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## Formulation of Buccal Strips using PEG 400 and Honey as a Plasticizers

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### ABSTRACT

Buccal films show rapid dissolution along with it also used to avoid first pass metabolism of the drug entrapped in the buccal film formulation because they get absorbed through buccal mucosa. The aim of present investigation was to explore the use of honey a plasticizers, compared with PEG400 as plasticizer.

Film of Fentanyl Citrate a narcotic opioid analgesic for cancer breakthrough pain is formulated by solvent casting method using HPMC E<sub>15</sub> as a film forming agent, Honey and PEG400 as plasticizers and Sodium Starch Glycolate as superdisintegrant. All the formulations were evaluated on the basis of Tensile strength, %Elongation, in-vitro drug release and folding endurance. Through optimization **F3** and **F6** proved to be best formulation through which formulation with PEG400 proved better than with honey. But honey as plasticizers gives satisfactory result and can be used further for formulating film with natural plasticizer.

**Key words:** plasticizer, superdisintegrant, tensile strength.

### 1. INTRODUCTION

In a few years various researches focused on patient compliance and convenience have brought out safer and new drug delivery system with increased patient choice due to the reason of rapid disintegrating or dissolution, self-administration even without water or chewing.<sup>1</sup>

When administration is considered, buccal cavity can be cited as one of the local effect and systemic effect respectively. Since vascularization in buccal mucosa is high, enzymatic activity compared to nasal, intestinal and rectal mucosa is minimal and it is less sensitive.<sup>2</sup>

Plasticizer is a substance used as an excipient, when added to polymer cause an increase in the flexibility, a decrease in glass-transition temperature of polymer which results in increase in flexibility. It works by entrapping between the polymer chain which keeps them apart that reduces the forces of attraction between them. Natural based plasticizers characterized by low toxicity and low migration required not only pharmaceutical and medical application.<sup>3</sup>

Honey is natural sweet mixture produced by bees. Honey is a viscous material contains fructose (33.3-43.0%), glucose (25.2-35.3%), Sucrose (0-2%) are present in amorphous state.

PEG400 is a clear colourless liquid used in many industries as a plasticizers. Typically derived from petroleum. It has shelf life up to one year from the date of manufacture. It is biodegradable and not-known to be toxic.

## 2. MATERIALS AND METHODS

### 2.1 Materials

Fentanyl Citrate was obtained as a gift sample (Verve healthcare Pvt. Ltd, New Delhi). It is official in most of the Pharmacopoeia i.e USP and BP. It was standardized as per official compendia and also characterised as per analytical profile of the substance provided by Florey. HPMC<sub>E15</sub>, PEG 400, Honey and Sodium starch glycolate.

### 2.2 Method (Method of Preparation)

Fast dissolving buccal films were formulated using Solvent Casting method. All ingredients including polymer, plasticizer and disintegrant were dissolved other than drug is mixed to form a clear viscous solution. Drug is dissolved separately with small amount of solvent and then mixed with above solution by continuous stirring, followed by making up the volume. The mixture was poured into lubricated petridish upto height 0.5cm. Dried the formulation in previously heated Hot air oven which was maintained at 40-60°C.<sup>4</sup>

### 2.3 Pre-formulation Studies

Pre-formulation testing is the first step in the rationale development of dosage forms of a drug substance. It can be defined as an investigation of physical and chemical properties of a drug substance alone and when combined with excipients. The overall objective of preformulation testing is to generate information useful for the formulator for the development of stable and bioavailable dosage form. Formulation batch at different concentration of Excipients is mentioned in Table 1.

### 2.4 Evaluation of Prepared Film

#### 2.4.1 Physical Appearance and texture analysis

In this, films were observe by feel and touch. It should be smooth, transparent and even all the sides by touching.

#### 2.4.2 Thickness measurements

Using Dial Thickness Guage were recorded for randomly selected 10 thin film. Films were placed between two anvils of screw guage while using knob, films were fitted.

#### 2.4.3 Folding endurance

The number of times the film folded till it breaks were recorded as folding endurance value.<sup>5</sup>

#### 2.4.4 Thermal Analysis study

DSC (differential scanning calorimetry) used for thermal analysis study.

#### 2.4.5 Tensile Strength

The maximum stress applied to a point at which film breaks known as Tensile Strength.

$$\text{Tensile Strength} = \frac{\text{Load at failure}}{\text{strip thickness} \times \text{strip width}} \times 100$$

#### 2.4.6 Percentage elongation

When stress is applied on a film of measures 2\*2cm<sup>2</sup>. It get stretched. The deformation of film before gets broken due to stress known as strain. Elongation increases as plasticizer content increases which is calculated by following formula:

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

#### 2.4.7 In vitro disintegration time

DT is the time when film starts break when comes in contact with water or saliva. The disintegration time for fast dissolving film should be in range of 5-30sec. Time is determined by dipping the film in 25 ml water in a beaker by shaking gently. Time was noted when starts breaks considered as disintegrating Time.

#### 2.4.8 In vitro dissolution studies

Dissolution can defined as amount of drug that dissolve in solution per unit time under given standardized condition include temperature and solvent concentration. Temperature of dissolution should be maintained at 37°C±0.5°C and rpm should be adjusted at 50.<sup>6</sup>

Data has been shown in Table 2 and Table 3.

## 3. RESULT AND DISCUSSION

### 3.1 Pre-formulation Studies

The physical appearance and melting point of drug were in accordance with the specification and certificate of analysis.

The drug was found to be freely soluble in water. The wavelength of maximum absorption ( $\lambda_{\text{max}}$ ) for pure drug sample was found to be 210 nm determined by scanning the dilution prepared using phosphate buffer pH 6.8 between 200-600 nm in UV spectrophotometer.

Drug Fentanyl Citrate showed the straight line with equation  $y = 0.000x + 0.167$  and Regression value of  $R^2 = 0.919$  which is showed in figure 3.

### 3.2 *In vitro* release study

The *in vitro* release study was performed for best optimized formulation F<sub>3</sub> and F<sub>6</sub>. The release was determined using phosphate buffer pH 6.8 as *in vitro* dissolution medium due to its similar pH as of Saliva. The release through F<sub>3</sub> is satisfactory than F<sub>6</sub>. Data has been shown in Table 4 and Fig 4.

The release data of formulation showed that 90% of drug release in 90 sec in case of Formulation F<sub>3</sub> and 80% of drug release

in 90 sec in case of Formulation F<sub>6</sub>. This release was corresponding to ratio of drug and polymers.

## 4. CONCLUSION

From present investigation it can be concluded that oral fast dissolving films prepared by HPMC E<sub>15</sub> and PEG 400 could show good mechanical strength, drug release and fast disintegration time than film containing honey as a plasticizer. Honey shows satisfactory result in forming fast dissolving film for fentanyl citrate also it provide coating for bitter taste of Fentanyl Citrate but when compared to PEG it comes second in choice as a plasticizer.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interests regarding the publication of this paper.

Table 1. Readings of different evaluation parameters of the prepared batches

Sr. No.	Formulation Code	Parameters		
		Thickness (mm)	Folding Endurance	Disintegration (Sec)
1	F <sub>1</sub>	0.02	125	52
2	F <sub>2</sub>	0.03	126	54
3	F <sub>3</sub>	0.02	152	40
4	F <sub>4</sub>	0.03	180	57
5	F <sub>5</sub>	0.03	100	51
6	F <sub>6</sub>	0.02	146	48

Table 2. Evaluation Parameters of all Batches

Sr. No.	Formulation Code	Parameters		
		Thickness (mm)	Folding Endurance	Disintegration (Sec)
1	F <sub>1</sub>	0.02	125	52
2	F <sub>2</sub>	0.03	126	54
3	F <sub>3</sub>	0.02	152	40
4	F <sub>4</sub>	0.03	180	57
5	F <sub>5</sub>	0.03	100	51
6	F <sub>6</sub>	0.02	146	48

Table 3. Optimized formulation with Drug and their evaluation

Sr. No.	Ingredients	Quantity (mg)		Evaluation Parameters	Formulation Code	
		F <sub>3</sub>	F <sub>6</sub>		F <sub>3</sub>	F <sub>6</sub>
				Thickness (mm)	0.02	0.02
1	Drug	0.1	0.1	Folding Endurance	152	146
2	HPMC E <sub>15</sub>	300	300	Disintegration (Sec)	40	48
3	PEG400	4		Tensile Strength (Newton)	2.2±0.12	1.84±0.5
4	Honey		4	Elongation (%)	6.67	6.34
5	SSG	5	5			
6	Water	10	10			

Table 4. % Drug release of Formulation F<sub>3</sub> & F<sub>6</sub>

Time (Sec)	% Drug Release	
	Formulation	
	F <sub>3</sub>	F <sub>6</sub>
30	70	60
60	85	72
90	90	80

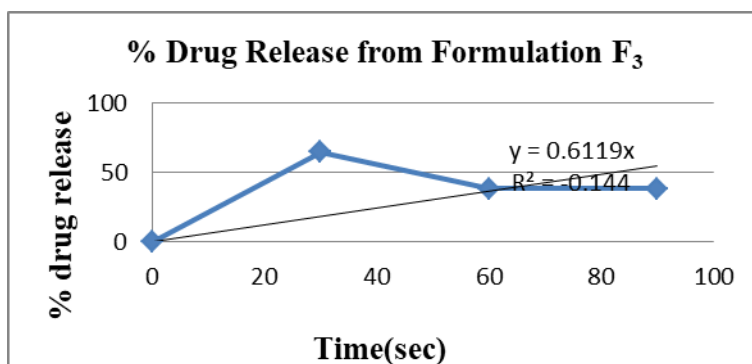


Fig 1. Drug release from Formulation F<sub>3</sub>

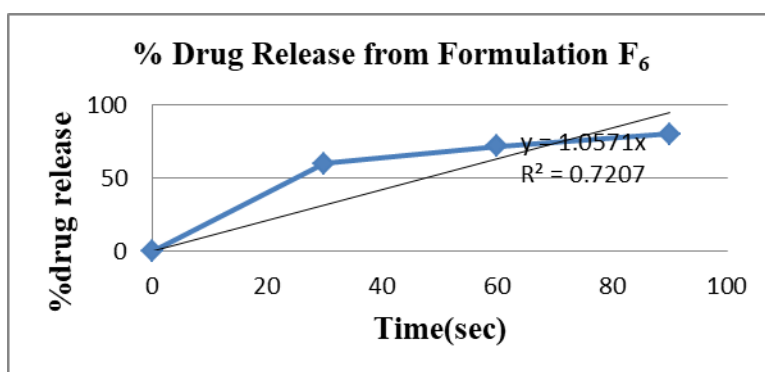


Fig 2. Drug release from Formulation F<sub>6</sub>

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