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FORMULATION AND EVALUATION OF FAST DISINTEGRATING TABLETS OF DICLOFENAC SODIUM USING TREATED BANANA POWDER

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ABSTRACT

The purpose of this research project was to prepare fast disintegrating tablets of Diclofenac sodium, an NSAID drug by direct compression method using natural superdisintegrant (treated banana powder) and evaluate their various in-vitro properties. Diclofenac sodium was chosen as the drug with an aim to develop fast disintegrating tablets by direct compression method, which disintegrates quickly and have a release of drug faster than conventional tablets. A natural superdisintegrant (treated banana powder) with different concentrations were used in the development of formulations by direct compression method. The prepared tablets were evaluated for pre and post compression parameters like angle of repose, bulk density, tapped density, drug content, wetting time, in-vitro disintegration time, in-vitro dissolution studies.

KEY WORDS: *Diclofenac sodium, treated banana powder, superdisintegrant, fast disintegrating tablet*

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INTRODUCTION

The fast disintegrating tablets (FDTs) have characteristic benefits in terms of patient compliance, rapid onset of action, increased bioavailability and good stability make these tablets popular as a dosage form of choice[1]. These tablets in contrast with conventional dosage form (tablets and capsules) take lesser time to dissolve (3-5 mins). The basic approach used in development of FDTs is the use of superdisintegrants. The major function of superdisintegrants is to oppose the efficiency of the tablet binder and physical forces that act under compression to structure of the tablet. Superdisintegrants are generally used at a low level in the dosage form, typically 1-10% by weight in relative to the total weight of the dosage unit. Diclofenac sodium was chosen as the drug with treated banana powder as natural superdisintegrants, with an aim to develop fast disintegrating tablets by direct compression method, which disintegrates quickly and have a release of drug faster than conventional tablets[2,3].

MATERIALS AND METHODS (10, 11)

Diclofenac sodium and other excipients were purchased from Medwin Chemicals Malapuram. Banana powder was purchased from Kasaragod. The purchased banana powder was allowed to swell for 3 days. The swollen residue was dried at room

temperature, and triturated well. It was then passed through sieve no. 100 to get treated banana powder.

Compatibility study of drug and excipients[5]

IR spectra of the physical mixture of Diclofenac sodium and natural super disintegrants were taken.

Preparation of powder blend:

Diclofenac sodium, super disintegrants, sublimating agents and all excipients were passed through mesh screen no: 100. The powder blend was prepared by thorough mixing of all ingredients except glidants. Glidants were later incorporated into the mixture before preparation of the tablets.

The physical mixture was subjected to direct compression using Rotary punching machine. Before tableting, the powder blend was subjected to preformulation studies.

PRE COMPRESSION STUDIES

1. Angle of repose

Angle of repose was determined using funnel method. The blend was poured through a funnel that can be raised vertically until a maximum cone height (h) was obtained. The studies were done for triplicate. Radius of the heap (r) was measured and the angle of repose (ɵ) was calculated using the formula

$$\theta = \tan^{-}(h/r)$$

2. Bulk density

The term bulk density (pb) refers to a measure used to describe the packing of particle. It is (gm/ml) and was determined by using a balance and measuring cylinder.

Fixed weight of pre sieved powder blend was poured into the measuring cylinder using a funnel.

Then the volume of the powder (Vb) was taken. Bulk density of the granules was calculated using following formula

Bulk Density =Weight of powder/ Volume of powder

3. Tapped density

Blend was tapped for a fixed (100) number of taps. The minimum volume (Vt) occupied in the cylinder and the weight (M) of the blend was measured. The tapped density was calculated using the formula

Tapped density = Weight of powder / Volume of powder

4. Compressibility Index

The compressibility index was determined by measuring both bulk density and tapped density of a powder. It is determined by the following equation

$$\text{Compressibility index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}}$$

5. Hausner's ratio

Hausner's ratio is an index of ease of powder flow. It is calculated by the following formula

Hausner's ratio = Tapped density / Bulk density

PREPARATION OF DICLOFENAC SODIUM FAST DISINTEGRATING TABLET BY DIRECT COMPRESSION METHOD[7]

Table-1 Formulations of Diclofenac sodium Fast Disintegrating tablets (F0-F5)

Sl No.	Ingredients	Formulation Code					
		F0	**F1**	**F2**	**F3**	**F4**	**F5**
1	Diclofenac sodium	0.0625g	0.0625g	0.0625g	0.0625g	0.0625g	0.0625g
2	Mannitol	0.16375g	0.15875g	0.15375g	0.14875g	0.14375g	0.13875g
3	Treated banana powder	0g	0.005g	0.01g	0.015g	0.02g	0.025g
4	Talc	0.005g	0.005g	0.005g	0.005g	0.005g	0.005g
5	Methyl carboxy cellulose	0.015g	0.015g	0.015g	0.015g	0.015g	0.015g
6	Magnesium stearate	0.00375g	0.00375g	0.00375g	0.00375g	0.00375g	0.00375g
7	Sodium saccharin	0.0005g	0.0005g	0.0005g	0.0005g	0.0005g	0.0005g

POST COMPRESSION STUDIES[8]

Thickness, Hardness, Friability, Weight variation test, Drug content of the prepared tablets were evaluated according to the procedure in IP 2007.

Wetting time

Five circular tissue papers of 10 cm diameter are placed in a petridish with a 10cm diameter. 10 ml of phosphate buffer 6 containing amaranth, a water soluble dye, is added to petridish. A tablet is carefully placed on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is noted as a wetting time. The test was done in triplicate.

Invitro Disintegration time

It was measured in 900 ml phosphate buffer pH 6 according to the USP 24 method without disc at 37 ± 0.5^0C temperature. The disintegration times of three individual tablets were recorded.

Water Absorption Ratio

In this test, initial weight of the tablet was noted before placing it on a Petri dish. After complete wetting, the wetted tablet was then weighed. The water absorption ratio, R, was determined using the equation,

$$R = 100 (Wa – Wb)/W b$$

In vitro Dissolution Study[5]

The dissolution test was performed using 900 ml of phosphate buffer of pH 6 at 37±0.5°C and 50 rpm. A sample (5 ml) of the solution is withdrawn from the dissolution apparatus at regular intervals of 30secs for 5mins. The samples are replaced with fresh dissolution medium of same quantity. The samples are filtered through a 0.45µ membrane filter. Absorbance of these solutions, after suitable dilutions are measured using PC Based Double Beam Spectrophotometer 2206 at 272nm. Cumulative percentage of drug release is calculated.

RESULTS AND DISCUSSION

Compatibility studies of drug and excipients

The IR Spectra of Diclofenac Sodium, the mixture of drug with polymer are given in the figure. All the samples were scanned over the wave number region 4000-400 cm^{-1} using KBr disk method. The selected formulation shows the characteristics peak similar to that obtained in the pure Diclofenac sodium indicating that there were no incompatibility between the drug and the excipients used (Fig-1).

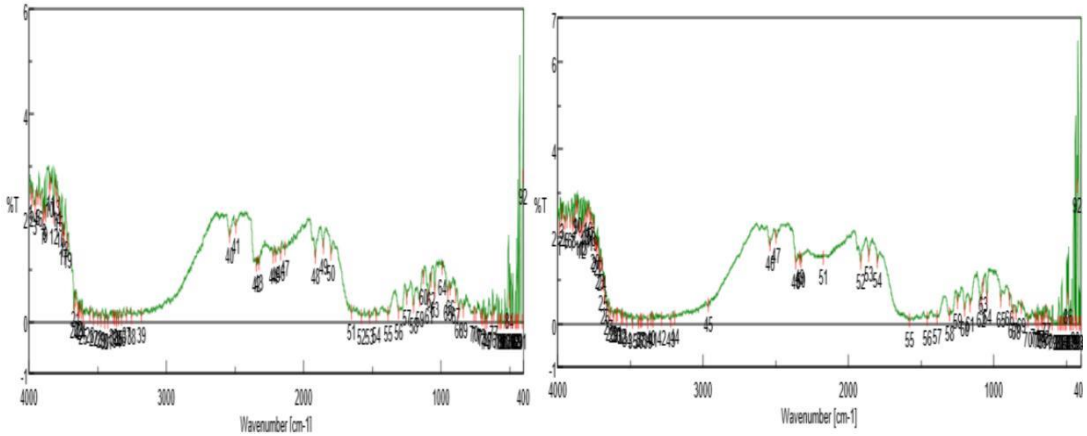

Fig-1 FTIR spectrum of Diclofenac Sodium and **Diclofenac Sodium + banana Powder**

From the IR spectrum it is clear that there were no incompatibility between the drug and the physical mixture used in the formulation of tablet.

POST COMPRESSION STUDY

Table-2 Post Compression Evaluation Parameters

Formulation code	**Hardness (kg/cm^2)**	**Thickness (cm)**	**Disintegration time(secs)**	**Friability (%)**	**Drug** Content (%)	**Wetting time (sec)**	**Water** Absorption ratio (%)	Weight variation on test (%)
F0	5±0.12	0.8±0.1	73±3.21	0.065	54±0.12	5.25±2.9	13.44±2.2	±15.56
F1	6±0.09	0.8±0.02	39.45±4.12	0.079	57±0.13	5.35±1.5	30.50±3.5	±10.99
F2	6±0.13	0.8±0.05	42.3±3.1	0.114	58±0.15	5.55±2.2	22.72±2.25	±17.94
F3	7±0.14	0.8±0.11	45.2±2.11	0.324	58±1.23	5.45±1.5	33.33±1.28	±4.30
F4	7±0.11	0.8±0.12	51.6±1.11	0.248	59±2.39	5.55±3.1	22.05±3.65	±8.65
F5	8±.12	0.8±0.08	53.85±3.5	0.316	60±3.45	5.65±3.2	35.25±4.29	±23.44

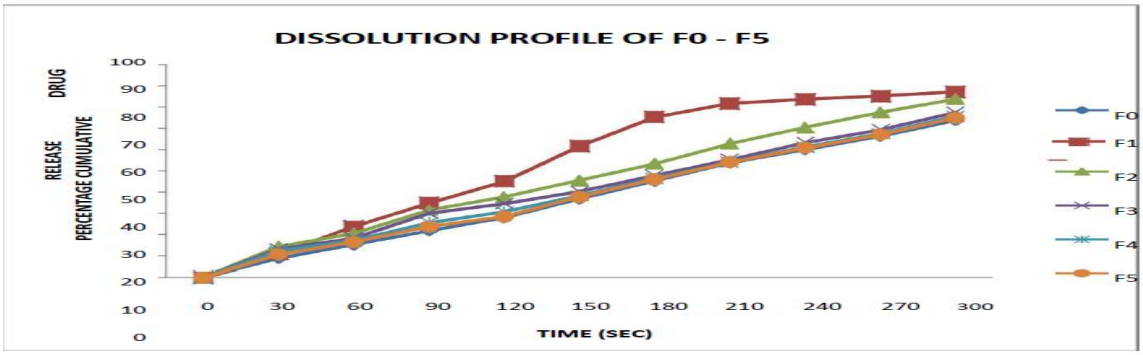

Fig-3 Cumulative percent drug release of tablets from formulations

Formulation development

Fast disintegrating tablets of Diclofenac Sodium in the present work were developed by direct compression technique with preliminary focus on *in vitro* disintegration time (DT) and dissolution profile, although other quality control parameters were evaluated. The direct compression method was for preparing tablets. This method requires a material that not only is free-flowing but also sufficiently cohesive to act as a binder. The direct compression excipients were chosen which had good flow and compression characteristics and prevented segregation of powders in the hopper and thereby helped in direct compression. Literature revealed that mannitol is used in direct-compression tablet applications, for which the granular and spray-dried forms are available, or in wet granulations. Granulations containing mannitol have the advantage of being dried easily. Directly compressible mannitol flows well and imparts improved flow properties to other materials. Hence, mannitol was preferred. This developmental approach suggested that there was improvement in *in vitro* disintegration time (DT) and dissolution profile.

Treated banana powder was chosen as superdisintegrant as it is a natural novel superdisintegrant. Its activity was found to be maximum at 10%w/w by doing a dummy FDT at a concentration range of 0-10%w/w.

Wetting Time

Wetting time is another important parameter related to water absorption ratio which needs to be assessed to give an insight into the disintegration properties of the tablets. Wetting time for all formulation batches showed wide variation in the range of 5.25 to 5.65 seconds.

***In vitro* disintegration time**

Disintegration is the first important step for drug absorption from a solid dosage form after oral administration. It was reported that tablet disintegration was affected by the particle size, the

degree of substitution, and extent of cross-linkage. An important factor affecting the disintegration is the tablet hardness and/or the compaction force. The hardness of the tablet has an influence on the disintegration time as it affects the porosity of the matrix and, accordingly, the ability of water to penetrate through the matrix.

In vitro disintegration time for all formulation batches showed wide variation in the range of 39 to 73 secs. This wide variation range was observed due to developmental changes in formulation to attain preliminary objectives.

***In vitro* Dissolution Study**

As discussed above, differences in the particle size generated in the disintegrated tablets could affect drug dissolution since breaking tablets into finer fragments may promote drug dissolution by providing larger total surface areas for drug dissolution to take place. F1 shows immediate drug release within 4 min.

Stability Studies

Stability studies for the developed formulation (F1) were carried out by storing for 30 days at accelerated conditions of temperature and humidity. After 30 days the formulation were evaluated for its fast disintegrating property. F1 shows the same drug release profile even after 30 days of accelerated studies.

CONCLUSION

From the studies the following conclusions can be drawn.Diclofenac sodium as anti-Inflammatory agents can be used to develop fast disintegrating tablets. The tablets prepared met the standard evaluation parameters with a slight deviation within the prescribed limits. The disintegration studies revealed that the tablet formulation prepared with treated banana powders as a natural super disintegrating agent in a concentration of 0.005g showed faster disintegration. Dissolution studies confirmed that tablets prepared with treated banana powders as a natural super disintegrating agent in a concentration of 0.005g showed faster drug release, within minutes.

Further it is advised that the same work should be confirmed for its therapeutic efficacy with the experimental and clinical trials.

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