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EVALUATION OF CRUDE BANANA POWDER AS FORMULATION ADDITIVES AND COMPARISON OF ITS MUCOADHESIVE PROPERTY WITH CARBOPOL 934P

[1]Mr. M. Ranadheer Kumar, [2]Dr. Ch. Kishore, [3]Mrs. S. Sabitha

[1]Assistant Professor,[23]Associate Professor

[123]Department Of Pharmaceutics

Vaagdevi Institute of Pharmaceutical Sciences, Bollikunta, Warangal. Telangana.

ABSTRACT

The current study compares the mucoadhesive characteristics of crude banana powder with carbapol 934P polymer and evaluates it as a formulation aid.

Diclofenac Potassium is a model medication used in tablet formulation and assessment. To extend the medicine's contact duration with the absorbing membrane, tablet formulations that adhere to the gastric mucus or the surface of epithelial cells are helpful in drug administration. Isopropyl alcohol was used in the direct compression, aqueous wet granulation, and non-aqueous wet granulation methods used to make the tablets. A total of fifteen formulations were made with different amounts of polyvinyl pyrrolidine, crude banana powder, and carbapol 934P. Weigh variation, hardness, friability, assay, disintegration, mucoadhesive strength, and an in vitro drug dissolution research were all assessed for the tablets. Using a USP dissolving apparatus type I, the in vitro release of diclofenac potassium was carried out under sink conditions (phosphate buffer PH6.8, 37±0.5ºC, rpm 50). The mucoadhesive properties of carbapol 934P were superior to those of banana flour when the polymer concentration was raised. Force of adhesion rose from 1.716 N to 4.684 N in the case of Carbapol 934P with an increase in polymer concentration from 10% to 60%, while force of adhesion increased from 0.662 N to 1.716 N upon an increase in banana flour concentration from 10% to 60%, respectively. This indicates that Carbapol 934P and crude banana flour both have mucoadhesive properties, but that Carbapol 934P has superior mucoadhesive properties. The aqueous wet granulation technique formulations of Carbapol 934P and banana flour had a prolonged effect; the F2 formulation for Carbapol 934P and the F6 formulation for crude banana exhibited the best sustained impact. When Carbapol 934P was included in the formulation, a more sustained effect was seen.

Keywords: crude banana powder, carbopol 934P, mucoadhesive strength, and in vitro dissolution.

1. INTRODUCTION

Oral route of drug administration is the widely used and most accepted route but due to different nature of drugs such as lipophilic, leads to unsatisfactory oral drug delivery system. It is due to insufficient retention time in GI tract and difference in gastric emptying rate. We can increase the bioavailability of such drugs by formulating into different formulation like controlled release, bioadhesion release, by coating to release drug at the targeted site (1,2). Mucoadhesive systems now play a major role in this field due to their interesting potential. Besides acting as platform for sustained release dosage forms bioadhesive polymers can themselves exert some control over the rate and amount of drug release. Thus, contributes to the

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therapeutic efficacy of mucoadhesive drug delivery system (3,4,5,6).

Bioadhesion is defined as an" ability of a material to adhere to a biological tissue for an extended period of time." In the case, where polymer attached to the mucin layer of a mucosal tissue, the term "mucoadhesion" is used. Mucoadhesive dosage forms have three distinct advantages a) These dosage forms are readily localized in the region applied to improve and enhance the bioavailability of drugs. b) These dosage forms facilitate intimate contact of the formulation with the underlying absorption surface. This allows modification of tissue permeability for absorption of macromolecules such as peptides and proteins. c) Mucoadhesive dosage forms also prolong the residence time of the dosage form at the site of application and absorption to permit once or twice a day dosing (7,8,9).

Banana fruit was chosen for study of its mucoadhesiveness as it contains lectin which is newer generation mucoadhesive and has following properties.

a) least effected by mucus turnover rates.

b) Site specific drug delivery is possible. Carbapol 934P is an mucoadhesive polymer which suitability was proved.

Hence, in the present work an attempt was to formulate mucoadhesive oral tablets for diclofenac potassium using different polymer in order to increase the retention time in gastrointestinal tract and bioavailability to obtain desired therapeutic efficacy (10,11,12).

2. MATERIALS AND METHODS

2.1 Materials

Diclofenac potassium was a gift sample from Deurali Janta Pvt. Ltd, Kathmandu. Ripe banana fruit, goat intestine mucosa were purchased from local market Banepa. Carbapol 934P, PVP were obtained from lab of Department of Pharmacy Kathmandu University.

2.2 Formulation of Mucoadhesive Tablets

The drug, polymers and excipients were mixed homogeneously over a butter paper for 15 min in ascending order of mixing process. The mixture (300 mg) was then compressed using an 10 mm, round punch in a single-stroke using 10-station rotary machine for formulation F1 to F4. For formulations F5 to F8 aqueous wet granulation was performed and compressed. For formulations F9 to F15 non aqueous wet granulation was performed and compressed (13,14,15,16,). The results are shown in Table I.

2.3 Evaluation 0f Mucoadhesive Tablets

2.3.1 Weight Variation

Twenty tablets from each formulation (F1 to F15) were weighed using an electronic balance and the average weight was calculated

2.3.2 Friability

Friability is the measure of tablet strength. Roche type friabilator was used for testing the friability using the following procedure. Twenty tablets were weighed accurately and placed in the tumbling apparatus that revolves at 25 rpm dropping the tablets through a distance of six inches with each revolution. After 4 min, the tablets were weighed and the percentage loss was determined.

$$\% \text{ Loss} = \frac{\text{final weight} - \text{initial weight}}{\text{initial weight}} \times 100$$

2.3.3 Thickness

The thickness of six randomly selected tablets from each formulation was determined in mm using a vernier calliper. The average values were calculated.

2.3.4 Hardness

Tablets require a certain amount of strength or hardness and resistance to friability, to withstand mechanical shocks of handling in manufacture,

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packaging and shipping. The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in Kg/cm2 . Five tablets were randomly picked from each formulation and the mean and standard deviation values were calculated and the results are shown in Table II.

2.3.5 Assay

Standard Preparation

Weigh accurately 75mg of Diclofenac potassium in 100 ml of volumetric flask and dissolve in sufficient 0.1M sodium hydroxide produce 100ml, Pipette 1ml of the resulting solution in 50ml volumetric flask and make up the volume with buffer solution of pH 6.8 (17,18,19).

Sample Preparation

Weigh accurately crushed and mixed pellets blend equivalent to 75 mg of Diclofenac in 100 ml volumetric flask, and dissolve in sufficient 0.1 M sodium hydroxide, solution to produce 100ml and stir for 1 hour. Pipette 1 ml of the resulting solution in 50 ml of volumetric flask and add sufficient buffer of pH 6.8 to produce 50 ml. Measure the absorbance of standard and sample solutions at 275 nm using pH 6.8 buffer as blank and calculate the result by comparison.

2.3.6 Mucoadhesion

Goat mucosa was used as a model mucosal surface for Bioadhesion testing. Immediately after slaughter, remove the mucosa from the goat and transport to laboratory in tyrode solution and keep it at 40º C. The composition of tyrode solution (g/L) is sodium chloride 8, potassium chloride 0.2, calcium chloride dihydrate 0.134, sodium bicarbonate 1.0, sodium dihydrogen phosphate 0.05 and glucose 1.0 (20)

2.3.7 Fabrication of Assembly

The goat intestinal mucosa was cut into strips/pieces and washed with tyrode solution. At time of testing a section of goat intestinal mucosa was secured keeping the mucosal side out, on the upper glass vial using thread. The vial with the goat intestinal mucosa was stored at 37°C for 2 hours. Then one vial with section of goat intestinal mucosa and another vial were fixed on height adjustable pan. To a lower vial a tablet was placed with the help of bilayered adhesive tape, adhesive side facing downward. The height of the lower vial was adjusted so that a tablet could adhere to the goat intestinal mucosa on the upper vial. A constant force was applied on the upper vial for 2 min, after which it was removed and the upper vial was then connected to the balance. Then the weight on right side pan was slowly added in an increment of 0.5 g, till the two vials just separated from each other. The total weight required to detach two vials was taken as a measure of Mucoadhesive strength. From this Mucoadhesive strength, the force of adhesive was calculated. (Figure 1) (20,21,22).

$$\text{Force of adhesion} = \frac{\text{Mucoadhesive strength}}{100} \times 9.81$$

2.3.8 Disintegration

For study of disintegration time, six tablets of each formulation were taken. Disintegration medium taken was water medium with volume of 900 ml at 370 C (18).

2.3.9 In-Vitro Dissolution

The In-vitro dissolution study was conducted as per the United States Pharmacopoeia (USP).The rotating basket method is use to study the drug release from the tablets. The dissolution medium consists of 900 ml of phosphate buffer (pH 6.8). The release is performing at 37°C ± 0.5°C, at a rotation of speed of 50 rpm. 10 ml samples are withdrawn at predetermined time intervals (1hour to 8 hours) and the volume is replace with fresh medium. The samples are filter and analyzed for Diclofenac potassium after appropriate dilution by UV spectrophotometer at

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276 nm. The % drug release is calculated in comparison with a standard solution having a known concentration of Diclofenac potassium reference standard in the same medium.

The calculation is done by using formula:

$$\%DP = \frac{As \times Cc}{Au \times Cs \times 900 \times 100 \times Df}$$

Au and As are absorbance obtained from the solution under test and standard solution respectively. Cs is the concentration of standard solution in mg/ml. Cc is the tablet label claim. 900 is total volume of dissolution medium. 100 is conversion factor to percentage. DF is dilution factor (17,18).

3. RESULT AND DISSCUSSION

3.1 Weight Variation

The weight variation test was conducted for each batch of all formulations F1 to F15 as per I.P and the results are shown in Table II. The weight variation test for all the formulations complies with the IP limit (± 7.5%).

3.2 Friability

The friability test for all the formulations were done as per the standard procedure I.P. The results of the friability test were tabulated in Table II. The data indicates that the friability was less than 1% in all formulations ensuring that the tablets were mechanically stable.

3.3 Thickness

The thickness of the tablets was found to be almost uniform in all formulations F1 to F15. The thickness was found to be in the range of 2.8 to 3.2 mm. None of the formulations (F1 to F15) showed a deviation. Hence, it is concluded that all the formulations complied the thickness test and the results are shown in Table II.

3.4 Hardness

The adequate tablet hardness is necessary requisite for consumer acceptance and handling.The measured hardness of the tablets of each batch of all formulations i.e. F1 to F15 were ranged between 27.0 to 57.8 Newton and the results are shown in Table II.

3.5 Assay

The assay of each batch of all the formulation (F1 to F15) was evaluated as per the standard protocol and the results are shown in the Table II. The results indicate that the percentage of drug content was found to be 95.33% to 104.84%. Hence it is concluded that all the formulations are following acceptable limits as per Indian Pharmacopoeia i.e. ± 5%.

3.6 Mucoadhesion

The in vitro mucoadhesive strength study was performed and the results are shown in the Table II. On the modified physical balance and measure the force (N) required detaching the tablet. The mucoadhesion characteristics were affected by the concentration of the mucoadhesive polymers. Increase in concentration of polymer increases mucoadhesive strength of formulation. F4>F3>F2>F8>F1>F7>F14>F13>F6>F12>F11 >F5>F10>F9>F15 is the adhesive force order.

3.7 Disintegration

The disintegration test was conducted for formulations F9 to F15. Disintegration was found in the range of 7 min 59 sec and 32 min 25 sec.

3.8 In-Vitro Dissolution

The formulations F1, F2, F3 and F4 containing drug and Carbapol 934P in amount of 10%, 20%, 40%, and 60% respectively. The in vitro cumulative drug release profile of formulations F1, F2, F3 and F4 showed 100.56%, 87.32%, 44.28% and 24.82%, respectively. Among these four formulations, F2 was found to be highest percentage drug release. During the study it was observed that the tablets were initially swell and shows sustained release over the period of 8

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hours except F1 which shows maximum release in 6 hours. (Figure 2).

Similarly the formulations F5, F6, F7 and F8 drug, containing Crude banana powder in amount of 10%, 20%, 40%, and 60% respectively. The in vitro cumulative drug release profile of formulations F5, F6, F7 and F8 showed 102.24%, 92.43.%, 77.19% and 99.42%, respectively. Among these four formulations, F8 was found to be highest percentage drug release. During the study it was observed that the tablets were non-erodible and shows sustained release over the period of 8 h (Figure 3). Similarly the formulations F9, F10, F11, F12, F13, and F14 drug, containing Crude banana powder in amount of 5%, 10%, 15%, 20%, 40%, and 60% respectively. These all formulations contain 15 mg PVP. The in vitro cumulative drug release profile of formulations F9, F10, F11, F12, F13 and F14 showed 95.69%, 98.69.%, 99.87%, 99.51%, 87.16% and 75.04%, respectively in 15 minutes, 30 minutes, 1 hour, 1 hour, 6 hours and 8 hours respectively. Among these four formulations, F11 was found to be highest percentage drug release. The formulation F15 contains 15 mg PVP only. The in vitro drug release is 95.99% in 15 minutes. (Figure 4). It was concluded that by increasing the concentration of Carbapol 934P in the formulation, the drug release rate from the tablets was found to be decreased. But by increasing the concentration of crude banana powder, the drug release rate was found to be decreased first then increased. This may be due to increased hydration (or) swelling characteristics of polymers with increased concentrations.

Table I: Formulation of oral mucoadhesive tablet.

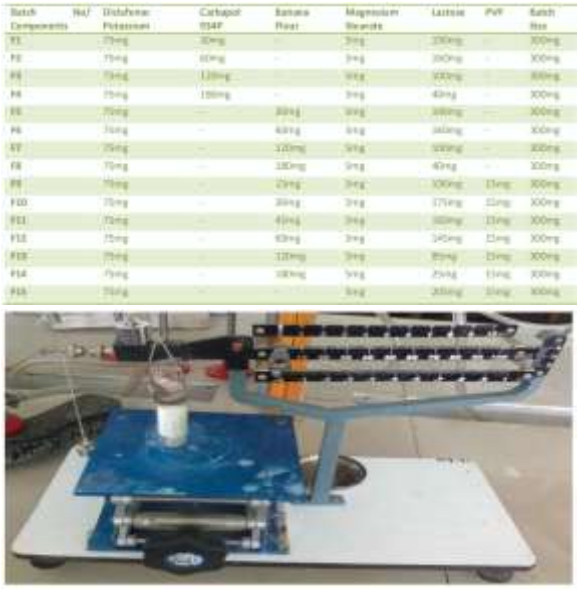

Figure 1: Fabrication of assembly for mucoadhesion

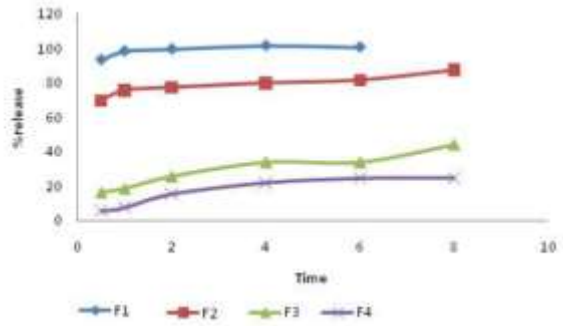

Figure 2: Dissolution Profile of Carbapol 934P

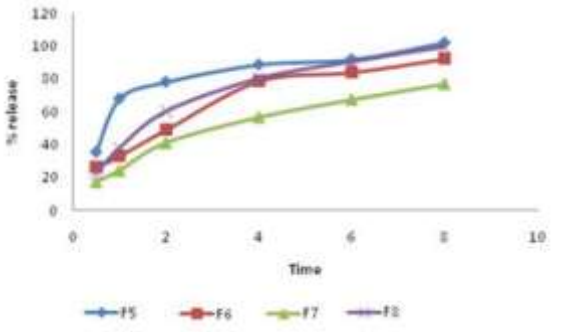

Figure 3: Dissolution Profile of Crude Banana Flour.

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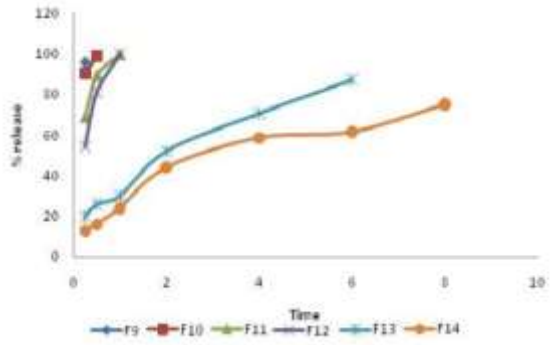

Figure 4: Dissolution Profile of Crude Banana Flour with PVP.

Table II: Physiochemical parameters of oral mucoadhesive tablets

Formulation code	Average weight (gram)	Hardness (Newton)	Friability	Thickness	Assay	Force of Mucoadhesion (Newton)
F1	0.2912 ± 0.01	±				
F2	0.3043 ± 0.01	±				
F3	0.3076 ± 0.01	±				
F4	0.3034 ± 0.01	±				
F5	0.2957 ± 0.01	±				
F6	0.3046 ± 0.01	±				
F7	0.2987 ± 0.01	±				
F8	0.2981 ± 0.01	±				
F9	0.3002 ± 0.01	±				
F10	0.3120 ± 0.01	±				
F11	0.3193 ± 0.01	±				
F12	0.3112 ± 0.01	±				
F13	0.3051 ± 0.01	±				
F14	0.3093 ± 0.01	±				
F15	0.3046 ± 0.01	±				

4. CONCLUSION

Banana flour was used to effectively create the Diclofenac potassium sustained release mucoadhesive tablets. The low mucin turnover rate of lectin, the polymer responsible for the mucoadhesive activity in bananas, has been reported (5,6,23,24). Thus, this discovery has opened the door to the idea of creating lectin-containing tablet formulations that may be administered to patients with altered mucin turnover rates in conditions such as ulcerative colitis, cystic fibrosis, and gastric ulcers in order to extend the tablet's retention period in the gastrointestinal tract.

Nonetheless, it was discovered that the mucoadhesive strength of the tablets containing banana flour was inferior than the tablets containing Carbapol 934P. It was discovered that the flour made from bananas has the binder quality. According to the research, a constant rise in disintegration time was shown with an increase in the concentration of banana flour. Therefore, this discovery may serve as a catalyst for the dawn of a new age in mucoadhesion and medicinal assistance in the years to come.

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