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An Overview of Fast Dissolving Oral Film

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ABSTRACT

Taste-masking techniques are applied to mask or overcome the bitter or unpleasant taste of active pharmaceutical ingredients/drugs to achieve patient acceptability and compliance. Oral administration of bitter or unpleasant tasting drugs is often the biggest barrier for patient groups, such as pediatrics and geriatrics [1, 2]. Unless the active ingredient is tasteless or does not have any unpleasant taste, taste-masking plays a key role in the success of a final solid oral dosage form. The efficiency of taste-masking is often a key determinant for the success of specialized dosage forms like orally disintegrating tablets and films, and chewable tablets [2]. The mechanisms of taste-masking techniques often rely on two major approaches: the first is to add sweeteners, flavors, and effervescent agents to mask the unpleasant taste, and the second is to avoid the contact of bitter/unpleasant drugs with taste buds. In the past few years, significant progress has been made in the area of taste-masking by applying novel strategies and techniques, such as hot-melt extrusion and microencapsulation.[1,3] The following presents an overview and current status of the industrial approaches and platforms used for taste-masking in oral dosage forms. [1, 2, 4] Many pharmaceutical companies are switching their products from tablets to fast dissolving oral thin films (OTFs).[6,7] Films have all the advantages of tablets (precise dosage, easy administration) and those of liquid dosage forms (easy swallowing, rapid bioavailability). Statistics have shown that four out of five patients prefer orally disintegrating dosage forms over conventional solid oral dosages forms. Pediatric, geriatric, bedridden, emetic patients and those with Central Nervous System disorders, have difficulty in swallowing or chewing solid dosage forms.[7,8] Many of these patients are non-compliant in administering solid dosage forms due to fear of choking.[9] OTFs when placed on the tip or the floor of the tongue are instantly wet by saliva. This technology provides a good platform for patent non- infringing product development and for increasing the patent life-cycle of the existing products. [10, 11]

Keywords: Fast Dissolving oral film, Tablet, Taste Masking Technique

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1. INTRODUCTION

Taste masking:-

Taste-masking techniques often go hand in hand with the formulation technology. In short, they need to be mutually compatible. For example, coated particles obtained after fluid-bed coating should be able to withstand the tablet compression process used for the final dosage form (tablet) manufacturing.[1,2,3]

The commonly used industrial techniques/methods of taste-masking include organoleptic methods, polymer coating, hot-melt extrusion, microencapsulation, complexation, and spray-drying.[1,2,5]

The Experience of Flavor

Meaning of the flavor is the potential to dissolved molecules and ions to the body. Human detects taste with flavor receptor cells which are onion formed organs known as flavor buds. Every flavor bud has a pore that opens out to surface of the tongue allowing molecules and ions taken into the mouth to attain the receptor cells.[2,3]

Table 1: herbal flavors. [4,5]

Juice	Raspberry
Extracts	Liquorices
Spirits	Lemon and Orange
Syrups	Blackcurrant
Tinctures	Ginger
Aromatic waters	Anise and cinnamon
Aromatic oils	Peppermint and Lemon

Fast dissolving Oral Film:-[6, 7, 9]

- This are the drug delivery system which fastly disintegrate in mouth with water
- It was first developed in 1970's alternative to tablet and capsule
- It consists of very thin oral strip which is placed on tongued and upon hydration it fastly release drug into oral cavity.
- In case of bitter drug, taste can be masked by using various techniques.

Figure 1: Bioavailability of fast dissolving oral film

Special Features of Fast Dissolving Films [6, 8, 10]

- Available in various size and shapes.
- Film should be thin and elegant.
- Unconstructive.
- It should adhere to the oral cavity easily.
- Should processes fast disintegration without water.
- Special Features of Fast Dissolving Films Rapid release.

Advantages of Fast Dissolving Films [7, 9, 10]

- No water needed.
- Convenient Dosing.
- 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.
- Availability of large surface area that leads to rapid disintegration and dissolution within oral cavity.
- Dose accuracy in comparison to syrup.

Disadvantage of Fast Dissolving Film [11, 12, 13, 27]

- The disadvantage of OS 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 of a Suitable Drug Candidate [8, 10, 13, 16]

- 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

Objectives:[6,16,18]

The main objective of the present study was "Formulation, Development, and Characterization of Taste Masked Fast Dissolving Oral Film" which could help to improve therapeutic efficacy of drug.

To achieve this following objective were thought of

1. The main objective of the present study is to Formulation, Development, and Characterization of Taste Masked Fast Dissolving Oral Film
2. To select suitable technique of taste masking & polymer for formulation of Oral fast dissolving films.
3. To evaluate physicochemical properties for the prepared formulation.
4. To carryout in vitro release study of oral fast dissolving films.
5. Compatibility studies between the drug and polymer by FTIR and DSC
6. Statistical analysis of all the results.
7. To conduct stability studies as per the ICH guidelines and predict the shelf life of the dosage form.

Classification of OTF [10, 12, 13]

There are three subtypes of oral fast dissolving films:

- Flash release.
- Mucoadhesive melt-away wafer.
- Mucoadhesive sustained release wafers.

Table 4 lists three types of oral fast dissolving films along with their properties.

Properties	Flash Release	Mucoadhesive Melt Away Wafers	Mucoadhesive Suastained Relese Wafers
Area	2-8	2-7	2-4
Thickness	20-70	50-500	50-250
Structure	Single layer	Single/multiple layer	multiple layer
Application	tounge	Gingival layer	Gingival layer
Dissolution	60s	In few min form gel	Max 8-10 h
Site Of Action	Sustemic or local	Sustemic or local	Sustemic or local

Standard Composition Of Oral Fast Dissolving Strip [14,15]

Oral dissolving film is a thin film with an area of 1-20 cm^2 (depends on dose and drug loading) containing drug. Drugs can be loaded up to a single dose of 30 mg. Formulation considerations (plasticizers, etc.) have been reported as important factors affecting mechanical properties of the films. Table lists the standard composition of fast dissolving strip along with the various ingredients used in the formulation of fast dissolving strips.

Film Forming Polymers [8,12,15]

A variety of polymers are available for preparation of fast dissolving oral films. The use of film forming polymers in oral films has attracted considerable attention in medical and nutraceutical applications. The selection of film forming polymers, is one of the most important and critical parameter for the successful development of film formulation. The polymers can be used alone or in combination to provide desired film properties. The polymers used in oral film formulation should be:

- Devoid of leachable impurities.
- Nontoxic and Nonirritant.
- Should not retard disintegration time of film.
- Tasteless.
- Should have good wetting and spread ability property.
- Should have sufficient peel, shear, and tensile strength.
- Readily available.
- Inexpensive.
- Sufficient shelf life.
- Should not aid in causing secondary infections in oral mucosa

2. Approaches Used for the Formulation of Fast Dissolving Films [9, 14, 15]

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

3. Evaluation Parameters:-[8, 10, 12, 13]

Evaluation Techniques Used for Taste Masked Preparation:-

Flavor, to consider, is a completely subjective perception. Relying on individuals, the perceived taste may also vary to extraordinary stages. If we've got properly controlled experimental installation, its miles viable to as it should be and reproducibly degree flavor thresholds. To quantitatively evaluate flavor sensation, following methods are[1,2,3,4]:

A. Panel trying out (human topics)

B. Multichannel taste sensor/ magic tongue

C. Spectrophotometric assessment

Evaluation Techniques Used for Fast Dissolving Oral Film :-

- Folding endurance
- Dryness/tack test
- Tensile strength
- Percent elongation
- Tear resistance
- Young's modulus
- Thickness
- *In vitro* dissolution studies
- Drug content uniformity
- Organoleptic test
- Surface pH test
- Contact angle
- Transparency
- Scanning electron microscopy
- Permeation studies
- Percentage moisture loss
- Determination of % yield of buccal patches

4. Applications of OTF In Drug Delivery Systems [13,14,15,18,20]

- Oral mucosal delivery via sublingual, buccal, and mucosal routes by use of oral thin film could become preferential delivery method for therapies requiring rapid drug absorption, including those used to manage pain, allergies, sleep, and central nervous system disorders.
- Topical applications: The use of dissolvable films may be feasible in delivery of active agents such as analgesic or antimicrobial agents in the wound care and other applications.
- Gastrorententive delivery system: Dissolvable films are being considered in the dosage form for which water soluble and poorly soluble molecules of various molecular weight are contained in film formate. Dissolution of film could be triggered by pH or enzyme secretion of gastrointestinal tract (GIT) and could

potentially be used for treatment of gastrointestinal disorder.

- Diagnostic devices: Dissolvable films may be loaded with sensitive reagent to allow controlled release when exposed to a biological fluid or to create isolation barriers for separating multiple reagents to enable a timed reaction within a diagnostic device.

5. Conclusion

Taste-masking technologies are available and used in the pharmaceutical industry today with new platforms being researched and developed constantly. The type of technology used depends largely on the physical and chemical properties of the drug substance and the desired final dosage form. Advances in taste-masking technologies throughout the past few years have enabled the pharmaceutical industry to provide commercial products with improved patient acceptability and compliance. Fast dissolving films are the novel approach in oral drug delivery systems. It promises patient compliance especially in case of pediatrics and geriatrics patients. They can also be used when quick action is required. They possess many advantages over conventional dosage form and can also be used in cases of dysphasia, Parkinson's disease, mucositis, or vomiting.[12,19,20,21]

6 Significance of Fast Dissolving Oral Film:-

Fast dissolving films are the novel approach in oral drug delivery systems. It promises patient compliance especially in case of pediatrics and geriatrics patients. They can also be used when quick action is required. They possess many advantages over conventional dosage form and can also be used in cases of dysphagia, Parkinson's disease, mucositis, or vomiting.

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