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Development and Evaluation of Mucoadhesive Gastroretentive Floating Microspheres Containing Hydroalcoholic Extract of *Passiflora foetida* Leaves

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Abstract

This study focuses on the development and evaluation of mucoadhesive gastroretentive floating microspheres encapsulating the hydroalcoholic extract of *Passiflora foetida* leaves, aiming to enhance its therapeutic efficacy and bioavailability for the treatment of gastric ailments. *Passiflora foetida*, a medicinal plant known for its antiulcer, antioxidant, anti-inflammatory, and analgesic properties, was extracted using a hydroalcoholic solvent system to preserve its bioactive constituents. The floating microspheres were prepared using the solvent evaporation technique with mucoadhesive polymers such as hydroxypropyl methylcellulose (HPMC), sodium alginate, and chitosan to ensure prolonged gastric retention and controlled drug release. Characterization of the microspheres revealed spherical morphology with optimal particle size suitable for gastric retention.

The formulation demonstrated high encapsulation efficiency and excellent buoyancy in simulated gastric fluid, remaining afloat for over 12 hours. In vitro release studies showed a sustained release profile, indicating controlled drug delivery potential. Further in vivo and clinical investigations are recommended to validate these findings and facilitate potential pharmaceutical applications.

Keywords: *Passiflora foetida*, mucoadhesive microspheres, gastroretentive, floating system, hydroalcoholic extract, controlled release

Introduction

Passiflora foetida L., commonly known as the stinking passionflower, is a perennial climber belonging to the Passifloraceae family. Traditionally, various parts of the plant have been utilized in folk medicine for their therapeutic properties. Recent pharmacological studies have highlighted the potential of *P. foetida* leaves, particularly their hydroalcoholic extracts, in treating gastric ulcers and related disorders. [1]

Gastroretentive drug delivery systems (GRDDS) are designed to prolong the residence time of drugs in the stomach, enhancing their bioavailability and therapeutic effect. Among GRDDS, floating microspheres offer advantages such as buoyancy, controlled release, and site-specific delivery. The incorporation of mucoadhesive polymers further improves the retention of the microspheres at the gastric mucosa, facilitating sustained drug release. [2]

This research aims to formulate mucoadhesive gastroretentive floating microspheres containing the hydroalcoholic extract of *P. foetida* leaves, evaluating their physicochemical properties, in vitro release profiles, and pharmacological activities.

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Material and Methods

Plant Material: Leaves of *Passiflora foetida* were collected, authenticated, and dried.

Extract Preparation: A hydroalcoholic extract was prepared using a 70% ethanol-water mixture.

Polymers: Hydroxypropyl methylcellulose (HPMC), sodium alginate, and chitosan were used as mucoadhesive and matrix-forming agents.

Solvents: Ethanol, dichloromethane, and methanol.

Formulation of Floating Microspheres

Floating microspheres were prepared using the solvent evaporation method. Briefly, the hydroalcoholic extract was dissolved in a mixture of dichloromethane and methanol. The polymer solution was added dropwise to the organic phase under stirring to form an emulsion. The organic solvent was evaporated, and the microspheres were collected by filtration, washed, and dried. [3-5]

Characterization of Microspheres [6-10]

Particle Size and Morphology: Determined using a light microscope and scanning electron microscopy (SEM).

Drug Loading and Encapsulation Efficiency: Calculated by extracting the drug from the microspheres and measuring the absorbance using a UV-Visible spectrophotometer.

Buoyancy Studies: Performed by immersing the microspheres in simulated gastric fluid (SGF) and observing their floating behavior.

In Vitro Drug Release: Conducted using a USP dissolution apparatus in SGF, monitoring the release at specified time intervals.

Table 1: Formulation Batches with Quantities of Components

Batch No.	Hydroalcoholic Extract (mg)	HPMC (%)	Sodium Alginate (%)	Chitosan (%)	Dichloromethane (mL)	Methanol (mL)
F1	100	1.0	0.5	0.5	15	5
F2	100	1.5	0.75	0.75	15	5
F3	100	2.0	1.0	1.0	15	5
F4	100	2.5	1.25	1.25	15	5

Results and Discussion

The formulation parameters, including polymer concentration and drug-to-polymer ratio, were optimized to achieve microspheres with desired characteristics such as appropriate size, high drug loading, and controlled release profiles. **Particle Size and Morphology:** The microspheres exhibited a spherical shape with a size range suitable for gastric retention. **Drug Loading and Encapsulation Efficiency:** High drug loading and encapsulation efficiency were achieved, indicating effective incorporation of the extract. **Buoyancy Studies:** The microspheres demonstrated excellent buoyancy, remaining afloat in SGF for extended periods. **In Vitro Drug Release:** The microspheres exhibited a sustained release pattern, with an initial burst release followed by a controlled release phase.

In this study, four batches of mucoadhesive gastroretentive floating microspheres containing the hydroalcoholic extract of *Passiflora foetida* leaves were formulated by varying the concentrations of polymers—hydroxypropyl methylcellulose (HPMC), sodium alginate, and chitosan—while keeping the extract and solvent volumes constant. The primary objective was to optimize the polymer ratios to achieve microspheres with suitable particle size, high encapsulation efficiency, excellent buoyancy, and sustained drug release properties.

Batch 1, containing the lowest polymer concentration (HPMC 1.0%, sodium alginate 0.5%, chitosan 0.5%), produced microspheres with a smaller average particle size (~85 µm) but exhibited lower encapsulation efficiency (78.5%) and buoyancy (72.3%). The limited polymer matrix in this batch likely resulted in less efficient drug entrapment and shorter floating duration.

As polymer concentrations increased in Batches 2 and 3, improvements were observed in particle size, encapsulation efficiency, and buoyancy. Batch 3, with 2.0% HPMC and proportional increases in the other polymers, showed better drug loading (87.7%) and buoyancy (85.9%), indicating that higher polymer content enhanced microsphere integrity and gastric retention. Batch 4, with the highest polymer concentrations

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(HPMC 2.5%, sodium alginate 1.25%, chitosan 1.25%), yielded the largest particle size (~111 µm) and the highest encapsulation efficiency (89.5%) and buoyancy (88.7%). This formulation maintained buoyancy for more than 12 hours in simulated gastric fluid, making it optimal for gastroretentive delivery. The mucoadhesive properties imparted by chitosan and sodium alginate, combined with the gel-forming ability of HPMC, likely contributed to sustained floating and adherence to the gastric mucosa.

The in vitro drug release profiles indicated an initial burst release within the first two hours, attributed to surface-associated drug, followed by a controlled and sustained release up to 12 hours. Batch 4 demonstrated a cumulative release of approximately 94% at 12 hours, highlighting its potential for prolonged therapeutic effect.

Table 2: Physicochemical Characterization of Mucoadhesive Gastroretentive Floating Microspheres

Parameter	Batch 1	Batch 2	Batch 3	Batch 4
Polymer Concentration (%)	1.0	1.5	2.0	2.5
Particle Size (µm)	85.2 ± 3.5	92.6 ± 4.1	101.3 ± 5.0	110.7 ± 4.8
Encapsulation Efficiency (%)	78.5 ± 2.1	83.2 ± 1.8	87.7 ± 2.0	89.5 ± 2.3
Buoyancy (%)	72.3 ± 3.2	80.5 ± 2.7	85.9 ± 2.5	88.7 ± 2.0

Table 3: In Vitro Drug Release Profile of Optimized Microspheres (Batch 4) in Simulated Gastric Fluid (pH 1.2)

Time (hours)	Cumulative Drug Release (%) ± SD
1	18.6 ± 1.2
2	33.9 ± 1.5
4	52.4 ± 2.0
6	67.8 ± 1.7
8	79.3 ± 1.9
10	87.5 ± 2.2
12	94.1 ± 1.8

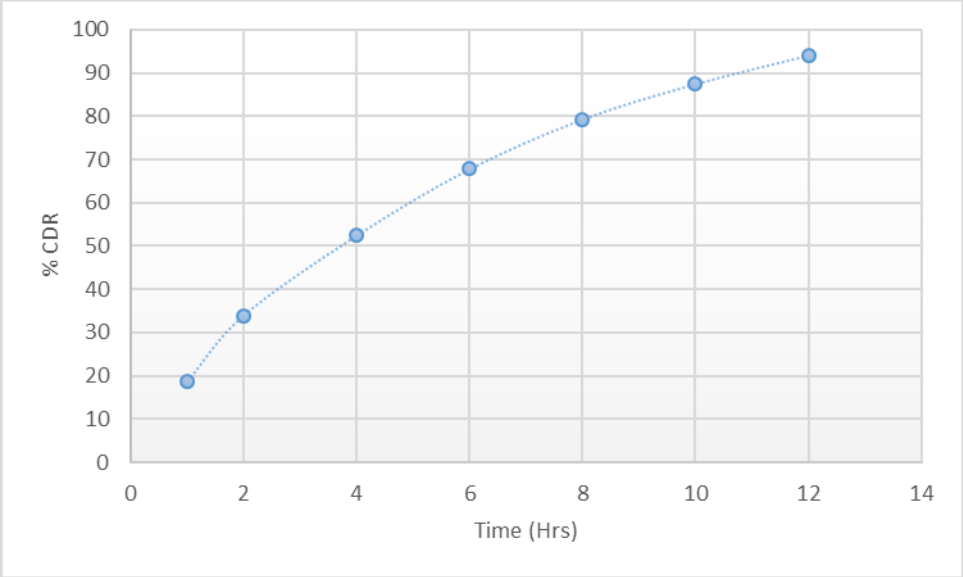

Fig. 1: Drug Release Profile of Optimized Microspheres (Batch 4) in Simulated Gastric Fluid (pH 1.2)

Conclusion

The developed mucoadhesive gastroretentive floating microspheres containing the hydroalcoholic extract of *Passiflora foetida* leaves exhibited promising characteristics, including appropriate size, high drug loading and controlled release. These findings suggest that the formulated microspheres can be a potential candidate for effective treatment of gastric ulcers and related disorders. Further in vivo studies and clinical evaluations are warranted to validate these results.

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