RESEARCH ARTICLE

Preparation and characterization of matrix tablet using natural gum extracted from *Mangifera indica*

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ABSTRACT

Sustained release tablets of diclofenac sodium were fabricated using *Mangifera indica* (mango) fruit gum, hydroxypropyl methylcellulose (HPMC), and carbopol. Diclofenac sodium was used as model drug. Natural gums are economic, easily available and found useful as tablet binder. The tablets were evaluated for physical characteristics such as hardness, weight variation, friability, and drug content. *In vitro* release of drug was performed for 12 h. All the physical characters of the fabricated tablet were within acceptable limits. The tablet with HPMC (Batch B-I) and carbopol (Batch C-I) exhibited greater drug content than those with mango gum and other batches of HPMC and carbopol. A better, sustained drug release (50.65%) was obtained with the matrix tablet (Batch C-III) made up of the carbopol than with the mango gum and HPMC. In conclusion, mango gum could be used well as a binding agent in the formulation of tablet dosage forms.

Keywords: Carbopol, diclofenac sodium, hydroxypropyl methylcellulose, *Mangifera indica* gum, tablet binder

Introduction

Dosage forms are designed to reduce the dosing frequency of drugs by altering the rate of drug absorption. For the designing of oral controlled release administration, continuous research is going on in the area of utilization of natural occurring biocompatible polymeric material. There are several advantages of using natural plant based excipients, *viz.*, low cost, natural origin, free from side effects, biocompatible, bioacceptable, renewable source; eco-friendly processing, and better patient tolerance.[1]

Binder is a pharmaceutical excipient which is usually used in tablet formulation to impact cohesion on the powder mix, and hence, it improves the flow properties on the granules. Basically, binders act by causing powder aggregation thereby form granules by the process of granulation.[2] Since many centuries, the mango tree (*Mangifera indica*, Family: Anacardiaceae) have been a primary part of life in India. Its part (bark, leaves, root, kernel, seed, and fruit) serves for a medicinal purpose, such as diuretic, astringent, aphthous stomatitis, diabetes, asthma, diarrhea, urethritis, dysentery, scabies, and other parasitic skin diseases.

Diclofenac sodium [2-[(2, 6-dichlorophenyl) amino] benzene acetic acid monosodium salt] is a drug which is sparingly soluble in water and freely soluble in organic solvents like methanol. It is classified as nonsteroidal anti-inflammatory drugs and therapeutically antiarthritic and anti-inflammatory. Pharmacokinetic profile of diclofenac sodium is after oral administration, diclofenac is rapidly and almost completely absorbed. Absorption is delayed by food. It is highly protein bound. Diclofenac undergoes first-pass metabolism, with 60% of unchanged drug reaching systemic circulation. About 40% to 60% is excreted in the urine; the balance is excreted in the bile.[3]

Therefore, the aim of this study is to evaluate the *M. indica* gum as a tablet binder employing diclofenac sodium as a model drug.

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Materials and Methods

Materials

Diclofenac sodium was purchased from Yarrow Chem Products, Mumbai, India. *M. indica* (family: Anacardiaceae) is a plant that is widely grown and widely distributed in all areas of India. The gum is a polysaccharide polymer obtained from the stem bark of the plant. Hydroxypropyl methylcellulose (HPMC), microcrystalline cellulose, magnesium stearate, talc, and potassium hydrogen

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phthalate were purchased from CDH, New Delhi. Other materials used were of analytical grade and procured from commercial sources.

Methodology

Preparation of granules

Wet granulation method was used to prepare granules of the drug. The formulation was developed using diclofenac sodium as model drug. The binder concentrations used were 2.5, 5.0, and 7.5% w/w (Table 1). All ingredients were dry mixed manually in mortar and water is used as granulating fluid. The wet mass was granulated by passing them manually through a number 12 mesh sieve. Granules were dried at 50°C in hot air oven and again received through number 16 mesh sieve no. 4.[4]

Evaluation of diclofenac sodium SR matrix tablets

Weight variation

To study weight variation, 20 tablets of each formulation were weighed using an electronic balance (Sartorius India, limited), and the test was carried according to the Indian Pharmacopoeia.[5]

Drug content

Five tablets were weighed individually, and the drug was extracted in pH 6.8 phosphate buffer. The drug content was determined according to the IP.[6]

Hardness and friability

The hardness and friability were determined using the Monsanto hardness tester and the friability testing apparatus (Indian equipment, Mumbai, India), respectively.[7]

In vitro drug release studies

The *in vitro* dissolution studies of the developed formulation (SR) were carried out using USP apparatus type II (Electro Lab, Mumbai, India) at 50 rpm. The dissolution medium consisted of 900 ml of phosphate buffer pH 7.2 from 0 to 10 h for the developed sustained release formulation maintained at 37°C ± 0.5°C. The drug release at different time intervals was measured by ultraviolet-visible spectrophotometer (Shimadzu) at specific λ_{max}.[8]

Table 1: Formulation table for diclofenac sodium loaded matrix tablet

Ingredients (mg/tablet)	Formulations		
	F1	F2	F3
Diclofenac sodium (mg)	100	100	100
HPMC (mg)	40	60	80
Mango gum (%)	2.0	4.0	6.0
Microcrystalline cellulose (mg)	54	34	14
Magnesium stearate (mg)	4	4	4
Talc (mg)	2	2	2

HPMC: Hydroxypropyl methylcellulose

Results and Discussion

All the tablets were prepared by wet granulation method, and the compositions of all the formulations were given in Table 1. The formulations were prepared by taking different concentrations of mango gum. In all the formulations, 100 mg of diclofenac sodium was incorporated, and final weight was made up to 200 mg. The formulated tablets were evaluated for weight variation, drug content, hardness, friability, and *in vitro* drug release profiles. The average weight of tablets was found to be within 199.28-201.86 mg. Three batches of tablets of each binder concentration were prepared. The prepared tablets were evaluated for drug content, hardness, friability, and disintegration time. The results are indicated in Table 2. All batches of tablets exhibited a good uniformity in content. The tablet hardness and disintegration time increased with increase in binder concentration. The friability values decreased with increase in binder concentration. All the evaluation parameters were found to be within the pharmacopeial limits at binder concentrations 2.0-6.0% w/w.

In vitro drug release profile

The *in vitro* drug release profile of the batches with different polymer levels is given in Table 2 and Figure 1. The rate of *in vitro* drug release was found to be decreased as the polymers level was increased. The batches formulated with 6.0% of the gum exhibited slower release when compared to other batches. Therefore, 6% of polymer level was found to be ideal concentration for the formulation of sustained release matrix tablets.

Conclusion

The formulated matrix tablets of diclofenac sodium using natural polymer mango gum, HPMC, and carbopol were capable of exhibiting sustained release properties. They are thus capable of reducing the dose, minimize the blood level oscillations, dose-related adverse effects, and cost thus ultimately improve the patient compliance. The evaluation of tablets reveals that the binding efficacy of tablets prepared using mango gum is of great significance. Therefore, it is concluded that mango gum could be used well as a binding agent in the formulation of tablet dosage forms.

Table 2: Evaluation parameters for matrix tablet formulations

Formulations	Average weight (mg)	Drug content	Hardness (kg/cm^2)	Friability (%)	Cumulative (%) *in vitro* drug release
F1	199.28	98.07	5.3	0.87	89.6
F2	200.93	97.49	5.5	0.75	92.3
F3	201.86	98.35	5.9	0.35	94.7

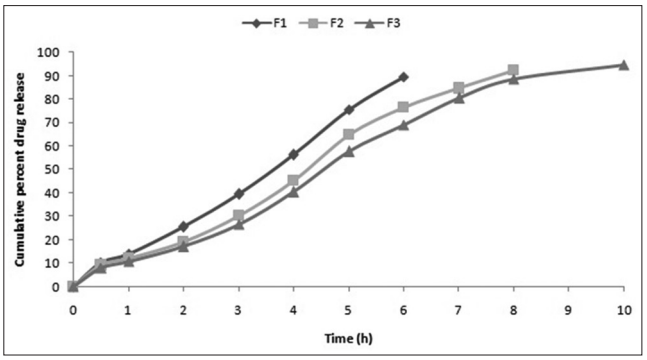

Figure 1: Cumulative *in vitro* drug release profile of matrix tablet formulations

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