of fast dissolving strip can cause side effects to the oral mucosa, so it is necessary to evaluate the surface pH of film. The surface pH of film should be 7 or close to neutral. For this purpose, a combined pH electrode can be used. With the help of water, OS was made slightly wet and the pH was measured by bringing electrode in contact with surface of oral film. This study should be done on at least six films of each formulation and their mean ± SD

can be calculated.[36] In another method to determine the surface pH, the films are placed on the 1.5%w/v agar gel and then the pH paper are placed on the film, change in color of pH paper gives surface pH of the film.

Transparency : To determine transparency of oral film, a simple ultraviolet(UV) spectrophotometer can be used. The film specimen is placed on the internal side of spectrophotometer cell. The transparency of films is calculated as follows: Transparency = (log T600)/b = −€c Where T600 is the transmittance at 600 nm and b is the film thickness (mm) and c is concentration.

Contact angle: Contact angle measurement predicts the wetting behavior, disintegration time, and dissolution of oral film. These measurements are performed with help of goniometer (AB Lorentzen and Wettre, Germany) and the measurements should be done at room temperature. The water used to determine contact angle should be double distilled water.[37] A drop of double distilled water is placed on the surface of dry film. Images of water droplet are recorded within 10 s of deposition by means of digital camera. Digital pictures can be analyzed by imageJ 1.28v software (NIH, USA) for angle determination.

Scanning electron microscopy: To study the surface morphology of film between different excipients and drug scanning, electron microscopy can be used. The film sample should be placed in sample holder and at ×1000 magnification, various photomicrographs can be taken using tungsten filament as an electron source.

Permeation studies: Even though permeability of oral mucosa is 4-1000 times greater than that of skin, permeation studies should be carried out. To study the permeability, modified Franz diffusion cell can be used along with porcine buccal mucosa. The Franz diffusion cell consists of a donor and a receptor compartment. In between the two compartments, mucosa is mounted and the size of the mucosa should be of the same size as that of the head of receptor compartment. The receptor compartment is filled with buffer and maintained at 37 ± 0.2°C and to maintain thermodynamics a magnetic bead stirring at a speed of 50 rpm is used. A film specimen moistened with a few drops of simulated saliva should be kept in contact with mucosal surface. The donor compartment should consist of 1 ml simulated saliva fluid of pH 6.8. At particular interval, samples are withdrawn and replaced by same amount of fresh medium. By suitable analytical method, percentage of drug permeated can be determined.

Percentage moisture loss: To determine percentage moisture loss films of area 2 × 2 cm2 are cut and weighed accurately on an electronic balance. After weighing, the films were kept in desiccators containing fused anhydrous calcium chloride. The films should be kept for 72 h in the desiccator. After 72 h, they are taken out and again weighed and the percentage moisture loss of films was measured by using the formula: Percent moisture loss = (Initial weight - Final weight)/Initial weight × 100 The percentage moisture loss studies are done to determine physical stability and integrity of the film.

Determination of % yield of buccal patches: [42] Percentage yield of buccal patches can be calculated by the following formula: % yield = Mass of the buccal patches obtained/Total weight of drug and polymer × 100.

Stability study: Stability study should be carried out according to the International Conference on Harmonization (ICH) guidelines. The prepared formulation was wrapped in a special way. Firstly, it was wrapped in a butter paper then above it an aluminum foil was wrapped and the packing should be placed in an aluminum pouch and make it heat sealed. The storage conditions at which formulations are kept should be 30°C/60% relative humidity (RH) and 40°C/75% RH. After 3 months, the films were evaluated for drug content, disintegration time, and physical appearance observation.

Storage and packaging of OS: Fast dissolving strips can be packed using single pouches, blister card with multiple units, multiple-unit dispenser, and continuous roll dispenser. There are certain patented packaging systems for fast dissolving films such as Rapidcard by Labtec and Core-peel by Amcor flexible. The rapid card is of same size as a credit card and holds three films on each side. Every dose can be taken out individually.

Conclusion:

Oral mouth dissolving strip 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 drug.

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