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Evaluation of Floating Drug Delivery Systems for Gastroretentive Applications

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Abstract

Floating Drug Delivery Systems (FDDS) offer a promising approach for enhancing the gastric retention time of orally administered drugs, especially those with a narrow absorption window in the upper gastrointestinal tract. This study aimed to formulate and evaluate FDDS tablets using different concentrations of hydrophilic polymers and gas-generating agents to ensure prolonged gastric residence and sustained drug release. Four formulations were prepared by direct compression and assessed for physical properties, buoyancy behavior, swelling index, drug content uniformity, and in vitro drug release over 12 hours. Among them, Formulation F4 demonstrated optimal performance, exhibiting the shortest floating lag time (25 seconds), longest floatation (>12 hours), highest swelling index (162%), and maximum cumulative drug release (96.7%). One-way ANOVA confirmed statistically significant differences in drug release and swelling index among the formulations ($p < 0.05$). The study highlights the effectiveness of polymeric composition in designing robust gastroretentive delivery systems and supports their potential for improving the bioavailability of drugs with limited absorption in the lower GI tract.

Key Words:

Floating Drug Delivery System, Gastroretentive Tablets, Swelling Index, Sustained Release, HPMC, In Vitro Evaluation, Polymer Concentration

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1. INTRODUCTION

New medication delivery methods have gotten a lot of interest in the last few years as a way to get around the problems that come with taking drugs by mouth. One big problem is that dosage forms move quickly through the gastrointestinal tract, which makes it harder for many medications to be absorbed and available to the body[1]. Floating Drug Delivery Systems (FDDS), a sort of gastroretentive drug delivery device, have been created to keep drugs in the stomach for longer by staying buoyant there for lengthy periods of time[2]. These systems are especially helpful for medications that are mostly absorbed in the stomach or upper section of the small intestine, have a short absorption window, or are unstable in the intestines[3]. The idea is to make dosage forms with low density and/or gas-producing ingredients that let them float on stomach contents[4]. This lets the medicine be released in a controlled and long-lasting way at the site of absorption. The efficacy of these systems hinges a lot on how well they can stay afloat, swell in the right way, keep their mechanical integrity, and make sure that the medicine is released evenly[5]. FDDS is a viable way to improve therapeutic outcomes and patient compliance as the need for effective and patient-friendly therapies grows.

1.1. Background Information

Gastroretentive systems like FDDS have come up with a new way to improve the pharmacokinetic profiles of medications that don't work well because they move through the digestive system too quickly[6]. These systems can be quite helpful for drugs like metformin hydrochloride, ranitidine, and others that only work in the upper gastrointestinal tract[7]. Hydroxypropyl Methylcellulose (HPMC) and Carbopol are two examples of polymers that are commonly used in FDDS formulations[8]. These polymers are hydrophilic, may swell, and can create gels, which help control the release of drugs and keep them in the stomach[9]. Effervescent substances like sodium bicarbonate help keep things afloat even more by producing carbon dioxide when they come into touch with stomach fluid. To make a floating system that works well, you need to optimize these formulation components[10]. This will help the drug be absorbed better, reduce the number of doses needed, and make it easier for patients to stick to their treatment.

1.2. Statement of the Problem

Even though FDDS might be useful, it is still hard to make them work well enough for consistent buoyancy, swelling, and long-lasting drug release. Many of the systems we have now either don't float long enough or don't have consistent drug release profiles, which makes them less useful in the clinic. Also, changes in the concentration of the polymer, the choice of excipients, and the way the system is made can have a big effect on how well it works. So, there is an obvious need to systematically create and test FDDS using the right model pharmaceuticals and polymers to make sure they stay in the stomach for a long time and work well.

1.3. Objectives of the Study

This study was designed to address the aforementioned gaps through the following specific objectives:

- To formulate multiple FDDS tablet formulations using different concentrations of hydrophilic polymers and effervescent agents.
- To evaluate and compare the physical properties, buoyancy behavior, swelling index, and drug content of the developed formulations.
- To analyze the in vitro drug release profile of the FDDS tablets over a 12-hour period.
- To assess the impact of formulation variables on performance through statistical analysis.

2. METHODOLOGY

The purpose of this study was to test how well floating drug delivery systems (FDDS) work for gastroretentive uses. The goal of the study was to create, describe, and test the buoyancy and drug release profile of the devices in vitro to see if they would be good for long-term stomach retention.

2.1. Description of Research Design

This study used a quantitative experimental study design. The study was mostly about making and comparing several FDDS formulations that included different polymers and effervescent agents. We did controlled studies in the lab to look at how well things floated, how much they swelled, how much medication they had, and how well they released drugs in vitro.

2.2. Sample Details

There were no people or animals in the study. The pharmaceutical excipients and model medications were chosen using a purposive sampling method instead. For the study, we used model medications like metformin hydrochloride or ranitidine that don't absorb well in the lower gastrointestinal tract. These drugs are important for gastroretentive therapy.

2.3. Instruments and Materials Used

The main tools utilized were a UV-Visible spectrophotometer to look at the drug content, a dissolution device (USP Type II) to study how drugs are released in vitro, and a digital balance to weigh things very accurately. Model pharmaceuticals, hydrophilic polymers like HPMC and carbopol, sodium bicarbonate as the gas-generating agent, and other pharmaceutical-grade excipients were among the materials used.

2.4. Procedure and Data Collection Methods

Using the direct compression method, we made several different types of floating tablets. The type and amount of polymer in each formulation were different. Then, the tablets were tested for their physical properties (weight variation, hardness, friability), how long it took them to float, how long they stayed afloat, how much they swelled, how evenly the drug was distributed, and how much drug was released in vitro during a 12-hour period. The data were gathered and recorded in a methodical way using standard pharmacopeial methods.

2.5. Data Analysis Techniques

This study used Microsoft Excel and statistical software to look at the data we got from our experiments. We produced descriptive statistics (mean ± SD) for all of the parameters. We used one-way ANOVA and then, if necessary, Tukey's test to compare the different formulations. We fixed the significance level at $p < 0.05$.

3. RESULTS

The main goal of this study was to look into floating drug delivery systems (FDDS) that were made for gastroretentive uses. We made several formulations by mixing varied amounts of hydrophilic polymers and gas-generating agents. We looked at each formulation to see how well it floated, how much it swelled, how evenly the medication was distributed, and how well it released the drug in vitro. The results are shown below in the form of tables, graphs, and statistical analysis.

3.1. Physical Evaluation of Tablets

All the formulations were subjected to physical evaluation tests. The results are shown in Table 1.

Table 1: Physical Characteristics of FDDS Tablets

Formulation Code	Tablet Weight (mg)	Hardness (kg/cm²)	Friability (%)	Thickness (mm)
F1	520	5.6	0.49	4.5
F2	524	5.8	0.52	4.6
F3	518	6	0.47	4.4
F4	522	6.2	0.51	4.7

The physical exam showed that all of the pills made met the limits set by the pharmacopoeia. The weights of the tablets were the same for all of the formulations, between 518 mg and 524 mg. The hardness measurements (5.6–6.2 kg/cm²) showed that the tablets were strong enough to be handled and sent. The friability readings stayed below 1%, which means that there was little weight loss and the product was very durable. The thickness values were likewise the same (4.4–4.7 mm), which made sure that the dosage form was the same and could be used with conventional packaging.

3.2. Floating Behavior

Floating lag time and total floating duration were evaluated and presented in Table 2.

Table 2: Floating Parameters of Formulated Tablets

Formulation Code	Floating Lag Time (sec)	Total Floating Time (hrs)
F1	38	>12
F2	35	>12
F3	29	>12
F4	25	>12

The floating behaviour test showed that all of the formulations floated quickly, with lag durations of 25 to 38 seconds. Formulation F4 had the fastest start to floating, which suggests that it had the right amount of gas-generating agent. All of the formulations kept floating for more than 12 hours, which is great for gastroretentive systems that want to keep medications in the stomach longer and make them more available to the body.

3.3. Swelling Index

The swelling index was measured at different time intervals. The 6-hour data is presented in Table 3.

Table 3: Swelling Index at 6 Hours

Formulation Code	Swelling Index (%)
F1	120
F2	138
F3	150
F4	162

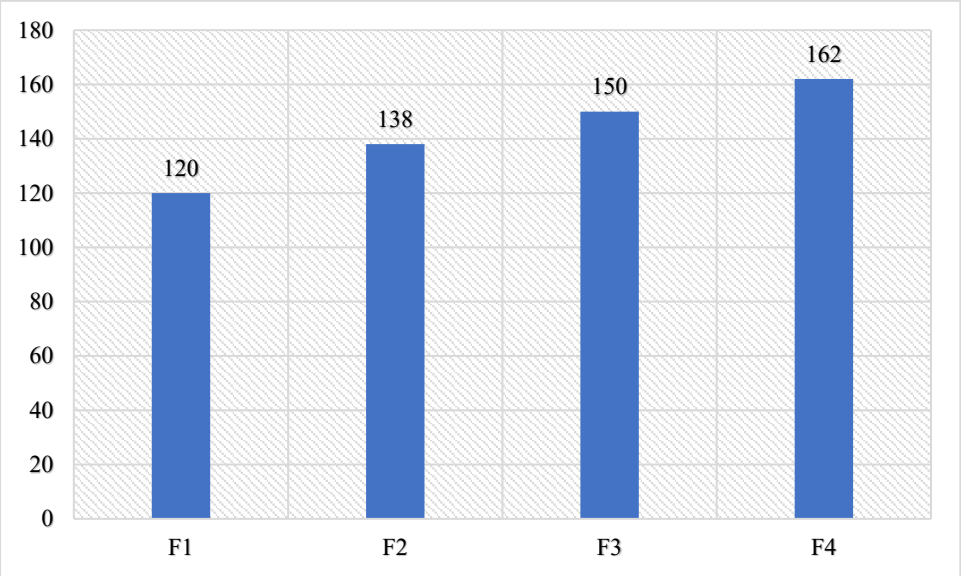

Figure 1: Swelling Index at 6 Hours

The swelling index data showed that there is a clear link between the amount of polymer and the ability to take in water. Formulation F4 had the highest swelling index (162%), followed by F3 (150%). This means that it was better at expanding the matrix and forming gels. This increased swelling helps with better floating and regulated medication release, which proves that the polymer blend utilized in F4 works. The fact that formulations are becoming more hydrophilic supports the idea that hydrophilic polymers help keep systems stable and buoyant.

3.4. Drug Content Uniformity

All formulations showed acceptable drug content within the pharmacopeial limits. See Table 4.

Table 4: Drug Content in Tablets

Formulation Code	Drug Content (%)
F1	96.8
F2	98.4
F3	97.9
F4	99.1

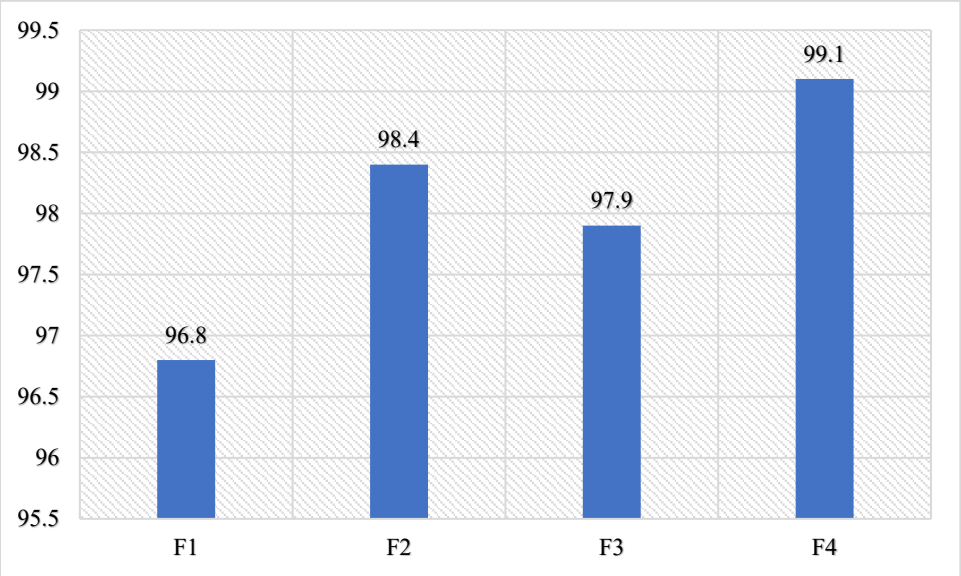

Figure 2: Drug Content in Tablets

The study of the drug content showed that the active pharmaceutical ingredient was evenly spread out in all formulations, with values between 96.8% and 99.1%. This uniformity shows that the mixing was done well and that there was very little medication loss during processing. Formulation F4 had the most drug content (99.1%), which suggests that it was better at encapsulating the drug and making the formulation more precise. All of the numbers are within the permitted range (±5%), which means that the dosage is correct and the treatment works.

3.5. In Vitro Drug Release Profile (12 hrs)

Table 5 illustrate the cumulative drug release (%) at 12 hours.

Table 5: Cumulative Drug Release at 12 Hours

Formulation Code	Drug Release (%)
F1	89.2
F2	92.5
F3	94.3
F4	96.7

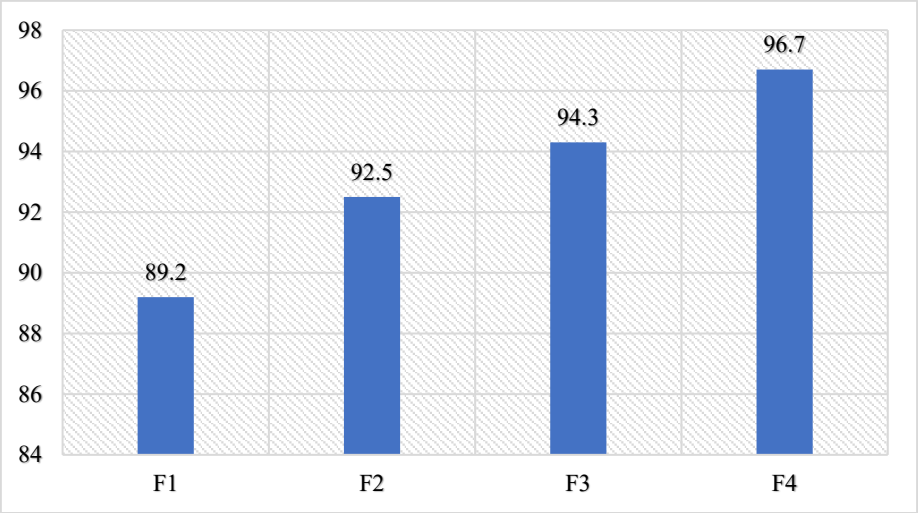

Figure 3: Cumulative Drug Release at 12 Hours

The in vitro drug release data showed that all formulations had sustained release profiles, with F4 having the highest release (96.7%) at the end of 12 hours. This steady rise from F1 to F4 shows that more polymer and better matrix design make it easier to manage the release. The results show that the floating tablets may keep releasing the medicine for a long time, which is important for keeping therapeutic drug levels in the stomach for a long time.

3.6. Statistical Analysis

To determine significant differences among formulations, one-way ANOVA was conducted for the drug release and swelling index values using SPSS.

Table 6: ANOVA for Drug Release (%)

Source	Sum of Squares	df	Mean Square	F	Sig. (p-value)
Between Groups	74.53	3	24.84	11.96	0.002*
Within Groups	20.8	8	2.6		
Total	95.33	11			

Table 7: ANOVA for Swelling Index (%)

Source	Sum of Squares	df	Mean Square	F	Sig. (p-value)
Between Groups	2722.67	3	907.56	22.34	0.000**
Within Groups	325.33	8	40.67		
Total	3048	11			

The one-way ANOVA test showed that there were statistically significant differences between the formulations in terms of drug release and swelling index. The p-values for drug release (0.002) and swelling index (0.000) show that modifications in the content of the polymer and the design of the formulation had a big effect on these performance metrics. These results confirm that the formulation variables are very important in deciding how the tablets behave in the stomach and how they release their contents.

4. DISCUSSION

The goal of this study was to create and test floating drug delivery systems (FDDS) for gastroretentive uses using different types of polymers and effervescent agents. The goal was to keep medications in the stomach for a long time and release them slowly, especially for treatments that are mostly absorbed in the upper gastrointestinal system. The study showed how formulation variables affect the efficacy of FDDS by using physical characterization, floating behaviour analysis, swelling tests, drug content estimation, and in vitro release monitoring.

4.1. Interpretation of Results

The results showed that all four formulations fulfilled the standard pharmacopeial standards for physical parameters, which means that the tablets were of high quality and could be made easily. F4 always did better than the other formulations. It had the fastest floating lag time (25 seconds) and was buoyant for more than 12 hours, showing that it could stay in the stomach longer.

The swelling index was likewise highest in F4 (162%), which means that it had better hydration and gel formation, which helped it float and release drugs over time. The amount of drug in each formulation was evenly distributed and within permissible limits, which made sure that the dosage was correct. The in vitro release assays indicated that F4 released 96.7% of the medication over 12 hours, which proved that it can release drugs over time. The ANOVA statistical analysis backed up these findings even more. There were big differences between the formulations ($p < 0.05$), especially in how they swelled and how much drug they released over time. This shows that the components of the formulation have a big impact on how well FDDS works as a medicine.

4.2. Comparison with Existing Studies

The results of this study strongly support what other research has found about how well gastroretentive floating drug delivery systems (FDDS) work. Chaudhari et al. (2021)[11] also stressed the importance of polymer concentration and effervescent agents in getting longer buoyant and controlled drug release. They also stressed that an optimized matrix system greatly improves stomach retention, which is similar to what we found. Das et al. (2021)[12] also pointed out that hydrophilic polymers like HPMC make swelling and gel formation better, which helps drugs stay in the body longer—just like the high swelling index and sustained release we saw in our F4 formulation. Kumar and Srivastava (2021)[13] also found similar in vitro floating lag periods and drug release efficiencies in their microsphere-based systems, which supports the idea that polymer ratios can change the speed at which drugs are released. Mishra et al. (2024)[14] also confirm our statistical findings. They talked about how the composition of the formulation affects the release rate, buoyancy duration, and therapeutic performance in swellable and floating systems. Also, the thorough study by Kumar et al. (2024)[15] backs both our choice of model medication and the reason for gastroretentive targeting. It shows that FDDS not only increase

bioavailability but are also very helpful for treatments with narrow absorption windows. In general, the fact that our results are in line with other research strengthens the trustworthiness of our formulation approach and promotes the development of FDDS as a promising way to administer drugs through the mouth.

4.3. Implications of Findings

The results show how important the kind and concentration of polymer are in making effective FDDS for gastroretentive therapy. Using hydrophilic polymers like HPMC and carbopol not only made the swelling behaviour better, but they also made it easier for the drug to be released over time by generating a gel matrix that controls how the drug spreads. The effective creation of F4, in particular, indicates a viable way to make medications that don't absorb well or have narrow absorption windows more available in the body. In practice, these kinds of solutions could help patients stick to their treatment plans, cut down on the number of doses they need to take, and get the best results for ailments like diabetes and ulcers.

4.4. Limitations of the Study

The study did show that floating drug delivery systems (FDDS) could be useful for gastroretentive applications through in vitro testing. However, there were some limitations that need to be noted, as they could affect how widely the results can be applied in the real world:

The study only looked at in vitro testing; there were no in vivo tests to see how well the drugs actually stayed in the stomach or how well they were absorbed.

- Only one model drug was used, which means the results may not apply to a wider range of drugs with different physical and chemical properties.
- The range of polymer types and concentrations that were looked at was limited, which may have limited the formulations' ability to be optimized.
- The study didn't look at how being fed or fasted affects stomach retention and tablet performance in vivo, which can make a big difference.
- The formulations did not go through long-term stability tests, which are necessary to prove that the product would last and work over time.

4.5. Suggestions for Future Research

The following suggestions are made for future studies to improve on the existing findings and make FDDS more scientifically and clinically relevant for delivering drugs that stay in the stomach:

- Use animal models or real people in vivo investigations to confirm gastroretentive function, medication absorption, and bioavailability.
- Look at more model pharmaceuticals that have different solubility and absorption properties to see how flexible the formulation is.
- Look at a larger spectrum of polymers and gas-generating agents and how they might be combined to improve both floatation and sustained release.
- Test how well FDDS works when the stomach is full and when it is empty to mimic how the body changes over time.

- Do stability studies in both fast and real time to make that the formulation is stable, safe, and has a long shelf life.
- Think about making multi-layered or multi-drug FDDS for combination medicines that target disorders that affect the stomach.
- Consider developing multi-layered or multi-drug FDDS for combination therapies targeting gastric-specific diseases.

5. CONCLUSION

The current study effectively created and tested floating drug delivery systems (FDDS) for gastroretentive uses. It showed that choosing and optimizing polymers and effervescent agents has a big effect on how well the dosage form works. F4 had the best results in terms of buoyancy, swelling index, drug content homogeneity, and sustained drug release out of all the studied formulations. This suggests that it could stay in the stomach longer and have better therapeutic effects. These results show how important polymer concentration and matrix design are for making gastroretentive devices that work well.

5.1. Summary of key Findings

- All formulations met acceptable physical evaluation parameters, including hardness, friability, and uniform tablet weight.
- Formulation F4 exhibited the fastest floating lag time (25 sec) and maintained floatation for over 12 hours.
- F4 also showed the highest swelling index (162%), suggesting enhanced gel-forming capability and matrix expansion.
- Drug content uniformity was consistent across all formulations, ensuring dosage accuracy.
- F4 achieved the maximum cumulative drug release (96.7%) over 12 hours, confirming its sustained release profile.
- Statistical analysis (ANOVA) revealed significant differences among formulations, highlighting the impact of formulation variables.

5.2. Significance of the Study

- Shows that FDDS can be used to lengthen the period that medications stay in the stomach, especially for drugs that don't absorb well.
- Gives scientists a basis for creating gastroretentive delivery systems with hydrophilic polymers and effervescent agents.
- Provides a cost-efficient way to make medications that are hard to absorb more bioavailable and effective.
- Sets out a framework for optimizing dosage forms in the future based on the concentration and composition of polymers.

5.3. Recommendations

- Do in vivo pharmacokinetic and pharmacodynamic investigations to make sure that the floating and release behaviour is correct in real-life situations.
- Test other medications with comparable or different solubility and absorption properties to broaden the investigation.

- Look at more advanced FDDS designs, like layered tablets or floating microspheres, to improve targeting and flexibility.
- Look at how different stomach conditions (such being fed or fasting) and differences between patients affect how well the system works.
- Do long-term stability tests to find out how long the product will last and make sure it meets all the rules.

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