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FAST DISSOLVING THIN STRIPS: AN EMERGING WAY FOR ORAL DRUG DELIVERY

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Abstract:

Various pharmaceutical dosage form are present in the market but all of the dosage forms possess some drawback most common is patient incompliance which is seen in all age groups. So from last few years focus is done on developing such dosage form which enhances safety, efficacy and patient compliance. In this manner, in late 1970 fast-dissolving drug delivery system came in existence which includes Fast dissolving tablets and fast dissolving thin strips means those dosage form which dissolves in the oral cavity when came in contact with saliva. Fast dissolving thin strips have various advantages over fast dissolving tablets like flexibility and no risk of choking so fast dissolving thin strips is suitable for pediatric, geriatrics and dysphasic patients which face difficulty in swallowing. Various methods have been employed in formulating Fast-dissolving thin strips but most preferred is solvent casting method in which hydrophilic polymers (natural & synthetic) along with other excipients are used. Fast dissolving thin strips have potential to enhance business and its market utilization because of their various advantages over fast dissolving tablets. The main aim of the present review is to focus on fast dissolving thin strips advantages, its types, composition, a method of preparation and evaluation.

Keywords:-*Fast dissolving thin strips (FDTS), Dysphasic, Bioavailability, Solvent casting.*

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INTRODUCTION:

For the administration of therapeutic agent first choice of most of the patient is oral route because of the avoidance of pain, low cost of therapy, ease of administration and a large number of the drug can be incorporated so it leads to high levels of patient compliance [1]. There are about 60% of oral solid dosage forms available in the market in form of tablet, capsules etc. [2]. After all these advantages oral drug delivery system still need some advancements because of some drawbacks which are generally seen in dysphasic (paediatric, geriatric) and bedridden patients and also inactive patients who are busy in traveling and may not have access to water and they are associated with many medical conditions and they facing difficulty in chewing or swallowing oral solid dosage forms. It is estimated that about 50% of the total population is affected by this problem, which results in a high chances of noncompliance and ineffective therapy.

Various research and development have been done in oral drug delivery system segment to overcome all these problems like the conversion of the dosage form from marketed simple conventional tablets or capsules to modified release tablets or capsules and in late 1970's Fast dissolving drug delivery system came into existence which consists of fast dissolving tablets and fast dissolving thin strips. [1, 3]

Fast dissolving drug delivery system consists of a solid dosage form which disintegrates or dissolves in the oral cavity in within seconds or minutes as they came in contact with saliva and gives better absorption hence provide quick onset of action and instant bioavailability. Fast dissolving thin strips may be designed as a single layer and multi-layer system depend upon the therapeutic need. Fast dissolving thin strips are generally placed on or under the tongue or into the buccal cheeks. [4]

Classification of Fast Dissolving Technology

Fast dissolving technology is divided into three groups:-

- ✓ Lyophilized system
- ✓ Compressed tablet-based systems
- ✓ Fast dissolving thin strips.

- **Lyophilized system-** In this technology system involves taking suspension or solution of active pharmaceutical ingredient along with other excipients than it is transferred into mold or blister pack, after some time there is the formation of tablet-shaped units. Then these tablets are frozen and lyophilized in the pack or mold. Resulting units or tablets have a very high porosity which allows rapid saliva penetration resulting in quick disintegration and faster onset of action. [4,5]
- **Compressed tablet based systems-** This type of system is generally produced by using standard tablet preparation technology by direct compression of active pharmaceutical ingredient and other excipients. The compressed tablet-based system has different levels of friability and hardness which depend on the method of preparation. In this system, the quick disintegration of the tablet is achieved by using water-soluble excipients, superdisintegrants, and effervescent substances which allow rapid penetration of saliva into the core of tablet and provide quick action. [4,5]
- **Fast dissolving thin strips-** Fast dissolving thin strips also known as oral wafers are the new drug delivery system in which the films are taken orally and can be placed on or under the tongue or in the buccal cheeks. When the films come in contact with saliva it has property to disintegrate or dissolve in seconds. Fast dissolving thin strips are proven and accepted technology for the systemic delivery of various active pharmaceutical ingredients for over the counter medication. [4,5]

Features of Fast Dissolving Thin Strips-

- Thin elegant strips.
- No need of water.
- Strips are available in various shapes and sizes.
- Strips show fast disintegration and dissolution.
- Rapid release hence quick onset of action
- Excellent mucoadhesion. [6,7,8]

Advantages of Fast Dissolving Thin Strips-

- No need of water.
- Larger surface area provide quick disintegration and dissolution.
- Minimise bypass effect.
- Increase bioavailability.
- Reduced GI irritation.
- No fear of chocking.
- Easy to carry. [9,10]

Disadvantages of Fast Dissolving Thin Strips:-

1. The larger dose cannot incorporate. [7].

Classification of Fast Dissolving Thin Strips:- [11].

Property	Flash release thin strips	Mucoadhesive melt away thin strips	Mucoadhesive sustained release thin strips
Area	2-8cm^2	2-7cm^2	2-4cm^2
Structure	Single layer	Single or multilayer	Multilayer
Thickness	20-70µm	50-500µm	50-250µm
Excipients	Highly hydrophilic polymers	Hydrophilic polymers	Low non-soluble polymers
Drug phase	Solid solution	Solid solution or suspended drug particles	Solid solution or suspension
Dissolution	Within 60 seconds	In few minutes	Maximum 8-10 hours
Application	Tongue (Upper portion)	Buccal or gingival region	Gingival or another part in oral cavity
Site of action	Systemic or local	Systemic or local	Systemic or local

Overview of Oral Cavity: - Fig 1- www.cancer.ca. (2017).

The oral cavity is the most important part of the digestive system of the human body because of its excellent accessibility and better patient compliance. The oral mucosal cavity is considered as an attractive site for delivery of drugs either locally or directly into the systemic circulation The oral cavity is the area of mouth delineated by the lips, cheeks, hard palate, soft palate, and floor of the mouth. The oral cavity consists of two regions,

- Outer oral vestibule, bounded by cheeks, lips, teeth, and gingiva (gums).
- Oral cavity proper, which extends from teeth and gums back to the faces (which lead to the pharynx) with the roof comprising the hard and soft palate. The tongue projects from the floor of the cavity.

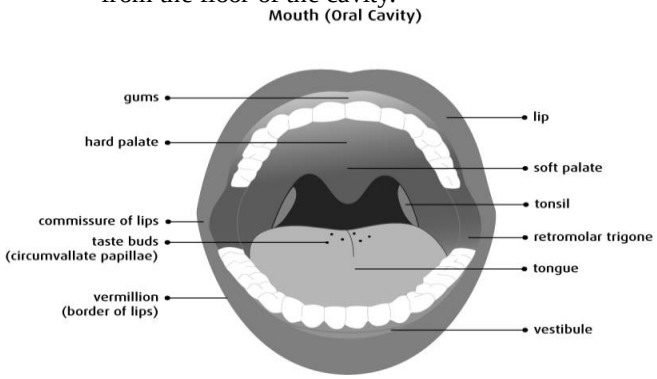


Fig. 1: Overview of Oral cavity

Anatomy of the Oral Mucosa -The surface area of the oral mucosa is about 200cm^2. The oral mucosa is the mucous membrane inside the mouth consist of two layers Stratified squamous epithelium generally termed as oral epithelium and an underlying layer of connective tissue which is the lamina propria. Beneath the selected areas of the oral mucosa, there is loose connective tissue known as submucosa.

Different parts of oral mucosa :- (Fig 2-Jangra et al., 2014).

- ➢ Epithelium- The epithelium may be keratinized or non-keratinized depending upon its location.
  - ✓ Keratinized epithelium
  - Stratum basale
  - Stratum spinosum
  - Stratum granulosum
  - Stratum corneum
  - ✓ Non-keratinized epithelium
  - Stratum basale
  - Stratum spinosum
  - Intermediate layer
  - Superficial layer
- ➢ Basement membrane- It is the interface between the connective tissue and the epithelium.
- ➢ Lamina propria- It is a connective tissue of variable thickness that supports epithelium. It is divided into two parts- Reticular and papillary.
- ➢ Sub-mucosa- It attaches the mucous membrane to the underlying structure [12].

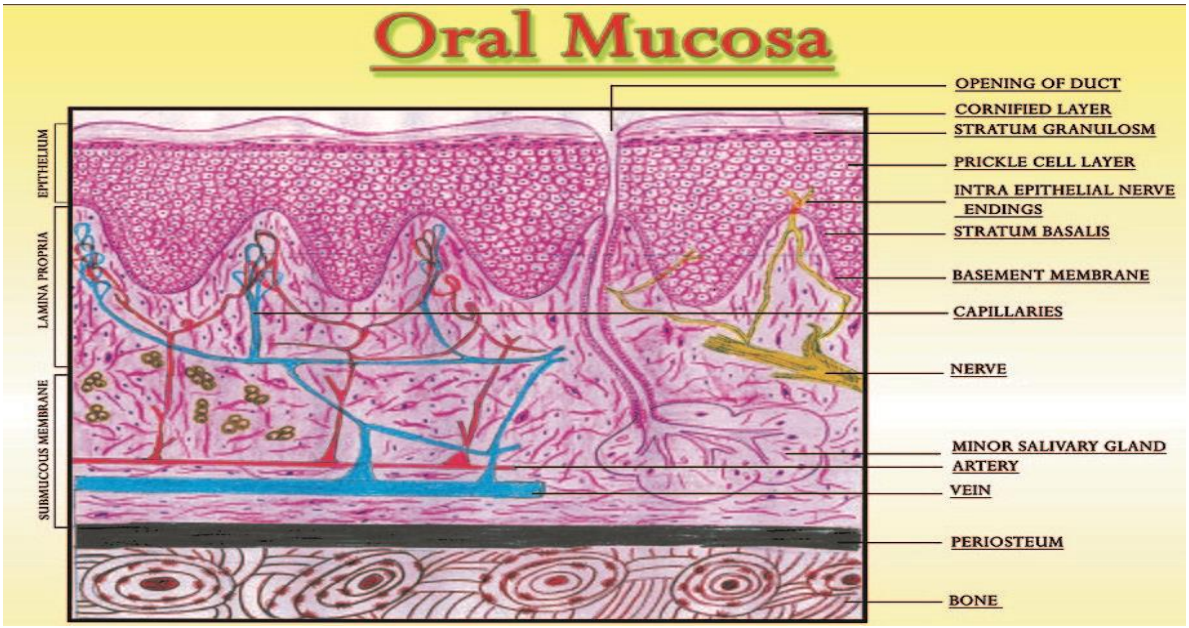


Fig. 2: Overview of Oral mucosa [11]

Formulation Consideration:-

Active Pharmaceutical Ingredients: - The composition of fast dissolving thin strips contain about 1-25% of API. A large number of API can be incorporated in fast dissolving thin strips including antiemetic, antidepressant, antiasthmatic, antianginal etc. The API having small dose is mostly preferred [13].

Ideal properties of Active pharmaceutical ingredient :-

- API must have a pleasant taste.
- The API should have low-dose up to 40mg.
- API must be freely soluble in water.
- API should be smaller in molecular weight.
- The API has the ability to permeate the oral mucosal tissue [14].

Film forming polymers: - The polymers which are generally used in the formation of thin strips must be hydrophilic in nature. The concentration of polymer must be 0-40%. Robustness of film mainly depends on the type of polymer used. They have used either alone or in combination.

Ideal property of film-forming polymers-

- Must be hydrophilic in nature.
- Non-toxic and non-irritant in nature.
- It must have the excellent film-forming capacity.
- It should tasteless & odorless.
- The polymer must show sufficient shelf life.
- The polymer must have good spreading and wetting property.
- It does not cause any infection in the oral mucosa[15].

Nowadays both natural and synthetic polymers are used in the preparation of fast dissolving thin strips [16].

Natural polymers	Synthetic polymers
Starch	Hydroxypropyl methylcellulose
Gelatin	Hydroxypropyl cellulose
Xanthan	Polyvinylpyrrolidone
Pectin	Polyvinyl alcohol
Maltodextrin	Hydroxyethyl cellulose
Polymerised resin	Carboxymethyl cellulose
Pullulan	Kollicoat

Plasticizers: - It is considered as an important component fast dissolving thin strips. The concentration of plasticizers must be 1-20%. Generally, it is used to provide flexibility and to reduce the brittleness of thin strips. The mechanical property of films like tensile strength and elongation of the films were also improved by the addition of plasticizers. The main function of plasticizers is to reduce the glass transition temperature of the polymer in the range of 40-60˚C for the non-aqueous system and below 75˚C for the aqueous system. Its selection depends upon its compatibility with polymer and type of solvent which is preferred for formation of thin strips [17]

Plasticizers	Polyethylene glycol- 400, Propylene glycol, Glycerol, Castor oil, Phthalate derivatives like diethyl and dimethyl phthalate etc.

Superdisintegrants: - These are the substance or mixture of substances which are added to drug

formulations which facilitate quick dispersion of films, tablets for quick dissolution [18].

Superdisintegrants	Sodium starch glycolate, Crosspovidone, Cross carmellose sodium

Sweetening agents: - Taste is generally considered as an important factor in case of the pediatric population. Fast dissolving thin strips generally disintegrate or dissolve in oral cavity so sweetening agents are generally used to mask the bitter taste of active pharmaceutical ingredient. The concentration of sweetening agents must be 3 to 6% either alone or in combination [5,11]. Both natural and artificial sweeteners are used to improve the palatability of fast dissolving dosage forms [14,19].

Type of sweeteners	Example
Natural sweeteners	Xylose, ribose, glucose, sucrose, maltose, stevioside etc.
Artificial sweeteners	Sodium or calcium saccharin salts, cyclamate salts, acesulfame- K etc.
Dipeptide based sweeteners	Aspartame
Protein-based sweeteners	Thaumatin I & II
Polyhydric Alcohols	Sorbitol, mannitol, isomalt, etc.

Saliva stimulating agents: - The main function of saliva stimulating agent is to increase the rate of production of saliva which results in fast disintegration and dissolution of fast dissolving thin strips so it can provide quick onset of action. The concentration of saliva stimulating agent must be 2 to 6% [5].

Saliva Stimulating agent	Citric acid, Tartaric acid, Ascorbic acid, Lactic acid, Malic acid

Surfactant: - It is generally used as wetting and solubilizing agent so that the fast dissolving thin strips gets immediately dissolve and provide quick onset of action [7].

Surfactant	Poloxamer 407, Sodium lauryl sulfate, Tween, Span

Flavouring agents: - It is generally used to mask the taste of Active pharmaceutical ingredient on the basis of flavor and strength. It's concentration ranging from 1 to 2% [5].

Types of flavours	Examples
Fruity Flavour	Vanilla, Citrus, Coffee, Cocoa
Fruit essence	Pineapple, Strawberry, Apple, Orange, Cherry, Mango
Flavour oil	Peppermint, Menthol

Coloring agents: - FD & C approved coloring agent are generally used. It's concentration ranging from 1 to 2% [14].

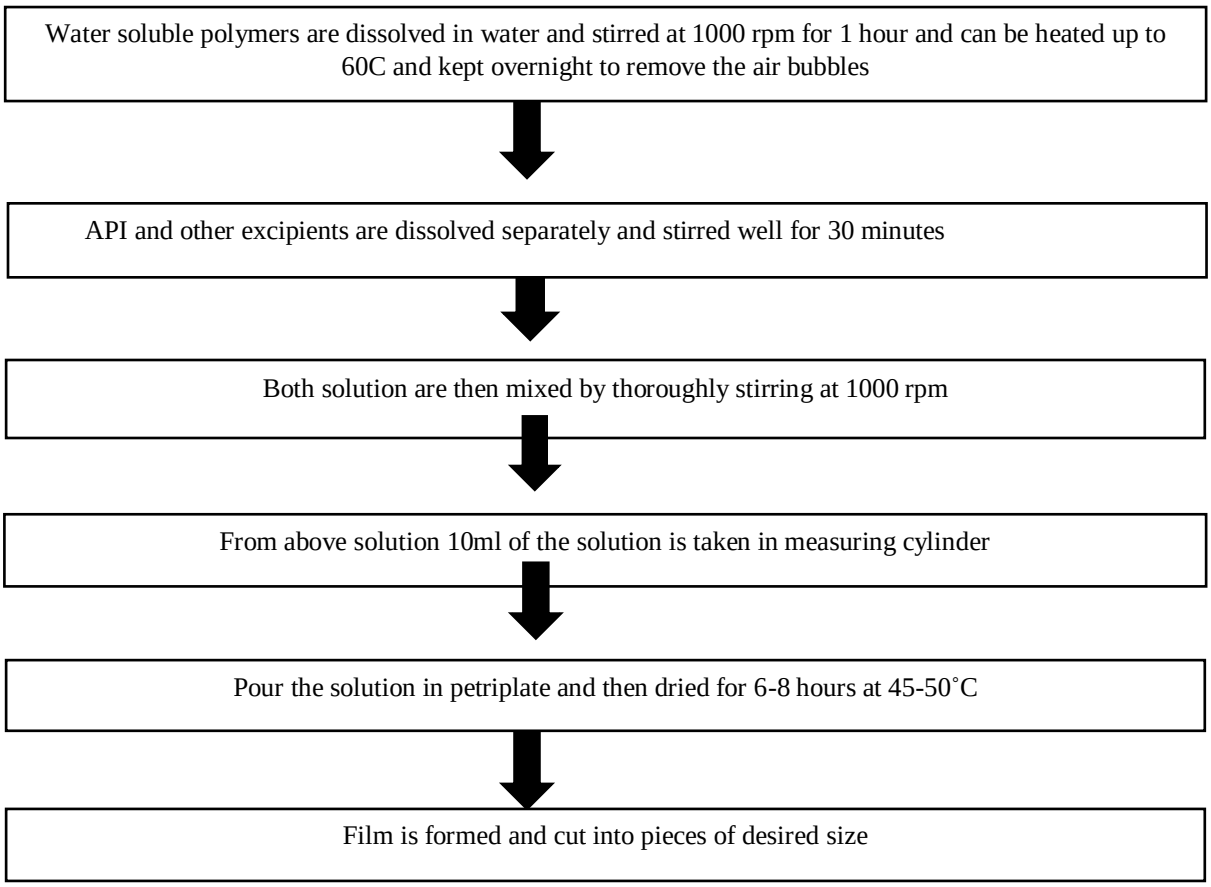
Colouring agents	Titanium dioxide, Sunset yellow

Method of preparation of Fast Dissolving Thin Strips

Different methods used for preparation of fast dissolving thin strips include-

- Solvent casting method.
- Semi-solid casting method.
- Hot melt extrusion method.
- Rolling method.
- Solid dispersion method[5].

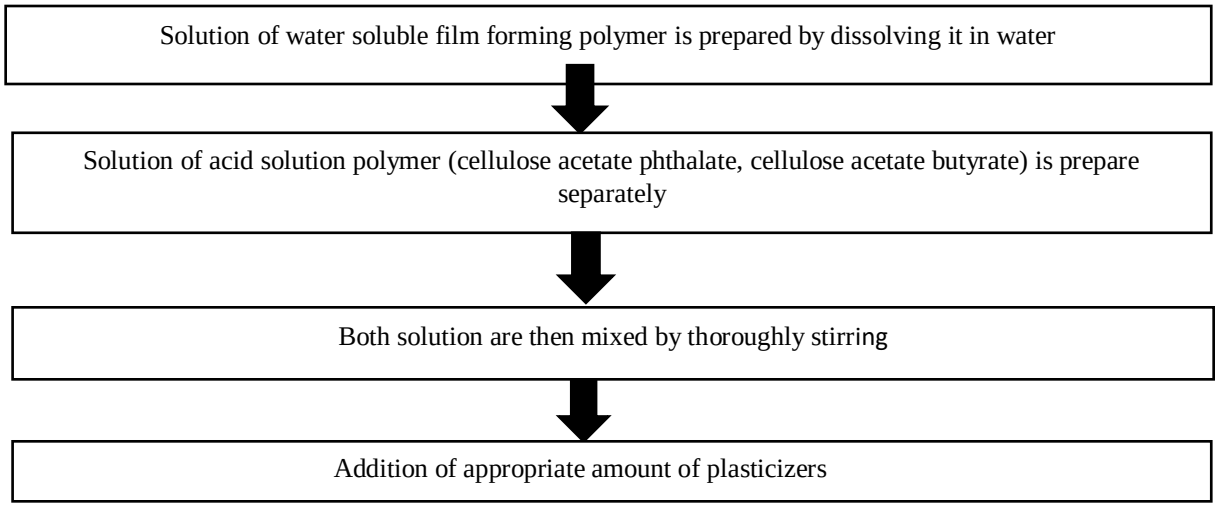
Solvent casting method: - This method is widely used for the preparation of fast dissolving thin strips as it is easy as compared to another method [8].



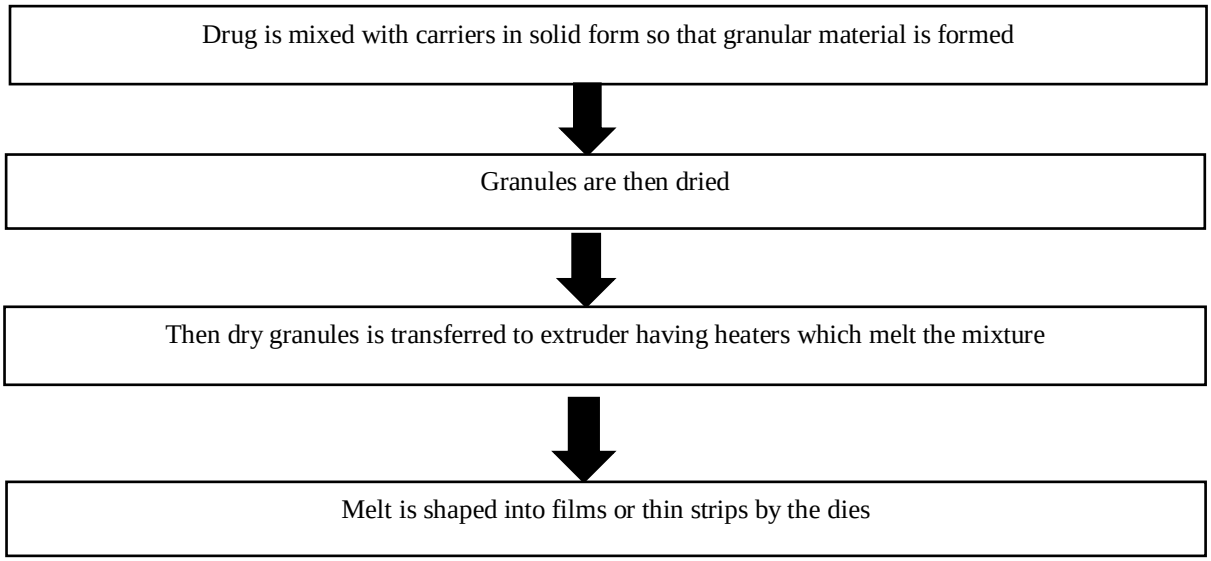
Advantages [14]

- Good clarity and good uniformity.
- Thin strips have better gloss and it is free from defects.
- More flexible.
- Good physical properties.

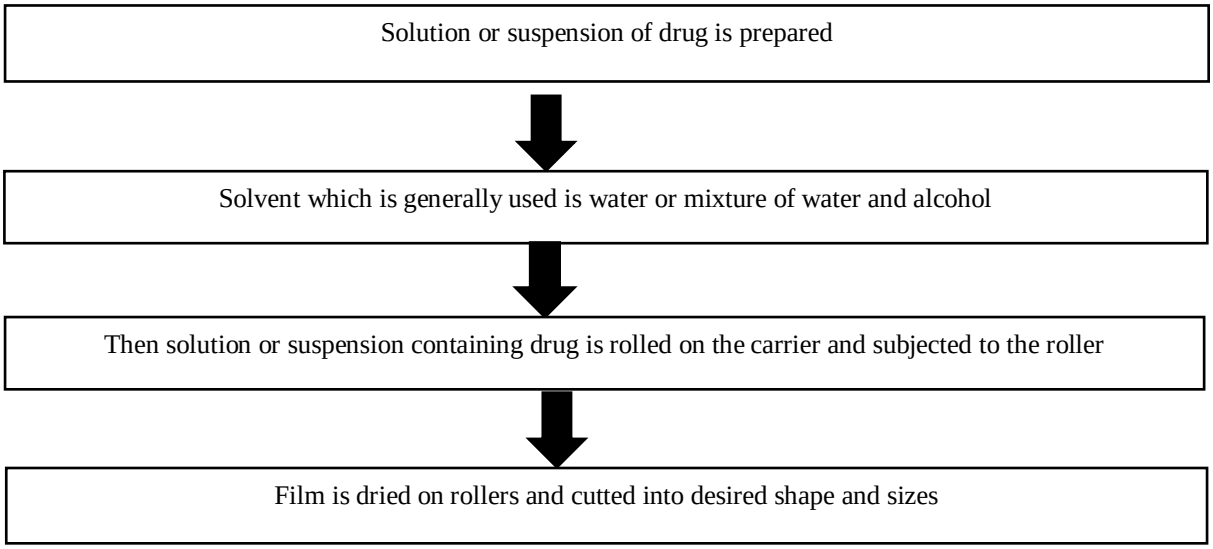
Semi-solid casting method: - This method is generally used when the acid-insoluble polymer is used in the formation of fast dissolving thin strips. The ratio of acid insoluble polymer and water soluble film forming polymer should be 1:4.The thickness of the film is about 0.015-0.05 inches [4,9].



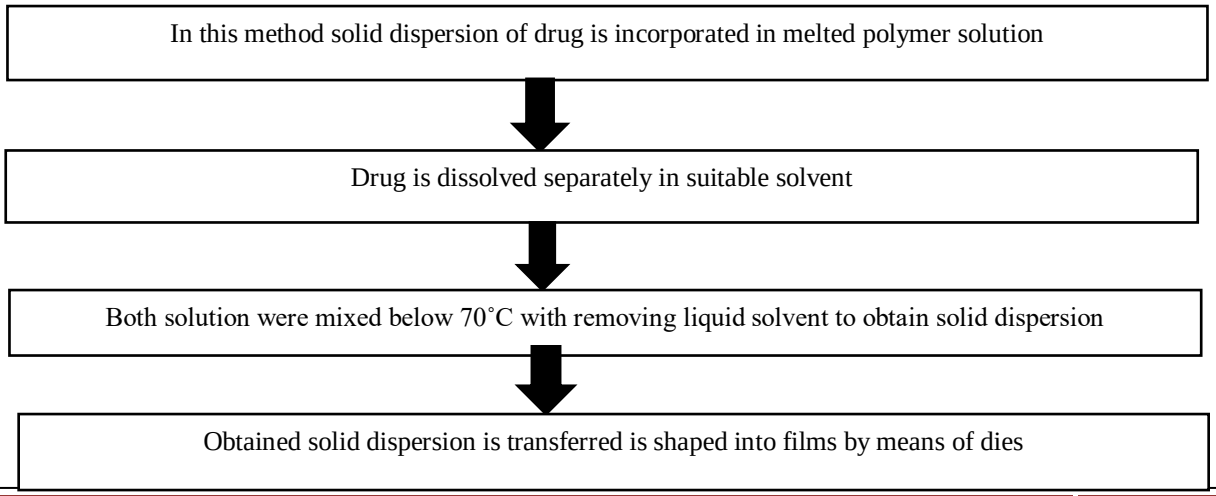
Hot melt extrusion method [1,20]:



Rolling method [1,5]:



Solid dispersion extrusion [21]:



Evaluation parameters: -

- Organoleptic properties
- Mechanical properties
  - ✓ Thickness
  - ✓ Tensile strength
  - ✓ Percent elongation
  - ✓ Elastic modulus
  - ✓ Tear resistance
  - ✓ Folding endurance
  - ✓ Film flexibility
- Swelling test
- Surface pH test
- Contact angle
- Transparency
- Assay/ Content uniformity
- Disintegration test
- In vitro Dissolution test

- **Organoleptic Properties**: - Since the fast dissolving thin strips intended to disintegrate or dissolve rapidly in the oral cavity so the film must possess acceptable and palatable organoleptic characteristics. The film must have the desired sweetness or flavor so it can be easily taken by a large number of the population, especially by pediatric population.

For the Organoleptic evaluation of the product, specially controlled human taste panels are used [22].

- **Mechanical Properties-**

  - ✓ Thickness- Thickness of the film is considered as an important parameter because it directly concerns with the drug content uniformity so it is necessary to assure the accuracy of the dose in the strip.

The thickness of the film is measured by micrometer screw gauze or calibrated digital Vernier calipers [5].

  - ✓ Tensile strength: - Tensile strength is defined as the maximum stress applied up to the point at which the strip starts breaking.

It is calculated by dividing applied load at breakage with a cross-sectional area of the strip [23].

Tensile strength = Load of breakage Strip thickness X Strip width

  - ✓ Percent Elongation: - When stress or tension is applied, a sample of film stretches and this referred as strain. Generally, increase in elongation of thin strips is observed when the content of plasticizer increases [8].

$$\% \text{ Elongation} = \frac{\text{Increase in length of strip}}{\text{Initial length of strip}} \times 100$$

  - ✓ Elastic Modulus: - Also known as Young Modulus. It is used to determine the stiffness of the oral film. It is represented as a ratio of applied stress over strain in the region of elastic deformation [8].

$$\text{Elastic modulus} = \frac{\text{Force at corresponding strain}}{\text{Cross-sectional area}} \times \frac{\text{Corresponding strain}}{}$$

  - ✓ Tear Resistance: - It is designed to measure the force to initiate tearing. It is defined as the maximum stress or force (generally found near the onset of tearing) necessary to tear the specimen is known as tear resistance.

Its value is in Newton's (Pounds-force) [5].

  - ✓ Folding Endurance: - It is determined by repeatedly folding the formed strips of uniform cross-sectional area and thickness at the same the same place until the strip breaks. The number of times film is folded without breaking is considered as the value of folding endurance [8].
  - ✓ Film Flexibility: - It is determined by using ASTH bend mandrel test (D4338-97).

    The film is bent over the mandrel and then the film is examined for cracks over the area of bend in a strong light [24].

- Swelling Test: - To determine the swelling properties of fast dissolving thin strips simulated saliva solution is generally used. It is determined by-

Degree of swelling = Final weight (W_t) - Initial weight (W_0) Initial weight (W_0)

W_t = Weight of film at time interval t

W_0 = Weight of film at time t [20]

- Surface pH Test: - The surface pH value of fast dissolving thin strips is considered an important parameter because it can cause side effect to the oral mucosa.

- Method 1- In this method, the film is placed on Petri plate and film is subsequently wet by using distilled water and the pH of the film is noted with the help of pH meter. This process is repeated for at least 6 films of each formulation and the mean is calculated [25].
- Method 2- In this method the formed films are placed on 1.5% w/w agar gel and then the pH paper is placed on the film. Change in the color of pH paper reflects the surface pH of the film[20].

➢ Contact Angle: - Contact angle of the film is generally measured at room temperature with the help of goniometer. At the surface of the dry film a drop of distilled water is placed. Water droplet images are taken within 10 seconds after the placement of the drop with the help of a digital camera. These pictures are then analyzed by using image 1.28V software for determination of contact angle. This process is repeated and mean is calculated [4].

➢ Transparency: - The transparency of the oral film is measured by using a simple UV spectrophotometer. The film sample is cut into a rectangular shape and placed on the internal side of spectrophotometer cell. The transmittance of the film is determined at 600nm. Formula for calculating transparency is:-

$$\text{Transparency} = \text{Log } T_{600} / b = -\text{€}C$$

Where T_{600} is the transmittance at 600 nm and b is the film thickness (mm) and c is concentration [20].

➢ Assay/ Content Uniformity: - It is determined by standard assay method described in any standard Pharmacopoeia (I.P., U.S.P., B.P.) for an active pharmaceutical ingredient.Content uniformity is determined by estimating the API content in the individual strip. Limit prescribed for content uniformity is about 85-115% [26].

➢ Disintegration Test: - Disintegration is defined as the process of breaking into smaller particles. Disintegration time is defined as the time (seconds) at which the film breaks when it came in contact with saliva in the mouth. Thickness and mass of the film play important role in determining physical properties of fast dissolving thin strips. The disintegration time limit of 30 seconds or less is applied to fast dissolving tablets described in CDER guidance can also be applied to fast dissolving thin strips.

- Slide frame method:- In this method one drop of distilled water is transferred into oral films with the help of pippete, then the films were clamped into slide frames and placed planar on a Petri dish. The time until the film dissolved or formation of the hole within the film was measured.
- Petri dish method: - In this method, 2 ml of distilled water is placed in a Petri dish and one film was placed on the surface of the water and the time required for thin strips dissolved completely is noted down [1].

➢ In-vitro Dissolution test: - This method is used to determine cumulative drug release and cumulative percent of drug retained. Dissolution test is performed by using USP paddle type apparatus. In-vitro dissolution studies were carried out at temperature 37C with stirring speed at 50rpm in a 900ml phosphate buffer having Ph 6.8. 5ml of the sample was withdrawn at predetermined time period 30sec, 60sec etc. and replaced with the same volume of buffer. The samples were collected and concentration of the drug is determined by using UV-visible spectrophotometer at the appropriate wavelength [1].

Table 1: Some marketed formulation of Fast Dissolving Thin Strips [26]

DRUGS	API	USE
Benadryl®	Diphenhydramine HCl	Antiallergic
Theraflu®	Dextromethorphan HBr	Antiallergic
Gas-X	Simethicone	Anti flatuating
Orajel®	Menthol/Pectin	Mouth ulcer
Triaminic®	Diphenylhydramine HCl	Antiallergic
Klonopin Wafers	Clonazepam	Anxiety
Suppress®	Menthol	Cough suppressants
Chloraseptic®	Benzocaine/Menthol	Sore throat

CONCLUSION:

The present review shows that the fast dissolving thin strips are a novel approach in the field of pharmaceutical sciences because it enhances safety, efficacy and patient compliance which is a common requirement. Fast dissolving thin strips are also suitable for pediatric, geriatric and dysphasic patients and it also increases the bioavailability of drugs because the oral mucosa is highly vascularized so drug directly enters into the systemic circulation by avoiding first-pass hepatic metabolism which leads to improving therapeutic response. So, we can conclude that a large number of drugs can be formulated as fast dissolving thin strips because it has certain advantages over conventional and fast dissolving tablets.

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