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Formulation and Assessment of Floating Sodium Alginate Beads of Analgesic Drug

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ABSTRACT
The main aim of this present research is to develop gastro retentive sustain release alginate beads of diclofenac sodium by ionotropic gelation method. Preparation of floating bead of diclofenac sodium was made by the dispersion of diclofenac sodium together with $CaCl_2$ into solution of sodium alginate. In this study an attempt was done to prepare a controlled release sodium alginate beads comprised of diclofenac sodium drug. Produced beads were evaluated for encapsulation efficiency, swelling index, in- vitro dissolution studies etc.

Keywords: Diclofenac Sodium, Gastro-Retentive, Swelling Index, Floating Beads

I. INTRODUCTION

In the current scenario of delivering the therapeutic agents to the target site requires an efficient drug delivery carrier [1-9] which can deliver the drug only to the site of interest. This is basically presented as targeted area. The concept of drug delivery by means of alginate beads has been revolutionized with the advancement in the drug delivery systems and it offers a sustained release in a controlled manner to the desired area of effect. The drug bioavailability of pharmaceutical dosage forms is influenced by various factors including gastric residence time (GRT) [10]. The gastric emptying process from the stomach to small intestine takes a few minute and lasts upto 12 hours [11]. This variability may even leads to an unpredictable bioavailability of an orally administered dosage form. The relatively short gastric emptying time leads to an incomplete release of drug from its dosage form. Floating drug delivery system (FDDS) is one of gastro-retentive dosage forms that could prolong GRT to obtain sufficient drug bioavailability [12-13]. FDDS have a lower density than gastric fluids and thus remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. In the present research work FDDS employed diclofenac sodium dispersed in an alginate matrix and calcium chloride (as cross linking agent). Alginate is a polysaccharide which contains varying amounts of 1,4'-linked β-D- mannuronic acid, α-L-glucouronic acid residues. As biocompatible and biodegradable biopolymer, it forms a bio-adhesive and stable gel with divalent cations [14]. These properties have enabled wide spread use of sodium alginate in sustained release of drugs. In acidic media alginate beads are stable and easily depredated in alkaline media.

In current study diclofenac sodium, an acid insoluble non steroidal anti-inflammatory drug was used as model drug. This drug requires multiple dosing due to its short biological half life and it may lead to fluctuation in the plasma drug concentration and may also fail to release the drug at the desired amount which often results in poor patient compliance and inefficient therapy.

II. MATERIALS AND METHODOLOGY

Diclofenac sodium (API) was obtained as sample from Medirose drugs and Pharmaceuticals Ltd. Sodium alginate, calcium chloride, calcium carbonate of standard grade was purchased from the local market. All other reagents used in the formulation were of analytical grades as specified. The beads are being formulated as specified below [15].

1. Firstly 100 ml water was taken in a beaker, add 2%w/v sodium alginate in 100ml of water and agitate it gently.
2. Diclofenac sodium, calcium carbonate were dispersed in alginate solution under constant stirring for uniform mixing.
3. The resultant dispersion was dropped through a 22 guage needle into 100ml of 20%v/v acetic acid at room temperature.
4. Obtained beads are allowed to remain dispersed in a solution for 15 minutes.

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5. Beads were filtered and subsequently oven dried for 60^0C for 4 hours.
6. Dried beads are then placed in the Desiccators'.

Table 1 Formulations Design Of Sodium Alginate Beads

Formulation code	Sodium alginate (gm)	Drug (gm)	$CaCO_3$ (gm)	$CaCl_2$ %
F_1	2.0	1.0	1.4	1
F_2	2.4	1.0	1.4	1
F_3	3.2	1.0	1.4	1
F_4	3.4	1.0	1.4	1
F_5	3.9	1.0	1.4	1

Evaluation Of Drug Loaded Sodium Alginate Beads

1. Determination of drug encapsulation: Weighed out 50 mg of beads from each formulation (F1-F5) in a mortar pestle. Beads were crushed and dissolved the crushed material in 100 ml of phosphate buffer at PH 7.4. Agitation of this solution was done on shaker at 200rpm for 2hours. Filtration of resultant dispersion was carried out which was further analyzed using UV spectrophotometer at 276nm. The encapsulation efficiency was determined by following formula

Encapsulation efficiency= (AQ/TQ) × 100

Where,

AQ is actual drug content of beads

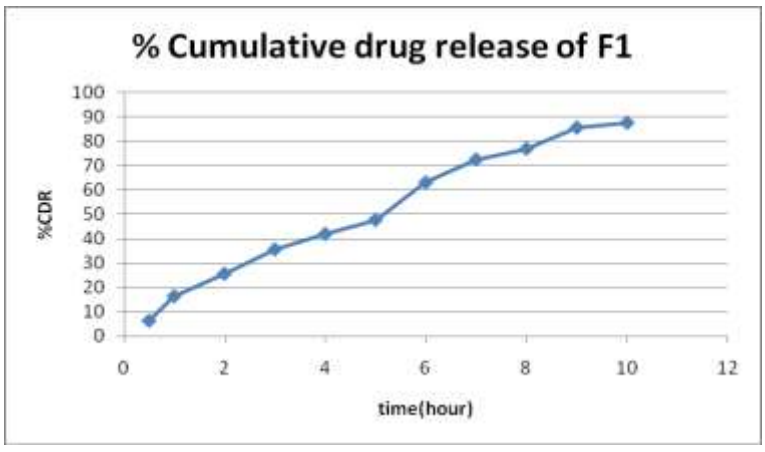
TQ is theoretical quantity of drug present in the beads

2. Bouyancy Test

The obtained beads were studied for buoyancy and floating time using paddle type USP Apparatus II. 10 Beads of each batch were placed in 900ml of 0.1NHCl having pH: 1.2 containing tween 80 in 0.02%w/v concentration. This was being further agitated at 50 rpm with temperature maintained at 37^0C.

3. In- Vitro Dissolution Studies

Accurately weighed formulated floating beads were taken into 900ml of 0.1 N HCl buffer at 37^0C temperature. Further, it was stirred at speed of 50 rpm. At half hour of time interval, a 10ml of aliquot of sample was taken out, volume was replaced with an equivalent amount of dissolution medium at 37^0C temperature. Filtered sample was than analysed at 276nm using UV visible spectrophotometer against 0.1 N HCl buffer with pH value 1.2 taken as a blank.



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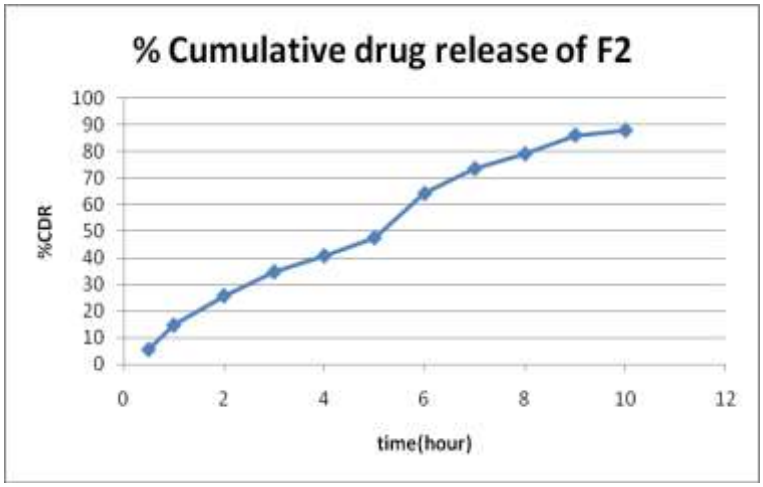

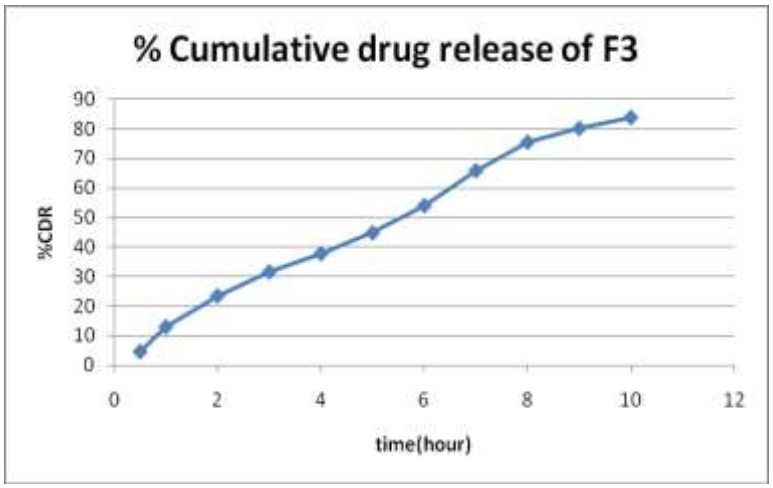

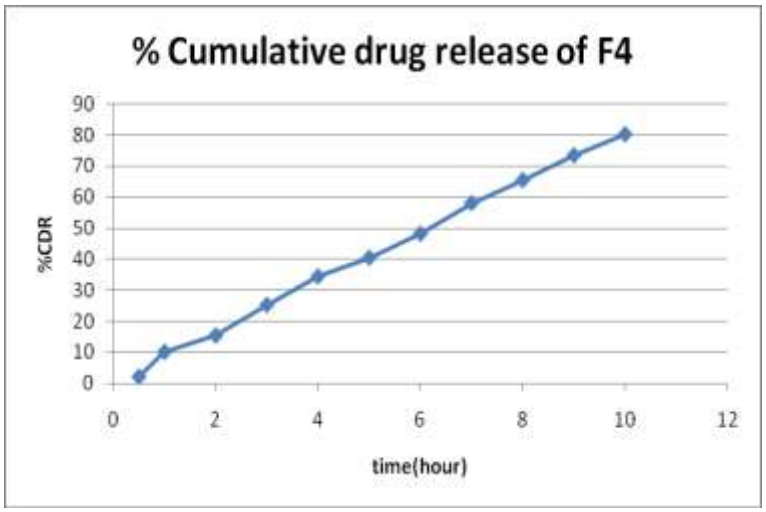

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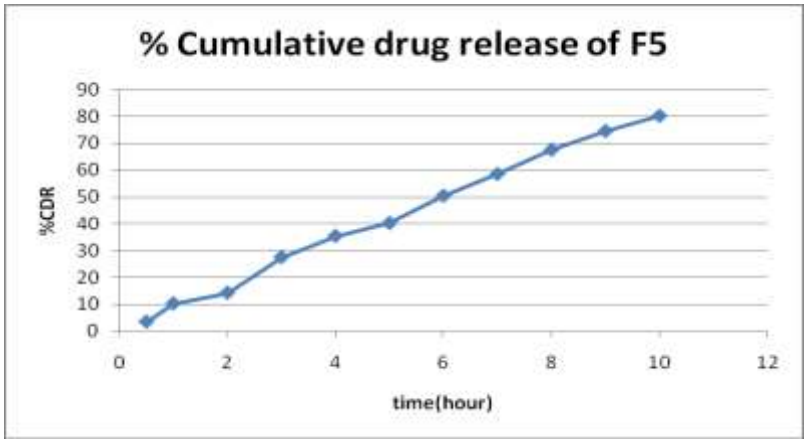

4. Swelling Index

Different solutions such as distilled water, buffer solution of different pH were taken and alginate beads were kept in wire basket and kept in above solution. Allowed it to swell at 37^0C temperature, weight variation is observed before and after swelling by taking weight periodically, wipes off using filter paper.

5. Particle Size Determination

To determine the particle size microspheres (50mg) were suspended in distilled water (5ml) containing 2%w/v of tween 20 and tween 80, to prevent microspheres aggregation, above suspension is sonicated in water bath and particle size is expressed as volume mean diameter in micrometer.

Table 2 Evaluation of the Formulated Beads

Formulation Code	Drug Entrapment (%)	Buoyancy time (hr)	Swelling Index	Particle Size(mm)	Particle Shape
F1	58	8.0	0.72	1	Spherical
F2	67	8.3	0.78	1	Spherical
F3	71	8.7	0.80	1.1	Spherical
F4	75	9.5	0.83	1.3	Spherical
F5	78	10	0.85	1.5	Spherical

III. CONCLUSION:

The present study presented that the formulated beads have potential as an oral sustained release dosage form for diclofenac sodium. This can provide prolonged pain relief and improved patient compliance. Further, formulation F5 is considered to be the best with maximum buoyancy as well as drug entrapment value. Moreover, some biopolymers can also be included in the formulation to enhance its bioavailability in the future.

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