

OVERVIEW ON FAST DISSOLVING FILMS**Mukesh Bhatt* and Ganesh Kumar Bhatt**

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Corresponding Author*Mukesh Bhatt**Shri Guru Ram Rai Institute
of Technology and Sciences,
Dehradun, Uttarakhand,
India.**ABSTRACT**

Fast dissolving oral films are the most advanced form of oral solid dosage form due to more flexibility and comfort. It improve the efficacy of APIs by dissolving within minute in oral cavity after the contact with less saliva as compared to fast dissolving tablets, without chewing and no need of water for administration. The FDOFs place as an alternative in the market due to the consumer's preference for a fast dissolving product over conventional tablets / capsules. The oral thin-film technology is still in the beginning stages and has bright future ahead because it fulfils all the need of patients. Eventually, film formulations having drug/s will be commercially launched using the

oral film technology. However, for future growth point of view the oral thin film sector is well-positioned. In US market the OTC films of pain management and motion sickness are commercialized. More importantly, prescription OTFs have now been approved in US, EU and Japan which are the three major regions. These approved Rx films, have potential to dominate over other oral dosage forms of the same drugs. It seems that the value of the overall oral thin film market will grow significantly.

INTRODUCTION

Recently Fast dissolving technology has been way out as a new drug delivery system that provides a very convenient means of taking medications and supplements. Formulation of new dosage form for the existing drugs is new area of concern in pharmaceutical field. Fast-dissolving drug- delivery systems were first developed in the late 1970s. Fast dissolving drug delivery system is a new generation delivery system also known as fast dissolving/disintegrating film for the oral delivery of the drugs. Oral film has started gaining popularity. It is alternative of tablets, capsules, syrups and other formulations. Oral film are the administration to pediatric and geriatric population where the difficulty in swallowing and

larger oral dosage forms is eliminated. Oral dissolving film is easy to administer and provides better patient compliance in the elderly, pediatric, mentally retarded, and uncooperative patients. Mouth dissolving films consist of a very thin oral strip, which is simply placed on the patient's tongue or any oral mucosal tissue and instantly wet by saliva. The film rapidly hydrates and adheres onto the site of application. Oral thin films (OTF) are thin, flexible films for drug delivery and fast dissolving film safe and accurate dosing without need for water. Oral films (ODFs) are disintegrate on a patient's tongue in a matter of seconds for the rapid release of one or more active pharmaceutical ingredients (APIs). oral dispersible film (ODF) were initially introduced in the market as breath fresheners. In European and united State pharmaceutical markets these dosage forms are available for therapeutic uses.

NEED OF INNOVATIVE DRUG DELIVERY SYSTEM

The orally administered drug delivery is standard system and most convenient and still considered safest, economical method of administration providing best route for patient compliance.

However in case of tablet and capsule having common disadvantage of difficulty in swallowing leading to poor compliance specially in geriatrics. To improve compliance and making the administration convenient, design of new dosage forms gained significant importance.

In this the drug is dissolved or swallowed and then enters into the systemic circulation to produce the desired effect need for self medication, ease of administration and avoidance of pain compared to parenteral route

Advantages

1. Ease of administration to pediatric, geriatric patients who refuse to swallow tablets.
2. No need of water to swallow the dosage form,
3. Rapid dissolution and absorption of drug, which may produce rapid onset of action.
4. Useful in cases where an rapid onset of action required such as in motion sickness, sudden episodes of allergic attack or coughing.
5. An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
6. Some drug absorbed from mouth and passes down into stomach which enhance bioavailability of drug.

7. As fast dissolving thin oral films are flexible, they are easy to carry, store and handle, which is not the case with orally disintegrating tablets.
8. As the oral mucosa is being highly vascularised, drugs directly enter the systemic circulation without undergoing first-pass hepatic metabolism. This results in improved oral bioavailability of molecules.

Disadvantage

1. Drugs which are unstable at buccal pH cannot be administered.
2. Drugs which irritate the mucosa cannot be administered by this route.
3. Drug with small dose requirement can only be administered.
4. Taste masking- Most drugs have bitter taste, and need taste masking.
5. Special packaging- OFDFs are fragile and must be
6. Protected from water so it needs special packaging.
7. High dose cannot be incorporated into the film

Manufacturing Methods

The manufacturing of orally dissolving films is done by various methods such as:

1. Solvent casting method
2. Hot melt extrusion method
3. Semisolid casting method
4. Rolling method
5. Solid dispersion extrusion

Solvent casting

In this method water soluble polymers are dissolved in water and the drug along with other ingredients is dissolved in suitable solvent. Then both the solutions are mixed, stirred, finally casted in to the petri plate and dried.

Hot melt extrusion

In hot melt extrusion method at first drug is mixed with carriers in solid form. Then the mixture is molten by the means of extruder having heaters. Lastly the melt is shaped in to films by the dies.

Semisolid casting

In this method at first a solution of water soluble film forming polymer is prepared. Then the resulting solution is added to a solution of acid insoluble polymer (e.g. cellulose acetate phthalate) which was prepared in ammonium or sodium hydroxide. The ratio of the acid insoluble polymer to film forming polymer should be 1:4. A gel mass is obtained on addition of suitable amount of plasticizer. By the means of heat controlled drums, finally the gel mass is casted in to the films or ribbons.

Rolling

Solvents mainly used in this method are water and mixture of water and alcohol. By the means of high shear processor, active agent and other ingredients are dissolved in small portion of aqueous solvent. Water soluble hydrocolloids are dissolved in water to form homogenous viscous solution. Then the resultant solution or suspension containing drug is rolled on a carrier. Finally obtained film is cut in to desired shapes and sizes.

Solid dispersion extrusion

Firstly solid dispersion is prepared by extruding immiscible components with drug and then shaped in to films by the means of dies.

EVALUATION PARAMETER**Thickness**

Vernier Calliper and micrometer screw is used for measuring the thickness of the film. The thickness should be evaluated at five different locations (four corners and one at centre). uniformity in the thickness of the film as this is directly related to the accuracy of dose in the film.

Weight

Mouths dissolving oral films were weighed on analytical balance and average weight can be determined for each film. The weight of each film was taken and weight variation was calculated. It is useful to ensure that a film contains the proper amount of excipients and API.

Folding Endurance

Folding endurance give the brittleness of a film. It is determined by repeated folding of the film at the same place till the film breaks. The number of time the film is folded without

breaking is computed as the folding endurance value. Typical folding endurance for film is between 100-150.

Tensile strength

Tensile strength is a maximum stress applied to a point at which the strip specimen breaks. It is calculated by applied load at rupture divided by the cross sectional area of the strip as given in the following equation:

$$\text{Tensile strength} = \text{Load at failure} \times 100 / \text{film thickness} \times \text{film width}$$

Percent elongation

When stress applied on the film, the specimen stretches which is referred as strain. Strain is defined as change in length of film divided by its original/initial length of the film specimen. Amount of plasticizer in the formulation was determined by the percent elongation.

It is calculated by the formula:

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

Disintegration

Disintegration time will vary depending on the formulation but typically the disintegration time varies from 5-30 sec. For oral film there is no official guideline for disintegration. United State Pharmacopoeia (USP) disintegration apparatus can be used to study disintegration time.

Young's modulus

Young's modulus or elastic modulus is the measure of stiffness of strip. It is represented as the ratio of applied stress over strain in the region of elastic deformation as follows:

$$\text{Young's modulus} = \text{Slope} \times 100 / \text{Strip thickness} \times \text{Cross-head speed}$$

Product	Manufacturer	Active Pharmaceutical Agent	Strength(mg)
Triaminic	Novartis	Dext romethorphan HBr	7.5
Triaminic	Novartis	Diphenhydramine HCl	12.5
Theraflu	Novartis	Dextromethorphan HBr 15	15
Gas X	Novartis	Simethicone	62.5
Sudafed	Pfizer	Phenylephrine HCl	10
Benadryl	Pfizer	Diphenhydramine HCl	12.5
Chloraseptic	Prestige	Benzocaine Menthol	3/3
Suppress	InnoZen	Menthol	2.5
Orajel	Del	Menthol/Pectin	2/30
Listerine	Pfizer	Cool mint	

Klonopin Wafers	Solvay Pharmaceuticals	Clonazepam	(0.125mg, 0.25mg, 0.5mg, 1mg and 2mg.)
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CONCLUSIONS

Recently pharmaceutical companies embraced fast dissolving films as a practical and accepted alternative to traditional medicines. The exclusive properties of oral film such as easy administration, quickly disintegration, consumer preference, rapid action, etc making it as a useful delivery form of medication proposed for geriatric, pediatrics patients who have difficult in swallowing tablets and capsule. Oral films can replace the over-the-counter (OTC) drugs, generic and name brand from market due to lower cost and consumer's preference.

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