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FORMULATION AND CHARACTERIZATION OF MUCOADHESIVE COLON TARGETING NANOSPONGES OF ANTI-INFLAMMATORY DRUG

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ABSTRACT

The present study was aimed at the formulation and evaluation of Olsalazine-loaded nanosponges to achieve controlled and sustained drug release. Nanosponges were prepared using different polymer ratios, and the formulations were evaluated for percentage yield, entrapment efficiency, particle size, zeta potential, surface morphology, and in-vitro drug release behavior. The percentage yield of the formulations ranged from 72.25 ± 0.41% to 85.65 ± 0.55%**,** while entrapment efficiency varied between 70.36 ± 0.25% and 82.85 ± 0.95%**.** Among all formulations, F5 exhibited the highest yield and entrapment efficiency, indicating optimal formulation parameters. Particle size analysis confirmed nanoscale dimensions with uniform distribution, and zeta potential studies demonstrated good stability of the nanosponges. Scanning Electron Microscopy revealed a spherical, porous morphology of the optimized formulation. In-vitro drug release studies showed a sustained release pattern for nanosponges compared to the plain drug, with 97.65% drug release over 12 hours. Release kinetics analysis indicated that the optimized formulation followed first-order kinetics with diffusion-controlled release behavior. The results suggest that Olsalazine-loaded nanosponges are a promising drug delivery system for controlled release, potentially enhancing therapeutic efficacy and patient compliance.

KEYWORDS: Olsalazine, Nanosponges, Controlled drug delivery, Entrapment efficiency, In-vitro drug release, Release kinetics.

INTRODUCTION

Inflammatory disorders of the colon, including ulcerative colitis and Crohn's disease, present major clinical challenges due to chronic inflammation localized in the lower gastrointestinal tract (Price et al., 1975). Conventional oral delivery of anti-inflammatory drugs often results in premature release and absorption in the stomach or small intestine, leading to systemic side effects, reduced therapeutic efficiency, and poor drug concentrations at the diseased colon site (Placha and Jampilek; 2021).

Consequently, colon-targeted drug delivery systems (CTDDS) have gained significant attention as strategies to improve drug localization, therapeutic efficacy, and patient compliance.

Nanosponges are an emerging class of porous, cross-linked polymeric particles capable of encapsulating a wide range of therapeutic agents and modifying drug release profiles. Their unique 3D network offers advantages such as high drug loading, controlled release, protection of labile drugs, and improved stability. When functionalized with mucoadhesive polymers, nanosponges can adhere to the colonic mucosa, prolonging residence time and enhancing drug absorption at the target site (Ghurghure et al., 2018).

Mucoadhesive colon targeting is particularly promising for anti-inflammatory therapy because it not only enhances site-specific drug concentration but also minimizes systemic distribution, thereby reducing adverse effects associated with traditional non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids. Polymers such as chitosan, carbopol, and polyacrylic acid derivatives have been widely investigated to confer mucoadhesive properties and sustain drug release in the colonic environment (CM and AC; 2011).

The present study focuses on the development, optimization, and physicochemical characterization of mucoadhesive nanosponges loaded with an anti-inflammatory drug, targeting controlled and sustained release specifically in the colon. Formulation parameters

such as polymer concentration, cross-linking density, particle size, surface morphology, drug entrapment efficiency, mucoadhesion strength, and in-vitro drug release behavior will be investigated. The overall aim is to design a robust colon-specific delivery system with improved therapeutic outcomes, reduced dosing frequency, and enhanced patient acceptability.

MATERIAL AND METHODS

Material

Olsalazine, an anti-inflammatory drug, was used as the model drug for the present investigation. Polymers and excipients required for nanosponge preparation and mucoadhesive formulation, including suitable cross-linking agents and stabilizers, were employed to develop colon-targeted nanosponges. Analytical grade solvents such as methanol and distilled water were used during formulation and evaluation studies. All chemicals and reagents utilized for characterization, including in-vitro drug release and kinetic studies, were of analytical grade and used without further purification.

Methods

Formulation Development of Mucoadhesive Nanosponges

Olsalazine-loaded mucoadhesive nanosponges (F1–F6) were prepared by the emulsion solvent diffusion method with varying concentrations of polyvinyl alcohol (PVA) as shown in Table 1. For each formulation, 100 mg of Olsalazine and 100 mg of Eudragit S-100 were dissolved in 10 mL of dichloromethane to form the organic (disperse) phase. This organic phase was then added dropwise into 100 mL of distilled water containing the specified quantity of PVA (150–900 mg) and 50 mg of Pluronic F68, which served as a stabilizer. The dispersion was continuously stirred at 1000 rpm on a magnetic stirrer for 2 hours to promote nanosponge formation. The formed nanosponges were collected by vacuum filtration, washed thoroughly with distilled water to remove unbound stabilizer, and dried in a hot air oven at 40 °C for 24 hours. The dried nanosponges were stored in a desiccator for further characterization (Mishra et al., 2021).

Table 6.4: Composition of Mucoadhesive nanosponges of Olsalazine.

Ingredients	F1	F2	F3	F4	F5	F6
Olsalazine (mg)	100	100	100	100	100	100
Polyvinyl alcohol (mg)	150	300	450	600	750	900
Eudragit S-100 (mg)	100	100	100	100	100	100
Pluronic F68 (mg)	50	50	50	50	50	50
Dichloromethane (ml)	10	10	10	10	10	10
10Distilled water (ml)	100	100	100	100	100	100

Characterization of Nanosponges

Percentage yield

The Olsalazine nanosponges obtained after drying was weighed (Pawar *et al.*, 2022). Percentage yield value was calculated as follows:

$$\% \text{ Yield} = \text{Weight of nanosponges} \times 100 / \text{Total solids weight}$$

Entrapment efficiency

UV spectrophotometric method was used to estimate entrapment efficiency of Olsalazine nanosponges (Shankar and Agarwal, 2015). A calibration curve was plotted for Olsalazine in pH 7.2 phosphate buffer in the range of 5-25 µg/mL (Beer's Lambert's range) at 233nm. A good linear relationship was observed between the concentration of Olsalazine and its absorbance (r^2=0.999, m=0.020, n=3). 10 mg of Olsalazine nanosponges of each batch were selected, powdered in a mortar and placed in 10 mL of pH 7.2 phosphate buffer. Olsalazine was extracted by centrifuging at 1000 rpm for 30 min, filtered and analyzed concentration from calibration curve data after necessary dilution. Percentage entrapment was calculated as follows:

$$\% \text{ Entrapment efficiency} = \text{Actual drug}$$

Particle size, polydispersity index

Average particles size, polydispersity index (PDI) of prepared nanosponges was determined using zetasizer (DTS were 4.10, Horriba instrument, India) (Srinivas and Reddy, 2015). The nanosponges formulation was diluted with deionized water (1:9 v/v) and analysed for average size and PDI.

Shape and surface morphology

The shape and surface morphology of the nanospongess were investigated using scanning electron microscopy (IISER, Bhopal) (Penjuri *et al.*, 2016). The nanospongess were fixed on supports with carbon-glue, and coated with gold using a gold sputter module in a high-vacuum evaporator. Samples were then observed with the Scanning Electron Microscope at 10 kV.

In vitro drug release from nanosponges

In-vitro dissolution is pharmaceutically defined as the rate of mass transfer of a drug from a solid surface into a dissolution medium under standardized conditions of temperature, solvent composition, and liquid–solid interface. It is a dynamic process that explains the formation of a homogeneous mixture of a solid or liquid in a solvent and determines the time required for a formulation to release a specific percentage of drug under defined conditions. In the present study, dissolution was carried out using 900 ml of pH 7.2 phosphate buffer as the medium in a USP type II (paddle) apparatus maintained at 37 ± 0.5°C. The paddle speed was set at 55 rpm**,** and samples were withdrawn at predetermined time intervals (0.5 to 12 h). The formulation was placed in the dissolution medium, and 5

ml aliquots were periodically withdrawn and replaced with fresh medium to maintain sink conditions. The samples were analyzed spectrophotometrically at 233 nm to determine the drug release profile.

RESULTS AND DISCUSSION

The present study successfully developed and evaluated Olsalazine-loaded nanosponges, with particular emphasis on formulation efficiency, physicochemical characteristics, and in-vitro drug release behavior.

Percentage yield of the formulations ranged from 72.25 ± 0.41% (F3) to 85.65 ± 0.55% (F5). The comparatively higher yield of formulation F5 indicates better process efficiency and optimal polymer–drug interaction, suggesting minimal material loss during preparation. Variations in yield among formulations may be attributed to differences in polymer concentration and cross-linking efficiency, which influence nanosponge formation.

Entrapment efficiency (EE) values varied between 70.36 ± 0.25% and 82.85 ± 0.95%, with F5 showing the highest EE. Higher entrapment efficiency reflects effective incorporation of Olsalazine within the nanosponge matrix, likely due to optimal polymer concentration and increased surface area facilitating drug accommodation. Lower EE in other formulations may be due to insufficient polymer network density, resulting in drug diffusion into the external phase during formulation.

Particle size analysis (Figure 1) demonstrated nanoscale dimensions with uniform distribution, which is desirable for enhanced dissolution and controlled drug release. The zeta potential graph indicated adequate surface charge, confirming nanosponge stability and reduced aggregation tendency. The observed zeta potential values suggest sufficient electrostatic repulsion, contributing to formulation stability during storage.

Scanning Electron Microscopy (SEM) of the optimized formulation F5 (Figure 2) revealed a porous, spherical morphology characteristic of nanosponges. The presence of surface pores supports the controlled and sustained release behavior observed during in-vitro studies.

The in-vitro drug release study showed a marked difference between plain drug and nanosponge formulation. The plain drug exhibited rapid release (up to 67.74% within 2 h), whereas nanosponges demonstrated a sustained release up to 12 h (97.65%). This confirms the ability of nanosponges to modulate drug release, reducing burst effect and improving therapeutic control.

Release kinetics analysis of optimized formulation F5 revealed the highest correlation with first-order kinetics (R^2 = 0.9782), indicating concentration-dependent drug release. A good fit with the Higuchi model (R^2 = 0.9198) suggests diffusion-controlled release from the porous matrix, while the Korsmeyer–Peppas model (R^2 = 0.9284) further supports a diffusion-dominant mechanism, possibly coupled with matrix relaxation.

Table 1: Percentage yield for different formulation

Formulation code	Percentage Yield*
F1	76.65±0.25
F2	74.54±0.36
F3	72.25±0.41
F4	78.98±0.32
F5	85.65±0.55
F6	73.32±0.69

***Average of three determinations (n=3)**

Table 2: Entrapment Efficiency for Different Formulation.

Formulation code	% Entrapment Efficiency
F1	73.32±0.45
F2	71.15±0.36
F3	70.36±0.25
F4	75.65±0.85
F5	82.85±0.95
F6	70.36±0.33

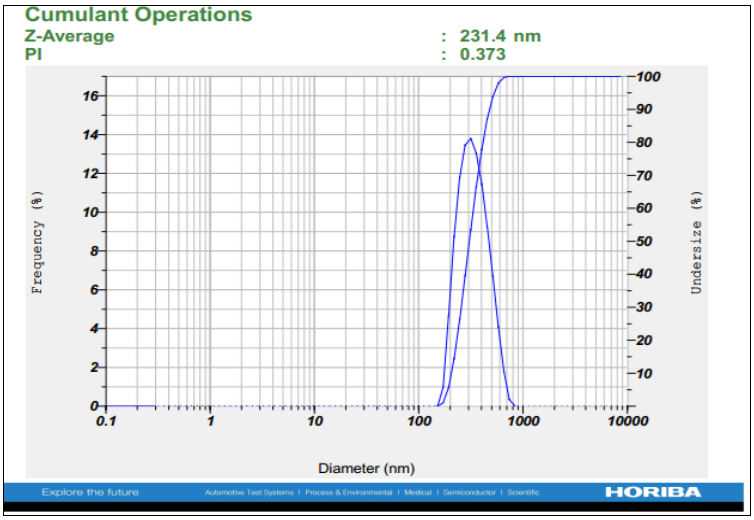

Figure 1: Measurement of mean particle size.

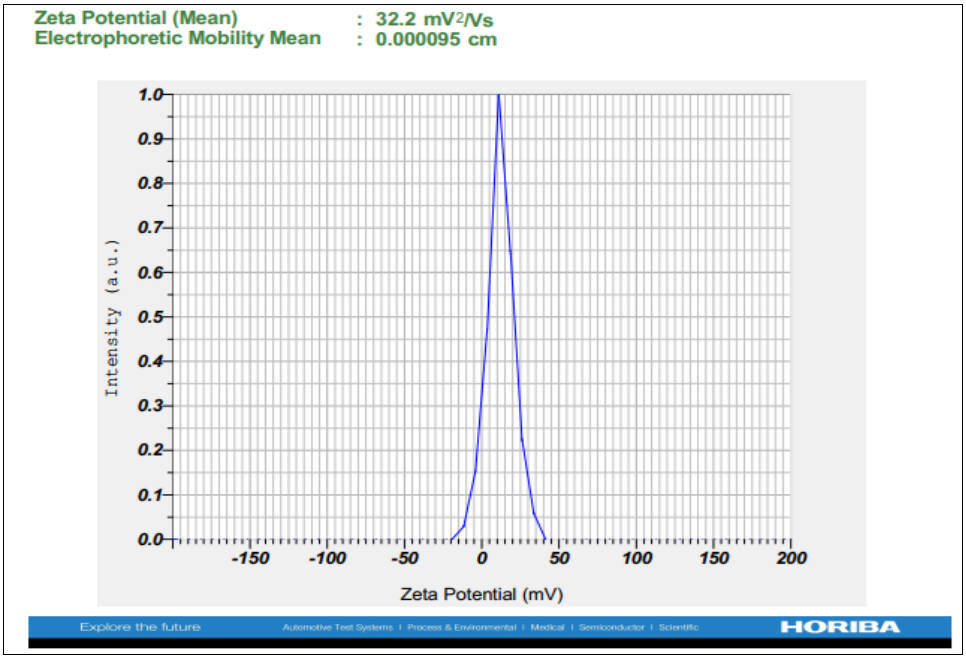

Figure 1: Graph of zeta potential.

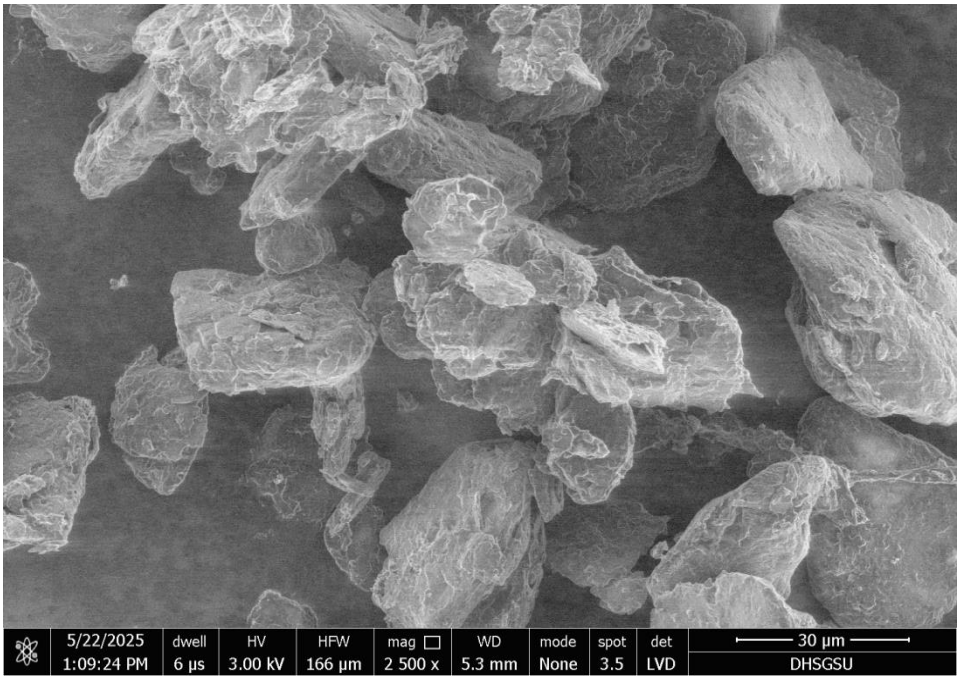

Figure 2: Scanning Electronic Microscopy of optimized formulation (F5).

Table 3: *In vitro* drug release study of Olsalazine loaded nanosponges.

S. No.	Time (hrs.)	Plain Drug	Nanosponges
1.	0.5	20.25	12.36
2.	1	36.65	22.85
3.	1.5	59.98	30.36
4.	2	67.74	49.98
5.	3	-	63.32
6.	4	-	73.32
7.	6	-	81.15
8.	8	-	86.65
9.	12	-	97.65

Table 4: *In-vitro* drug release data for optimized formulation F5.

Time (h)	Square Root of Time(h)$^{1/2}$	Log Time	Cumulative*% Drug Release	Log Cumulative % Drug Release	Cumulative % Drug Remaining	Log Cumulative % Drug Remaining
0.5	0.707	-0.301	12.36	1.092	87.64	1.943
1	1	0	22.85	1.359	77.15	1.887
1.5	1.225	0.176	30.36	1.482	69.64	1.843
2	1.414	0.301	49.98	1.699	50.02	1.699
3	1.732	0.477	63.32	1.802	36.68	1.564
4	2	0.602	73.32	1.865	26.68	1.426
6	2.449	0.778	81.15	1.909	18.85	1.275
8	2.828	0.903	86.65	1.938	13.35	1.125
12	3.464	1.079	97.65	1.990	2.35	0.371

Table 5: Regression analysis data of Olsalazine loaded nanosponges.

Batch	Zero Order	First Order	Higuchi	Korsmeyer Peppas
	R^2	R^2	R^2	R^2
F5	0.7976	0.9782	0.9198	0.9284

The present study successfully demonstrated the formulation and characterization of mucoadhesive colon-targeted nanosponges of an anti-inflammatory drug (Olsalazine) for sustained and site-specific drug delivery. Nanosponges were effectively prepared using suitable polymers, resulting in acceptable percentage yield and high entrapment efficiency, indicating efficient drug incorporation within the nanosponge matrix. Among the developed formulations, F5 emerged as the optimized formulation, exhibiting superior yield, maximum entrapment efficiency, nanoscale particle size, and good surface charge, confirming its stability. Mucoadhesive and morphological evaluations revealed that the nanosponges possessed a porous, spherical structure, favorable for prolonged retention at the colonic mucosa and controlled drug release. In-vitro drug release studies demonstrated a sustained release profile up to 12 hours, significantly reducing the initial burst effect observed with the plain drug. Kinetic modeling confirmed that drug release followed first-order kinetics with diffusion-controlled mechanism, supporting the suitability of nanosponges for controlled delivery.

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