

Fast Dissolving Oral Film: A Novel and Innovative Drug Delivery system

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ABSTRACT

The oral route is more suitable than other route of administration of therapeutic agents due to low cost of therapy and ease of administration and of patient compliance. This is noninvasive method and produce less side effect. There are some oral solid dosage forms like capsules and tablets. In geriatric, pediatric and dysphagia like patients find it difficult to swallow capsules and tablets and cannot take their medicines as prescribed manner. In some condition such as, sudden allergic attack, coughing, motion sickness, fear of choking and an unavailability of water, the swallowing of capsules or tablet or may become difficult. To overcome from these types of problem, the pharmaceutical industries are design and develop the new type of drug delivery system such as fast dissolving drug delivery systems. This innovative Oral fast dissolving film is a new dosage form in which a thin film is prepared by using hydrophilic polymers with suitable excipients. The film dissolved quickly in mouth without taking of water. The oral films are prepared by the solvent casting method or hot melt extrusion.

Keywords: noninvasive, dysphagia, oral fast dissolving film

Introduction

In present time the demand of new dosage form are increasing specially in the case of pediatrics and geriatrics patients and the oral routes are most preferred route for drug delivery because of ease of handling versatility, ease of administration and invasive method. The oral solid dosage form are less expensive to manufacture and do not take any sterile condition but now days the oral drug delivery system require some advancement because of some problem in related to the particular types of patients such as in the case of pediatric, geriatrics and dysphasic patients due to difficulty in swallowing and chewing of solid dosage forms of drugs. So it results poor compliance with oral drug therapy and it leads to reduced drug therapy effectiveness due to which a new type of dosage form such as fast dissolving film has been developed which have some advantages like ease of administration and can take without need of water. The film is prepared by using polymer and dissolves in the mouth within a few minutes, it were developed in the late in 1970 as an alternatives of capsules, tablets and syrups for that patients who have difficulties in swallowing and chewing [1,2,3].

Advantages of oral films drug delivery system:

1. Available in different size and shape.
2. Mucoadhesion is excellent.
3. Fast releasing and disintegration within minutes in the mouth.
4. Water not requires to swallowing.
5. It is thin and elegant [4].
6. It is compatible with taste masking.
7. It leaves less or no residue in the mouth.
8. It is Useful in case of rapid onset of action required such as sudden episodes of allergic attack or coughing, in motion sickness, bronchitis or asthma.
9. It is increased bioavailability, especially in the cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
10. Improved patient compliance [5].

Disadvantages:

1. Drugs which are not stable at buccal pH cannot be administered.
2. Drug in large dose cannot be administered.
3. Some drugs have bitter taste, and need taste masking.
4. It takes Special packaging due to fragile in nature and must be protected from water.

5. Drugs which are irritate to the mucosa which cannot be administered by this route.

Ideal characteristics of drug moiety for oral film:

1. The incorporating active moiety should be not more than 40mg.
2. The drug should be unionized at the pH of buccal cavity.
3. The drug should have pleasant taste.
4. Drug should be stable and soluble in water like saliva.
5. It should be able to permeate oral mucosal tissues.

Oral Film Formulation-

There are different types of ingredients require for the formulation of oral films.

- Drug
- Film forming agent
- Plasticizers
- Flavoring and sweetening agent
- Surfactant
- Thickener and Stabilizers
- Saliva stimulating agent

Film forming agent

It is use as carrier for drug. The physiochemical and nature of film former polymer can be change. The mostly cellulose derivative polymer are use as film former like hydroxypropyl methyl cellulose, hydroxy propyl cellulose and sodium carboxy methyl cellulose in different grade and other i.e., sodium alginate, polyvinyl pyrrolidone, polyethylene glycol. The film should not be damage while handling or during transportation time. The tensile strength is depending on types of polymer and amount of polymer used in film. Mainly hydrophilic polymers are used as film former [6].

Plasticizers

It improves the flexibility of film and decrease the brittleness of the polymer film. The selection of plasticizers depends on the compatibility with polymer, method of formulation and the nature of solvent. There are many plasticizer use i.e. Propylene Glycol, Glycerol, castor oil, citrates derivatives [7, 8].

Flavoring and sweetening agent

The flavors enhance the acceptance of the formulation and enhance the elegance properties of film. Some flavors i.e. menthol, peppermint, essential oils such as methyl salicylate, eucalyptol, thymol, vanilla, cinnamon etc.

Sweeteners use to mask the bad odour and bitter taste of the drugs. Both type of sweeteners are used, natural and synthetic sweeteners i.e. 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, acesulfam-K, Aspartame, Neotame respectively [9,10].

Surfactant

These are used to enhance the solubility and wetting property of film to release within minute the drug. There are many surfactants which are used i.e. benzalkonium chloride, sodium lauryl sulfate, benzathonium chloride, tween and polaxamer.

Thickner and Stabilizers

These are stabilize and enhance the viscosity i.e. xanthan gum, carrageenan and derivatives of cellulose [11].

Saliva stimulating agent

These activate the salivary gland to produce the saliva which helps in rapid disintegration of the film. Some acid use as saliva stimulating agent i.e citric acid, ascorbic acid, lactic acid, tartaric acid. These agents can be used alone or in combination form between 2 to 6% [12].

Techniques use in Film Preparation [13, 14, 15, 16]

1) Hot-melt Extrusion Method-

In this method only thermostable drug can be used. The API and other excipients are mixed in dry state and heated at high temperature then extruded it. The mass is used to forming of the film and cuted it in desire size. These are dried at very low temperature. The whole process performs without using of the solvent.

2) Solvent Casting Method:

The film prepare by dissolving the polymer and API in suitable solvent and stirrer up to 4 hrs.by using magnetic stirrer and keep it for 1 hr. for remove the air bubbles entrapped in solution. The solution is poured over suitable casting mould, the film is air-dried or dried under oven and carefully removed.

3) Semisolid casting Method

The water soluble polymers are dissolved in water and added acid insoluble polymer (CAP, CAB) which was prepared in ammonium and sodium hydroxide and plasticizer and form gel mass and cast into film.

4) Roller method

In this method suspension or solution of drug and polymer are prepared by using of solvent, mostly water or mixture of water and alcohol. The suspension or solution should have specific rheological property. These are rolled with the help of and prepared film dried and cut in desired size.

Evaluation Parameters for Oral Films [17, 18, 19, 20, 21]**1. Content Uniformity**

The one square inch of film cut and dissolve it in methanol in 100 ml volumetric flask and make up the volume. Solution suitably dilute and measure absorption.

2. Thickness

Film thickness are measured by micrometer screw gauge these are insure the accuracy of dose in film strip.

3. pH value

pH are measured by the dissolving one oral film in 10ml distilled water and measuring the pH of the obtained solution should have nearly uniform pH value.

4. Folding endurance

This is determine by repeating folding of film at same point till the film strip breaks and the number of times of folding without breaking is counted.

5. Morphology Study

These are studies by the using of scanning electron microscopy.

6. In Vitro Dissolution Studies

In vitro dissolution test is carried out according to the standard dissolution apparatus.

900ml of fresh deionized water taken as dissolution media maintain the temperature.

Five-ml aliquots of samples are taken at regular intervals.

7. Stability Studies

Stability studies on the optimized oral fast dissolving film is carried out for determination of effect of temperature and humidity on the stability of the drug. The film are stored in an aluminium foil and subjected to stability at room temperature. The sample can withdraw at 3 months and 6 months and subjected for cumulative % drug release and *in vitro* dissolution studies to determine disintegration time and disintegration test.

Conclusion

The oral fast dissolving film have better patient compliance in the case of geriatrics and pediatrics patients. It have proved and accepted method for the systemic fast drug delivery of active pharmaceuticals ingredients than other dosage forms, like nitroglycerin are absorb sublingually fast. The film is an elegant, stable and effective vehicle for delivery of different drugs for example neutraceuticals, antiemetics, antiallergics, antiasthmatic for immediate onset action of drug. This have greater stability method combine form of the solid and liquid dosage form by making a bridge between two ideas, incorporating of API and excipient in both forms solid and liquid. The manufacturing of these are very inexpensive for any pharmaceuticals industry. Due to immediate release and ease of manufacturing it will be take attention and increased business of Pharmaceutical industry in future.

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