



FORMULATION AND CHARACTERIZATION OF ACECLOFENAC LOADED STARCH MICROSPHERE

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ABSTRACT

Microspheres are a new category of novel drug delivery system which targets to increase the bioavailability and is formulated expediently to obtain prolonged or controlled drug delivery system in the body. Aceclofenac; a non steroidal anti inflammatory drug, is used to treat hurting rheumatic conditions such as osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. It eases pain and reduces inflammation at various sites. Aceclofenac acts by blocking the effect of chemical mediators called cyclo-oxygenase (COX) enzymes which are released at inflamed regions. The aim of this research was to formulate Aceclofenac loaded starch microspheres and evaluate its in vitro properties to enhance the bioavailability of aceclofenac tablet. Aceclofenac loaded starch microspheres were prepared using emulsion cross linking method. Aceclofenac microspheres loaded with starch polymer were characterized, evaluated and it was found to influence all the parameters. The microspheres prepared showed great entrapment efficiency. *In vitro* release of all prepared polymeric formulations was quite good.

Keywords: Aceclofenac, Inflammation, Microsphere, Cross linking method, Starch.

1. INTRODUCTION

Aceclofenac is widely used potent analgesic and anti-inflammatory drug. The drug is analogous to indomethacin and diclofenac but due to its preferential COX-2 blockade activity, better safety and less side effects on gastrointestinal tract and cardiovascular system, aceclofenac is used mostly for treatment of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis [1]. It is a phenyl acetic acid derivative, administered orally, dosing frequency of 2 or 3 times a day at a dose of 100 mg due to its short biological half life of 3-4 hr. Modified release or sustained release preparations of aceclofenac can be formulated to reduce the dosing frequency and improve patient compliance [2, 3]. For prolonging the drug release parameter, the widely and useful method is 'microencapsulation' which is helpful in reducing the adverse effects also if any. Microspheres developed through sustained release dosage forms are in demand now days due to reduced dosage of drug, reduced side effects [4]. Emulsion cross linking method can be used for preparing microspheres for water insoluble drug and polymer. In this study

aceclofenac microspheres were prepared by solvent evaporation technique using Eudragit S100 as a delayed release agent. The prepared microspheres were evaluated for drug content, particle size, shape and surface morphology, drug entrapment efficiency, DSC and invitro drug release profile of the drug [5].

2. MATERIAL AND METHOD

2.1. Material

Aceclofenac drug was received from Cadila Health Care Pvt. Ltd. Ahmedabad as a gift sample. Starch, Span 85, acetone, Eudragit S-100 and light liquid paraffin was purchased from Central Drug House Pvt. Ltd. All the other reagents used during the whole experiment were of analytical grade.

2.2. Methods

2.2.1. Method of preparation of starch microspheres

Starch microspheres were prepared by emulsion cross linking method. For each batch, the aqueous phase was prepared by dissolving 8gm of soluble starch in 12 gm of 2 M NaOH solution through mechanical stirring. The

aqueous phase was pre emulsified in 100 ml of cyclohexane-chloroform mixture ratio 4:1 (v/v) containing 0.5% (v/v) of span 60 [5]. The emulsion was continuously homogenized by high speed mechanical stirring for 3 min. Sodium Tri Meta Phosphate (STMP) was added in a suitable amount and added under stirring at 1000 rpm. The process of stirring was maintained continuously at 40°C for 18h. Microspheres formed were isolated by centrifugation. It was washed twice with cyclohexane and distilled water. The prepared microspheres were freeze dried and kept in an airtight closed container [6, 7].

2.2.2. Microsphere coating by Eudragit S-100

Eudragit polymer was coated on the surface of prepared starch microspheres. Coating solution (5%) was prepared by dissolving Eudragit S 100 in 10 ml of mixture of acetone and ethanol in the ratio 1:1. 50 mg of prepared starch microsphere was dispersed in organic phase and poured in 70 ml of light liquid paraffin which contained 1%w/v span 85. It was stirred using mechanical stirrer at 1000 rpm at room temperature for 3 hrs to allow the evaporation of solvent. At the end, the coated microspheres were collected by centrifugation process, washed with solvent n-hexane, freeze dried overnight and was kept in airtight container for further studies [5].

2.2.3. Evaluation

2.2.3.1. Particle size measurement

Particle size and its size distribution of prepared microsphere formulation were measured using an optical microscope. Calibrated ocular micrometer was used to measure the particle size and mean particle size was calculated. Average particle size was expressed in mean volume diameter in micrometers [6].

2.2.3.2. Shape and surface morphology

Prepared microspheres were suspended in water and a drop of it was placed on a glass slide, it was then covered with a cover slip and examined under optical microscope for their shape. Surface morphology was examined under Scanning Electron Microscope (SEM), samples for SEM analysis were prepared by placing the microspheres powder on a adhesive tape which was stuck to an aluminium stub. The sample was placed and randomly scanning was done and at good resolution better photomicrographs were taken [7].

2.2.3.3. Drug entrapment efficiency

Prepared microspheres (100 mg) were triturated with ethanol and distilled water and the mix was transferred

to 50 ml volumetric flask, mixed well and volume was made upto 10 ml. The mix was kept aside for 12 hrs. It was then filtered using membrane filter (0.45 µm) and absorbance was checked at 275nm for measuring the drug content in it. Drug entrapment efficiency was calculated by the formula: [8]

$$\text{Entrapment efficiency} = \{(\text{Estimated \% DrugContent})/(\text{Theoretical \% DrugContent})\} \times 100$$

2.2.3.4. Percentage yield

Prepared microspheres were weighed and percentage yield was calculated by [8, 9].

$$\% \text{Yield} = [\text{Weight of microspheres}/\text{weight of drug} + \text{polymer}] \times 100$$

2.2.3.5. Differential scanning calorimetry

Differential Scanning Calorimetry (DSC) studies were performed of the drug polymeric mixture (aceclofenac and starch {1:1}), blank and drug (aceclofenac) loaded starch microspheres. The samples were heated at a temperature between 30°C to 350°C at the heating rate of 10°C/min and nitrogen gas flow rate of 20ml/min. This study was performed on JADE DSC instrument type Pyris 6 DSC with software version 9.0.1.0174 [10] and thermograms were obtained.

2.2.3.6. In-vitro drug release study

In vitro release studies of prepared microspheres were carried out in simulated gastric fluids. 100 mg microspheres were weighed and gently spread over 900ml of freshly prepared dissolution medium. The dissolution apparatus was rotated at 37±0.5°C. The simulation of GI transit was achieved by altering the pH of dissolution medium at different time intervals. pH was maintained at 1.2 for 2 hrs using 0.1 N HCL. For adjusting the pH to 6.8 KH₂PO₄ (1.6 g) and Na₂HPO₄ (2.1 g) were added with 0.1 M NaOH and release study was continued further for 2 hrs. After 4 hrs, pH of dissolution medium was adjusted to 7.4 with 0.1 M NaOH and maintained up to 24 hrs. Later the medium was filtered through membrane filter (0.45µm) and residue on filter was added immediately to next medium [10, 11]. At various time intervals, 5 ml sample was withdrawn from the medium using a glass pipette and drug release was analyzed using a spectrophotometer at 261nm. Concentration of aceclofenac was calculated using regression equation of calibration curve obtained [6, 12, 13].

3. RESULTS AND DISCUSSION

Starch loaded drug microspheres for sustained release serve as the potential to be an efficient, safe, viable and

cost effective system for administration of aceclofenac for their biocompatibility and suitability of oral delivery. The microspheres were prepared using emulsion cross linking method. The prepared microspheres were coated by Eudragit S-100. On increasing the polymer concentration from 200mg to 500mg, the particle size of prepared microspheres also increased from $138.8 \pm 3.25 \mu\text{m}$ to $169.8 \pm 2.37 \mu\text{m}$. More viscous dispersion was produced on increasing the polymer concentration. Drug entrapment efficiency was found to be increased from 65.53 ± 0.67 to 70.31 ± 1.58 as the concentration increased (Table 1). The increase in size of microspheres remained unchanged after 5% starch concentration. The possible reason for this could be the complete entrapment of available drug in the matrix of microspheres prepared. High % yield and drug entrapment efficiency was found in batch PC₃ and the size of microsphere in this batch was also sufficiently low, and therefore we selected this batch for our further studies. Various concentrations of drug also showed difference in particle size and drug entrapment efficiency. Increasing the drug concentration from 25 to 100mg showed increase in particle size from $147.15 \pm 2.19 \mu\text{m}$ to $168.13 \pm 2.73 \mu\text{m}$. The drug entrapment efficiency also increased from 66.14 ± 2.34 to 71.52 ± 1.32 (Table 2). The results indicated that on changing the concentration of drug, size of microspheres also changed and drug entrapment efficiency increased up to 20%. Highest % yield and entrapment efficiency was found in batch DL₄ and therefore it was selected as optimum. On increasing the emulsifier concentration from 0.50% to 1.25%, the particle size of starch microspheres decreased from $173.39 \pm 3.28 \mu\text{m}$ to $155.72 \pm 4.32 \mu\text{m}$. This occurred due to stabilization of the emulsion droplets which avoided their coalescence and reduced interfacial tension between starch and oil droplets resulting in formation of small microspheres. The drug entrapment efficiency increased from 69.21 ± 1.58 to 72.34 ± 1.12 and highest entrapment efficiency was found in ES₃ (Table 3). Drug entrapment efficiency was large due to available of large surface area for drug entrapment. ES₃ gave the optimum result and it was selected. Increasing concentration of cross linking agent from 1ml to 2ml (1M) to 1ml to 2ml (2M), the particle size of starch microspheres showed little difference from $162.32 \pm 1.35 \mu\text{m}$ to $180.72 \pm 0.83 \mu\text{m}$ and drug entrapment efficiency increased from 66.18 ± 1.52 to 70.22 ± 0.78 . CA₁ showed highest entrapment efficiency and it was selected (Table 4). Particle size decreased from $172.11 \pm 0.34 \mu\text{m}$ to $160.37 \pm 0.33 \mu\text{m}$ when stirring rate was increased from

500 rpm to 1250 rpm. Control on stirring rate gave varied results in particle size. On slow stirring speed, the microspheres formed were of good shape. Higher speed of 1520 rpm produces irregular microspheres. Drug entrapment efficiency was increased from 66.32 ± 1.11 to 72.22 ± 0.27 . Stirring rate of 1000 rpm of batch SR₃ have best results and was selected (Table 5). Scanning Electron Microscopy was used to study the morphology as well as particle size of starch microspheres. Fig. 1 displayed that microspheres prepared were spherical in shape and had a smooth surface. Presence of drug did not change the morphological properties of microspheres. Differential Scanning Calorimeter was used to identify and study the physical state of drug in prepared microspheres. By this study, influence of microspheres in in-vitro drug release can be found. Drug and polymer mixture can co-exist in the polymeric carriers such as i) amorphous drug in either crystalline or an amorphous polymer ii) crystalline drug in either an amorphous or a crystalline polymer. Fig. 2 and 3 showed DSC thermograms of pure aceclofenac, starch, Eudragit S-100, drug and polymer mixture (1:1), blank starch microsphere and aceclofenac loaded starch microsphere respectively. Pure aceclofenac showed endothermic melting peak at 115.1°C . Mixture of drug and polymer showed 158°C and 115.1°C . Melting peak of aceclofenac totally disappeared in the thermo gram of drug loaded microsphere which stated the absence of crystalline form of drug inside microspheres. It can be concluded that aceclofenac in the microspheres was in amorphous phase of a molecular dispersion. *In-vitro* drug release study was performed in simulated gastrointestinal fluid medium at different pH. The effect of different parameters like drug concentration, polymer concentration, cross linking agent concentration and stirring rate showed varied results. Initial release of aceclofenac was bursting effect, which may be due to probability of presence of aceclofenac on the surface of prepared microspheres. After 24 hr, it was seen that drug release decreased from $20.14 \pm 0.74\%$ to $14.61 \pm 0.56\%$ with increasing polymer concentration. It was so due to the increase in the polymer matrix resulted in slower rate of diffusion through this matrix. Drug release rate increases from $12.37 \pm 1.52\%$ to $32.87 \pm 0.48\%$ with increasing amount of aceclofenac in the formulation. Higher concentration of drug caused more pore formation leading to higher drug release. Increased the concentration of emulsifier agent the drug release rate were increase from $15.85 \pm 0.27\%$ to $24.37 \pm 0.75\%$. Microsphere size decreased and the drug release was

increased due to higher surface area. Drug release from microspheres was controlled by the degree of cross-linking. The release of aceclofenac from the microspheres decreased from $20.0 \pm 0.78\%$ to $17.28 \pm 0.31\%$ with increased cross-linking agent concentration due to increase the rigidity of the polymer membrane.

Drug release was increased from $20.45 \pm 1.52\%$ to $22.53 \pm 0.82\%$ with increasing the stirring rate. Increasing the stirring rate caused a faster drug release. One explanation for this phenomenon could be the reduction of particle size result of the increase in surface

area. The in-vitro release profile of various starch microspheres (Table 6-12) showed the cumulative percent drug release of aceclofenac from starch microspheres in Simulated Gastric Fluid and Simulated Intestinal Fluid after 4 hours were varied from $3.17 \pm 0.16\%$ to $10.96 \pm 0.46\%$. As desired the drug release in simulated colonic fluid having pH 7.4 after 24 hours study, was varied from $20.93 \pm 0.71\%$ to $30.52 \pm 2.51\%$ for starch microspheres and Eudragit coated microsphere was found to be release after 24 hours $15.45 \pm 1.52\%$ to $19.53 \pm 1.82\%$.

Table 1: Effect of different polymer concentration on particle size and drug entrapment efficiency of microspheres

Batch code	Polymer concentration (mg)	(%) Yield	Particle Size (μm)	% Drug entrapment efficiency
PC ₁	200	71.49 ± 6.25	138.8 ± 3.25	65.53 ± 0.62
PC ₂	300	72.23 ± 5.02	143.4 ± 2.19	68.16 ± 1.51
PC ₃	400	70.34 ± 6.28	150.7 ± 3.50	70.27 ± 0.51
PC ₄	500	71.75 ± 4.37	169.8 ± 4.37	69.31 ± 1.58

Values represent Mean \pm SD (n=3)

Table 2: Effect of different drug concentration on particle size and drug entrapment efficiency of microspheres

Batch code	Drug concentration (mg)	(%) Yield	Particle Size (μm)	% Drug entrapment efficiency
DL ₁	25	80.36 ± 0.75	147.15 ± 2.19	66.19 ± 2.34
DL ₂	50	81.45 ± 0.67	152.37 ± 3.23	68.24 ± 0.76
DL ₃	75	80.23 ± 0.82	165.42 ± 4.12	71.37 ± 2.23
DL ₄	100	82.34 ± 0.57	168.13 ± 2.73	70.52 ± 1.32

Values represent Mean \pm SD (n=3)

Table 3: Effect of different emulsifier concentration on particle size and drug entrapment efficiency of microspheres

Batch code	Emulsifier concentration (mg)	(%) Yield	Particle Size (μm)	% Drug entrapment efficiency
ES ₁	0.50%	79.13 ± 0.82	173.39 ± 3.28	69.21 ± 0.93
ES ₂	0.75%	80.78 ± 0.87	165.26 ± 1.39	70.52 ± 0.52
ES ₃	1.0%	81.32 ± 1.66	161.31 ± 2.73	71.72 ± 0.79
ES ₄	1.25%	82.64 ± 1.39	155.72 ± 2.32	72.34 ± 1.12

Values represent Mean \pm SD (n=3)

Table 4: Effect of different concentration of cross linking agent on particle size and drug entrapment efficiency of microspheres

Batch code	Cross linking agent (ml)	(%) Yield	Particle Size (μm)	% Drug entrapment efficiency
CA ₁	1 (1M)	76.13 ± 0.62	162.32 ± 1.32	66.19 ± 1.52
CA ₂	2 (1M)	79.92 ± 0.89	169.76 ± 1.21	68.23 ± 0.55
CA ₃	1 (2M)	71.37 ± 1.32	174.61 ± 0.76	70.32 ± 1.22
CA ₄	2 (2M)	78.32 ± 1.72	180.72 ± 0.83	69.22 ± 0.78

Values represent Mean \pm SD (n=3)

Table 5: Effect of stirring speed on particle size and drug entrapment efficiency of microspheres

Batch code	Stirring rate	(%) Yield	Particle Size (μm)	% Drug entrapment efficiency
SR ₁	500	76.33 ± 0.12	172.31 ± 0.72	66.32 ± 1.11
SR ₂	750	71.14 ± 0.73	168.11 ± 0.34	68.44 ± 0.44
SR ₃	1000	74.11 ± 1.22	165.29 ± 0.12	72.77 ± 1.78
SR ₄	1250	80.23 ± 1.52	160.37 ± 0.33	70.22 ± 0.27

Values represent Mean \pm SD (n=3)

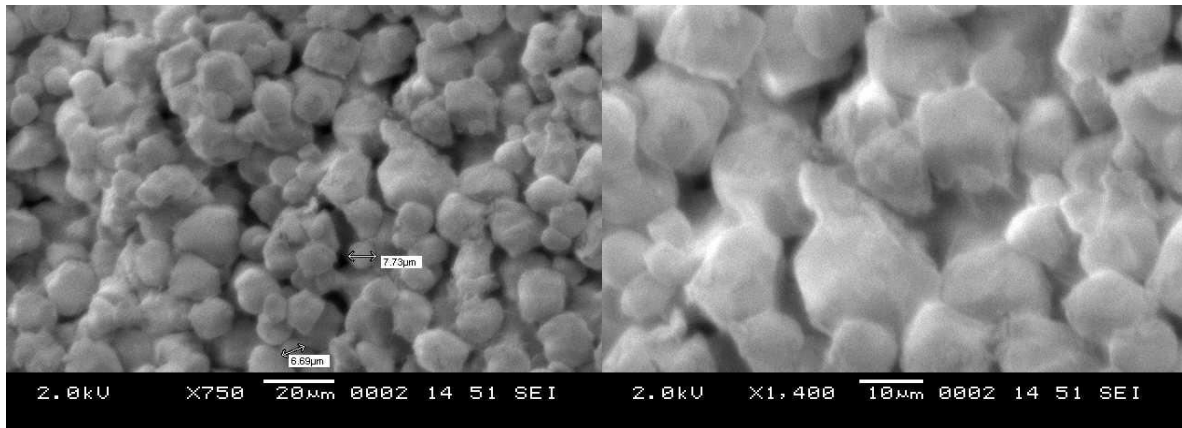


Fig. 1: Particle size of microspheres

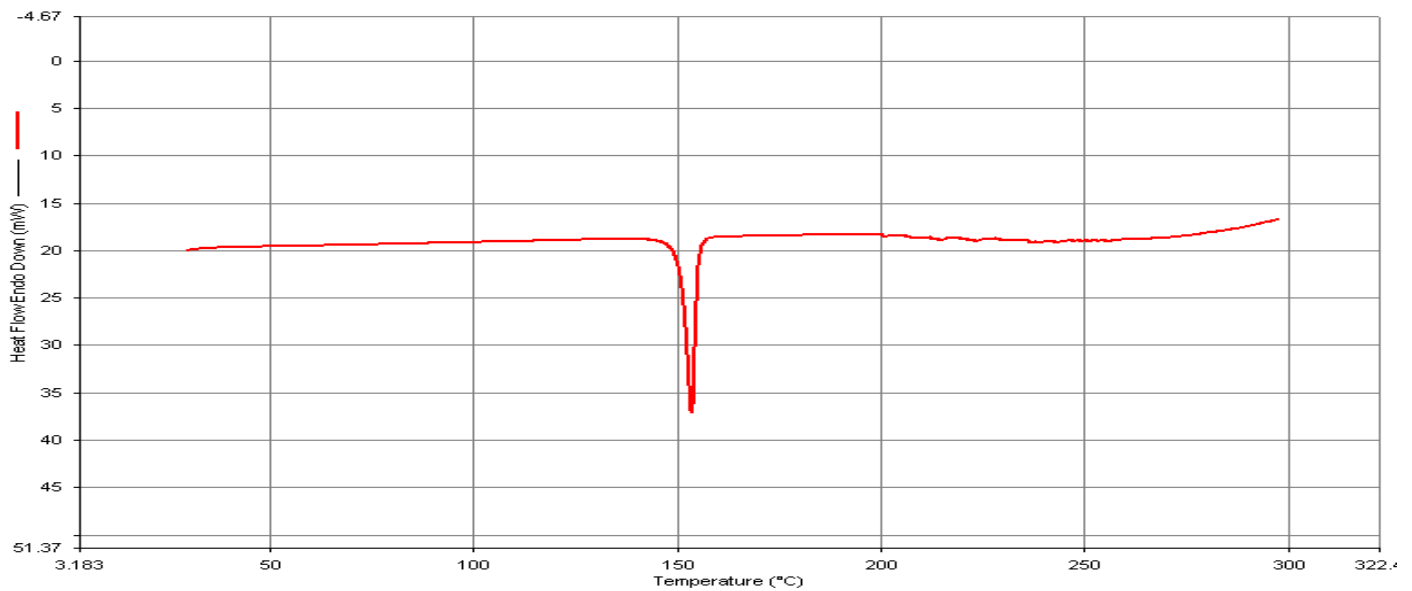


Fig. 2: DSC thermo gram of aceclofenac

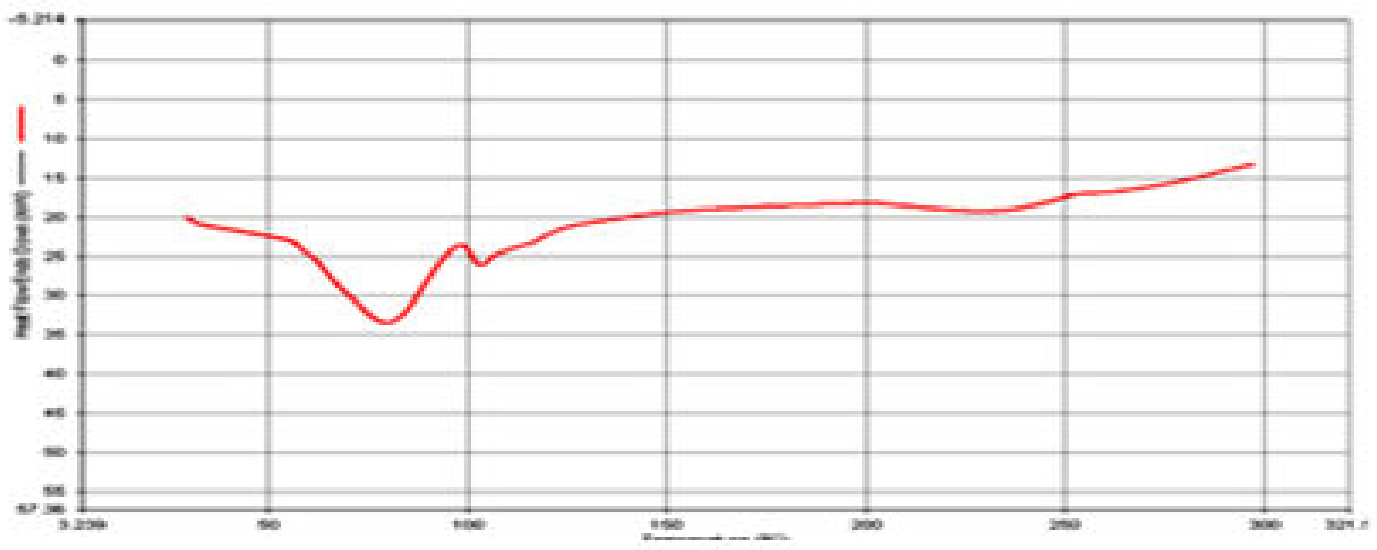


Fig. 3: DSC thermo gram of aceclofenac loaded eudragit coated starch microsphere

Table 6: Batch code and composition of different starch microspheres

Batch Code	Polymer Concentration (mg)	Drug Concentration (mg)	Emulsifier Concentration (%)	Cross-linking agent (ml)	Stirring Rate (rpm)
PC ₁	200	50	1.0	1 (2M)	1000
PC ₂	300	50	1.0	1 (2M)	1000
PC ₃	400	50	1.0	1 (2M)	1000
PC ₄	500	50	1.0	1 (2M)	1000
DL ₁	400	25	1.0	1 (2M)	1000
DL ₂	400	50	1.0	1 (2M)	1000
DL ₃	400	75	1.0	1 (2M)	1000
DL ₄	400	100	1.0	1 (2M)	1000
ES ₁	400	50	0.50%	1 (2M)	1000
ES ₂	400	50	0.75%	1 (2M)	1000
ES ₃	400	50	1.0%	1 (2M)	1000
ES ₄	400	50	1.25%	1 (2M)	1000
CA ₁	400	50	1.0%	1 (1M)	1000
CA ₂	400	50	1.0%	2 (1M)	1000
CA ₃	400	50	1.0%	1 (2M)	1000
CA ₄	400	50	1.0%	2 (2M)	1000
SR ₁	400	50	1.0%	1 (2M)	500
SR ₂	400	50	1.0%	1 (2M)	750
SR ₃	400	50	1.0%	1 (2M)	1000
SR ₄	400	50	1.0%	1 (2M)	1250

Table 7: Effect of Polymer concentration on dissolution rate of Aceclofenac loaded starch microspheres

S. No.	Time (hrs)	% Cumulative drug release			
		PC ₁	PC ₂	PC ₃	PC ₄
1	1	5.01±0.36	4.96±0.79	4.50±0.30	3.91±0.51
2	2	6.11±0.48	5.43±0.13	5.33±0.50	4.59±0.77
3	3	8.28±0.44	6.21±0.73	6.11±0.85	5.27±0.25
4	4	9.86±0.11	7.50±0.80	7.09±0.74	6.26±0.24
5	5	10.49±1.33	8.90±0.89	8.60±0.94	7.44±0.76
6	6	10.64±0.53	9.35±0.10	8.97±0.76	8.25±0.84
7	7	11.31±0.67	10.55±0.70	9.78±0.92	8.75±0.74
8	8	13.11±0.75	11.97±0.50	10.94±0.83	9.54±0.69
9	12	15.11±0.84	13.58±0.61	11.24±0.77	10.24±0.24
10	24	20.14±0.74	18.32±0.65	15.56±0.21	14.61±0.56

Values represent Mean ± SD (n=3)

Table 8: Effect of drug concentration on dissolution rate of Aceclofenac loaded starch microspheres

S. No.	Time (hrs)	% Cumulative drug release			
		DL1	DL2	DL3	DL4
1	1	3.35±0.27	4.42±0.43	4.54±0.71	5.59±0.62
2	2	4.20±0.56	5.43±0.29	5.97±0.24	6.37±0.27
3	3	5.24±1.1	6.48±0.69	6.78±0.47	7.52±0.47
4	4	6.29±1.2	7.97±0.72	8.95±0.62	9.27±0.34
5	5	7.89±0.72	8.46±0.42	10.32±0.8	12.58±0.48
6	6	8.92±0.62	10.32±0.52	12.39±0.76	14.32±0.68
7	7	9.26±0.78	12.92±0.62	15.52±0.32	19.37±0.75
8	8	10.27±0.64	15.39±0.76	20.12±0.56	25.72±0.13
9	12	11.21±1.32	18.54±0.12	25.15±0.92	28.79±0.45
10	24	12.37±1.52	20.32±0.32	30.17±0.52	32.87±0.48

Values represent Mean ± SD (n=3)

Table 9: Effect of emulsifier concentration on dissolution rate of Aceclofenac loaded starch microspheres

S. No.	Time (hrs)	% Cumulative drug release			
		ES1	ES2	ES3	ES4
1	1	2.27±1.06	3.23±0.82	3.97±0.42	4.34±0.25
2	2	3.52±0.87	4.32±0.51	4.78±0.75	5.18±0.52
3	3	4.62±0.76	5.20±0.72	6.13±0.37	6.78±0.37
4	4	5.13±1.22	6.19±0.30	7.53±0.62	8.92±0.72
5	5	6.30±1.13	7.35±0.62	8.73±0.73	11.02±0.14
6	6	7.22±0.6	8.73±0.32	10.59±0.90	13.24±0.71
7	7	8.36±1.01	9.35±0.45	12.73±0.81	15.32±0.19
8	8	9.63±0.87	12.53±0.69	15.98±0.17	18.53±0.26
9	12	13.31±0.68	15.97±0.87	19.32±0.32	20.39±0.64
10	24	15.85±0.27	18.92±0.28	22.37±0.79	24.37±0.75

Values represent Mean ± SD (n=3)

Table 10: Effect of cross linking agent on dissolution rate of Aceclofenac loaded starch microspheres

S. No.	Time (hrs)	% Cumulative drug release			
		CA1	CA2	CA3	CA4
1	1	3.12±0.75	4.14±0.62	3.97±0.25	2.08±0.24
2	2	4.92±0.59	5.34±0.19	4.26±0.04	3.65±0.27
3	3	6.23±0.42	7.04±0.13	6.69±0.89	4.15±0.86
4	4	8.24±0.27	9.33±0.38	8.72±0.57	5.56±0.45
5	5	10.06±0.22	10.58±0.67	9.38±0.75	6.98±0.84
6	6	11.87±0.42	12.88±0.25	11.76±0.62	8.25±0.43
7	7	13.85±0.33	13.97±0.36	12.15±0.71	9.65±0.25
8	8	14.67±0.64	14.48±1.02	13.76±0.17	11.15±0.57
9	12	16.30±0.87	16.37±0.17	15.98±0.76	14.27±0.32
10	24	20.01±0.78	29.79±0.13	18.97±0.68	17.28±0.31

Values represent Mean ± SD (n=3)

Table 11: Effect of stirring rate of microspheres on dissolution rate of Aceclofenac loaded starch microspheres

S. No.	Time (hrs)	% Cumulative drug release			
		SR1	SR2	SR3	SR4
1	1	3.54±1.92	3.32±1.62	3.82±1.21	4.02±1.14
2	2	4.76±1.32	4.94±1.14	5.26±1.71	6.22±1.31
3	3	5.86±1.36	7.12±1.13	7.69±1.84	8.82±1.38
4	4	6.31±1.61	7.08±1.44	9.81±1.42	10.81±1.52
5	5	7.45±1.43	9.43±1.25	10.45±1.53	12.27±1.67
6	6	8.87±1.12	11.91±1.54	13.85±1.31	14.36±1.80
7	7	10.76±1.37	12.63±1.24	14.12±1.43	15.68±1.61
8	8	12.36±1.8	15.23±1.49	17.02±1.40	16.72±1.52
9	12	15.69±0.98	19.57±1.32	18.92±1.22	18.92±1.77
10	24	20.45±1.52	21.43±1.57	20.57±1.76	22.53±1.82

Values represent Mean ± SD (n=3)

Table 12: Effect of Eudragit S-100 concentration on dissolution rate of Aceclofenac loaded Starch microsphere

S.No.	Time (hrs)	% Cumulative drug release			
		ER1	ER2	ER3	ER4
1	1	2.54±1.92	3.32±1.62	3.82±1.21	4.02±1.14
2	2	3.76±1.32	3.94±1.14	4.26±1.71	5.22±1.31
3	3	4.86±1.36	5.12±1.13	6.69±1.84	7.82±1.38
4	4	5.31±1.61	6.08±1.44	8.81±1.42	9.81±1.52
5	5	6.45±1.43	7.43±1.25	9.45±1.53	10.27±1.67
6	6	7.87±1.12	10.91±1.54	12.85±1.31	13.36±1.80
7	7	8.76±1.37	11.63±1.24	13.12±1.43	14.68±1.61
8	8	11.36±1.8	13.23±1.49	14.02±1.40	15.72±1.52
9	12	13.69±0.98	15.57±1.32	16.92±1.22	17.92±1.77
10	24	15.45±1.52	17.43±1.57	18.57±1.76	19.53±1.82

Values represent Mean ± SD (n=3)

4. CONCLUSION

The present study clearly indicates that starch microspheres had the potency in delivery of aceclofenac effectively to the colon region through conventional drug delivery route. Different modifications in variables were done which affected the size, shape and drug release pattern of microspheres. Starch is a biocompatible polymer; we expect it to cause no harmful effects, if used for prolonged periods. Starch microspheres showed good entrapment % yield and spherical particles. Starch microspheres bear aceclofenac, maintain its integrity in the hostile environment of stomach and small intestine and this system does not show any pH dependent drug release in GI tract. In the upper part of GI tract, starch microspheres show small amount of drug release. The biodegradable polymeric colloidal systems made using starch can entrap aceclofenac and provide a colon targeted drug delivery system. Hence, it can be concluded that starch microspheres can be utilized for the site specific delivery of the drug to the colon. We can conclude that starch microspheres of aceclofenac showed extended drug release profile in pH progression medium. Therefore, designed drug delivery system can be effectively used for the treatment of pain and inflammation.

Conflict of interest

None declared

Source of funding

None declared

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