

Design And Optimization Of Natural Polymer Based Floating Tablets Of Famotidine

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ABSTRACT

Background: Famotidine, a histamine H₂-receptor antagonist, suffers from low oral bioavailability and short half-life, necessitating frequent dosing. Developing floating controlled-release tablets can enhance gastric retention, improve bioavailability, and sustain drug release.

Objective: This study aimed to design, optimize, and evaluate floating Famotidine tablets using natural polymer-treated ghee-residue and oyster mushroom powder as novel excipients.

Methods: Floating tablets were prepared by direct compression employing a 3² factorial design, with polymer concentration and gas-generating agent concentration as independent variables. Tablets were assessed for pre- and post-compression parameters, buoyancy, swelling index, drug content, dissolution profile, release kinetics, FTIR compatibility, and stability.

Results: All formulations exhibited acceptable physicochemical properties, buoyancy for >15 hours, and compliance with pharmacopeial standards. Dissolution studies revealed Zero-order release kinetics, with the Korsmeyer–Peppas model indicating non-Fickian diffusion. Treated ghee-residue formulations showed more sustained drug release compared to oyster mushroom powder. Among all, formulation F3 (Famotidine: ghee-residue at 1:1.5 ratio) demonstrated optimal floating lag time (1.59 min), prolonged release (12 h), and stable performance under accelerated conditions.

Conclusion: Treated ghee-residue proved superior to oyster mushroom powder in sustaining Famotidine release, highlighting its potential as a cost-effective, sustainable, and efficient natural polymer for gastro-retentive formulations.

Keywords: Famotidine, floating tablets, gastro-retentive drug delivery, natural polymers, oyster mushroom powder, treated ghee-residue

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1. INTRODUCTION

Famotidine, a widely prescribed histamine H₂-receptor antagonist, is limited by poor oral bioavailability (40–45%) and a short half-life (2.5–4 hours), requiring frequent dosing to maintain therapeutic efficacy. This results in reduced patient compliance and inconsistent therapeutic outcomes in the management of gastric ulcers, duodenal ulcers, Zollinger–Ellison syndrome, and gastro esophageal reflux disease (GERD). In the management of benign gastric and duodenal ulceration, the recommended oral dose is 40 mg once daily at bedtime for a duration of 4 to 8 weeks¹. Conventional dosage forms fail to ensure prolonged gastric residence, as the drug is absorbed mainly in the upper gastrointestinal tract. To address these limitations, gastro-retentive floating tablets provide a promising approach by extending gastric residence time and sustaining drug release. While synthetic polymers are often employed in such systems, their high cost, limited

biocompatibility, and environmental impact reduce their suitability. Natural excipients such as treated ghee-residue, a by-product of the dairy industry, and oyster mushroom powder, rich in nutritional and functional components, represent potential alternatives. Despite their availability and benefits, their application in gastro-retentive formulations has not been thoroughly investigated. The challenge, therefore, lies in designing an optimized floating tablet of Famotidine using natural polymers that can enhance bioavailability, provide controlled drug release, and promote the sustainable use of readily available natural resources. India, being the world's largest producer of milk, generates a considerable amount of ghee residue as a by-product. This residue contains valuable nutrients such as proteins, calcium, and phospholipids, making it a promising candidate for effective utilization rather than being discarded as waste. Ghee residue has potential applications in animal feed, biofuel production, and as an ingredient in the food and pharmaceutical industries. The concept of by-product utilization has gained increasing global attention due to the rapid generation of such wastes, and researchers are now focusing on valorization strategies that not only address waste management but also add value. Therefore, exploring innovative approaches for the pharmaceutical application of ghee residue represents a sustainable and novel utilization pathway². The white oyster mushroom (*Pleurotus ostreatus*) is an edible mushroom known for its wide range of health benefits. It contains proteins, carbohydrates, dietary fiber, vitamins, minerals, and essential amino acids. These bioactive components exhibit various pharmacological properties, including antioxidant, anti-tumor, and anti-hypercholesterolemic effects, as well as immunomodulatory activity that helps in improving the body's immune status³. The study aims to design, optimize, and evaluate floating controlled-release tablets for Famotidine, a histamine H₂-

receptor antagonist, using natural polymers like treated ghee-residue and oyster mushroom powder as novel excipients to improve bioavailability and drug release.

2. MATERIALS AND METHODS

Famotidine was obtained as a gratis sample from Hetero labs, Hyderabad. Oyster mushroom powder gum and Treated Ghee-residue were purchased from local market. Citric acid and Sodium bicarbonate were purchased from Qualigens fine chemicals, Mumbai. All other ingredients were of analytical grade.

Treatment and Processing of Ghee-Residue:

Ghee-residue is initially soft and smooth in texture but progressively hardens during storage. The change in textural characteristics occurs rapidly, particularly within the first 15 days, and by the end of one month, it becomes hard and gritty. To overcome these undesirable characteristics, the residue was processed to obtain a soft and smooth texture suitable for edible and pharmaceutical applications. The lumps were first broken and pulverized by passing through a 40-mesh sieve. The residue was then washed with 50% alcohol, followed by boiling in 1% sodium bicarbonate solution. Subsequent autoclaving of the residue after incorporating 2% vinegar reduced the moisture content and further improved the texture of the product⁴.

Preparation of Oyster Mushroom (*Pleurotus ostreatus*) Powder:

Fresh oyster mushrooms (3 kg) were cleaned, weighed, and cut into small pieces. To reduce the characteristic mushroom odor, the pieces were treated with 2% salt solution for 1 hour. The treated mushrooms were then dried in a hot-air oven at 60 °C for 48 hours, pulverized using a blender, and passed through a 200-mesh sieve. The obtained powder (approximately 200 g) was collected and stored in airtight jars for further use⁵.

Preparation of Famotidine floating tablets

Famotidine was mixed with required quantities of treated ghee-residue /oyster mushroom powder, sodium bicarbonate and citric acid by geometric mixing. The tablets were formulated by employing direct compression method. Magnesium stearate and talc were used as lubricant and glidant respectively. The final blend was compressed into tablets using 12 mm punches and corresponding dies on rotary tablet compression machine⁶. The composition of each formulation was given in Tables 1.

Evaluation Parameters

Flow properties of powder blend: The powder blend was evaluated for the Bulk density, Tapped density, Carr's index, Hausner's ratio and Angle of repose⁷.

Evaluation of Famotidine floating tablets:

The tablets were evaluated for hardness, Weight variation and Friability⁸.

a) Swelling Index: Formulated tablets were weighed individually (W_0) and placed separately in Petri dish containing 50 ml of 0.1N Hydrochloric acid. The Petri dishes were placed in an incubator maintained at $37 \pm 0.5^\circ\text{C}$. The tablets were removed from the petri dish, at predefined intervals of time and reweighed (W_t), and the % swelling index was calculated using the following formula⁹.

$$\% W_U = (W_t - W_o / W_o) \times 100$$

Where:

W_U – Water uptake

W_t – Weight of tablet at time t

W_o – Weight of tablet before immersion

b) In vitro buoyancy study: This test is characterized by floating lag time and total floating time. The test was performed using USP-Type II paddle apparatus using 900 ml of 0.1N Hydrochloric acid at paddle rotation of 100 rpm at $37 \pm 0.5^\circ \text{C}$. The time required for tablet to rise to surface of dissolution medium and duration of time the tablet constantly float on dissolution medium was noted as floating lag time and total floating time¹⁰.

c) Drug content: 20 tablets were weighed and powdered the powder weight equivalent to 40mg of Famotidine was dissolved in 100ml of 0.1N Hydrochloric acid and filtered. 5ml of this was diluted to 50ml with water and drug content was estimated at 266nm by UV spectrophotometer¹¹.

d) In vitro dissolution test: The release of Famotidine from the tablet was studied using USP-Type II paddle apparatus. Drug release profile was carried out in 900 ml of 0.1N Hydrochloric acid maintained at $37 \pm 0.5^\circ \text{C}$ temperatures at 100 rpm. 5 ml of samples were withdrawn at regular time intervals. The samples were replaced by its equivalent volume of dissolution medium and was filtered through 0.45 μm Whatman filter paper and analyzed at 266 nm by UV spectrophotometer¹².

Drug Excipient Compatibility Studies:

Fourier Transform Infrared (FTIR) Spectroscopy studies were used for the evaluation of physicochemical compatibility and interactions, which helps in the prediction of interaction of the drug with treated ghee-residue or oyster mushroom powder used in tablet formulations¹³.

Stability studies of optimized floating matrix tablets:

The optimized floating matrix tablets were separated in to two groups. Each group of formulations were placed separately in stability chamber which is maintained at $25 \pm 5^\circ \text{C}/60\% \text{ RH}$ and $40 \pm 5^\circ \text{C}/75\% \text{ RH}$ respectively for three months and every month the formulations from each group were subjected to dissolution studies and % drug release was calculated¹⁴.

3. RESULTS AND DISCUSSION

Gas-generating agents are key excipients in the formulation of floating tablets, a type of gastro-retentive drug delivery system. Commonly used agents such as sodium bicarbonate and citric acid react in the presence of gastric fluid to produce carbon dioxide gas. This generated gas becomes entrapped within the tablet matrix, decreasing its density and allowing the tablet to float on the gastric contents. The buoyancy achieved through this mechanism ensures prolonged gastric retention, enhancing the drug's bioavailability by maintaining it at the absorption site for an extended period. Therefore, gas-generating agents are critical for the effective performance of floating tablets, enabling controlled and sustained drug release. Floating tablets were prepared by using two independent variables, OysterMushroom powder and combination of sodium bicarbonate and citric acid, to varying degrees, as described by a 32-factorial design, a three level, two factor experimental design. As dependent variables, time taken for 50 % of drug release (T_{50}) and floating lag time (FLT) were used. For the Final Equations, significance terms were selected at a 95% confidence interval ($p < 0.05$). Factor X1 (OysterMushroom powder) has three concentration levels of 10%, 20%, and 30%, while factor X2 (combination of sodium bicarbonate and citric acid) has three concentration levels of 7.5%, 11.25%, and 15%. The strategy for the preparation of the Famotidine floating tablet was developed based on percentage composition relative to the average tablet weight of 200 mg.

Using chosen X1, X2, combos of the two elements according to the 32 Factorial, nine different formulations of Famotidine floating tablets were prepared. These formulations were then assessed to determine the importance of the mixed results of X1, X2, in order to determine the optimal blend as well as the focus needed to achieve the desired drug release in 12 hours. Three concentration levels of oystermushroom powder were chosen and assigned the codes -1 = 10%, 0 = 20%, and +1 = 30%.

Using DESIGN EXPERT 7 software, polynomial equations were produced for the floating lag time (FLT) and time taken for 50 % of drug release (T_{50}). Figure 1-2 displays the response surface and contour plots for the floating lag time (FLT) and time taken for 50 % of drug release (T_{50}) applying X1 and X2, respectively, on both axes. The formula $Y = b_0 + b_1 X_1 + b_2 X_2 + b_{12} X_1 X_2 + b_{11} X_1^2 + b_{22} X_2^2$ is the polynomial equation for 3^2 full factorial designs. If Y represents the dependent variable, b_0 is the nine batches' mathematical mean answer, and b_1 is the factor X1 estimated co-efficient. The average effect of adjusting each factor one from a low to a high value over time is represented by the primary effects (X1 and X2). When two factors are altered at the same time, the response changes as indicated by the interaction term ($X_1 X_2$).

The polynomial expressions (X_1^2 and X_2^2) are included in order to explore non-linearity. The correctness of the obtained equations was proved by generating one check point formulations of intermediate concentration (VF). The polynomial equation for formulae for the floating lag time (FLT) is

$$Y_1 = 3.15759 - 1.67667X_1 - 0.59667X_2 + 0.53345X_1^2 - 0.03655X_2^2 + 0.18500X_1X_2$$

and time taken for 50 % of drug release (T_{50}) is

$$Y_2 = 4.51276 + 0.87500X_1 + 0.30500X_2 - 0.11466X_1^2 + 0.02534X_2^2 + 0.08500X_1X_2.$$

The results illustrated that the percentage of Oyster Mushroom powder and combination of sodium bicarbonate and citric acid have an impact on how long it takes for a medication to release and floating lag time. As the findings indicate that the time needed for the dosage form to float decreases with an increase in gas generating agent altered by carefully choosing the X_1 and X_2 levels. To display consequences of X_1 and X_2 on floating lag time (FLT) and time taken for 50 % of drug release (T_{50}), Plots of response surfaces were displayed. The reliability of the developed equations for the dependent variables is indicated by the proximity of the observed and predicted values for floating lag time (FLT) and time taken for 50 % of drug release (T_{50}). The floating lag time was set at 119 seconds, and time taken for 50 % of drug release was found to be 5.69 hours, in order to validate the validity equation. The verification formula produced a time taken for 50 % of drug release was found to be 5.69 hours having a 119 seconds floating lag time. Based on floating parameters for drug release and lag time, the OF9 formulation is deemed the best formulation out of the nine. The results showed that 32 factorial design optimizations can be used to successfully achieve the necessary medication release for Famotidine. In the present study, floating matrix tablets of Famotidine were formulated for twice-daily administration with the objectives of enhancing bioavailability and achieving sustained drug release over a 12-hour period. To evaluate the effect of polymer type and concentration on drug release, tablets were prepared using varying concentrations of Treated Ghee-residue (Formulations F1–F3) and Oyster Mushroom Powder (Formulations F4–F6). The powder blends used for tablet formulation were assessed for flow properties, and results confirmed that all blends exhibited acceptable flow characteristics, as presented in Table 4. Post-compression evaluation of the floating tablets revealed that the hardness ranged between 4.5–4.7 kg, indicating sufficient mechanical strength. Friability values were below 1%, satisfying standard limits and suggesting good durability. Drug content ranged from 99.30% to 100.45%, indicating excellent uniformity. All formulations complied with the weight variation requirements, staying within the $\pm 5\%$ pharmacopoeia limit.

Overall, all prepared tablets met the standard pharmacopoeial specifications for physical parameters, indicating high-quality formulations suitable for further in vitro release and floating behavior studies. All the tablets were formulated using combination of sodium bicarbonate and citric acid as effervescent agent at the concentration of 15%. All the prepared formulations floated within 180 seconds after placing into the beaker and the floating was maintained more than 15 hrs. It was observed that the carbon dioxide generated from the combination of sodium bicarbonate and citric acid in presence of dissolution medium (0.1N HCL) was trapped in the polymer gel matrix formed by the hydration of polymer which decreases the density (<1) and makes the tablet buoyant. The results of various physical properties and *in vitro* buoyancy studies were tabulated in table 5. *In vitro* dissolution studies of all the formulations of floating matrix tablets were carried out in 0.1N HCL. The drug release from formulation F3 containing drug and natural polymer in 1:1.5 ratio showed a maximum drug release at end of 12 hours. The dissolution profile for the formulations F1- F3 was shown in figure 5 and the dissolution profile for the formulations F4- F6 was shown in figure 6.

To ascertain the mechanism of drug release, the dissolution data was analyzed by zero order, first order, and Higuchi and Peppas equations. The correlation coefficient values (r) revealed that the dissolution profiles followed Zero order kinetics and the mechanism of drug release was governed by Peppas model. The n values are found to be more than 0.5 ($n > 0.5$) indicated that the drug release was predominantly controlled by non-fickian diffusion. The in-vitro drug release kinetic data was shown in Table 6. The swelling index studies showed a gradual increase with increase in concentration of natural polymer and were shown in Table 7. The characteristic peaks confirmed the structure of Famotidine (Figure 7). The same peaks were also reported in all drug loaded matrix tablets (Figure 8&9). There was no change or shifting of the characteristic peaks in matrix tablets suggested that there was no significant drug polymer interaction which indicates the stable nature of the drug in all formulations. Drug release from optimized formulations before and after storage under varying conditions were evaluated periodically at the regular interval of every month. The drug release profiles of all the formulations did not change significantly after storage at $25 \pm 2^\circ \text{C} / 60 \pm 5\% \text{RH}$ and $40 \pm 2^\circ \text{C} / 75 \pm 5\% \text{RH}$ for a period of 3 months. There is no significant difference in the drug content and release rate constants. The results indicated that the drug release from the optimized formulations were found to be quite stable. From the above results, it is evident that the in vitro release of Famotidine from the floating tablets was significantly influenced by the nature of the natural polymer used. Formulations containing treated ghee-residue demonstrated a more sustained drug release profile compared to those prepared with oyster mushroom powder. This retarding effect is attributed to the polymeric characteristics of the treated ghee-residue, which likely contributed to a slower drug diffusion rate. Among all the formulations, the F3 formulation comprising Famotidine and treated ghee-residue in a 1:1.5 ratio exhibited the most optimized release profile, indicating its potential suitability for sustained drug delivery applications.

Table 1: Formulae of Famotidine Floating Tablets (OF1-OF9) as per 3² factorial design

Ingredients	OF ₁ (mg)	OF ₂ (mg)	OF ₃ (mg)	OF ₄ (mg)	OF ₅ (mg)	OF ₆ (mg)	OF ₇ (mg)	OF ₈ (mg)	OF ₉ (mg)
Famotidine hydrochloride	40	40	40	40	40	40	40	40	40
Oyster mushroom powder	20	40	60	20	40	60	20	40	60
Sodium bicarbonate	10	10	10	15	15	15	20	20	20
Citric acid	5	5	5	7.5	7.5	7.5	10	10	10
Micro crystallinities cellulose	120	100	80	112.5	92.55	72.5	105	85	65
Magnesium stearate	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Talc	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Total weight	200	200	200	200	200	200	200	200	200

Table 2: *In vitro* drug release kinetic data off Famotidine floating tablets as per 3² factorial designs

Formulation	Correlation Coefficient Value				Release Rate Constant (mg/hr)k ₀	T ₅₀ (hr)	T ₉₀ (hr)	Floating Lag time (min)
	Zero Order	First Order	Matrix	Peppas				
OF ₁	0.9990	0.9112	0.9279	0.9982	6.0	3.33	6.00	6.10
OF ₂	0.9994	0.8961	0.9249	0.9990	5.7	3.50	6.31	5.39
OF ₃	0.9997	0.8700	0.9213	0.9993	5.27	3.79	6.83	4.54
OF ₄	0.9992	0.8671	0.9324	0.9984	4.70	4.25	7.65	3.76
OF ₅	0.9995	0.8248	0.9246	0.9996	4.44	4.5	8.10	3.24
OF ₆	0.9998	0.8160	0.9223	0.9990	4.14	4.82	8.64	2.56
OF ₇	0.9978	0.7622	0.9230	0.9957	4.12	4.89	8.69	2.36
OF ₈	0.9986	0.7732	0.9312	0.9974	3.78	5.29	9.49	2.07
OF ₉	0.9982	0.7864	0.9367	0.9978	3.49	5.69	10.29	1.59

Table 3: Composition of Famotidine floating tablets formulated with different natural polymers

Ingredients	F ₁ (mg)	F ₂ (mg)	F ₃ (mg)	F ₄ (mg)	F ₅ (mg)	F ₆ (mg)
Famotidine hydrochloride	40	40	40	40	40	40
Treated Ghee residue	20	40	60			

Oyster mushroom powder				20	40	60
Micro crystalline cellulose	105	85	65	105	85	65
Sodium bicarbonate	20	20	20	20	20	20
Citric acid	10	10	10	10	10	10
Magnesium stearate	2.5	2.5	2.5	2.5	2.5	2.5
Talc	2.5	2.5	2.5	2.5	2.5	2.5
Total weight	200	200	200	200	200	200

Table 4: Micromeritic properties of powder blend of Famotidine floating tablets formulated with different concentrations of natural polymers

Formulation code	Angle of repose (°)	Bulk density (gm/cm ³)	Tapped density (gm/cm ³)	Carr's index (%)	Hausner's ratio
F ₁	26.53	0.523	0.620	15.68	1.186
F ₂	26.15	0.525	0.621	15.49	1.184
F ₃	25.74	0.528	0.623	15.28	1.181
F ₄	27.87	0.525	0.622	15.62	1.187
F ₅	27.35	0.529	0.626	15.53	1.185
F ₆	26.76	0.532	0.628	15.32	1.182

Table 5: Physical properties of Famotidine floating tablets formulated with different concentrations of natural polymers

Formulation	Hardness (kg/cm ²)	Weight variation (mg)	Friability (%)	Drug content (%)	Floating Lag time	Total floating time (hrs)
F ₁	4.5±0.014	200.19±0.13	0.57±0.011	100.45±0.05	2.22 min	>15
F ₂	4.6±0.017	200.22±0.13	0.39±0.017	99.37±0.12	2.07 min	>15
F ₃	4.7±0.018	199.35±0.18	0.26±0.012	99.27±0.13	1.59 min	>15
F ₄	4.5±0.014	200.13±0.18	0.57±0.014	99.61±0.13	2.24 min	>15
F ₅	4.6±0.025	200.15±0.14	0.44±0.012	99.71±0.12	2.07 min	>15
F ₆	4.7±0.020	199.36±0.17	0.27±0.011	99.83±0.11	1.66 min	>15

Table 6: *In vitro* drug release kinetic data of Famotidine floating tablets formulated with different concentrations of natural polymers

Formulation	Correlation Coefficient Value				Release Rate Constant (mg/hr) k_0	Exponential Coefficient (n)	T ₅₀ (hr)	T ₉₀ (hr)
	Zero Order	First Order	Matrix	Peppas				
F ₁	0.9991	0.6858	0.9272	0.9967	3.96	0.8731	5.09	9.10

F ₂	0.9984	0.8084	0.9353	0.9984	3.62	0.8652	5.49	9.89
F ₃	0.9966	0.7451	0.9356	0.9987	3.32	0.8595	6	10.79
F ₄	0.9978	0.7622	0.9230	0.9957	4.12	0.8668	4.89	8.69
F ₅	0.9986	0.7732	0.9312	0.9974	3.78	0.8637	5.29	9.49
F ₆	0.9982	0.7864	0.9367	0.9978	3.49	0.8528	5.69	10.29

Table 7: Swelling index values of Famotidinefloating tablets formulated with different concentrations of natural polymers

Formulation code	Swelling index		
	Time in hours		
	after 1 hour	after 2 hours	after 8hours
F ₁	23.46	33.81	75.21
F ₂	26.73	49.45	89.69
F ₃	30.68	57.14	97.48
F ₄	23.46	33.83	75.21
F ₅	26.73	49.45	89.69
F ₆	30.68	57.14	97.48

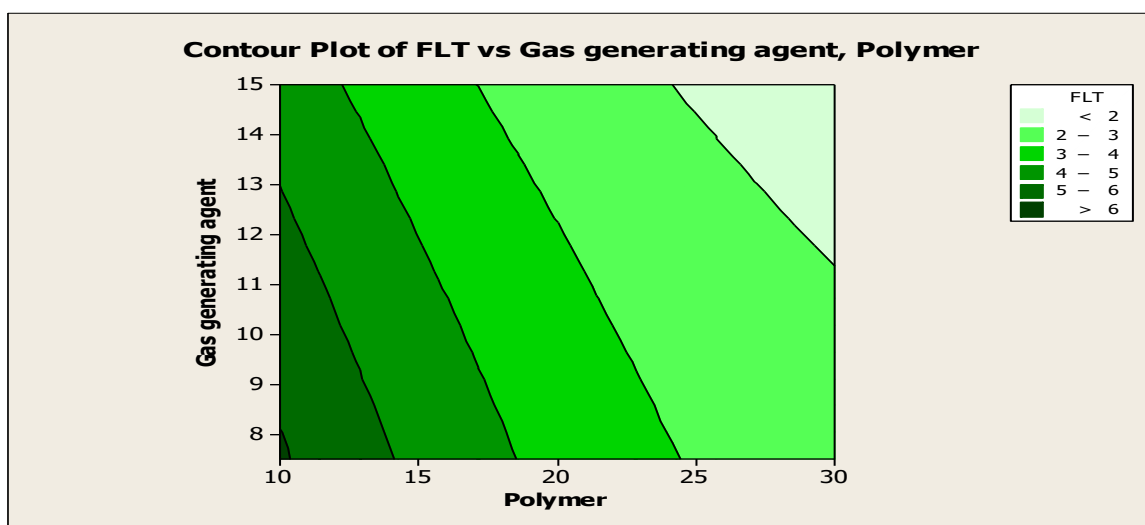


Figure1: Contour Plot for Floating Lag Time

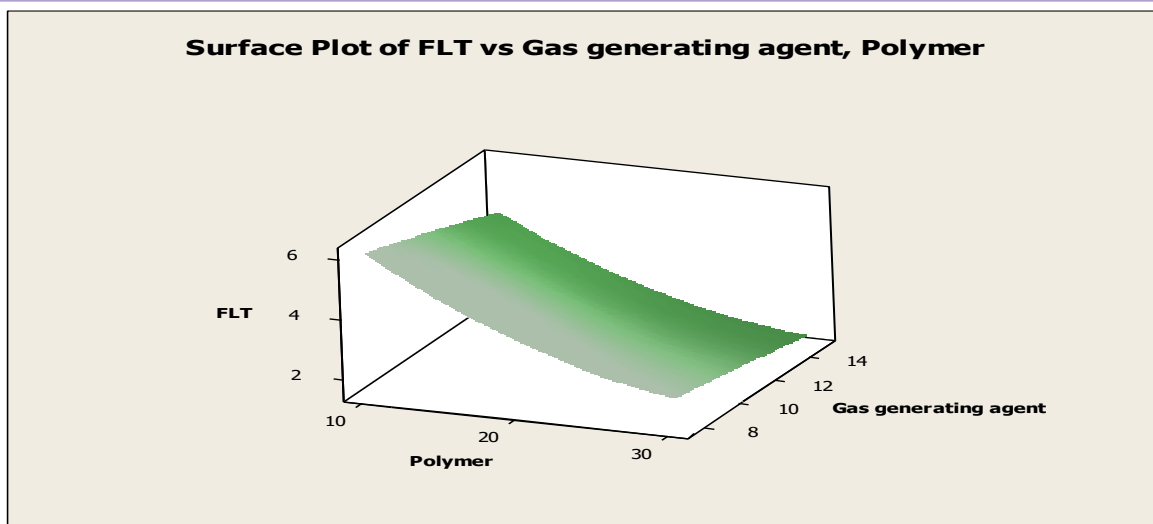


Figure 2: 3D surface Plot for Floating Lag Time

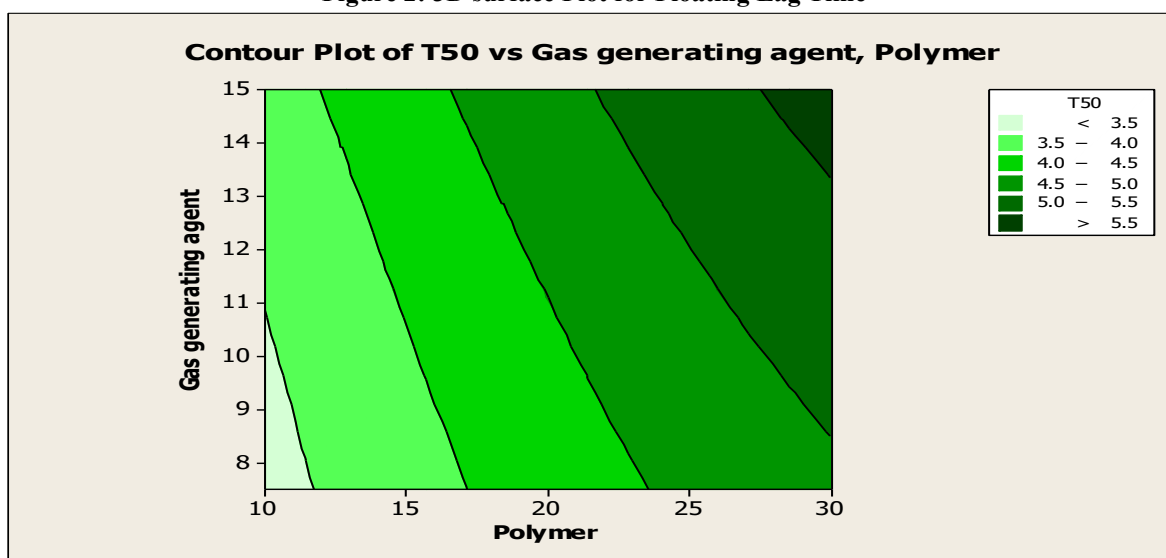


Figure 3: Contour Plot for time taken for 50 % of drug release (T₅₀)

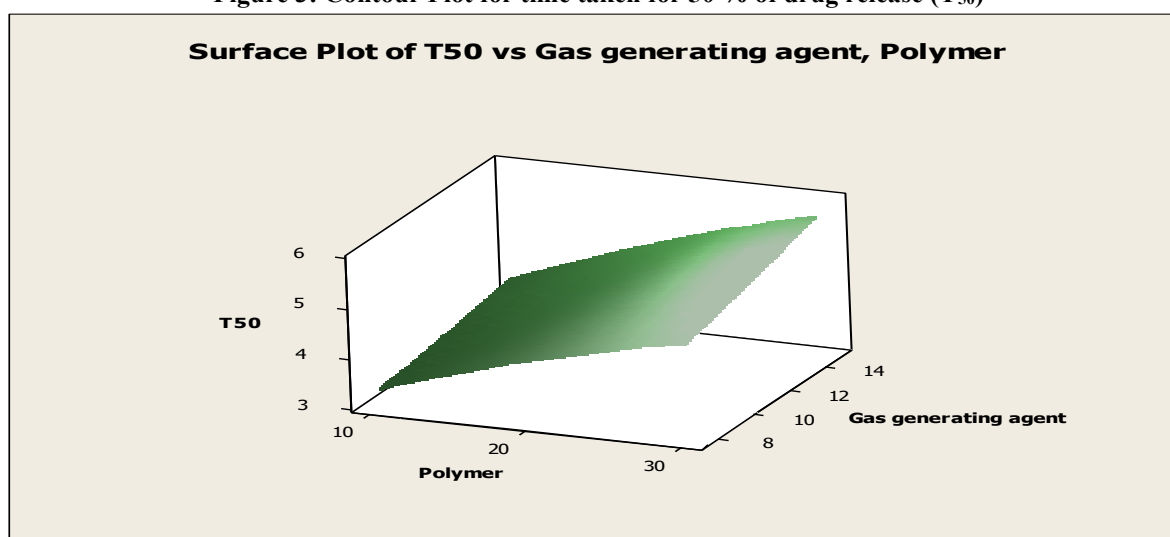


Figure 4: 3D surface Plot for time taken for 50 % of drug release (T₅₀)

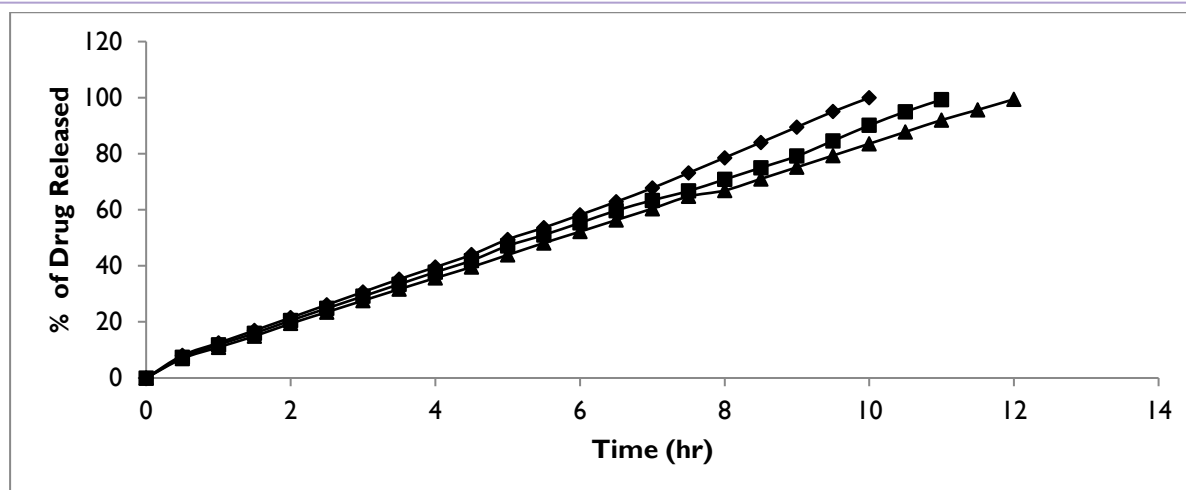


Figure 5: Comparative *in vitro* drug release profile of Famotidine floating tablets formulated with different concentrations of Treated Ghee-residue

(-♦-) Floating tablets formulated with drug and Treated Ghee-residue in 1:0.5 ratio

(-■-) Floating tablets formulated with drug and Treated Ghee-residue in 1:1 ratio

(-▲-) Floating tablets formulated with drug and Treated Ghee-residue in 1:1.5 ratio

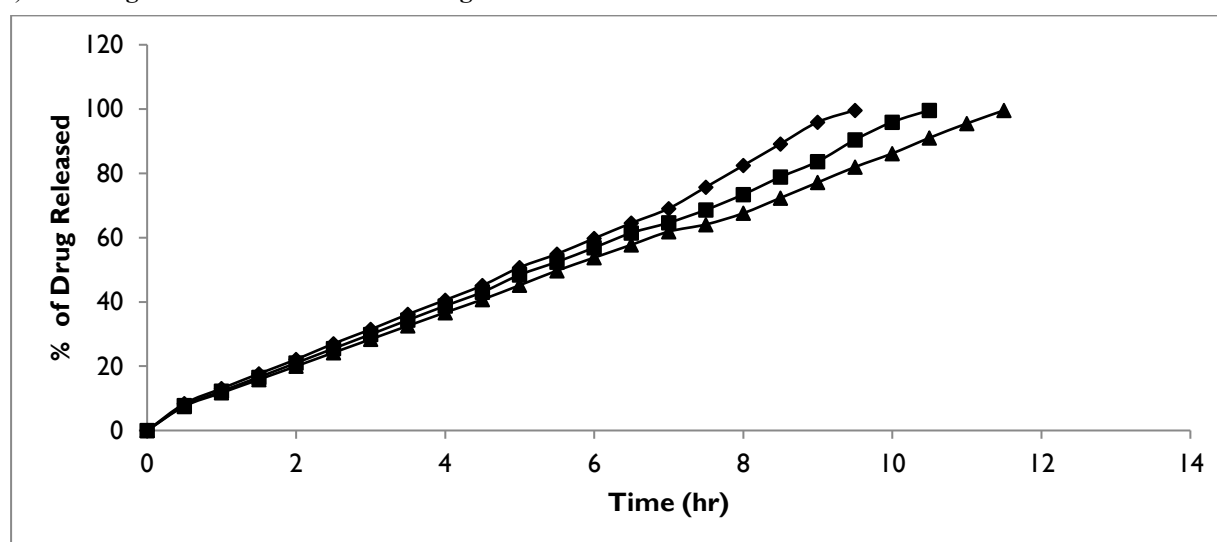


Figure 6: Comparative *in vitro* drug release profile of Famotidine floating tablets formulated with different concentrations of Oyster mushroom powder

(-♦-) Floating tablets formulated with drug and Oyster mushroom powder in 1:0.5 ratio

(-■-) Floating tablets formulated with drug and Oyster mushroom powder in 1:1 ratio

(-▲-) Floating tablets formulated with drug and Oyster mushroom powder in 1:1.5 ratio

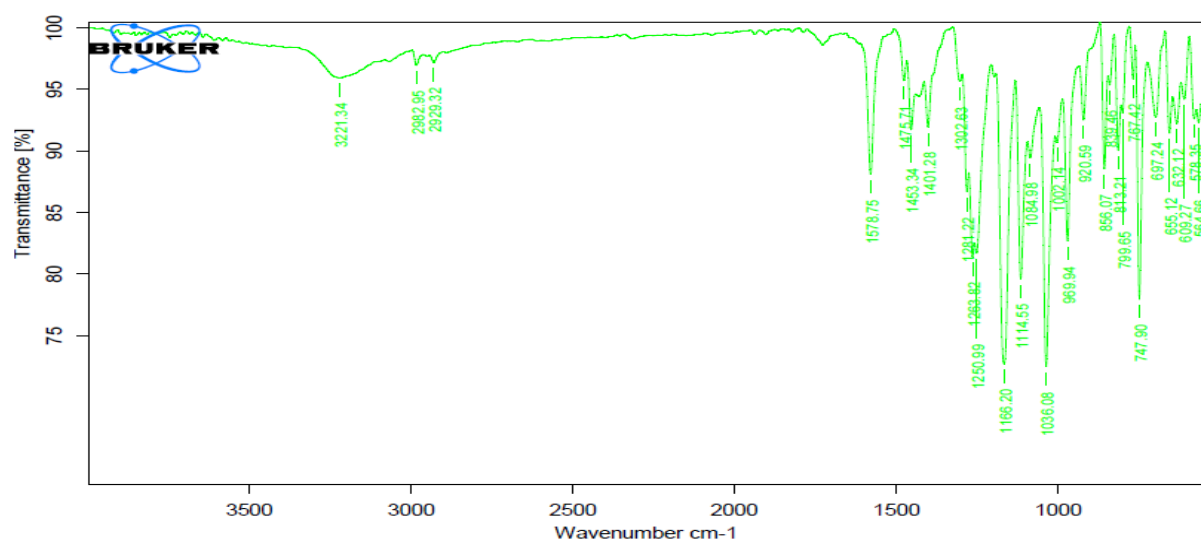


Figure 7 - FTIR spectrum of Famotidine

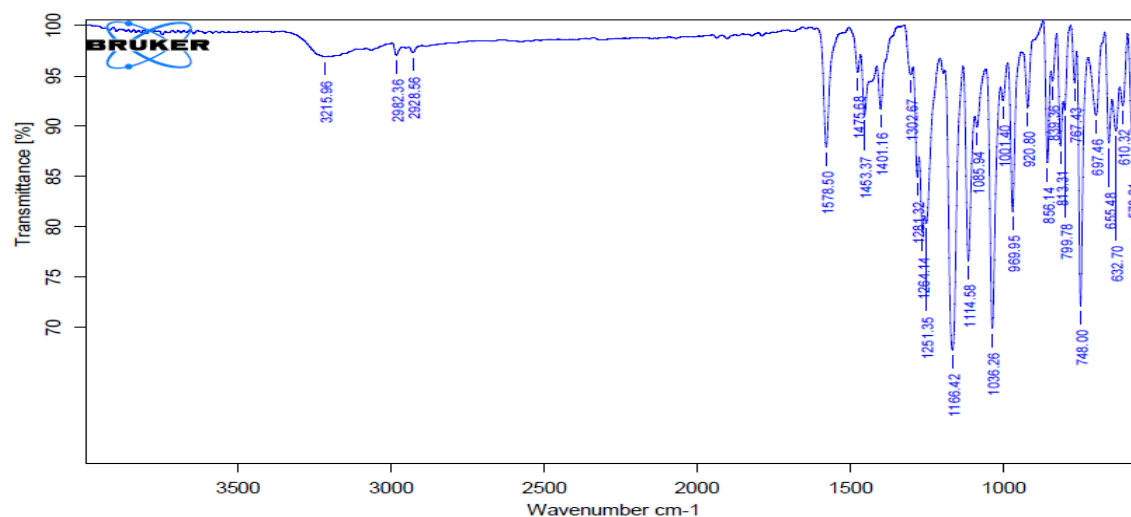


Figure 8- FTIR spectrum of Famotidine floating tablet prepared with Gum Kondagogu

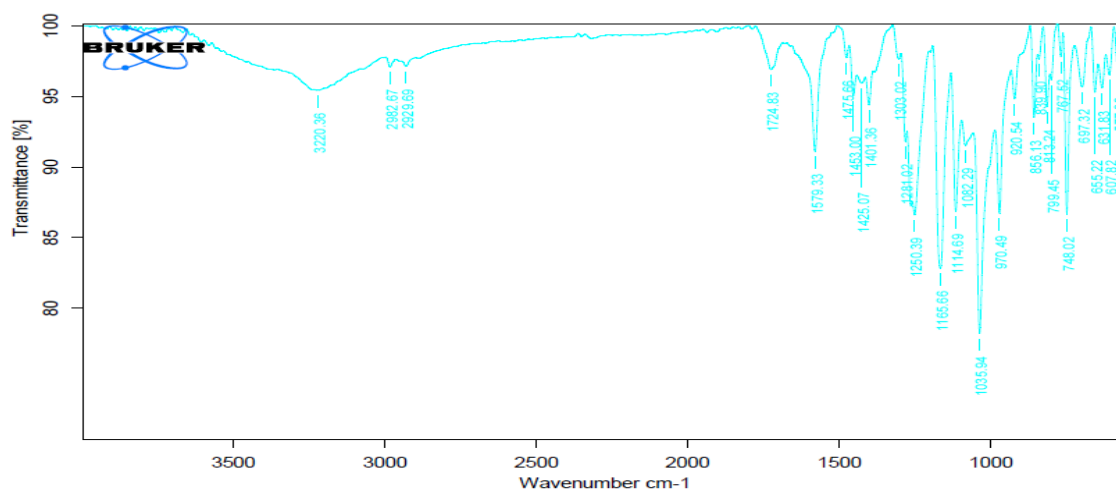


Figure9 - FTIR spectrum of Famotidine floating tablet prepared with oyster mushroom powder

4. CONCLUSION

The present study successfully developed and optimized floating Famotidine tablets using natural polymers, with the aim of enhancing gastric residence time and achieving sustained drug release. Both oyster mushroom powder and treated ghee-residue served as eco-friendly excipients; however, their performance varied in terms of release kinetics and buoyancy. Formulations containing treated ghee-residue consistently demonstrated superior results, with prolonged floating ability, higher swelling index, and more controlled release profiles compared to oyster mushroom-based formulations. Among the tested formulations, F3 (Famotidine: ghee-residue at 1:1.5 ratio) emerged as the optimized batch, offering an ideal balance between floating lag time, mechanical strength, and 12-hour sustained drug release. The drug release followed Zero-order kinetics and was best described by the Korsmeyer–Peppas model, indicating a non-Fickian diffusion mechanism governed by both diffusion and polymer relaxation. FTIR analysis confirmed the absence of drug–polymer interactions, and stability studies further validated the robustness of the optimized formulation. Overall, this research highlights the potential of treated ghee-residue as a sustainable and effective excipient for gastro-retentive drug delivery systems. Its ability to repurpose a dairy by-product for pharmaceutical use not only enhances therapeutic efficacy but also contributes to value-added waste utilization, supporting both clinical and environmental benefits.

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Declaration of Interest statement

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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