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Fast Dissolving Film :- A Novel Approach To Oral Drug Delivery System

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ABSTRACT :

Orally fast dissolving strip is a novel drug delivery dosage form design and develop as an alternative to orally conventional drug delivery system such as tablet, capsule , syrup . Recent trends are shifting towards developing an innovative drug delivery system to improve safety , efficacy and patient compliance by fast dissolving technologies , which dissolves within a minute in oral cavity .

Introduction:

Recent developments in the technology have presented viable dosage alternatives from oral route for pediatrics, geriatric, bedridden, nauseous or noncompliant patients. Buccal drug delivery has recently become an important route of drug administration. Various bio-adhesive mucosal dosage forms have been developed, which includes adhesive tablets, gels, ointments, patches and more recently the use of polymeric films for buccal delivery, also known as mouth dissolving film.[1] Oral route is most preferred and patient-convenient means of drug administration. Most of the drugs are being taken in the form of tablets and capsules by almost all patients, including adult, Pediatric and geriatric patients. However, around 26 – 50% of patients find it difficult to swallow tablets and hard gelatin capsules. These patients mainly include, elderly , Pediatric patients and others which include the mentally ill, developmentally disabled, patients who are uncooperative, on reduced liquid-intake plans or nauseated, and traveler who may not have access to water.

The surface of buccal cavity comprises of stratified squamous epithelium which is essentially separated from the underlying tissue of lamina propria and submucosa by an undulating basement membrane.[2] It is

interesting to note that the permeability of buccal mucosa is approximately 4-4,000 times greater than that of the skin, but less than that of the intestine.[3] Hence, the buccal delivery serves as an excellent platform for absorption of molecules that have poor dermal penetration.[4] The primary barrier to permeability in oral mucosa is the result of intercellular material derived from the so-called 'membrane coating granules' present at the uppermost 200 µm layer.[5] These dosage forms have a shelf life of 2-3 years, depending on the active pharmaceutical ingredient but are extremely sensitive to environmental moisture.[6]

An ideal fast dissolving delivery system should have the following properties: High stability, transportability, ease of handling and administration, no special packaging material or processing requirements, no water necessary for application, and a pleasant taste. Therefore, they are very suitable for pediatric and geriatric patients; bedridden patients; or patients suffering from dysphagia, Parkinson's disease, mucositis, or vomiting. This novel drug delivery system can also be beneficial for meeting current needs of the industry. Rapidly dissolving films(RDF) were initially introduced in the market as breath fresheners and personal care products such as dental care strips and soap strips. However, these dosage forms are introduced in the United States and European pharmaceutical markets for therapeutic benefits.

Fig :- strips

GENERAL PROCEDURE

- Mix API with distilled water in first beaker.
- Mix hydrophilic polymer in another beaker.
- Add plasticizer.
- Add saliva stimulating agent.
- Add surfactant .
- Add sweetener and flavoring agent .
- Pour solution into the second beaker (mixture).
- Add dye for better color and appearance .
- Electro-spraying apparatus used to spray the polymeric blend onto carrier (petri-dish).
- Set the over for drying process.

- Dry the sprayed polymeric blend for 24hrs.
- Once the film formed , peel the film.
- Cut the film into desired size.
- Store the film into suitable packaging system

LITERATURE REVIEW

- Rajni Bala et al (2013)
  They give study on fast dissolving buccal film formulation and their evaluation parameters . This provides both marketing advantage and increase patient compliance.
- Hema Jaiswal (2014)
  Have reported the oral strip technology encompassing materials used in this method of preparation , evaluation, applications, commercial technologies and future business prospects of this technology.
- Singh et al. (2015)
  They reported the evaluation methods for mucoadhesive oral strips, focusing on
  the bio adhesion strength and in-vitro retention properties. Their research demonstrated that films with better mucoadhesive properties could provide prolonged contact with the oral mucosa ,enhancing the therapeutic effect for mouth ulcers .
- A review by Reddy et al. (2017)
  They study on the application of oral films for pediatric and geriatric populations, where difficulty swallowing pills is a common issue. The study concluded that FDDS is particularly suitable for these populations, offering ease of use and improved compliance in the treatment of oral conditions.
- Gupta et al. (2018)
  Have reported the dissolution and release kinetics of active drugs from fast dissolving
  oral strips. The study emphasized the importance of controlling the drug release
  profile to achieve the desired therapeutic effect in the treatment of conditions like mouth ulcers
- Inder kumar et al (2019)
  They reported the study on the formulation aspects , manufacturing methods patent technologies , evaluation parameters and marketed products.
- A.karandikar et al(2020)
  Have reported the advantages of oral dispersible films over other oral dosage form and especially over oral dispersible tablets and their application are discussed.
  Overview of all the ingredients used in the formulation of fast dissolving films with the evaluation of these films.

- Hemavathy S. et al (2022)
  Have reported formulation aspects , manufacturing methods , evaluation parameters and an overview on packaging available and some marketed product.
  Agarwal et al. (2009) highlighted the potential of Fast-Dissolving Drug Delivery Systems (FDDS) for improving patient compliance, especially in individuals who have difficulty swallowing tablets or capsules. FDDS technologies, including oral films, are advantageous due to their rapid disintegration, providing quick relief for localized conditions like mouth ulcers
- Poonam P Patil et al (2022) :-
  She reported the recent advancement regarding fast dissolving strips formulation and their evaluation parameters with its advantages , disadvantages and also their formulation aspects.
- Piyush Y.Neware et al (2024)
  The research highlights the growing interest in buccal drug administration, emphasizing its potential for rapid onset of action focusing on formulating oral disintegration strips of levetiracetam an anticonvulsant crucial for epilepsy treatment.

SPECIAL FEATURES OF FAST DISSOLVING FILMS[7]

- Film should be thin and elegant.
- Available in various size and shapes.
- Unobstructive.
- It should adhere to the oral cavity easily.
- Should processes fast disintegration without water.
- Rapid release.
- Excellent muco-adhesion

ADVANTAGES OF FAST DISSOLVING FILMS

- Convenient dosing.
- Water is not needed for administration of oral film. Film uses saliva in oral cavity for disintegration and dissolution
- No risk of chocking
- Taste masking.
- Enhanced stability
- Improved patient compliance
- The drug enters the systemic circulation with reduced hepatic first pass effect.
- Site specific and local action.
- more flexible , easily handled storage and transportation .
- Dose accuracy in comparison to syrup.
- It reduces side effects associated with drug.

DISADVANTAGE OF ORAL STRIP

- The disadvantage of oral strip is that high dose cannot be incorporated into the strip. The dose should be between 1-30 mg.

• There remain a number of technical limitations with use of film strips; the thickness while casting the film. Glass Petri plates cannot be used for casting.
• The other technical challenge with these dosage forms is achieving dose uniformity
• Packaging of films requires special equipments and it is difficult to pack.

IDEAL CHARACTERISTICS

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

CLASSIFICATION OF FAST DISSOLVING TECHNOLOGY

For ease of description, fast dissolve technologies can be divided in to three broad groups.[1]

1) Lyophilized systems.
2)Compressed tablet-based systems
3) OTF

Table 1: Standard composition of fast dissolving films[14]

Ingredients	Amount	Examples
Drug	5-30%w/w	Antiallergic, antiemetic, antiepileptic, antimigrant
Water soluble polymer	45%w/w	HPMC E3, E5 and E15 and K-3, Methyl cellulose A-3, A-6 and A-15, Pullulan, carboxmethylcellulose cekol 30, polyvinylpyrollidone PVP K-90, pectin, gelatin, sodium, alginate, hdroxypropylcellulose, polyvinyl alcohol, maltodextrins
Plastisizers	0-20%w/w	Glycerol, dibutyl pthallate, polyethylene glycol, etc.,
Surfactants	q.s.	Sodium lauryl sulfate, benzalkonium chloride, Tween, etc.,
Sweetening agents	3-6%w/w	Saccharin, cyclamate, and aspartame
Saliva stimulating agents	2-6%w/w	Citric acid, malic acid, lactic acid, and ascorbic acid
Fillers, colors, flavors	q.s.	FD and C colors, US FDA approved flavors

Table 2: Polymers used in the formulation fast dissolving film

Polymer	Examples
Natural polymer	Pullulan, starch, gelatin, pectin, sodium alginate, maltodextrins, polymerized rosin
Synthetic polymer	Hydroxypropyl methylcellulose, sodium carboxymethylcellulose, polyethylene oxide, hydroxypropyl cellulose, polyvinylpyrrolidone, polyvinyl alcohol, ethyl cellulose

APPROACHES USED FOR THE FORMULATION OF FAST DISSOLVING FILMS.

Conventional approaches
- Solvent casting method
- Hot-melt extrusion
- Semisolid casting
- Rolling Process .

SOLVENT CASTING METHOD
- Strip forming agent , plasticizers and saliva stimulating agent are dissolved in distilled water , the solution is then stir up to 4 hours continuously in a magnetic stirrer at 60^0c and 1000 rpm.
- After that the solution is kept stand for 1hr to remove all the air bubbles entrapped
- At the same time in a separate container remaining excipients like sweetening agent , disintegrating agent, flavoring agent and drug are dissolve in distilled water with continuous stirring for 45 minutes
- Both the solution are mixed together in a magnetic stirrer at room temperature and 1000 rpm.
- Stand by the solution for 1 hour to let the foams settle down.
- Finally the solution is cast and dried at 60^0 c and cut the strip into the desires size.

Fig :- solvent casting method

HOT MELT EXTRACTION [10]

- The described process of Orally Disintegrating Strips (ODS) production involves the following steps:
- Drug and carrier Mixing Drugs are combined with a carrier in solid form.
- The carrier serves as a medium to facilitate the processing and formation of the strips.
- Extrusion The solid mixture of drug and carrier is then passed through an extruder. Within the extruder, heaters are employed to melt the mixture.
- The application of heat results in the transformation of the solid mixture into a molten state.
- Shaping Strips The molten mixture is shaped into strips using dies.
- Dies are molds or tools that give the strips their final form and dimensions.
- This process of extrusion and shaping allows for the creation of Orally Disintegrating Strips in a continuous and controlled manner.
- The choice of carriers and the extrusion conditions can impact the properties of the strips, ensuring they meet the desired characteristics for rapid dissolution or disintegration in the oral cavity.

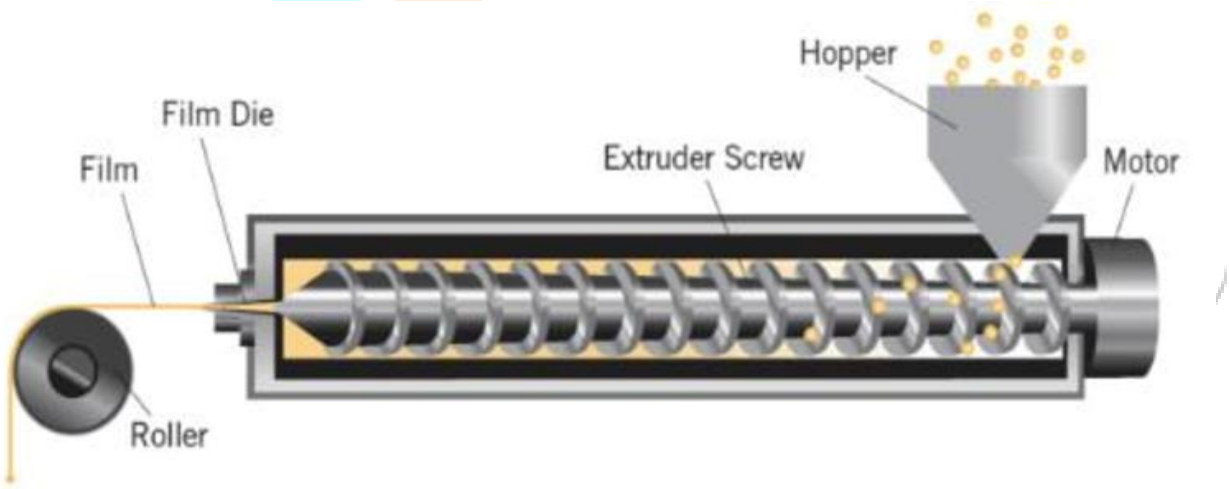

Fig :- hot melt extraction

SEMISOLID CASTING

- In the described process of Orally Disintegrating Strips (ODS) production:
- Polymer Mixture Water-soluble polymers are combined with acid-insoluble polymers to create a viscous and homogeneous solution.
- The choice of polymers may depend on their solubility characteristics and the desired properties of the ODS.
- Coating The viscous and homogenous polymer solution is coated onto a non-treated casting film.
- The non-treated casting film serves as a substrate for the ODS.
- It's emphasized that a specific ratio of 1:4 should be maintained, with acid-insoluble polymer to water-soluble polymer.
- This ratio is likely optimized to achieve the desired properties and characteristics of the ODS.
- This production process ensures the creation of ODS with controlled composition and uniformity, ultimately influencing the performance and quality of the final dosage form.
- Sonication After coating, sonication is employed.

- Sonication involves the use of ultrasonic vibrations to aid in the uniform spreading and distribution of the polymer solution on the casting film.

ROLLING PROCESS

- The described process of Orally Disintegrating Strips (ODS) production involves several steps:
- Premixing Prepare a premix containing a film-forming polymer, polar solvent, and other additives, excluding the drug. This premix serves as the base for the ODS formulation
- Master Batch Preparation Add the premix to a master batch feed tank
- Metering and Mixing Use a first metering pump and control valve to feed the premix to either the first or second mixer, or both. Incorporate the required amount of the drug into the desired mixer. Blend the drug with the master batch premix to achieve a uniform matrix.
- Feeding to pan A specific amount of the uniform matrix is fed to the pan through a second metering pump. The pan is the platform where the film formation process takes place.
- Film Formation The film is formed on a substrate within the pan. The substrate can be a material that supports the formation and handling of the ODS.
- Drying The formed film is carried away via a support roller.
- Drying of the film occurs, typically using bottom drying methods.
- This comprehensive process results in the production of Orally Disintegrating Strips, where the film serves as the carrier for the drug and other essential components, providing a convenient dosage form for rapid dissolution or disintegration in the oral cavity.

MECHANISM

- The delivery system of Orally Disintegrating Strips (ODS) involves straightforward placement on the tongue or within the buccal cavity.
- Upon contact, the ODS rapidly becomes wetted by saliva, facilitated by the presence of hydrophilic agents within the film.
- Subsequently, the film undergoes hydration and dissolution, thereby releasing the medication or active constituents incorporated within.
- The dissolved drug molecules are then readily available for absorption via the oral mucosa, facilitating oromucosal absorption.

EVALUATION 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.[12] The thickness should be evaluated at five different locations (four corners and one at centre) 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 or 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.[13]

- Tensile Strength

  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.

- Youngs 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 is measured by manually. The strip is folded repeatedly at the same place until it broke. The time at which the strip is folded without breaking is called folding endurance value. Generally, 3×2cm diameter strip (an area of 6 m2) is used for folding endurance. 48

- Content Uniformity

  Content uniformity of oral strip is determined for estimating API content in a single strip. Standard methods for all API are given in Standard Pharmacopoeias. The limit of content uniformity is up to 85 - 115%. 60 .

- Moisture Content

  Brittleness and friability of the strip are affected by moisture content present in the strip. Karl Fisher Titration method or by the weighing method is used to determine the moisture content. Typically, the preweighed strip with a specific size is heated to 100-120C until it attains constant weight. The difference in weight gives the amount of moisture content present in a strip. 44

  Moisture content can be determined by:

  $$\% \text{ moisture content} = \frac{initial\ weight - final\ weight}{initial\ weight} \times 100$$

- 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]

- 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.

- Contact angle

  It gives the information about wetting behavior, disintegration time and dissolution of oral film. This can be performed with the help of goniometer at room temperature. For this purpose, double distilled water should be used. A dry film is taken and a drop of double distilled water is placed on surface of the dry film. Images of water droplet are taken by a means of digital camera within 10 s of deposition. Digital pictures should be analysed by image J 1.28v software (NIH, USA) for angle determination.

- Transparency:

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

  Transparency = (logT600)/b = - €c

  Where T600 is the transmittance at 600 nm, b is the film thickness (mm) and c is concentration.

- Stability studies

  Stability testing of the prepared formulation is mainly done to check whether it is a stable product or not. It is also used for the determination of effect of temperature and humidity on the stability of the drug for the proper storage, initially the formulation is wrapped in a butter paper followed by aluminium foil wrapping over it, then this is packed in an aluminium pouch and heat sealed. Formulation should be stored at 45oC / 75 % RH for 3 months. During the period of stability studies, triplicate samples are taken at three sampling intervals i.e. 0, 1 and 3 month and films should be evaluated for physical changes and drug content.

PACKAGING OF FAST DISSOLVING FILM

The material selected must have the following characteristics

a) They must protect the preparation from environmental conditions.

b) They must be FDA approved.

c) They must meet the applicable tamper-resistant requirement .

d) They must be non-toxic.

e) They must not be reactive with the product.

f) They must not impart to the product tastes or odors.

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. 64

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. The aluminum pouch is the most commonly used pouch. 66

Blister card with multiple units

The blister container comprises of two segments: the blister, which is the framed cavity that holds the item, and the top stock, which is the material that seals to the blister. The blister package is shaped by warm – softening a sheet of thermoplastic gum and vacuum-drawing the mollified sheet of plastic into a formed shape. Subsequent to cooling the sheet is discharged from the shape and continues to the filling station of the packaging machine. The semiinflexible blister beforehand shaped is loaded up with the item and lidded with the warmth sealable sponsorship material. The film choice ought to be founded on the level of insurance required. For the most part, the cover stock is made of the aluminum thwart. The material used to shape the cavity is normally a plastic, which can be intended to shield the measurement frame from dampness.5, 64

Barrier Films

Many drug preparations are extremely sensitive to moisture and therefore require high barrier films. Several materials may be used to provide moisture protection such as Polychlorotrifluoroethylene (PCTFE) film, Polypropylene. Polypropylene does not stress crack under any conditions. It is an excellent gas and vapor barrier. Lack of clarity is still a drawback. 67, 68

S. No.	Product/ Brand Name	Manufacturer/ Distributor	Indication/ Uses
1	Diphenhydramine Hydrochloride films	MonoSol RX	Antihistaminic
2	Triaminic Thin Strips®	Novartis Pharmaceuticals	Nasal decongestant
3	Klonopin Wafers	Solvay Pharmaceuticals	Treatment of anxiety
4	Benadryl	Pfizer	Anti-allergic
5	Theraflu	Novartis	A cough suppressant
6	Dextromethorphan fast dissolving films	Hughes medical corporation	Antitussive agent
7	Caffeine films	Dow chemical company	CNS stimulant.
8	Ondansetron Rapid films®	Labtec Pharma	Postoperative nausea and vomiting
9	Suppress®	InnoZen®, Inc.	A cough suppressants
10	Orajel	Del	Mouth ulcer
11	Gas-X	Novartis	Anti flatuating
12	Folic acid-fast Dissolving films	Huges Medical Corporation	Anemia
13	Chloraseptic® Relief strips	Innozen Inc	A minor irritation, pain, and sore throat.
14	Sudafed PE	Wolters Kluwer Health, Inc.	Relieving Congestion
15	Chloraseptic	Prestige	A sore throat
16	Listerine Cool Mint Pocket Paks	Pfizer, Inc.	Mouth Fresheners
17	Zuplenz	MonoSol Rx	Prevent nausea and vomiting caused by cancer drug treatment
18	Ondissolve	Labtec Pharma	Prevent nausea and vomiting
19	Suboxone	MonoSol Rx	Treatment of opioid
20	Setofilm	Labtec Pharma	Nausea and vomiting

Table 4: List of the Marketed Formulation of Oral Strips[15] 16-17

CONCLUSION

Oral strip have proved to be an innovative drug delivery system for all groups of population. Oral strip have proved to be valuable whenever rapid onset of action is essential like in case of asthmatic attack , cardiac heart failure and in epilepsy.A lots of research reffework is going on and will be started in the near future

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