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A Path for Horizing Your Innovative Work

EXPLORATION OF DIFFERENT POLYMERS AND OPTIMIZATION OF CONCENTRATION OF PLASTICIZER IN THE FORMULATION OF ORAL FAST DISSOLVING STRIPS

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Abstract: In the recent years, many of the pharmaceutical groups are focusing their research on rapid dissolving technology. Amongst the rapid drug releasing products, Oral film technology is gaining much attention. The main advantage of this technology is the administration to pediatric and geriatric patient population where the difficulty of swallowing larger oral dosage forms is eliminated. The Aim behind this study was to explore the film forming properties of various film formers used in oral film technology and optimization of concentration of plasticizer for good tensile strength and also the folding endurance. The films were prepared by solvent casting method. Prepared strips were evaluated for film forming capacity, visual appearance, disintegration time, tensile strength and their folding endurance. The different polymers used for formulation of film were HPMC E5, HPMC K100, PVA, PVP, Gelatin, HPMC in combination with Xanthan gum and plasticizer used was polyethylene glycol (PEG 400) in different proportions (0.1, 0.2, and 0.3). Very transparent visual appearance, Best film forming capacity and least disintegration time of HPMC E5 and HPMC k100 polymers were observed in the study. So HPMC E5 is the best film forming agent among all film forming polymers with PEG400 in proportion of 0.2ml for good tensile strength and folding endurance.

Keywords: Fast dissolving film, Solvent casting method, Pediatric and geriatric patients, Polymers**.**

INTRODUCTION

The oral route of drug administration is the most important method of administration of drug for systemic effect, despite of tremendous advancement in drug delivery system. Its ease of administration, pain avoidance and various advantages over other routes is the reason that the oral route achieved such popularity. But the most evident drawback of oral dosage forms like tablets and capsules is difficulty in swallowing, leading to patient's incompliance particularly in case of pediatric and geriatric, bedridden, nauseous patients. A renewed interest has been addressed to oral solid dosage forms designed for prompt availability of therapeutic dose. Mouth dissolving products (tablets and films) may show greater patient acceptability and convenience. Fast-dissolving oral delivery systems are solid dosage forms, which disintegrate or dissolve within 1 min when placed in the mouth without drinking of water or chewing[1-2]. After disintegrating in mouth, enhanced the clinical effect of drug through pre-gastric absorption from mouth pharynx and esophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablet dosage form. More recently, Fast-dissolving buccal film drug delivery systems have rapidly gained acceptance as an important new way of administering drugs. They are usually used for pharmaceutical and nutraceutical products. It is the newest frontier in drug delivery technology that provides a very convenient means of taking medications and supplements. FDFs are also applicable when local action in the mouth is desirable such as local anesthetic for toothaches, oral ulcers, cold sores, or teething[3-5]. Fast dissolving film is prepared using hydrophilic polymers that rapidly dissolve/disintegrate in the mouth within few seconds without water and eliminates the fear of chocking as an alternative to fast dissolving tablets. Basically the fast dissolving film can be considered as an ultra thin strip of postage stamp size with an active pharmaceutical ingredient and other excipients. Most fast dissolving films are having taste masked active ingredients. These masked active ingredients are swallowed by the saliva of patients along with the soluble and insoluble excipients.

The advantages of convenience of dosing and portability of mouth dissolving film have led to wider acceptability of this dosage form by pediatric as well as geriatric population equally. Because of

fast dissolving behavior and fast adherence to the mucosa, fast dissolving films cannot be spit after application on to the tongue. They also impart unique product differentiation, thus enabling use as line extensions for existing commercial products. This novel drug delivery system can also be beneficial for meeting the current needs of the industry are improved solubility/stability, biological half life and bioavailability enhancement of drugs. Today, OFDFs are a proven and accepted technology for the systemic delivery of APIs for over-the-counter (OTC) medications and are in the early- to mid-development stages for prescription drugs[6].

Fast dissolving film dosage form should have the property to disintegrate in seconds when placed in mouth and deliver the drug to the oral cavity instantaneously. As the film forming polymer (which forms the platform for the FDFs) and plasticizer are the most essential and major component of the FDFs, at least 40-50 % w/w of polymer and up to 20% (total weight of polymer) of plasticizer should generally be present based on the total weight of dry FDFs[7]. Plasticizer is one of the vital ingredients of the RDFs formulation. It helps to improve the flexibility of the strip and reduces the brittleness of the strip. Plasticizer significantly improves the film properties by reducing the glass transition temperature of the polymer. In present study various film forming polymers were used and evaluated for various film forming properties like, film forming capacity, appearance, mechanical properties, disintegration time and dissolution time.

MATERIALS AND METHODS

All the chemicals used were of analytical grade and were used without further purification. Distilled water was used throughout the study.

Preparation of oral fast dissolving strips

Oral fast-dissolving film was prepared by the solvent-casting method. Film forming polymer was dissolved in half the quantity of distilled water and was allowed to stand for swelling of the polymer. In remaining water, citric acid (the saliva stimulating agent) was added. Both the solutions were mixed and plasticizer was added and stirred to obtain a homogenous solution. The solution was kept for some time for the removal of any bubbles and then casted onto the Petri-dishes (area of 44.196cm^2). Petri dishes were kept in hot air oven for 24hrs at 40°C. After drying films were removed and cut into 2cm×2cm size

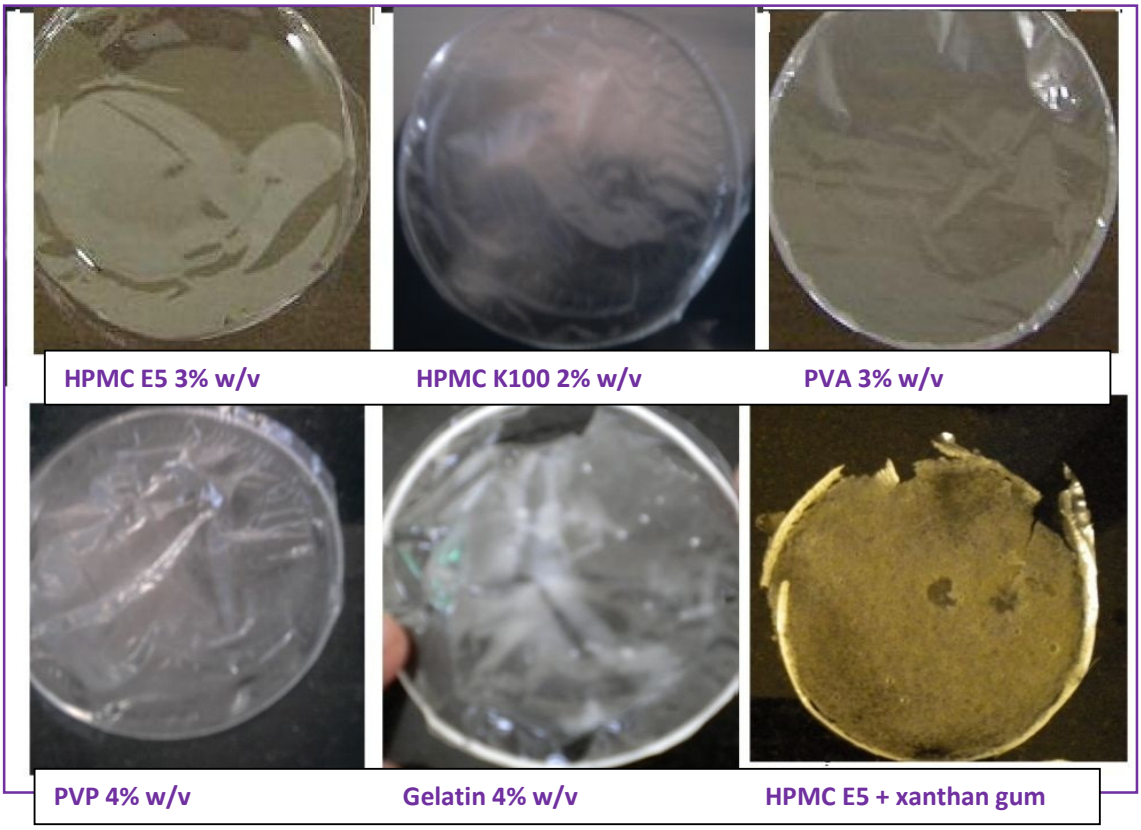

Figure 1. Pictures of FDFs prepared with different polymers.

EVALUATION OF FAST DISSOLVING FILMS

The fast dissolving films were evaluated for physical appearance, surface texture, folding endurance. The physical appearance was checked with visual inspection of films and texture by feel or touch.

Folding endurance

The folding endurance was determined by repeatedly folding one film at the same place till it broke or folded up to 300 times which is considered satisfactory to reveal good film properties. The number of times the film could be folded at the same place without breaking gives the value of the folding endurance.

Film forming capacity

It is ability of film formers to form desired films. It is categorized according to strip forming capacity such as very poor, poor, average, good, very good[9].

Appearance of films

Appearances of films were evaluated by visual observation such as transparent, semi-transparent, hazzy[10].

Disintegration time

The required size of film (2×2 cm^2) was placed in a beaker containing 10 ml of pH 6.8 buffer solution. The disintegration time is noted which is the time when the film starts to break or disintegrates. All studies were performed in triplicate for each batch.

RESULTS AND DISCUSSION

Folding endurance of films with PEG400 (0.2ml) were found to have good folding endurance and tensile strength, so PEG400 in proportion of 0.2ml gave satisfactory results. Determination of film forming capacity, appearance, disintegration time of all the formulations with PEG400 (0.2ml) were shown in Table 2.

HPMC E5, HPMC K100 polymers found to have good film forming capacity with good tensile strength, and PVA polymer also gave average film forming capacity. Disintegration time of HPMC E5, HPMC k100, PVA, PVP, Gelatin and HPMC E5 + Xanthan gum was found to be 29sec, 28sec, 35sec, 39sec, 45sec and 42sec respectively. Appearances of all the films were transparent except Gelatin film was semi-transparent and HPMC E5 + xanthan gum film was found to be hazy in appearance. Films with HPMC E5 and HPMC k100 were showed excellent film forming capacity and better tensile strength, disintegration time. Optimized oral fast dissolving films should have good film forming capacity, better appearance, lowest disintegration, good folding endurance and the tensile strength.

Table 1

Formulation of fast dissolving films.

Ingredients	F1	F2	F3	F4	F5	F6
Polymers	HPMC E5	HPMC K100	PVA	PVP	Gelatin	HPMC E5 + Xanthan gum
Citric acid	4 %	4%	4%	4%	4%	4%
PEG400 (a)	0.1	0.1	0.1	0.1	0.1	0.1
(ml) (b)	0.2	0.2	0.2	0.2	0.2	0.2
(c)	0.3	0.3	0.3	0.3	0.3	0.3
Water (ml)	10	10	10	10	10	10

*Quantities are expressed in %w/w of polymer

Table 2

Evaluation of fast dissolving films.

Polymers	Film forming capacity	Appearance	Folding Endurance (PEG400-0.2ml)	Tensile Strength (N/mm^2)	Disintegration time (sec)
HPMC E5	Very good	Transparent	>300	12.094	29
HPMC K100	Good	Transparent	>300	10.162	28
PVA	Average	Transparent	>300	08.610	35
PVP	Poor	Transparent	211	04.162	39
Gelatin	Very Poor	Semi-transparent	205	02.098	45
HPMC E5 + Xanthan gum	Very Poor	Hazzy	189	01.610	42

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