

## Research Article

## Formulation and Evaluation of Diclofenac Sodium Dispersible Tablets Using Natural Substances As Disintegrant

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### ABSTRACT

Dispersible tablets are uncoated tablets that produce a uniform dispersion or suspension in water at room temperature without stirring. Due to decline in swallowing ability with age, many elderly patients complain that it is difficult to take medication in the form of tablets. The dispersible tablets allow dissolution or dispersion in water prior to administration. Dispersible tablets are easier to administer or swallow than capsules for pediatric, dysphasic patients, mentally ill, uncooperative and nauseated patients, those with conditions of motion sickness, sudden episodes of allergic attack or coughing. Some times it may be difficult to swallow conventional products due to unavailability of water.

In the present study dispersible tablets of diclofenac sodium, a low solubility drug were prepared using natural substances as disintegrant such as ispaghula husk powder in different concentration by direct compression method. Formulations were evaluated for the standards of dispersible tablets and were compared with marketed products. It was observed that all the formulations were acceptable with reasonable limits of standard required for dispersible tablets. The study reveals that natural gums used as disintegrants were effective in low concentration.

**Keywords:** dispersible tablets, diclofenac sodium, natural disintegrant, ispaghula husk powder.

### INTRODUCTION

Excipients play an important role in dosage forms such as tablets, capsules, lotions, suspensions, syrups and ointments. Recent trend towards the use of the vegetable and nontoxic products demand the replacement of synthetic with natural one. Mucilage as excipients is preferred for its non-toxic, low cost and free availability. They are utilized in manufacturing of different pharmaceutical dosage forms. They possess a variety of pharmaceutical properties, which includes binding, disintegrating, suspending, emulsifying and sustaining properties at different proportion in different pharmaceutical dosage forms.

Ispaghula husk consist of dried seeds of the plant known as plantago ovate. It contains mucilage, which is present in the epidermis of the seeds. Plantago ovate seed husk has high swellability and gives uniform and slightly viscous solution. Hence, it is used as a suspending agent.<sup>(1-3)</sup>

Recent advances in novel drug delivery systems (NDDS) aim to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for administration and to achieve

better patient compliance. One such approach is fast disintegrating tablets.

In present work, an attempt was made to evaluate the disintegrant property of Ispaghula husk and comparing its disintegrant property with the available marketed diclofenac sodium dispersible tablets.

Diclofenac sodium is aryl acid derivative. Its efficacy similar to naproxen. It inhibits PG synthesis. It has analgesic, anti-pyretic and anti-inflammatory activities. It is an inhibitor of cyclooxygenase. Its potency is substantially greater than that of indomethacin and naproxen.<sup>(4)</sup>

### MATERIAL AND METHODS

Diclofenac sodium was provided as a gift sample by J.B. Chemical, Mumbai. Ispaghula husk powder was provided by Prasad Traders Pusad authenticated by Agakar research institute, pune. All the materials used were of standard analytical grade.

## METHOD

### A) Preparation of Dispersible Tablet<sup>5</sup>

Dispersible tablets of Diclofenac sodium were prepared using direct compression method after incorporating disintegrant named as Isapgula husk powder in a concentration 5%, 10%, 15%. The composition of formulation is given in Table No.1.

Where Isapgula husk powder was used as disintegrates, lactose as a diluents, starch as a binder, aspartame as sweetener, purified talc as lubricant and magnesium stearate as glidant. The drug and other ingredients were mixed together and passed through sieve no. 22. Then compressed into tablets using 8mm round concave punches in a rotary tablet machines. (Rimek, RSB-4 mini press Cad mach, Ahmadabad, India).

### B) Evaluation of tablets<sup>6-10</sup>

#### Weight Variation

Randomly twenty tablets were selected after compression and the mean weight was determined. The sample tablets were weighted individually and the deviation from the mean weight was calculated (USPXXVII).

#### Drug Content

Twenty tablets were weighted and powdered. An amount of the powder equivalent to 20 mg of diclofenac sodium was dissolved in 100ml of pH 6.8 phosphate buffer, filtered, diluted suitably and formulations estimated for the drug content at 284 nm using UV-Visible spectrophotometer (UV 160 – Shimadzu, Japan).

#### Hardness

The crushing strength of the tablets was measured using a Monsanto hardness tester. Six tablets from each formulation batch were tested randomly and the average reading noted.

#### Friability

Twenty tablets were weighed and placed in a Roche Friabilator and rotated at 25 rpm for 4 min. The tablets were taken out, dedusted and reweighed. The percentage friability of the tablets was calculated by the formula,

$$\text{Percentage friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

#### In-vitro disintegration time

In vitro disintegration time was measured by placing a tablet in 100ml water maintained at

25°C. The time taken for the tablet to disintegrate completely was noted.

#### Wetting time

A piece of tissue paper (12cmx10.75cm) folded twice was placed in a Petri dish containing 6ml of water. A tablet was placed on the paper and the time taken for complete wetting of tablet was noted three tablets from each formulation were randomly selected and the average wetting time was noted.

#### C) Dissolution studies

Dissolution studies were performed using a dissolution test apparatus USP XXII (Basket assembly) at 100 rpm using 750 ml of acetate buffer (pH-4.0) and temperature was maintained at 37±0.50 throughout the study. Ten millimeter of the sample was withdrawn at a regular interval and replaced with an equal volume of phosphate buffer. Samples were filtered and drug content was estimated by UV spectrophotometer at 284 nm.

## RESULT AND DISCUSSION

The formulations of diclofenac sodium were prepared using powder of Isapgula as disintegrating agent in different ratio and compressed into tablets. Table 2 shows the results of all the formulated batches of tablets and marketed tablet. Figure 1 shows % drug release plot of all the formulated batches of tablets and marketed tablet. The hardness was maintained between 3.5-4.5Kg/cm<sup>2</sup> for all the formulations and the inclusion of Isapgula powder improved the tablet properties with respect to wetting time and *in-vitro* disintegration time. The *in-vitro* disintegration time of the tablets was found to be decreased with the increase in concentration of Isapgula powder. The formulation F3 was found to have similar disintegration property compared to marketed formulation. Weight variation and the drug content proved that all the tablets had good uniformity in drug content. The prepared tablets exhibits good friability values indicating that they can withstand the pressure during transportation and handling.

The study reveals that formulations prepared by using 15% Isapgula husk exhibited good dissolution and uniform dispersion characteristics necessary for dispersion tablets as compared to marketed disintegrating tablets of Diclofenac Sodium.

**CONCLUSION**

In the present study the disintegrating properties of the Isaphgula powder (*Plantago ovata*) had been studied in comparison with other commercially available marketed formulation. The natural disintegrant exhibits faster drug dissolution in comparison to marketed

formulation thereby helping in effectively used as disintegrants in tablet formulations.

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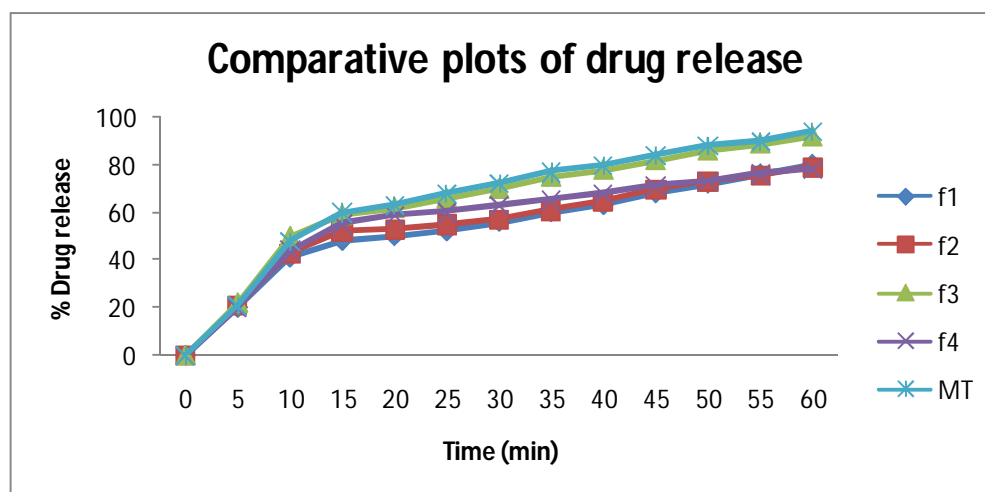
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**Table 1: Composition of different batches of Diclofenac Sodium Tablets**

Ingredient	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)
Diclofenac sodium	50	50	50	50
Isaphgula husk	5	10	15	20
Lactose	41	36	31	26
Magnesium stearate	0.5	0.5	0.5	0.5
Talc	1	1	1	1
Starch	0.5	0.5	0.5	0.5
Aspartame	2	2	2	2

**Table 2: Evaluation of Diclofenac sodium Tablets**

Formulation	Weight Variation (mg)	Drug content (%)	Hardness (Kg/cm <sup>2</sup> )	Friability (%)	Invitro Disintegration time (sec)	Wetting time (sec)
F1	101±2	99.2	4.4±0.2	0.30	35	9±1
F2	103±3	99.1	4.3±0.1	0.32	33	8±3
F3	101±1	99.3	4.1±0.2	0.33	29	8±2
F4	102±2	98.9	3.9±0.1	0.34	28	7±1
MT	101±1	99.4	4.2±0.1	0.32	30	7±2



**Fig. 1: Drug release plot of Isaphgula containing diclofenac sodium dispersible tablets**

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