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Original Article

OPTIMIZATION & SCREENING OF DIFFERENT FILM FORMING POLYMERS AND PLASTICIZERS IN FAST DISSOLVING SUBLINGUAL FILM

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ABSTRACT

The purpose of the present investigation was to explore the use of different polymers in the formulation of fast dissolving sublingual films. Fast dissolving sublingual film i.e. Oral dissolving film technology (ODFT) can be administered in the sublingual route which gives better therapeutic action and are highly useful for rapid local action.

The technique of ODFT is useful for pediatric and geriatric patients who feel difficulty in swallowing larger dosage forms. ODFT was prepared by solvent casting method. Prepared strips were evaluated for film forming capacity, visual appearance, disintegration time and tensile strength. The films were casted using polymers such as HPMC E-15, HPMC E-5, PVA & PVP K-30. Plasticizers tried were PEG400 and glycerin. Among all polymers used, HPMC E-5 showed desired film forming capacity with transparent nature showing least disintegration time.

Keywords: Fast Dissolving Sublingual Film, Solvent Casting Method, Polymers, Plasticizers.

INTRODUCTION

Bio-adhesive formulations have a wide scope of application, for both systemic and local effects of drugs. The mucosa is relatively permeable with a rich blood supply. The oral transmucosal drug delivery bypasses liver and avoids pre-systemic elimination in GI tract and liver. These factors make the oral mucosa a very attractive and feasible site for systemic drug delivery.[1] Many pharmaceutical companies have directed their research activity in reformulating drugs into new dosage forms. One such relatively new dosage form is oral strip, a thin film that is prepared using hydrophilic polymers that rapidly dissolves on tounge or buccal cavity.[2] The sublingual route has been investigated as a site for drug delivery for a quick time. About 60% of total dosage forms are administered by oral route [3,4]. Many peadiatric and geriatric patients are unwilling to take solid preparations due to fear of choking [3,5,6]. In order to assist these patients, several fast-dissolving sublingual drug delivery systems have been developed. Oral fast dissolving drug delivery system (OFDDS) is one such novel approach to increase consumer acceptance by virtue of rapid disintegration, self-administration without water or chewing [3,8]. Fast dissolving sublingual films evolved over the past few years from the confection and oral care markets in the form of breath strips that became a novel and widely accepted form by consumers for delivering vitamins and personal care products. 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 [3,9].

As the fast dissolving strip utilizes sublingual route, rapid absorption of drug is possible, which finally leads to quick onset of drug action [10]. New and novel oral drug delivery system dissolves or disperses quickly in few seconds after placement in the mouth without drinking and chewing. When quick dispersing films are placed in the mouth, the dosage form disintegrates instantaneously or within a few seconds releasing the drugs, which dissolve or disperse in saliva. The sublingual mucosa is relatively permeable due to thin membrane and large veins [3,10]. It gives rapid absorption and instant bioavailability of drugs due to high blood flow. Here attempt is made to explore different polymers for use in the formulation of fast dissolving strips.

MATERIALS AND METHODS

Materials

Hydroxy propyl methyl cellulose (HPMC) E15, HPMC E5, Ploy vinyl acetate (PVA), Poly vinyl Pyrrolidone (PVP) K-30, Poly ethylene glycol (PEG)-400 and Glycerin were purchased from Yarrowchem pvt. Ltd., Mumbai. All other chemicals were used of analytical grade. Deionized double-distilled water was used throughout the study as a solvent.

Method

Preparation of first dissolving sublingual films

Fast dissolving sublingual films were prepared by the solvent-casting method. First of all film-forming polymers were dissolved in distilled water and were allowed to stand for swelling. Plasticizer was added in a drop wise and stirred to obtain a homogenous solution. The solution was kept for some time for the removal of bubbles and then casted into the lubricated Petri-dishes (area of 50.24 cm2). Petri dishes were kept at maintained room temperature for 48 hrs and an inverted funnel was placed over the petridis to prevent fast evaporation of the solvent or in hot air oven for 24hrs at 40°C. After drying films were removed and cut into desired size i.e.1×1 cm2, packs in aluminum foils untill further use. Different batches of formulations have shown in the table no.1.

Evaluation of fast dissolving sublingual films

General appearance

The fast dissolving films were evaluated by visual observation such as transparent and semitransparent nature of strip. [11]

Film forming capacity

It is ability of polymer about formulation of desired strip. It is categorized according to strip forming capacity such as very poor, poor, average, good, better, excellent. [3,5,12]

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. [13,14]

Disintegration time

The disintegration time is noted which is the time when the film starts to break or disintegrates. The Disintegrating test was carried out in 10 ml phosphate buffer (pH 6.8) in a beaker at 37±0.5 0C. All studies were performed in triplicate for each batch. [12,15].

RESULTS AND DISSCUSION

General appearance

The physical appearance was checked with visual inspection of films and texture by feel or touch. Appearances of all the films were transparent. Determination of appearance of all the formulations with PEG 400 and Glycerine (30% w/w) were shown in Table 2.

Film forming capacity

The result reviled that the film forming capacity of HPMC E5 is excellent and using HPMC E15 polymers found to have good film forming capacity with plasticity. PVA also gave average film forming capacity. Determination of film forming capacity of all the formulations with PEG 400 and Glycerine (30% w/w) were shown in Table 2.

Folding endurance

Folding endurance of films with PEG400 (30% w/w) were found to have good folding endurance, so PEG-400 in proportion of 30 % w/w gave satisfactory results. All the data has shown in table 2.

Disintegration time

Determination of disintegration time of all the formulations with PEG 400 and Glycerine (30% w/w) were shown in Table 2. Disintegration time of HPMC E5, HPMC E15, PVA and PVP K30 was found to be 15sec, 22sec, 35sec and 47sec, respectively with PEG 400 and 16sec, 28sec, 37sec and 50sec respectively for Glycerine. Films with HPMC E5 and HPMC E15 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.

Table 1: Formulation of Fast Dissolving Sublingual Film

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8
HPMC E-5 (mg)	200	-	-	-	200	-	-	-
HPMC E-15 (mg)	-	200	-	-	-	200	-	-
PVA (mg)	-	-	200	-	-	-	200	
PVP K-30 (mg)	-	-	-	200	-	-	-	200
PEG-400 (%w/w)	30	30	30	30	-	-	-	-
GLYCERINE (%w/w)	-	-	-	-	30	30	30	30
WATER (ml)	10	10	10	10	10	10	10	10

Table 2: Evaluation of Fast Dissolving Sublingual Film

Batch	Appearance	Disintegration Time(Sec)	Film forming capacity	Folding Endurance
F1	Transparent	15	Excellent	155
F2	Transparent	22	Good	142
F3	Transparent	35	Poor	97
F4	Transparent	47	Very Poor	74
F5	Transparent	16	Excellent	182
F6	Transparent	28	Good	146
F7	Transparent	37	Average	77
F8	Transparent	50	Poor	59

CONCLUSION

Based on the appearance, film forming capacity and disintegration time, HPMC E5 & PEG 400 is considered as best film-forming agent and plasticizer accordingly.

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