

STUDY OF IN-VITRO DRUG RELEASE OF DICLOFENAC MICROSPHERE S WITH DIFFERENT POLYMERS

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ABSTRACT

This research aims to develop diclofenac sodium microspheres using sodium alginate and other polymers such as ethyl cellulose, eudragit and HPMC. The microspheres were prepared using the ionotropic gelation method. The polymer “concentrations were varied to study their effect on the in-vitro drug release of the microspheres. The microspheres followed zero order kinetics and had a drug release pattern that was divided into different ranges.

KEYWORDS: Diclofenac Sodium, Sodium alginate, Methylcellulose, Eudragit, Ionotropic gelation technique.

1. INTRODUCTION

Microspheres are in essence empty particles with a spherical shape. Because of this, the terms microspheres and microcapsules are used interchangeably. Other related terms include beads and microbeads. Morphology-wise rigid particles can also be spherical. Once microspheres are dried, they form free-flowing powders. Ideally, they are composed of proteins or synthetic polymers that are biodegradable, and their size is less than 200 μm . Solid, biodegradable microspheres that contain a drug dispersed or dissolved throughout the particle matrix can be used for controlled drug release. Recently, there has been a surge of interest in using these microspheres for the controlled release of drugs as well as for targeting drugs, especially anti-cancer drugs to tumors.^[1]

2. MATERIALS AND METHODOLOGY

Diclofenac sodium, Sodium alginate, Sodium Carboxy Methyl Cellulose, Hydroxy Propyl Methyl Cellulose, Polyvinyl Pyrrolidone K-30, Calcium chloride.

2.2. Formulation of Microspheres

In this study, microspheres of Diclofenac sodium were prepared using the ionotropic gelation technique. Three different types of microspheres were formed by combining sodium alginate with other polymers such as sodium CMC, HPMC, PVP K30, and Calcium Chloride as counter ions.

Ionotropic gelation technique

Diclofenac microspheres were prepared by the ionotropic gelation technique. This involves the reaction of sodium alginate with polyatomic ions, in this case calcium, to form calcium alginate hydrogel. To prepare the polymer suspension, sodium alginate was dissolved in distilled water (100 mL) and stirred until the polymer was completely dissolved. The drug was then added to the polymer solution and stirred until a viscous drug suspension was formed. A 22G needle was used to mix the drug suspension with an aqueous solution of 5% (w/v) calcium chloride. While stirring the calcium chloride solution at 200 rpm, the suspension was slowly added. The suspended microspheres in calcium chloride were left for 30 minutes to allow the curing reaction to

complete. The microspheres were then decanted and washed several times with distilled water to remove calcium impurities.

Table no 1: Formulation of Diclofenac sodium microspheres.

Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)	F7 (mg)	F8 (mg)	F9 (mg)
Diclofenac sodium	100	100	100	100	100	100	100	100	100
Sodium alginate	1000	2000	3000	1000	2000	3000	1000	2000	3000
Sodium CMC	100	200	300	-	-	-	-	-	-
HPMC	-	-	-	100	200	300	-	-	-
PVP K30	-	-	-	-	-	-	100	200	300
Calcium chloride	4000	4000	4000	4000	4000	4000	4000	4000	4000
Water	Q. S.	Q. S.	Q. S.	Q. S.	Q. S.	Q. S.	Q. S.	Q. S.	Q. S.

2.3 Preparation of Microspheres

The ionotropic gelation method was used to produce the diclofenac microspheres. This method involves the reaction of sodium alginate with polyvalent ions, such as calcium, to form a hydrogel of calcium alginate. There have been a total of 9 formulations of Diclofenac sodium, prepared using 3 types of polymers, namely Sodium CMC, HPMC, PVP K30, and different concentrations. To begin, a homogenous solution was formed by dissolving 1000mg, 2000mg, and 3000mg of sodium alginate polymer in 100ml of distilled water with continuous stirring, and was allowed to gel. Once the gel matrix was formed, drug and polymer in the ratio of 1:1, 1:2 and 1:3 was added to the sodium alginate solution.

3. EVALUATION OBTAINED MICROSPHERES

3.1 In-vitro drug release studies: (13,18)

Diclofenac sodium microspheres were packed in baskets lined with 100 mesh nylon cloth to prevent bead loss, and dissolution studies were conducted in 6.8 pH phosphate buffer using the USP I basket dissolution

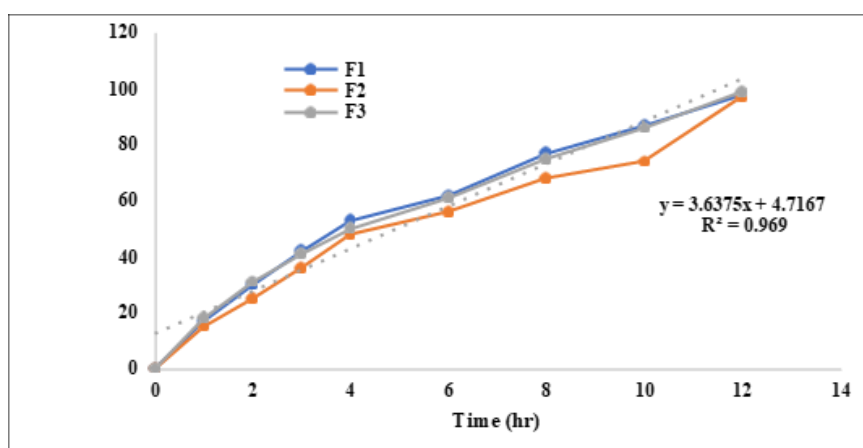
apparatus. The baskets were agitated at 50 rpm in 900 ml of phosphate buffer dissolution medium. Continuous sampling was done for 12 hours. The sink condition was maintained by replacing the collected samples with fresh phosphate buffer solution at regular intervals. The absorbance of the sampled buffer was measured, and the percentage cumulative drug release was calculated using the formula given below.

$\% \text{ CDR} = \text{Amount of drug released} / \text{Amount of drug loaded} \times 100$

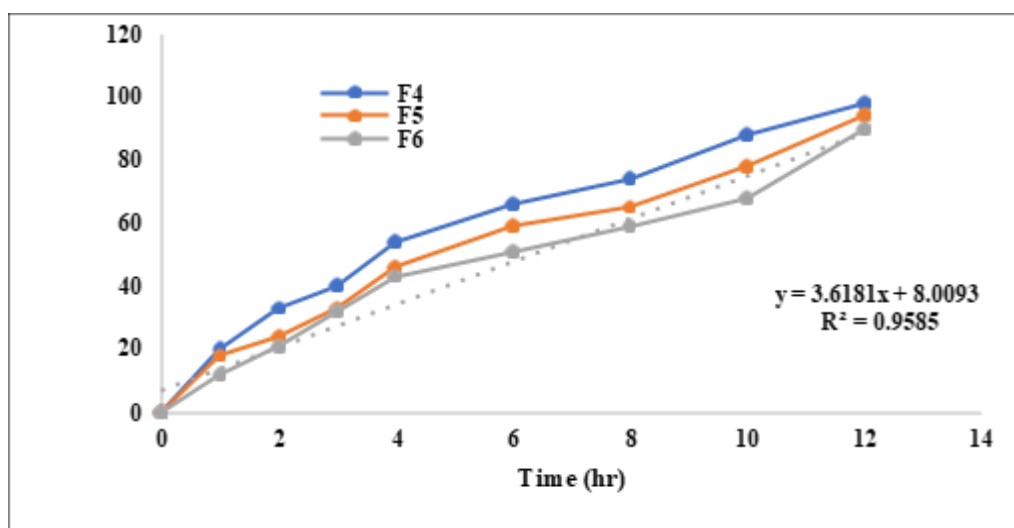
4. RESULTS AND DISCUSSION

4.1 In-vitro drug release studies

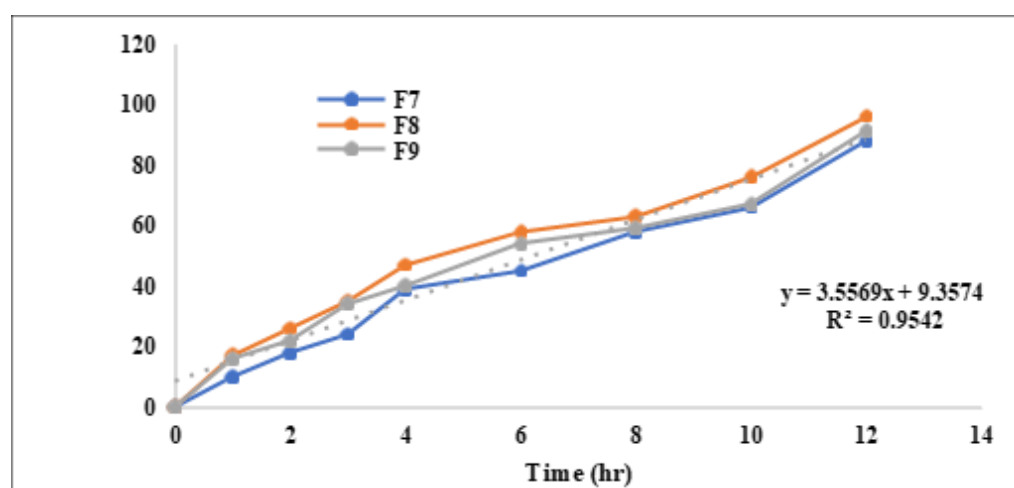
Time versus % CDR graphs were made for all formulations and are shown in Figure 6. The drug release was controlled and sustained for 12 hours with some formulations based on the nature of sodium alginate and the drug to polymer ratio. Of the formulations studied, F3 was able to sustain a 99% drug release over 12 hours. The higher the concentration of sodium alginate, the lower the amount of drug released.



[a]



[b]



[c]

Figure 6: (a) In-vitro drug release of F1-F3, (b) In-vitro drug release of F4-F5, (c) In-vitro drug release of F6-F9.

CONCLUSION

The objective of this work was to develop Sustained Release Microspheres of Diclofenac Sodium.

These microspheres are used in the treatment of rheumatoid arthritis. The ionotropic gelation method was used to formulate the microspheres with sodium CMC, HPMC, and PVP K30 as the retarding polymers. The analysis of percentage yield, particle size, entrapment efficiency, moisture content, and swelling index was conducted. The morphology of the microspheres was determined by SEM. Further, FTIR analysis was conducted to validate the drug-polymer interaction.

A higher percentage yield and entrapment efficiency were observed with sodium alginate microspheres. The nature of the polymer, concentration, stirring speed, and the type of combination of polymers used were the determining factors for particle size, entrapment efficiency and yield.

Decreasing the ratio of polymer to drug causes more

drug to be released. Increasing the density of the polymer matrix leads to slower rates of drug release. The swelling control mechanism governs the drug release profile. Phosphate buffer solution was used to conduct in-vitro drug release studies. The F3 formulation released the highest amount of drug, at 99%. The order of kinetics was determined, and the Zero order Kinetic model was able to fit the drug release rate with a regression coefficient value of 0.97. From the above analysis, it was concluded that the best formulation was the microspheres containing Sodium CMC and 3% Sodium alginate, which enabled a 99% release of the drug within 12 hours. More studies are needed on Na alginate and other sustained release polymers with different concentrations of calcium chloride.

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