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FORMULATION AND EVALUATION OF FAMOTIDINE FLOATING MICROSPHERES WITH SUITABLE POLYMERS

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ABSTRACT

The study aimed to develop and evaluate floating microspheres of Famotidine for prolonged gastric retention and controlled drug release using the ionic gelation method. Polymers such as Sodium Alginate, HPMC, and Sodium Bicarbonate were used to enhance buoyancy and sustain release. The prepared microspheres exhibited good floating ability, uniform shape, and high drug entrapment with controlled release characteristics. FTIR and DSC analyses confirmed the absence of drug–polymer interaction, ensuring formulation stability. The optimized formulation showed effective buoyancy, swelling, and sustained release over an extended period. The drug release followed zero-order kinetics, indicating a constant release rate independent of concentration. The developed floating microspheres proved to be a promising gastroretentive system for improved therapeutic efficacy and patient compliance in the treatment of gastric ulcers.

KEYWORDS: Famotidine, Floating microspheres, Ionic gelation, Sustained release, Gastroretentive drug delivery system, Gastric ulcer.

INTRODUCTION

Oral administration is the most convenient and widely used method of drug administration, and developing stomach-specific oral controlled-release drug delivery systems is a difficult job due to pH variations in different segments of the gastrointestinal tract, fluctuations in

gastric emptying time, and the difficulty of localizing an oral delivery system in a specific region of the gastrointestinal tract. Rapid gastrointestinal transit can prevent the absorption of full drug in the absorption zone and reduce the efficacy of the administered dose since the majority of drugs are absorbed in stomach or the upper part of small intestine.[1]

Among the different dosage forms for prolonged gastric residence, our study has been dedicated to floating systems. Such systems seem to be useful for drugs acting locally in the gastrointestinal tract and drugs unstable in intestinal fluids, but well absorbable in the stomach.[2]

A Floating Drug Delivery System is a type of gastroretentive drug delivery system designed to prolong the residence time of a dosage form in the stomach by enabling it to float on gastric fluids without affecting the gastric emptying rate. The system remains buoyant in the stomach for an extended period, allowing for sustained drug release at the desired site of absorption, thereby improving bioavailability and therapeutic efficacy of drugs that are absorbed primarily in the stomach or upper small intestine.[3]

Floating microspheres are low-density, hollow spherical particles designed to float on gastric fluid and prolong the residence time of the drug in the stomach, thereby enhancing drug absorption and providing sustained release.[4]

A gastric ulcer is a type of peptic ulcer that develops on the inner lining of the stomach due to the erosion of the protective mucosal layer. This erosion occurs when there is an imbalance between the stomach's defensive mechanisms, such as mucus and bicarbonate secretion, and aggressive factors like hydrochloric acid, pepsin, or infection by Helicobacter pylori.[5]

Common causes include chronic use of nonsteroidal anti-inflammatory drugs (NSAIDs), bacterial infection, excessive alcohol consumption, smoking, and stress. Gastric ulcers often present with symptoms such as burning pain in the upper abdomen, nausea, vomiting, and bloating. If left untreated, they can lead to serious complications including bleeding, perforation, and obstruction, making timely diagnosis and management essential.[6]

MATERIALS AND METHODS

Materials

Famotidine was purchased from Dham tech pharma, Mumbai, Sodium Alginate, Hydroxy Propyl Methyl Cellulose, Sodium bicarbonate, Calcium chloride, procured from SD fine chemicals, Mumbai. All other chemicals and reagents used were LR grade.

Preformulation Studies

The drug was characterized for melting point (capillary method) and DSC, λmax in phosphate buffer pH 1.2 (UV scan 200–400 nm), and calibration curve (5–30 µg/ml at 287 nm). Drug–excipient compatibility was assessed using FTIR spectra (4000–500 cm^{-1}) of pure drug and physical mixtures with polymers.[7,8]

Method of Preparation of floating microsphere

The floating microspheres were prepared by Ionic gelation method. The polymeric solution was prepared by dissolving suitable polymers in distilled water. The drug was dissolved in the polymeric solution. The prepared drug-polymer solution was added dropwise by a syringe into Calcium chloride, being stirred. The formed microspheres further allowed to stir in the solution of crosslinking agents for an additional 1h.[9]

Table 1: Formulation Design for Floating Microspheres.

Formulation code	Famotidine (mg)	Sodium alginate (%)	HPMC (%)	Sodium bicarbonate (%)	Calcium Chloride (%)
F1	80	1	0.2	10	3
F2	80	1	1	5	3
F3	80	1	0.2	10	3
F4	80	3	1	5	3
F5	80	3	0.2	10	3
F6	80	3	0.2	5	3
F7	80	1	0.2	5	3
F8	80	3	1	10	3

Evaluation of Famotidine floating microsphere[10-14]

The prepared floating Microsphere formulation were evaluated for different parameters like Drug-Excipient's compatibility, Surface morphology, Particle size analysis, Drug content, Entrapment efficiency, swelling index, buoyancy study, In vitro dissolution study, and Stability studies as per ICH guidelines.

Invitro buoyancy study

In vitro floating ability of prepared floating microsphere was determined by placing 1 gms of each formulation in USP type 2 dissolution test apparatus containing simulated gastric fluid of pH 1.2. The medium was stirred at 100 rpm at 37±0.5o C. After 12hr, both fraction of microsphere (floating and settled microsphere) was collected, dried and weighed separately.

In vitro drug release

The drug release study was carried out in the United States of Pharmacopeia (USP) dissolution apparatus II using the formulation containing 100 mg equivalent drug at 37±0.50C. For the simulation of physiological conditions, the study was carried out at pH 1.2. Initially, the drug release was determined in 900mL of 0.1N (pH 1.2) hydrochloric acid for 12 hrs. The samples were withdrawn at suitable intervals and replaced with fresh medium and analysed UV spectrophotometrically at 287nm. The drug release mechanism was determined by finding the best fit of the release data.

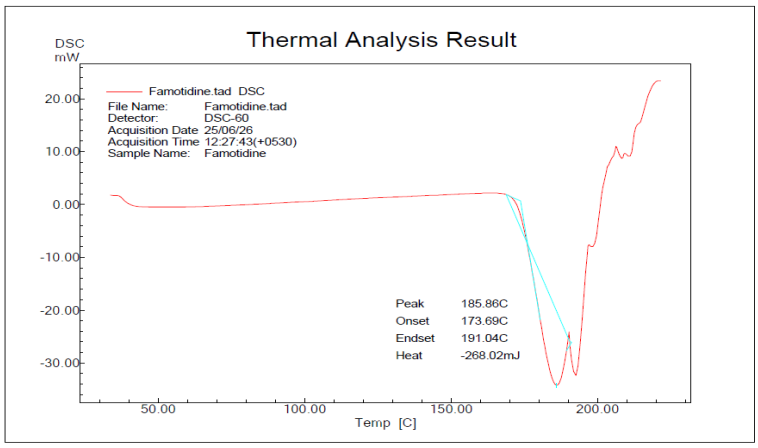

Figure 1: DSC graph of pure Famotidine.

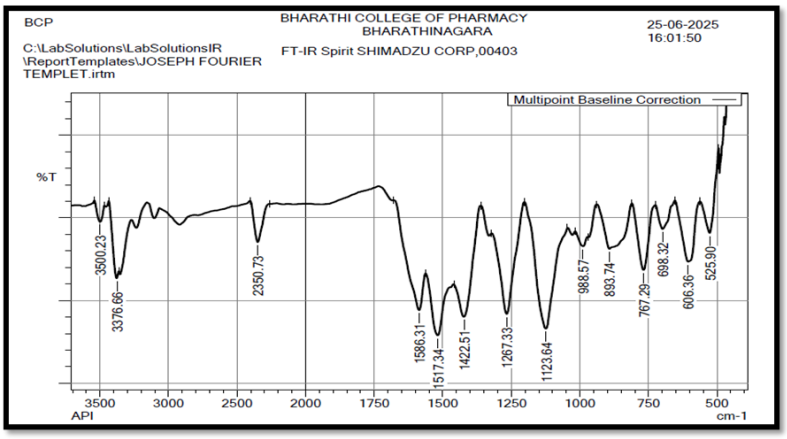

Figure 2: FT-IR Spectra of Famotidine.

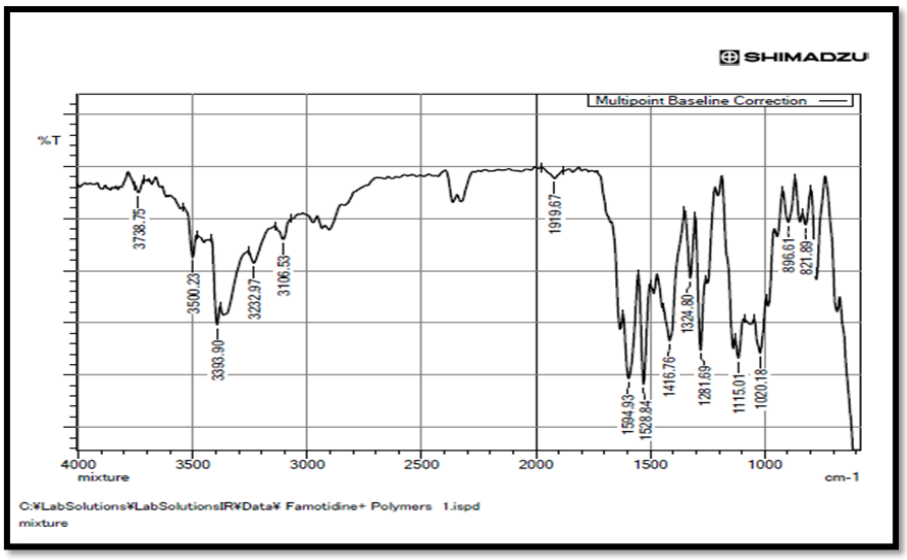

Figure 3: FT-IR Spectra of drug and physical mixture.

Table 2: Results of Evaluation Parameters (Formulation F1–F8).

F. code	Drug Content (%)	Entrapment efficiency	Swelling index (%)	Buoyancy study (at 12hrs) (%)
F1	87.0	88.3	80.0	88
F2	88.8	90.9	88.6	86
F3	89.6	91.5	85.3	90
F4	90.8	93.9	91.1	93
F5	90.3	93.1	82.0	92
F6	90.1	92.1	90.4	89
F7	88.3	90.5	88.6	85
F8	92.7	94.1	92.3	94

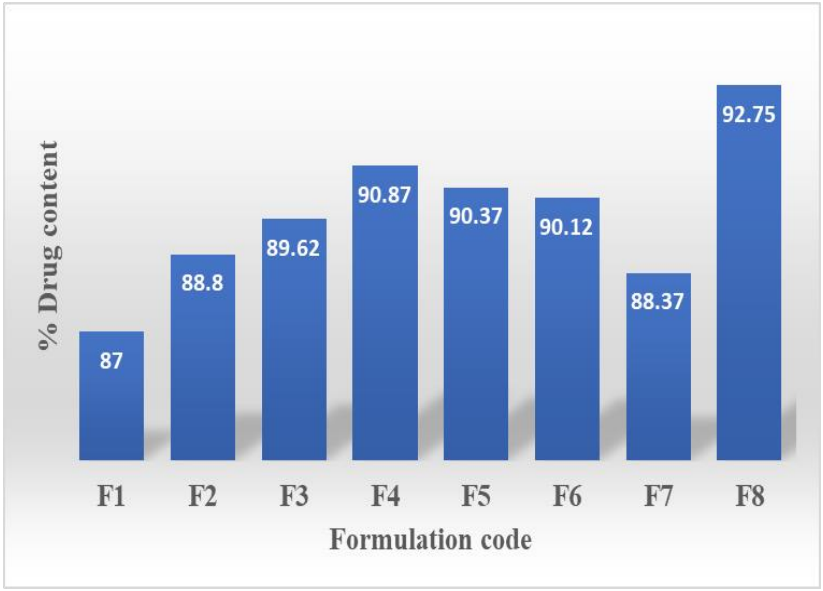

Figure 4: Drug content of formulation F1-F8.

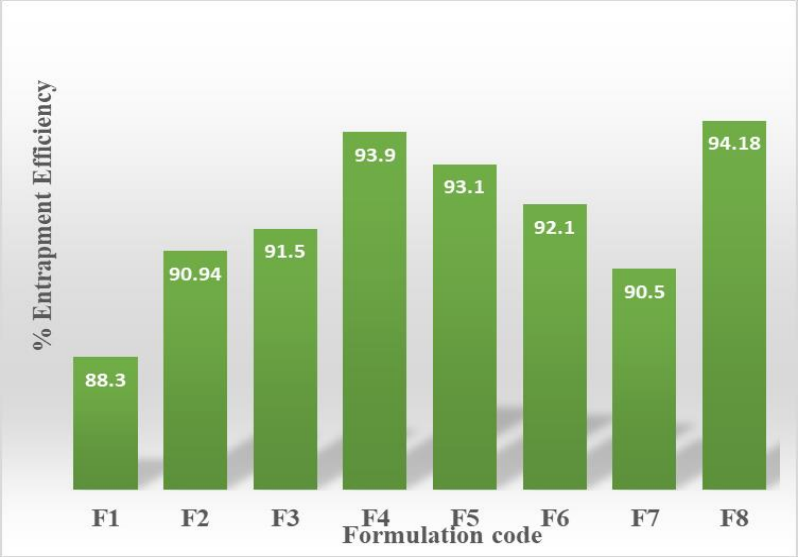

Figure 5: Entrapment efficiency of formulation F1-F8.

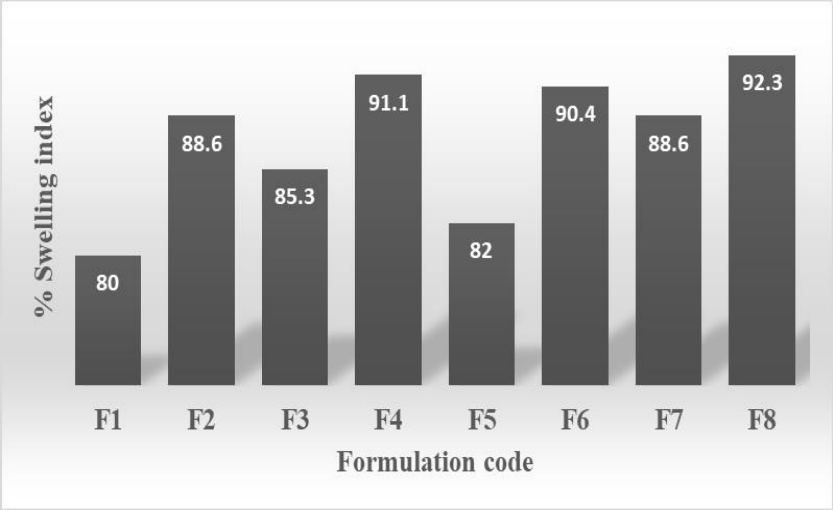

Figure 6: Swelling index of formulation F1-F8.

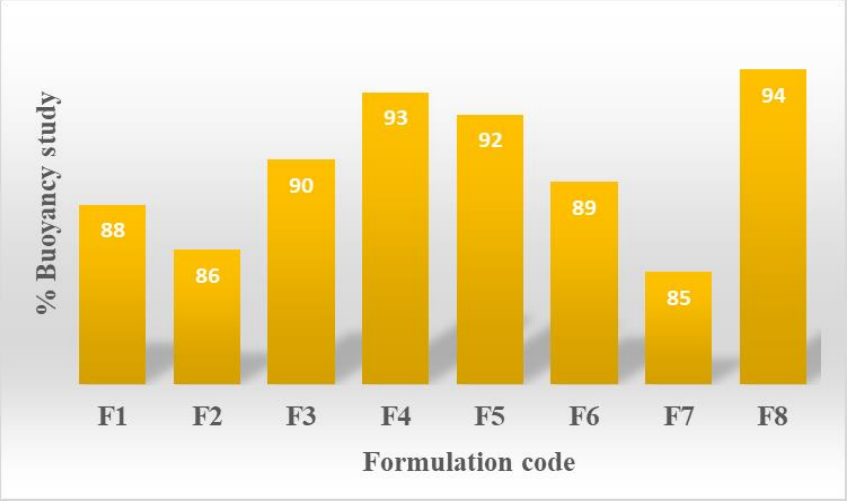

Figure 7: Buoyancy study of formulation F1-F8.

Table 3: *in vitro* drug release profile of formulation F1-F8.

Time (hrs)	F1	F2	F3	F4	F5	F6	F7	F8
0	0	0	0	0	0	0	0	0
1	8.372	6.279	8.372	8.372	8.372	7.674	8.372	9.070
2	17.442	14.651	16.744	18.140	14.651	14.651	13.953	19.535
4	29.302	30.698	34.186	29.302	30.698	28.605	32.093	35.581
6	46.744	44.651	56.512	45.349	49.535	39.070	49.535	49.535
8	66.279	59.302	68.372	57.907	62.093	49.535	63.488	64.884
10	77.442	70.465	78.140	62.791	73.256	62.093	70.465	79.535
12	89.302	81.628	89.302	77.442	86.512	78.140	84.419	91.395

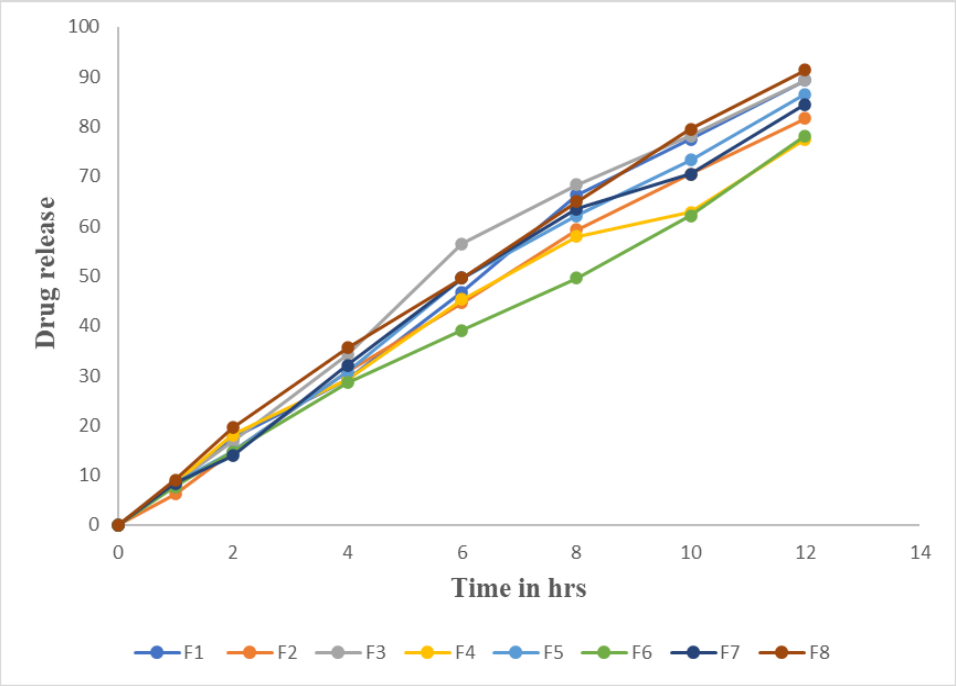

Figure 8: *in vitro* drug release profile of formulation F1-F8.

Table 4: Data for different kinetic model.

Formulation code	KINETIC MODELS (r^2 VALUE)			Peppas model	
	Zero order	First order	Higuchi	r^2	'n' value
F1	0.998	0.942	0.870	0.994	1.369
F2	0.998	0.973	0.882	0.972	1.129
F3	0.993	0.967	0.913	0.989	1.153
F4	0.993	0.975	0.891	0.990	1.313
F5	0.998	0.955	0.909	0.996	1.346
F6	0.998	0.943	0.905	0.993	1.231
F7	0.995	0.967	0.902	0.994	1.263
F8	0.997	0.928	0.914	0.995	1.140

RESULTS

The floating microspheres of Famotidine were successfully prepared using the ionic gelation method with varying concentrations of Sodium Alginate, HPMC, Sodium Bicarbonate, and

Calcium Chloride. The prepared formulations (F1–F8) were evaluated for drug content, entrapment efficiency, swelling index, buoyancy, and in vitro drug release. The drug content ranged from 87.0% to 92.7%, while the entrapment efficiency varied between 88.3% and 94.1%, with formulation F8 showing the highest value. The swelling index was found between 80.0% and 92.3%, and the buoyancy percentage after 12 hours ranged from 85% to 94%, indicating good floating ability of all formulations. The in vitro drug release study showed a sustained release pattern for 12 hours, with formulation F8 showing the highest cumulative release of 91.39%, while other formulations exhibited controlled release between 77.44% and 89.30%. Drug release kinetic studies revealed that all formulations followed zero-order kinetics with high correlation coefficients (r^2 = 0.993–0.998), indicating concentration-independent drug release. The Peppas model showed n-values >1, suggesting super case-II transport, dominated by both diffusion and polymer relaxation mechanisms.

DISCUSSION

The results indicate that polymer concentration and composition significantly influenced the physicochemical and release properties of Famotidine floating microspheres. The increase in Sodium Alginate concentration enhanced entrapment efficiency and sustained drug release due to the formation of a stronger gel matrix. The addition of HPMC improved viscosity and swelling capacity, contributing to controlled diffusion of the drug from the matrix.

Sodium Bicarbonate, acting as a gas-generating agent, produced CO_2 that got entrapped within the polymer network, enabling the microspheres to remain buoyant in gastric fluids. A higher concentration of Calcium Chloride increased crosslinking density, improving mechanical strength but slightly reducing drug release due to decreased porosity.

Formulation F8, containing higher concentrations of both Sodium Alginate and HPMC, exhibited the best combination of buoyancy (94%), entrapment efficiency (94.1%), and sustained release (91.39% at 12 hrs).

The FTIR and DSC analyses confirmed no significant interaction between the drug and polymers, ensuring drug stability within the microsphere matrix. These findings demonstrate that optimized formulation parameters can effectively control the floating behaviour and release kinetics of Famotidine microspheres for prolonged gastric retention.

CONCLUSION

The study successfully developed and evaluated floating microspheres of Famotidine using the ionic gelation method to achieve prolonged gastric residence and controlled drug release. Among all the formulations, F8 was found to be the most optimized, providing excellent buoyancy, high drug entrapment, and sustained release over 12 hours. The release followed zero-order kinetics with super case-II transport, confirming the diffusion and polymer relaxation-controlled mechanism.

Thus, the formulated floating microspheres of Famotidine can serve as a promising gastroretentive drug delivery system, potentially improving therapeutic efficacy, reducing dosing frequency, and enhancing patient compliance in the management of gastric ulcer and related disorders.

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