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MOUTH DISSOLVING FILMS: A REVIEW

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ABSTRACT

Oral route is considered as one of the most convenient routes for administration of various pharmaceutical dosage forms like, tablet, capsule, syrup, suspension and emulsion. Fast Dissolving Drug Delivery systems have developed various fast disintegrating preparations like mouth dissolving film, MDT. Oral thin film are new dosage form that are prepared from hydrophilic polymer which are when placed in mouth, buccal cavity disintegrate rapidly. Mouth dissolving film is superior as compare to mouth dissolving tablet as the cost of production is low. Geriatric and paediatric patients are facing difficulty in swallowing of tablet and capsule, the oral film can bypass it, along with that it has other advantages like self-administrable, fast dissolving, rapid absorption that make it versatile dosage form. The aim of present study is to enlighten specifically different polymer along with their concentrations and applications. This study also focuses on use of plasticizer, polymer, sweetener, different methods which are used for the preparation of oral films and various evaluation parameter of the film.

KEYWORDS: Mouth Dissolving Tablet, oral films, pediatric patients, evaluation, Buccal cavity, dosage forms, Tensile strength.

INTRODUCTION

Oral route is most preferred route by medical practitioners and manufacturer due to highest acceptability of patients. About 60% of all dosage forms available are the oral solid dosage form. The lower bioavailability, long onset time and dysphagia patients turned the manufacturer to the Parenterals and liquid orals.[1]

Definition

fast dissolving oral film (FDOF) is defined as “an ultra-thin film containing active ingredient that dissolves or disintegrates in the saliva at a remarkably fast rate, within few seconds without the aid of water or chewing”. Fast dissolving oral films (FDOFs) are the most advanced form of oral solid dosage form due to more flexibility and comfort. It improves the efficacy of APIs by dissolving within minute in oral cavity after the contact with saliva without chewing and no need of water for administration. It gives quick absorption and instant bioavailability of drugs due to high blood flow and permeability of oral mucosa is 4-1000 times greater than that of skin. FDOFs are Oral route is most preferred route by medical practitioners and manufacturer due to highest acceptability of patients. About 60% of all dosage forms available are the oral solid dosage form. The lower bioavailability, long onset time and dysphagia patients turned the manufacturer to the Parenterals and liquid useful in patients such as paediatric, geriatrics, bedridden, emetic patients, diarrhoea, sudden episode of allergic attacks, or coughing FDOFs are prepared using hydrophilic polymer that rapidly dissolves on the buccal cavity, delivering the drug to the systemic circulation via buccal mucosa.[2]

The concept of Oral Dissolving Film

This system has a thin-film. When placed on tongue, immediately it dissolves within few seconds(sec) therefore avoids first- pass metabolism, hence increase bioavailability of drug. Accessibility of larger SA leading quick disintegration &dissolution in mouth. FDFs dissolves in mouth as a cotton candy.[3]

Classification of Oral Films There are 3 types of oral films, they are:

4.1 Flash release/Fast dissolving films (placed on the tongue)

4.2. Mucoadhesive melt away films (gingival or buccal region)

4.3. Mucoadhesive sustained release films (adhere to the buccal mucosa).[4]

Categories of Fast Dissolving Technology Fast-dissolve technologies can divide into 3 broad groups:

- ✓ Lyophilized systems
- ✓ Compressed tablet-based types
- ✓ Oral thin films

Lyophilized systems: This technology involves taking a suspension or solution of drug with other structural excipients, by using mould or blister pack, which forms tablet-shaped units.

Compressed Tablet based-systems: The standard tablet technology by direct compression of excipients is used to produce this system. The tablet technologies have different levels of hardness and friability depending on method of manufacturing.

Oral Thin Films: It is also called as oral wafers. Form the past few years the oral thin films are evolved in confection and oral care markets in the form of breath strips

Advantages of Oral FDFs

- ✓ ODFs can be administered without water, anywhere& anytime.
- ✓ Larger superficial area (LSA) films aid in rapid disintegration as well as in dissolution of the bodies oral cavity.
- ✓ Promoting mouth-freshening property[5]

Disadvantages

- ✓ Drugs that are required in high doses made difficult formulate into thin films. For instance, Rifampin (600mg), Ethambutol(1000mg).[6]
- ✓ Thermal process of drying affect drug & polymer stability.
- ✓ Require packing(special) for products stability & safety

Anatomical & physiological features of the oral cavity

It was explained by the surface of the oral mucosa

1. And overall it is about 100cm.
2. It has the following parts like

- Buccal epithelium
- Basement membrane
- Sub mucosal membrane which contains nerves & blood vessels & contains bone or muscle.

Formulation considerations

Formulation considerations are important factors affecting the mechanical properties of films such as, shifting the glass transition temperature to lower temperature.[7] Formulation of ODFs involves the intricate application of aesthetic and performance characteristics such as taste masking, fast dissolving, physical appearance, mouth-feel etc. The area of drug loaded FDF should be between 1-20 cm2. The drug can be loaded up to a single dose of 30mg.[8]

Active Pharmaceutical Ingredients (API)

It has 1-30%w/w - API. Always use low dose active pharmaceutical ingredients used because high dose of drug is difficult to incorporate in fast dissolving film micronized API is useful because it enhances the texture of the film and improved dissolution and uniformity in the 8 fast dissolving.[9]

Film Forming Polymers

Polymers are the most important ingredient of the oral fast dissolving film.[10]

Ideal Properties

It should non-toxic and non-irritant.

It must be hydrophilic.

Polymer should have low molecular-weight (MW)

Technologies used in manufacture of FDFs[14]

- ✓ Solvent casting process
- ✓ Semisolid casting method
- ✓ Hot-melt extrusion-process
- ✓ Solid-dispersion extrusion
- ✓ Rolling- method

Application of FDFs

- o Topical application
- o Gastro retentive dosage systems
- o Diagnostic devices.[15]

Criteria for Fast dissolving Drug Delivery System: The tablets should

- ✓ Not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.
- ✓ Be compatible with taste masking.
- ✓ Be portable without fragility concern.
- ✓ Have a pleasant mouth feel. Leave minimum or no residue in the mouth after oral administration.
- ✓ Exhibit low sensitive to environmental condition as temperature and humidity.
- ✓ Allow the manufacture of the tablet using conventional processing and packaging Equipment's at low cost.

Salient Feature of Fast Dissolving Drug Delivery System

- ✓ Ease of Administration to the patient who can not swallow, such as the elderly, stroke victims, bedridden patients, patient affected by renal failure and patient who refuse to swallow such as pediatric, geriatric & psychiatric patients.
- ✓ No need of water to swallow the dosage form, which is highly convenient feature for patients who are

traveling and do not have immediate access to water.
- ✓ Rapid dissolution and absorption of the drug, which will produce quick onset of action.
- ✓ Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases bioavailability of drug is increased.
- ✓ Pregastric absorption can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.
- ✓ Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient.
- ✓ The risk of chocking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.
- ✓ New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
- ✓ Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra-rapid on set of action required.
- ✓ An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- ✓ Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.[16,17]

EVALUTION PARAMETER

1. Thickness: The thickness of the all-different films was measured using a baker precision measuring instrument, China. It was measured by placing each film between the anvil and the presser foot of the dial gauge is 5 different location and the average thickness was calculated.[37]

2. Tensile strength: Tensile strength is maximum stress applied to at which film specimen breaks. It is calculated by the load at rupture divided by the cross-section area of the film.[38]

Tensile strength = F max/A film

3. Youngs modulus: - It is use to estimate stiffness. It is found as balance applied stress to the strain in the region. it is determined by Youngs modulus = force of corresponding strain/cross sectional area.[39]

4. Tail Flick Test: The ventral surface of the tail of the animal was placed on the heating coil of digital analgesiometer and the basal reaction times were noted. About 3-5 basal coxib was fixed of 10 mg/kg body weight.[40]

5. Thermodynamic Stability Test: Optimize formulations then subjected to different thermodynamic stability study test namely centrifugation and freeze thaw cycles by thermodynamic stability test.

6. Viscosity: Evaluate the viscosity of the optimized formulation by Brookfield viscometer.[41]

7. Drug Content: Determine the percentage of drug content of formulation from the calibration curve by using uv spectrometer.

8. Weight of Films: Oral fast dissolving films can be weighed on analytical balance and average weight can be determined for each film. It is desirable that films should have nearly constant weight. It is useful to ensure that a film contains the proper amount of excipients and APIs.

9 pH value: PH is 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.[43]**

10. Elongation: When stress is applied, a film sample stretches and this is referred to as strain. Strain is basically the deformation of film divided by original dimension of the sample. Generally elongation of film increases as the plasticizer content increases.[44]

Percent elongation= L*100/Lo

L = Increase in length of film Lo = Initial length of film

11. Swelling property: Each film sample is weighed and placed in a pre-weighed stainless steel wire mesh. Then he mesh containing film sample is submerged into 15ml medium (simulated saliva solution) in a plastic container. Increase in the weight of the film was determined at preset time interval until constant weight was observed

Degree of swelling = Wt – Wo/ Wo

Where, Wt is weight of film at time t, and Wois weight of film at time zero.

12 Stability Studies: Stability studies on the optimized oral fast dissolving film is carried out for determination of effect of temperatures 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.[17-25]

CONCLUSIONS

Recently pharmaceutical companies embraced fast dissolving films as a practical and accepted alternative to traditional medicines. This technology is good for increasing patent life of existing product in pharmaceutical company. Fast dissolving oral films have better patient compliance and improve efficiency and better safety, compared with conventional oral dosage forms. Industrially feasible approach to overcome the problems of low oral bioavailability associated with the lipophilic drugs. This study explores the possibilities of loading a wide variety of plant actives as their scale up is convenient and economical.

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