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Preparation and Evaluation of Xanthan Gum-Based Floating Tablets Bearing Ibuprofen

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ABSTRACT

This study investigates the development and evaluation of floating tablet formulations (F1, F2, F3, and F4) for controlled drug delivery in the gastric environment. The physical properties, floating behavior, and drug release profiles of the tablets were assessed. All formulations exhibited desirable characteristics, including adequate thickness (2.87 ± 0.024 mm to 4.0 ± 0.034 mm), good hardness (4.37 ± 0.03 kg/cm² to 6.0 ± 0.03 kg/cm²), low friability (0.2% to 0.7%), and acceptable weight variation (2.0% to 2.63%), ensuring stability and uniformity. Floating lag time ranged from 60 seconds (F1) to 200 seconds (F4), with all formulations demonstrating sustained buoyancy for over 6 hours, crucial for prolonged gastric retention. The drug release profiles indicated that F1 exhibited the fastest release, with 45.2% of the drug released after 7 hours, followed by F2 (36.7%), F3 (32.9%), and F4 (24.7%). These results suggest that F1 is ideal for rapid drug absorption, while F4 is more suited for controlled release applications. The successful development of these floating tablets with variable release profiles provides flexibility in designing drug delivery systems tailored to specific therapeutic needs. Further optimization may enhance their clinical efficacy in treating conditions requiring prolonged drug release in the stomach.

Keywords: *floating, oscillation, intake, compliance*.

1. INTRODUCTION

The oral route is increasingly being employed to deliver therapeutic drugs since it is simple to administer and has a low cost, which results in high patient compliance. Oral medication delivery methods make up more than half of all drug delivery systems on the market **(1).** Drug release is provided by controlled release drug delivery systems (CRDDS) at a planned, predictable, and regulated rate. Controlled-release drug delivery systems can maintain optimal therapeutic drug concentration in the blood with predictable and reproducible release rates for extended periods of time, improve the activity of short-half-life drugs' durational effects, eliminate side effects, reduce frequency of dosing and drug waste, optimise therapy, and improve patient compliance. **(2, 3).** Understanding these three elements of the system is necessary for the effective development of oral controlled medication delivery systems.

1. The physiochemical characteristics of the drug

2. Anatomy and Physiology of GIT and Characteristics of Dosage forms

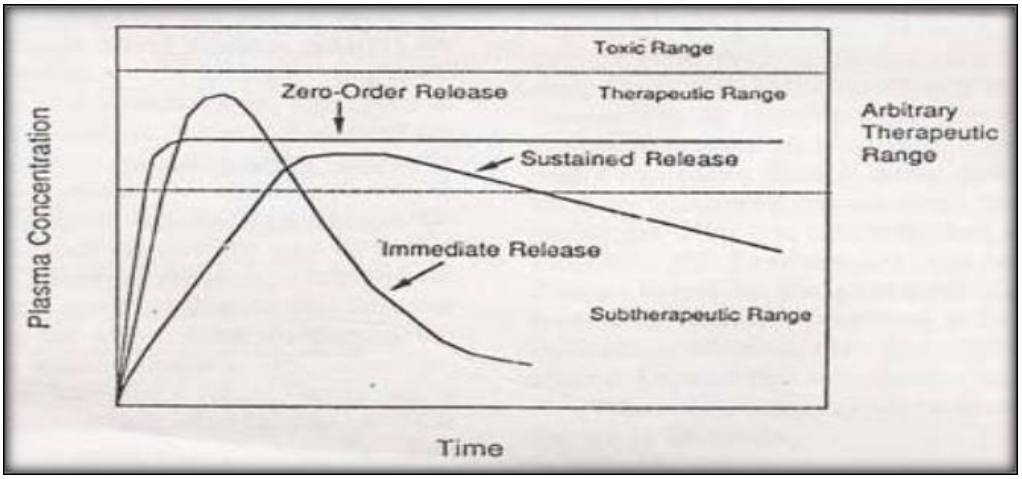

Figure 1: Drug level verses time profile showing differences between zero order, controlled releases, slow first order sustained release and release from conventional tablet

Floating Drug Delivery Systems and its Mechanism

Floating drug delivery systems (FDDS) have a bulk density less than gastric fluids and so remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. (4) While the system is floating on the gastric contents the drug is released slowly at the desired rate from the system. After release of drug, the residual system is emptied from the stomach. This results in an increased GRT and a better control of the fluctuations in plasma drug concentration.

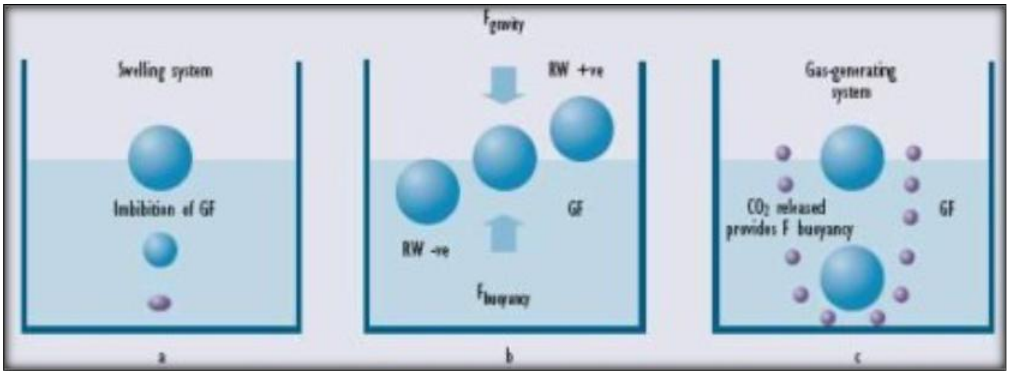

Figure 2: The Mechanism of Floating Systems

Classification of Floating Drug Delivery Systems (FDDS)

Floating drug delivery systems are classified depending on the use of 2 formulation variables: effervescent and no effervescent systems.

- **Effervescent Floating Dosage Forms-(5)**

These are matrix types of systems prepared with the help of swell able polymers such as methylcellulose and chitosan and various effervescent compounds, e.g.: sodium bicarbonate, tartaric acid, and citric acid.

- **Non-Effervescent Floating Dosage Forms-(6)**

Non-effervescent floating dosage forms use a gel forming or swellable cellulose type of hydrocolloids, polysaccharides, and matrix forming polymers like polycarbonate, polyacrylate, polymethacrylate, and polystyrene. The formulation method includes a simple approach of thoroughly mixing the drug and the gel-forming hydrocolloid.

Drugs Suitable for Gastro-retention

Delivery of the Drugs in continuous and controlled manner have a lower level of side effects and provide their effects without the need for repeated dosing or with a low dosage frequency. (7). Sustained release in the stomach is also useful for therapeutic agents that the stomach does not readily absorb, since sustained release prolongs the contact time of the agent in the stomach or in appropriate candidates for controlled release gastro retentive dosage forms are molecules that have poor colonic absorption but are characterized by better absorption properties at the upper parts of the GIT.

Advantages & Disadvantage

- **Advantages**

1. The gastroretentive systems are advantageous for drugs absorbed through the stomach. E.g.

Ferrous salts, antacids.

2. Acidic substances like aspirin cause irritation on the stomach wall when come in contact with it. Hence HBS formulation may be useful for the administration of aspirin and other similar drugs.

3. The gastroprotective systems are advantageous for drugs meant for local action in the stomach. e.g. antacids.

- **Disadvantages**

1. Floating system is not feasible for those drugs that have solubility or stability problem in G. I. Tract.

2. These systems require a high level of fluid in the stomach for drug delivery to float and work efficiently-coat, water.

3. Some drugs present in the floating system causes irritation to gastric mucosa.

2. MATERIALS AND METHOD-

MATERIALS-

Tablet 1: List of Chemicals used in the present investigation

S. No.	Material used	Manufacturers/Suppliers
1.	Ibuprofen	Sun Pharmaceuticals, Vadodara
2.	HPMC	Central drug house(P)LTD
3.	Xanthan gum	Central drug house(P)LTD
4.	Hydrochloric acid	Central drug house(P)LTD
5.	Microcrystalline cellulose	Fisher Scientific, Thermo electron LLS INDIA
6.	Poly vinyl pyrrolidone	Central drug house(P)LTD
7.	Talc	Central drug house(P)LTD
8.	Lactose	Central drug house(P)LTD

Table 2: List of Instruments Used in the present Investigation:

S. No.	Name of Instruments	Manufacturer/Suppliers
1.	digital electronic balance	Citizen, India
2.	UV spectrophotometer	Shimadzu(UV-1800)UV spectrophotometer
3.	dissolution test apparatus	Eletro lab TDT-08Lumumba,India
4.	hot air oven	MAC(CAT No:MSW-211)
5.	pH meter	Labtronics, India
6.	usp-1 tap density test apparatus	Eletro lab (India)PVT.LTD

3. METHOD-

Preparation of Floating Tablets:(8)

Ingredients were weighed accurately and mixed thoroughly. All the ingredients were mixed together except magnesium stearate and talc. Granules were prepared by wet granulation method using 5 % polyvinyl pyrrolidone solution as a binder

and the granules were dried at 30 ° C in oven. Magnesium stearate and talc was added in the granules and compressed to form a tablet by using single punch tablet machine. The tablets were white round and flat.

4. EVALUATION OF GRANULES-

Evaluation of bulk and tapped densities of the granules-(9)

The volume of a known quantity of the granules from each batch was obtained before and after tapping. The volume before tapping was used to determine the bulk density while the volume after tapping was employed to determine the tap density mathematically. Furthermore, Hausner's quotient and Carr's compressibility index used to determine the flow and compressibility properties of granules were obtained from the equations:

Hausner's quotient =Tapped density/ Bulk density

Carr's compressibility =Tapped density- Bulk density/Tapped density *100

- **Assessment of rate of flow and angle of repose**

A simple method whereby weighed quantity of granules from each batch was allowed to flow through an orifice (funnel) at a fixed height was used to determine flow rate. The time taken for the weighed granules to flow out completely from the orifice was recorded. This was performed in triplicate.

Flow rate was obtained by the equation below:

Flow rate = Weight of granules/Time (sec)

Furthermore, the angle of repose was determined by calculating tan ɵ from the height and radius of the cone formed by the granules as they flowed out of the orifice and subsequently obtaining the inverse of tan ɵ.

5. EVALUATION OF THE BATCHES OF TABLETS-

Compendial and non-compendial tests were undertaken to assess the quality and performance of the batches with different binders in comparison with one another. These tests include uniformity of weight and diameter, hardness, friability, Disintegration and dissolution.

- **Mechanical strength of tablets (Hardness)**

Pfizer hardness tester was used for the determination of the hardness. The tablet was placed in contact between the plungers and the handle was pressed, the force of the fracture was recorded. In this work, for each formulation the hardness of 5 tablets was evaluated.

- **Weight variation test**

In weight variation test twenty tablets were selected at a random and average weight was calculated. Then individual tablets were weighed and the weight was compared with an average weight.

- **Thicknesses**

The crown-to-crown thicknesses of ten tablets from each batch were determined using vernier calipers.

- **Friability test**

The Friability of the tablets was determined using Roche friabilator (Electro lab, Mumbai). This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. Pre weighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were dedusted and reweighed.

The friability (F) is given by the formula:

$$F(\%) = \frac{(W_{initial}) - (W_{final})}{(W_{initial})} X\,100$$

Where, W0 is the weight of the tablets before the test and W is the weight of the tablet after

the test.

- **In vitro drug release-**

studies for the prepared tablets were conducted for a period of 1 hrs. using a 8 station USP dissolution apparatus (USPXXII) Type2 (paddle) at 37±0.5°C and at 50 rpm speed. Each of vessels of dissolution machine contained 900 ml of the prepared 0.1 N HCl pH 1.2. Aliquotes were withdrawn at different time intervals from the dissolution medium and replaced with fresh

medium to maintain the volume constant. The aliquots after filtration and appropriate dilution, the sample solutions were analyzed at 220 nm by a UV-Visible spectrophotometer for cumulative drug release. (10)

6. RESULTS -

Table 3: Formulation table:

S. No.	Ingredients	F1	F2	F3	F4
1.	Drug	200	200	200	200
2.	HPMC	100	75	50	25
3.	Xanthan gum	25	50	75	100
4.	Sodium bicarbonate	50	50	50	50
5.	Micro Crystalline Cellulose	60	60	60	60
6.	Citric acid	25	25	25	25
7.	Lactose	30	30	30	30
8.	Magnesium stearate	5	5	5	5
9.	Talc(mg)	5	5	5	5
Tablet weight 500 mg					

Table 4: Flow properties of the granules

S. No.	Formulation	Carr's index	Hausner's Ratio	Angle of repose
1.	F1	16.74± 1.5	1.24±0.02	25.78±0.90
2.	F2	16.62±1.2	1.19±0.06	21.29±0.96
3.	F3	18.75±1.8	1.05±0.04	26.65±0.88
4.	F4	16.66±0.9	1.20±0.04	23.79±1.96

Table 5: Evaluation parameter of floating tablets:

S. No.	Formulation	Thickness (mm)	Hardness ($Kg/cm^{2)}$	Friability (%)	Weight variation (%)
1.	F1	2.87±0.024	4.37±0.03	0.7	2.63
2.	F2	2.99±0.091	6.0±0.01	0.4	2.54
3.	F3	3.42±0.061	6.0±0.03	0.2	2.12
4.	F4	4.0±0.034	5.4±0.06	0.6	2.0

Table 6: In Vitro Buoyancy study of floating tablets

S. No.	Formulation	Floating lag time	Floating time
1.	F1	60 sec	>6 hrs
2.	F2	120sec	>6 hrs
3.	F3	170 sec	>6 hrs
4.	F4	200 sec	>6 hrs

DRUG RELEASE-

Table 7: Cumulative percent Ibuprofen released from various concentrations of Xanthan gum Containing Ibuprofen formulation.

Time (hrs)	F1 (Mean ± SD)	F2 (Mean ± SD)	F3 (Mean ± SD)	F4 (Mean ± SD)
0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
1	8.2 ± 0.8	7.9 ± 0.8	6.4 ± 0.6	4.5 ± 0.5
2	11.9 ± 1.2	10.9 ± 1.1	9.8 ± 1.0	7.9 ± 0.8
3	18.3 ± 1.8	15.8 ± 1.6	14.7 ± 1.5	9.3 ± 0.9
4	24.8 ± 2.5	20.7 ± 2.1	18.9 ± 1.9	12.7 ± 1.3
5	30.8 ± 3.1	24.6 ± 2.5	22.7 ± 2.3	16.2 ± 1.6
6	38.7 ± 3.9	28.9 ± 2.9	26.7 ± 2.7	20.6 ± 2.1
7	45.2 ± 4.5	36.7 ± 3.7	32.9 ± 3.3	24.7 ± 2.5

IN-VITRO DRUG RELEASE-

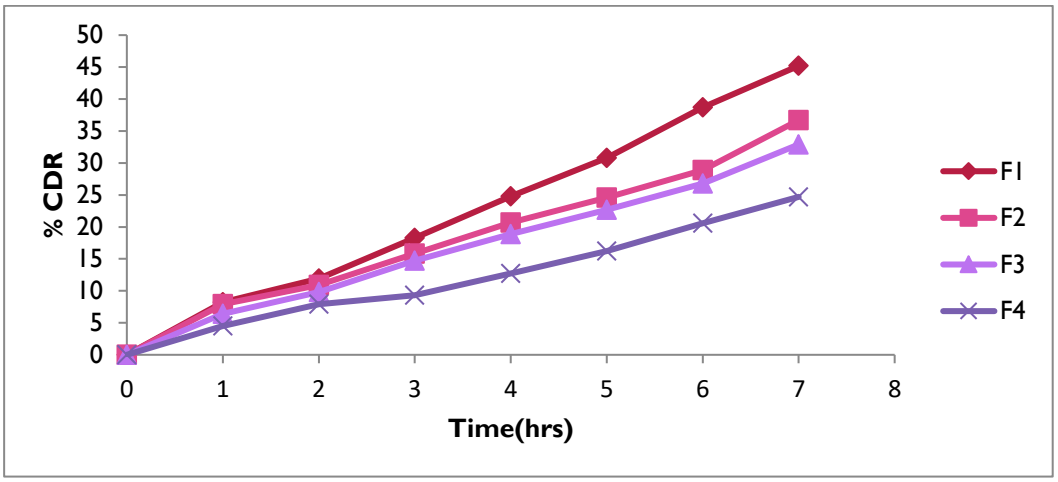

Figure 3: Dissolution profile of Xanthan gum tablets of Ibuprofen F1 to F4 formulations

7. DISCUSSION-

The formulations F1, F2, F3, and F4 exhibited Carr's Index values ranging from 16.62 ± 1.2 to 18.75 ± 1.8. These values suggest that all formulations have moderate flowability (generally, Carr's Index values between 15–25 indicate good flowability). The lowest Carr's Index was observed in F2 (16.62 ± 1.2), indicating slightly better flow properties than the other formulations, while F3 (18.75 ± 1.8) had the highest value, suggesting relatively poorer flow characteristics compared to the other formulations. Hausner's Ratio values for all formulations ranged from 1.05 ± 0.04 (F3) to 1.24 ± 0.02 (F1). A Hausner's Ratio between 1.2 and 1.5 indicates good flowability, while a ratio less than 1.2 is considered excellent. Formulation F3, with a Hausner's Ratio of 1.05 ± 0.04, exhibited the best flow properties, followed by F2 (1.19 ± 0.06) and F4 (1.20 ± 0.04). Formulation F1 (1.24 ± 0.02) showed the least favorable flow characteristics among the formulations. The angle of repose values for the formulations ranged from 21.29 ± 0.96° (F2) to 26.65 ± 0.88° (F3). The angle of repose is an indicator of powder flowability, where lower values represent better flowability. All formulations showed an angle of repose lower than 30°, indicating that they all have acceptable flow properties. F2 had the lowest angle of repose, suggesting it had the best flow among the formulations, while F3 showed the highest angle, which may indicate slightly poorer flow properties compared to the others. The physical properties of floating tablets are essential for ensuring consistent performance and successful drug delivery. Based on the results of the evaluated formulations. The thickness of the formulations varied slightly, with F4 showing the greatest thickness (4.0 ± 0.034 mm), which might indicate the presence of excipients that contribute to the tablet's floating ability. This thickness is acceptable and ensures that the tablets remain buoyant in the gastric environment for an extended period, crucial for floating tablet formulations.The hardness values suggest that all formulations are sufficiently strong to resist mechanical stress during handling. F2 and F3 exhibited the highest hardness values, which would

contribute to better resistance against breakage. F4's hardness of 5.4 ± 0.06 kg/cm² is also adequate, ensuring the tablet maintains its structural integrity during transportation and usage. All formulations exhibited low friability values, which is crucial for maintaining the integrity of the floating tablets. F3 showed the lowest friability (0.2%), which is ideal as it indicates the tablet is robust and unlikely to break into smaller pieces during handling. F4, with 0.6% friability, also demonstrates good stability and would be well-suited for distribution without significant loss of material. The weight variation of the formulations was within the acceptable range, indicating uniformity in the tablet manufacturing process. F4, with the lowest weight variation (2.0%), shows the best consistency in tablet weight and ensures uniform drug content in each tablet. F1, showed slightly higher weight variation (2.63%), which may reflect minor inconsistencies in tablet preparation but still falls within the acceptable limits. The physical properties of the floating tablet formulations were evaluated to assess their suitability for sustained release. The thickness of the tablets ranged from 2.87 ± 0.024 mm (F1) to 4.0 ± 0.034 mm (F4), all within an acceptable range for floating tablets. Hardness values showed that F2 and F3 had the highest hardness (6.0 ± 0.03 kg/cm²), ensuring their mechanical strength, with F4 (5.4 ± 0.06 kg/cm²) also demonstrating adequate resistance to breakage. Friability values were low for all formulations, with F3 exhibiting the lowest friability (0.2%), indicating superior durability. Weight variation was within the acceptable limit for all formulations, with F4 showing the least variation (2.0%). These results indicate that the formulations possess appropriate characteristics to withstand mechanical stress, ensuring stability during storage and transit. F3 demonstrated the best mechanical strength and stability, while F4 showed the best weight uniformity. F1 had slightly higher friability and weight variation, suggesting room for optimization. Overall, all formulations are suitable for floating tablet development, with F3 and F4 being the most promising candidates for further development. The floating lag time (the time taken for the tablet to start floating after being placed in the dissolution medium) varied from 60 seconds (F1) to 200 seconds (F4). F1 exhibited the shortest floating lag time, while F4 had the longest. All formulations exhibited a floating time of more than 6 hours, indicating that they maintained their buoyancy in the dissolution medium for a prolonged period. This is crucial for floating tablets to ensure extended drug release in the stomach. The floating lag time is a key parameter that affects the onset of floating behaviour. Formulation F1 exhibited the shortest floating lag time (60 seconds), which suggests that it quickly reaches the surface of the dissolution medium, potentially enhancing the initial release of the drug. F2 and F3 showed slightly longer lag times (120 seconds and 170 seconds, respectively), while F4 had the longest floating lag time of 200 seconds. Despite the differences in floating lag time, all formulations showed a floating time of more than 6 hours, which is ideal for ensuring that the tablets remain in the gastric environment for extended drug release. Longer floating times are beneficial for sustained release systems, as they allow the tablet to remain in the stomach for prolonged periods, ensuring gradual drug absorption. The formulations with shorter floating lag times (F1, F2, and F3) may offer a quicker onset of floating behaviour, potentially improving the overall drug release rate. However, the increased lag time in F4 could be attributed to differences in the excipients or polymer composition, which might slow down the buoyancy. Overall, all the formulations demonstrated good floating behaviour, indicating that they are suitable for floating drug delivery systems. The drug release profiles for the different floating tablet formulations (F1, F2, F3, and F4) over time are presented in the table. At 1 hour, F1 exhibited the highest drug release (8.2%), followed by F2 (7.9%), F3 (6.4%), and F4 (4.5%). This indicates that F1 starts releasing the drug at a faster rate compared to the other formulations. By 3 hours, the drug release had increased substantially for all formulations. F1 showed a release of 18.3%, F2 released 15.8%, F3 released 14.7%, and F4 released 9.3%. This continued trend suggests that F1 maintains a faster drug release profile compared to the other formulations. Cumulative Release at 6 Hours At 6 hours, the drug release for F1 reached 38.7%, followed by 28.9% for F2, 26.7% for F3, and 20.6% for F4. F1 consistently demonstrated the highest cumulative drug release, while F4 exhibited the lowest, reflecting slower drug release over time. Final Release at 7 Hours, F1 reached 45.2% cumulative drug release, F2 reached 36.7%, F3 reached 32.9%, and F4 reached 24.7%. The drug release for all formulations continued to increase over time, with F1 showing the most significant release, suggesting a faster drug release rate. The drug release profiles of the floating tablet formulations show a gradual increase in drug release over time. Formulation F1 exhibited the fastest drug release, with the highest cumulative release at each time point. This could be attributed to the formulation's composition, which may Favor faster disintegration and drug release. F2 and F3 exhibited moderate release profiles, with F2 showing slightly better release than F3 at all time points. F4 demonstrated the slowest drug release, which could be due to its formulation characteristics, such as thicker or more resistant polymers, which slow down the release rate. The slow release observed in F4 can be beneficial for controlled release applications, where the goal is to provide a sustained, steady release over a longer period. However, F1's faster release profile may be advantageous for drugs that require rapid absorption in the gastrointestinal tract. In conclusion, all the formulations exhibited sustained drug release, with F1 providing the fastest release and F4 the slowest, offering flexibility in designing floating tablet formulations based on the desired release profile.

8. CONCLUSION-

In this study, floating tablets of various formulations (F1, F2, F3, and F4) were designed and evaluated for their physical properties, floating behaviour, and drug release profiles. The formulations demonstrated promising characteristics suitable for controlled drug delivery in the gastric environment. All formulations showed adequate physical properties, including acceptable thickness (ranging from 2.87 ± 0.024 mm to 4.0 ± 0.034 mm), good hardness (ranging from 4.37 ± 0.03 kg/cm² to 6.0 ± 0.03 kg/cm²), and low friability (ranging from 0.2% to 0.7%), indicating good mechanical strength and stability. The

weight variation was within acceptable limits (2.0% to 2.63%), ensuring uniformity in drug content. The floating lag time varied from 60 seconds (F1) to 200 seconds (F4), with all formulations maintaining buoyancy for more than 6 hours. F1 exhibited the shortest floating lag time, while F4 had the longest. The extended floating times for all formulations ensure prolonged gastric retention, crucial for sustained drug release. The drug release profiles showed that F1 had the fastest release, with 45.2% of the drug released after 7 hours, followed by F2 (36.7%), F3 (32.9%), and F4 (24.7%). The release data indicated that F1 provided a rapid drug release, while F4 exhibited the slowest release, making it suitable for controlled release applications.

Overall, Formulation F1 demonstrated the highest drug release rate, making it ideal for drugs requiring quick absorption, while Formulation F4 showed the slowest release, making it more appropriate for sustained drug delivery. The successful development of floating tablets with varying release profiles offers flexibility in designing dosage forms tailored to different therapeutic needs, such as those requiring rapid or controlled drug absorption in the stomach. Further optimization of these formulations could enhance their clinical applicability and efficacy in treating diseases requiring prolonged drug release in the gastric region.

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