RESEARCH PAPER

Formulation and Evaluation of Mucoadhesive Microspheres Containing Tridax Procumbens Extract for Peptic Ulcer Treatment

V. Swaminathan[1*], R. Manivannan[2], G. Sureshkumar[3], S. Chandru[4], R. Manonmani[4], B. Pavithra[4], B. Sivasurya[4]

[1] Assistant Professor, Department of Pharmaceutics, Excel College of Pharmacy, Komarapalayam, Namakkal, Tamil Nadu, India. Email: swaminathan016@gmail.com

[2] Principal, Excel College of Pharmacy, Komarapalayam, Namakkal, Tamil Nadu, India.

[3] Professor, Department of Pharmaceutical Biotechnology, Excel College of Pharmacy, Komarapalayam, Namakkal, Tamil Nadu, India.

[4] Department of Pharmaceutics, Excel College of Pharmacy, Komarapalayam, Namakkal, Tamil Nadu, India.

ABSTRACT

Peptic ulcer disease (PUD) is a common gastrointestinal disorder caused by an imbalance between aggressive factors such as gastric acid, pepsin, Helicobacter pylori, and protective mucosal mechanisms. The present study aimed to formulate and evaluate mucoadhesive microspheres containing Tridax procumbens extract for improved ulcer management. The plant extract was prepared using Soxhlet extraction with ethanol and incorporated into microspheres using the solvent evaporation technique with ethyl cellulose and hydroxypropyl methylcellulose (HPMC K15M) as polymers. The prepared microspheres were evaluated for percentage yield, particle size, swelling index, mucoadhesion, and in-vitro drug release. The formulation exhibited a percentage yield of 77.27% with an average particle size of 200.5 µm. The swelling index was found to be 45%, and mucoadhesion was 95%, indicating excellent adhesion properties. In-vitro drug release studies demonstrated sustained release, with 97.2% drug release observed over 8 hours. The results suggest that the developed mucoadhesive microspheres provide prolonged gastric residence time and controlled drug release, making them a promising gastro-retentive drug delivery system for effective management of peptic ulcer disease.

Keywords: Tridax procumbens, Mucoadhesive microspheres, Peptic ulcer, Controlled drug release, Gastro-retentive drug delivery system

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INTRODUCTION:

Peptic ulcer disease (PUD) is a widespread gastrointestinal disorder characterized by the development of lesions in the gastric or duodenal mucosa due to an imbalance between aggressive factors and mucosal defense mechanisms. The primary causative factors include excessive gastric acid secretion, pepsin activity, infection with *Helicobacter pylori*, and prolonged use of non-steroidal anti-inflammatory drugs (NSAIDs). These factors disrupt the integrity of the mucosal barrier, leading to inflammation, erosion, and ulcer formation. Globally, PUD remains a significant health concern, affecting approximately 5–10% of the population during their lifetime and contributing to considerable morbidity and healthcare burden [1,2].

Conventional treatment strategies for PUD primarily focus on reducing gastric acid secretion and eradicating *H. pylori*. Proton pump inhibitors (PPIs) and H_2-receptor antagonists are widely prescribed for ulcer management due to their ability to suppress acid production. However, long-term use of these medications has been associated with several adverse effects, including nutrient malabsorption, increased susceptibility to infections, and recurrence of ulcers. Additionally, the emergence of antibiotic resistance has reduced the effectiveness of *H. pylori* eradication therapies. These limitations highlight the need for alternative therapeutic approaches that are safe, effective, and capable of targeting multiple pathways involved in ulcer pathogenesis [3,4].

Medicinal plants have gained considerable attention as potential therapeutic agents due to their diverse

pharmacological activities and relatively lower side effects. Herbal medicines contain a wide range of bioactive phytoconstituents such as flavonoids, alkaloids, tannins, and phenolic compounds, which exhibit antioxidant, anti-inflammatory, and cytoprotective properties. These compounds can enhance mucosal defense, reduce oxidative stress, and promote tissue healing, making them suitable candidates for the management of PUD. Furthermore, plant-based therapies often act through multiple mechanisms, providing a holistic approach to disease treatment [5,6].

Tridax procumbens, commonly known as coat buttons, is a medicinal herb widely distributed in tropical regions and traditionally used for the treatment of various ailments. Phytochemical investigations have revealed that the plant contains flavonoids, terpenoids, phenolic compounds, and tannins, which contribute to its pharmacological activities. Previous studies have demonstrated that *T. procumbens* possesses antioxidant, anti-inflammatory, antimicrobial, and wound-healing properties. These biological activities suggest its potential role in protecting gastric mucosa and promoting ulcer healing by reducing oxidative damage and inflammatory responses [7,8].

Despite the therapeutic potential of herbal extracts, their clinical effectiveness is often limited by poor bioavailability, rapid degradation in the gastrointestinal tract, and short residence time at the site of action. To overcome these challenges, novel drug delivery systems have been developed to enhance the efficacy of herbal formulations. Among these, mucoadhesive drug delivery systems have emerged as a promising approach for improving drug retention and localized action. Mucoadhesion involves the adhesion of a drug delivery system to the mucosal surface, thereby prolonging its residence time and enhancing drug absorption. This approach is particularly beneficial in gastric disorders, where prolonged contact with the mucosa is essential for therapeutic effectiveness [9,10].

Microspheres are an advanced drug delivery system that offers controlled and sustained release of drugs. These systems consist of polymeric matrices that encapsulate the active ingredient, allowing gradual drug release over an extended period. When combined with mucoadhesive properties, microspheres can adhere to the gastric mucosa, resist gastric emptying, and maintain a localized drug concentration at the site of ulceration. Polymers such as ethyl cellulose and hydroxypropyl methylcellulose (HPMC) are commonly used in the formulation of mucoadhesive microspheres due to their biocompatibility and excellent film-forming and swelling properties [11,12].

The integration of herbal medicine with advanced drug delivery systems provides a novel strategy for improving therapeutic outcomes in PUD. By incorporating *Tridax procumbens* extract into mucoadhesive microspheres, it is possible to enhance gastric retention, achieve sustained drug release, and improve bioavailability of the active phytoconstituents. This approach not only addresses the limitations of conventional therapy but also offers a safer and more effective alternative for ulcer management. Therefore, the present study focuses on the formulation and evaluation of mucoadhesive microspheres containing *Tridax procumbens* extract as a potential gastro-retentive drug delivery system for the treatment of peptic ulcer disease.

METHODOLOGY:

Collection Of Plants

The fresh whole plants of Tridax procumbens were collected in the month of June from Edappadi, Salem district, Tamil Nadu, India. The collected plant materials were washed thoroughly with distilled water to remove adhering soil and impurities. The plants were shade-dried for 14 days at room temperature and pulverized into coarse powder using a mechanical grinder. The powdered material was stored in an airtight container for further studies.

Authentication Of Plant

The collected plant material was authenticated by Dr. P. Radha, Research Officer (Botany), Sci-II, I/C, Siddha Medicinal Plants Garden (SMPG), Mettur Dam, Tamil Nadu - 636401. The authentication was carried out based on morphological characteristics and comparison with standard herbarium specimens. The authentication certificate was obtained and documented for record.

Preparation Of Plant Extract

The dried powdered plant material was subjected to Soxhlet extraction using ethanol as solvent. 50 g of powdered material was packed in a thimble and extracted with 250 mL of ethanol for 4 hours. The extraction temperature was maintained at 65-70°C. After completion of extraction, the extract was filtered using Whatman No. 1 filter paper. The filtrate was concentrated using a hot air oven maintained at 55°C until a semi-solid mass was obtained. The concentrated extract was further dried to constant weight and stored in an airtight container for formulation studies [13].

Fig 1: Soxhlet Extraction

Formulation Of Mucoadhesive Microspheres

Table 1: Formulation of Mucoadhesive Microspheres

S.No	Ingredient	Quantity
1	*Tridax procumbens* extract	1 g
2	Ethyl Cellulose (EC)	1 g
3	Hydroxypropyl Methylcellulose (HPMC K15M)	0.20 g
4	Ethanol	10 mL
5	Ethyl acetate	10 mL
6	Liquid paraffin	40 mL
7	Acacia (0.5% w/v)	0.20 g
8	Petroleum ether	q.s

- The organic phase was prepared by dissolving Ethyl Cellulose (EC) and *Tridax procumbens* extract in ethanol and ethyl acetate under magnetic stirring until a clear solution was obtained.
- Hydroxypropyl Methylcellulose (HPMC K15M) was added gradually to the above solution and stirred to obtain a homogeneous mixture.
- The external oil phase was prepared by dispersing acacia in liquid paraffin.
- The organic phase was added dropwise into the external oil phase under continuous stirring at 1000 rpm using a magnetic stirrer.
- Stirring was continued for 3 hours at room temperature (28 ± 2°C) to allow solvent evaporation and formation of microspheres.
- The formed microspheres were collected by filtration and washed with petroleum ether to remove residual oil.
- The microspheres were dried in a hot air oven at 40°C until constant weight was obtained and stored in airtight containers [14].

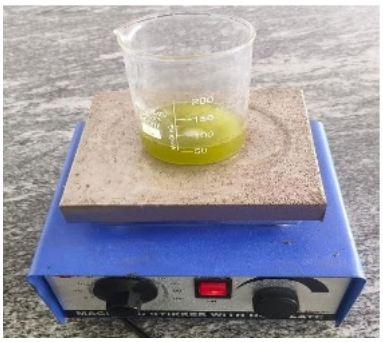

Fig 2: Formulation of *Tridax Procumbens*

EVALUATION OF MUCOADHESIVE MICROSPHERES

The prepared mucoadhesive microspheres were subjected to various physicochemical and functional evaluation tests to determine their suitability for gastric drug delivery. The evaluation parameters included percentage yield, particle size analysis, swelling index, in-vitro mucoadhesion study, and in-vitro drug release study.

Percentage Yield:

The percentage yield of the prepared microspheres was determined to evaluate the efficiency of the preparation method. After completion of the formulation process, the microspheres were collected by filtration and dried in a hot air oven at 40 °C until constant weight was obtained. The dried microspheres were accurately weighed using an analytical balance. The percentage yield was calculated by comparing the practical weight of microspheres obtained with the theoretical weight of the total drug and polymer used in the formulation [15].

The percentage yield was calculated using the following formula:

$$\text{Percentage Yield} = \frac{\text{Weight of microspheres obtained}}{\text{Total weight of drug and polymers}} \times 100$$

Particle Size Analysis:

The particle size of the prepared microspheres was determined using an optical microscope. A small quantity of dried microspheres was placed on a clean glass slide and spread evenly. A drop of glycerine was added to prevent particle movement, and the preparation was covered with a cover slip. The microspheres were observed under the microscope (45x). The diameter of approximately 10–20 microspheres was measured using a calibrated ocular micrometre. The average particle size was calculated by taking the mean value of the measured diameters [15].

Swelling Index:

The swelling behavior of the microspheres was studied to evaluate the ability of the polymer matrix to absorb gastric fluid. Accurately weighed microspheres were placed in a beaker containing 0.1 N hydrochloric acid solution maintained at 37 °C to simulate gastric conditions. After a specified time interval, the microspheres were removed and gently blotted with filter paper to remove excess surface liquid. The swollen microspheres were weighed immediately using an analytical balance [16].

The swelling index was calculated using the following formula:

$$\text{Swelling Index} = \frac{W_t - W_0}{W_0}$$

Where,

W_0= Initial weight of microspheres

W_t= Weight of swollen microspheres after specified time.

***In-Vitro* Mucoadhesion Test:**

The mucoadhesive property of the microspheres was evaluated using fresh chicken intestinal mucosa. Fresh chicken intestine was obtained from a local poultry shop and washed thoroughly with normal saline to remove adhering contents. The intestine was cut longitudinally and the mucosal surface was exposed. The mucosal tissue was mounted on a glass slide with the mucosal surface facing upward. A known quantity of microspheres (100 mg) was spread evenly over the mucosal surface and allowed to interact for about 20 minutes. The slide was then placed in a beaker containing 0.1 N hydrochloric acid and subjected to gentle agitation to simulate gastric movement. After a fixed period, the microspheres remaining adhered to the mucosal surface were carefully collected and weighed [16].

The percentage mucoadhesion was calculated using the following formula:

$$\text{Mucoadhesion} = \frac{\text{Weight of microspheres adhered}}{\text{Weight of microspheres applied}} \times 100$$

Determination of λmax:

The maximum absorption wavelength (λmax) of the ethanolic extract of *Tridax procumbens* was determined using a UV–Visible spectrophotometer to identify the wavelength at which the extract shows maximum absorbance.

Method:

Accurately weighed 10 mg of *Tridax procumbens* extract was transferred into a 10 mL volumetric flask and dissolved in ethanol to obtain a stock solution with a concentration of 1000 µg/mL. From this stock solution, 1 mL was pipetted and diluted up to 10 mL with 0.1 N hydrochloric acid to obtain a working solution of 100 µg/mL. The prepared solution was scanned in a UV–Visible spectrophotometer over the wavelength range of 200–400 nm using 0.1 N hydrochloric acid as the blank. The wavelength at which the extract exhibited maximum absorbance was recorded as the λmax and used for further analytical studies [17].

Preparation of Calibration Curve:

A calibration curve of the ethanolic extract of *Tridax procumbens* was prepared to establish the relationship between concentration and absorbance using a UV–Visible spectrophotometer. **Method:**

A stock solution of *Tridax procumbens* extract was prepared by accurately weighing 10 mg of the extract and dissolving it in ethanol in a 10 mL volumetric flask to obtain a concentration of 1000 µg/mL. From this stock solution, suitable aliquots were withdrawn and diluted with 0.1 N hydrochloric acid to obtain a series of working standard solutions with concentrations of 10, 20, 30, 40, and 50 µg/mL.[45]

The absorbance of each solution was measured at the previously determined λmax (275 nm) using 0.1 N hydrochloric acid as the blank. The absorbance values were recorded, and a calibration curve was constructed by plotting concentration (µg/mL) on the X-axis against absorbance on the Y-axis. The calibration curve showed a linear relationship within the selected concentration range and was used for further quantitative analysis of the extract [18].

***In-Vitro* Drug Release Study:**

The in-vitro drug release study of the prepared microspheres was carried out using a United States Pharmacopeia (USP) Type II dissolution apparatus (paddle method). The dissolution medium consisted of 900 mL of 0.1 N hydrochloric acid maintained at 37 ± 0.5 °C. The paddle speed was maintained at 50 rpm throughout the experiment. A quantity of microspheres equivalent to a predetermined amount of drug was placed in the dissolution medium. At predetermined time intervals, 5 mL samples were withdrawn from the dissolution medium and replaced with equal volume of fresh medium to maintain sink conditions. The withdrawn samples were filtered and analysed using a UV–Visible spectrophotometer at the predetermined λ max of the extract. The cumulative percentage drug release was calculated

and plotted against time to evaluate the release profile of the microspheres. The in-vitro drug release profile of the formulated Tridax procumbens mucoadhesive microspheres was evaluated in 0.1 N HCl (pH 1.2) to simulate gastric conditions. The samples withdrawn at predetermined time intervals were analyzed using a UV-Visible spectrophotometer at a λmax of 275 nm, and the drug concentration was determined using the calibration curve [19].

RESULTS AND DISCUSSSION:

Percentage Yield:

The percentage yield of the prepared microspheres was calculated to determine the efficiency of the formulation process.

Formula

$$\text{Percentage Yield}(\%) = \frac{\text{Weight of microspheres obtained}}{\text{Total weight of drug and polymers}} \times 100$$

Given Data

Weight of microspheres obtained = 1700 mg Total theoretical weight of formulation components: Drug (*Tridax procumbens* extract) = 1 g

Ethyl cellulose = 1 g HPMC K15M = 0.20 g

Total weight of drug and polymers

$= 1 + 1 + 0.20$

$= 2.20g$

$= 2200mg$

Calculation

Percentage Yield = $\times 100$

$= 77.27\%$

The percentage yield of microspheres was determined in order to evaluate the efficiency of the solvent evaporation technique used for the preparation of microspheres. The total weight of dried microspheres obtained after formulation and drying was 1700 mg. The theoretical weight of the formulation components (drug and polymers) was 2.20 g. The calculated percentage yield was 77.27%. The moderate yield obtained may be attributed to the loss of fine microsphere particles during washing and filtration processes as well as adhesion of polymeric material to the walls of the stirring vessel. Similar observations have been reported in microsphere formulations prepared using solvent evaporation techniques. However, the obtained yield was considered acceptable for further evaluation studies.

Particle Size Analysis:

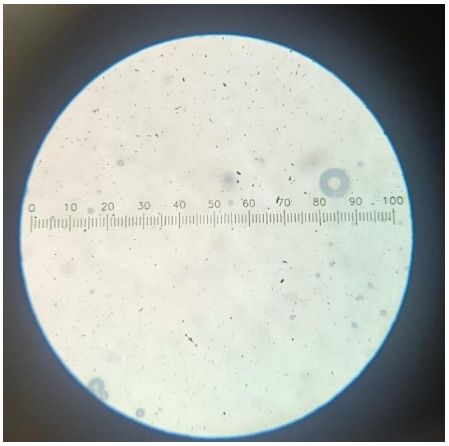

Fig 3: Microspheres under Optical Microscope

Formula

$$\text{Average Particle Size} = \frac{\sum d}{n}$$

Where:

d = Diameter of individual microsphere (µm)

n = Number of microspheres measured

Calculation

$\sum d = 180 + 210 + 195 + 205 + 190 + 220 + 200 + 215 + 185 + 205$

$\sum d = 2005$

Table 2: Particle size analysis

S.No	Diameter (µm)
1	180
2	210
3	195
4	205
5	190
6	220
7	200
8	215
9	185
10	205

Number of particles measured:

$n = 10$

Average Particle Size:

Average Particle Size =
= 200.5 µm 2005

10

The particle size of the prepared microspheres was determined using an optical microscope. Ten microspheres were randomly selected and their diameters were measured using an ocular micrometer. The average particle size was calculated and found to be 200.5 µm, indicating uniform particle distribution and successful formation of polymeric microspheres.

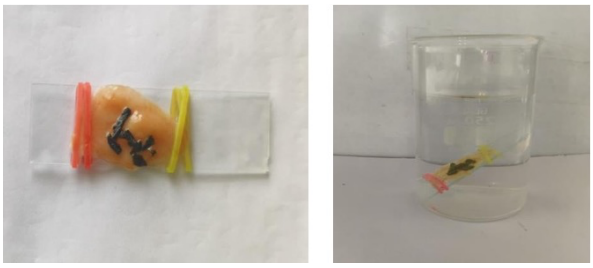

Fig 4: In-Vitro Mucoadhesion Strength test

***In-Vitro* Mucoadhesion:**

Formula

W

eight adhered
Percentage
Mucoadhesion =
Weight applied × 100

= 96.4%

Weight of microspheres applied = 100 mg
Weight of microspheres adhered after 1 hour = 96.4 mg

Calculation:

Percentage Mucoadhesion = 96.4 ×100
100

The obtained mucoadhesion value of 96.4% indicates excellent adhesion of microspheres to the mucosal surface. This strong adhesion is beneficial for gastric drug delivery as it prolongs the residence time of the formulation in the stomach and enhances localized therapeutic action for peptic ulcer treatment.

Swelling Index:

Fig 5: Swelling Index test

Formula

$$\text{Swelling Index} = \frac{W_t - W_0}{W_0}$$

Where,

W_0= Initial weight of microspheres
W_t= Weight of swollen microspheres

Data

Initial weight of microspheres W_0= 100 mg Weight after swelling W_t= 145 mg

Swelling percentage

The observed swelling index of 45% indicates good hydration behavior of the microspheres. The swelling property is mainly due to the presence of HPMC K15M, a hydrophilic polymer capable of absorbing gastric fluid and forming a gel layer. Adequate swelling enhances mucoadhesion and helps in sustaining the drug release.

Determination of λmax:

The ethanolic extract of *Tridax procumbens* showed maximum absorbance at 275 nm, which was taken as the λmax for further analytical studies and calibration curve preparation.

Wavelength (nm)	Absorbance
250	0.210
260	0.325
265	0.410
270	0.512
275	0.650

Table 3: Determination of λmax

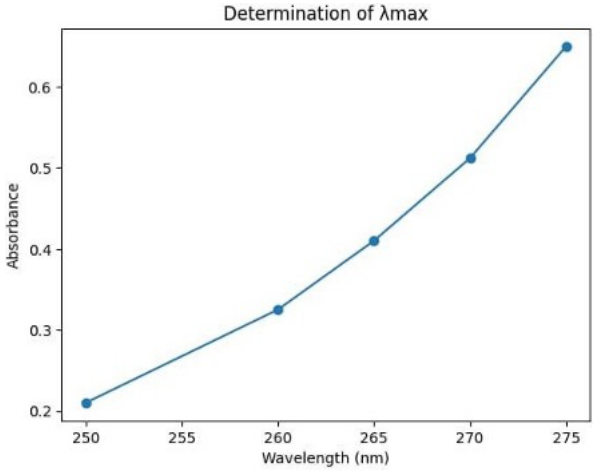

Fig 6: Determination of λmax curve

Preparation of Calibration Curve:

Table 4: Preparation of calibration

Concentration (µg/mL)	Absorbance at 275 nm
10	0.152
20	0.268
30	0.395
40	0.525
50	0.650

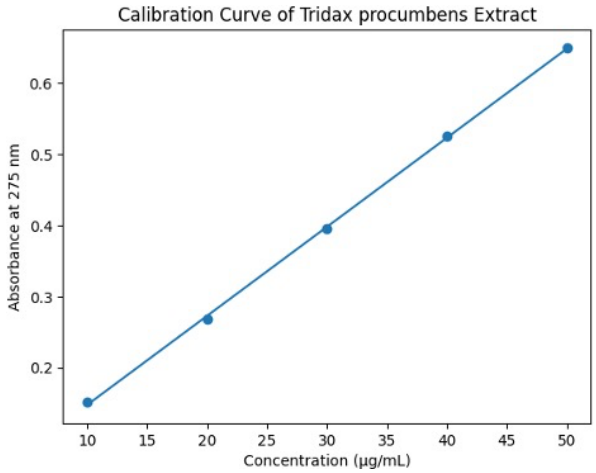

Fig 7: Calibration curve

***In-Vitro* drug release:**

The in-vitro drug release profile of the formulated mucoadhesive microspheres containing *Tridax procumbens* extract was evaluated for a period of 8 hours. The cumulative percentage drug release was determined at predetermined time intervals.

The results indicated a gradual and controlled release pattern of the drug from the microspheres. An initial drug release of 16.2% was observed within the first hour, which may be attributed to the release of the drug present on the surface of the microspheres. The cumulative drug release increased progressively with time, reaching 28.8% at 2 hours, 42.3% at 3 hours, and 56.7% at 4 hours.

Further increase in drug release was observed with 70.2% at 5 hours and 81.9% at 6 hours, indicating sustained release of the drug from the polymeric matrix. The drug release continued to increase and reached 90.9% at 7 hours and finally 97.2% at the end of 8 hours.

The sustained release behavior can be attributed to the presence of ethyl cellulose and HPMC K15M polymers, which control drug diffusion from the microsphere matrix. These results indicate that the formulated mucoadhesive microspheres provide a sustained drug release profile which may enhance gastric residence time and improve the therapeutic effectiveness in the treatment of peptic ulcer.

Table 5: In-vitro Drug Release

Time (hr)	Absorbance	Concentration (mg/mL)	Drug Released (mg)	Cumulative % Release
1	0.152	0.018	16.2	16.2%
2	0.268	0.032	28.8	28.8%
3	0.395	0.047	42.3	42.3%
4	0.525	0.063	56.7	56.7%
5	0.650	0.078	70.2	70.2%
6	0.760	0.091	81.9	81.9%
7	0.845	0.101	90.9	90.9%
8	0.910	0.108	97.2	97.2%

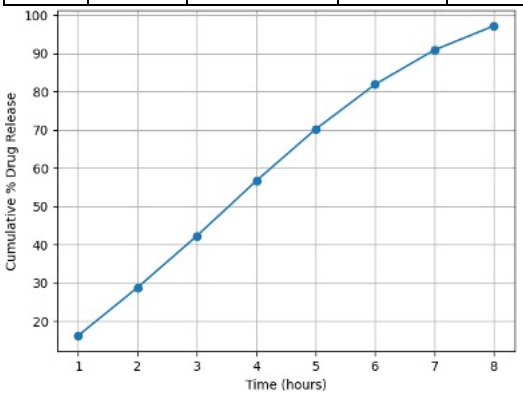

Fig 8: In-Vitro Drug Release Profile of Tridax procumbens Loaded Mucoadhesive Microsphere

CONCLUSION

The present study successfully formulated and evaluated mucoadhesive microspheres containing *Tridax procumbens* extract for potential application in the treatment of peptic ulcer. The microspheres were prepared using the solvent evaporation technique with Ethyl Cellulose as the matrix-forming polymer and Hydroxypropyl Methylcellulose (HPMC K15M) as the mucoadhesive polymer. The prepared formulation was evaluated for various physicochemical parameters including percentage yield, particle size analysis, swelling index, in-vitro mucoadhesion, and in-vitro drug release. The microspheres exhibited satisfactory formulation characteristics with a percentage yield of 77.27% and an average particle size of approximately 200 µm, confirming the successful formation of spherical and discrete microspheres. The swelling index of 45% indicated good hydration ability of the polymer matrix, which contributes to enhanced mucoadhesion and controlled drug release. The in-vitro mucoadhesion study demonstrated 95% adhesion, suggesting strong interaction between the microspheres and mucosal surface, which may prolong gastric residence time and improve drug retention at the site of action. The in-vitro drug release study revealed a sustained drug release profile, with approximately 97% drug release was observed over 8 hours, indicating effective controlled release behavior of the formulation. The sustained release pattern can be attributed to the polymeric matrix formed by Ethyl Cellulose and HPMC K15M, which regulates drug diffusion from the microspheres. Overall, the results of the present study indicate that the formulated mucoadhesive microspheres possess desirable physicochemical properties, strong mucoadhesive characteristics, and sustained drug release behavior. These findings suggest that the developed microsphere formulation could serve as a promising gastro-retentive drug delivery system for improving the therapeutic effectiveness of *Tridax procumbens* in the management of peptic ulcer. Further studies including in vivo evaluation and clinical investigations would be required to confirm its therapeutic potential and safety for clinical applications.

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