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Research Article

Formulation and evaluation of floating tablets of amla and ginger extract for prolonged gastric retention

Vasundhara Subhash Patil, Jameel Ahmed S. Mulla*, Mukesh Vinod Kapse

Department of Pharmaceutics, Shree Santkrupa College of Pharmacy, Ghogaon- Karad, Maharashtra- 415111, India.

***Correspondence**
Jameel Ahmed S. Mulla
jameelahmed5@gmail.com

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The primary objective of this study was to develop and evaluate floating herbal tablets containing extracts of amla (*Emblica officinalis*) and ginger (*Zingiber officinale*). These herbal ingredients were selected for their well-documented health benefits, including antioxidant, anti-inflammatory, and digestive properties. The aim was to enhance the gastric residence time of the tablets, thereby improving the bioavailability and therapeutic efficacy of the herbal extracts. Floating tablets were prepared using a combination of effervescent agents (sodium bicarbonate) and hydrophilic polymers (HPMC K100 and Sodium Alginate) to achieve the desired buoyancy and controlled release characteristics. Physical parameters like hardness, friability, and weight variation were measured for the prepared tablets. The floating lag time and total floating duration were measured *in vitro* buoyancy studies in simulated gastric fluid (0.1 N HCl) at 37°C. The release profile of active ingredients from the tablets was also measured *in vitro* release studies. The optimized formulation showed a floating lag time that was less than 20 seconds and a total floating duration exceeding 12 hours. The developed floating herbal tablets of amla and ginger extracts successfully achieved prolonged gastric retention and controlled release, which can potentially enhance the therapeutic efficacy of these herbal ingredients.

Keywords: *floating herbal tablets, amla extract, ginger extract, buoyancy, controlled release, effervescent agent*

Introduction

The concept of gastroretentive drug delivery systems (GRDDS) has become a focal point in pharmaceutical research due to their ability to enhance the bioavailability and therapeutic efficacy of drugs with a narrow absorption window in the upper gastrointestinal tract (Chawla et al., 2003; Mandal at al., 2010). Among various GRDDS, floating drug delivery systems (FDDS) have shown promising potential by maintaining buoyancy in the gastric fluids, thereby prolonging the drug's gastric residence time and enabling controlled drug release (Singh & Kim, 2000; Potekar et al., 2017, Tipugade et al., 2022). Floating tablets, a type of FDDS, have garnered particular interest for the delivery of herbal medicines, which often comprise active compounds that benefit from prolonged gastric retention. Herbal medicines are renowned for their therapeutic efficacy and lower incidence of side effects compared to synthetic drugs, making them an attractive option for incorporation into advanced drug delivery systems (Ekor, 2014). Amla (*Emblica officinalis*) and ginger (*Zingiber officinale*) are two well-known medicinal herbs with a wide range of therapeutic properties. Amla is rich in vitamin C which boosts immunity, fights oxidative stress, and promotes skin health and exhibits immunomodulatory effects (Baliga et al., 2011). Amla (Indian Gooseberry) has strong antioxidant properties, which help protect cells from damage and support overall health. It aids in digestion and can be used in formulations aimed at improving gut health. Amla has anti-inflammatory properties, making it beneficial for conditions like arthritis. It helps in maintaining metabolism and is often included in weight management formulations (Scartezzini & Speroni, 2000). Ginger, on the other hand, is widely recognized for its digestive benefits, anti-inflammatory, and antioxidant properties (Ali et al., 2008). Ginger is well-known for its ability to improve digestion and reduce nausea which is beneficial in formulations for motion sickness or morning sickness. It's commonly used in formulations targeting

digestive health. Ginger helps in boosting the immune system, making it useful in cold and flu formulations. Like Amla, ginger has strong anti-inflammatory properties, which can help in managing pain and inflammation (Ernst & Pittler, 2000). The combination of these herbs in a floating tablet formulation could offer synergistic benefits, improving overall therapeutic outcomes. The aim of preparing herbal tablets of amla and ginger is to provide a natural, holistic, and safer alternative for health management, leveraging the therapeutic benefits of plant-based ingredients with fewer side effects, lower risk of resistance, and support for the body's natural healing processes. Herbal tablets are often preferred for their holistic approach, cultural acceptance, and potential cost-effectiveness, making them an attractive option for those seeking more sustainable and gentle forms of treatment.

Materials and Methods

Amla Extract (*Emblica officinalis*) and Ginger Extract (*Zingiber officinale*) were purchased from Bixa Botanical, India. HPMC K100, Magnesium Stearate and Sodium Bicarbonate were obtained from Research Lab Fine Chem, Mumbai. Talc obtained from Loba Chemiepvt. Ltd, Mumbai.

Formulation of floating tablets

The floating tablets were prepared by the direct compression method. The composition of each tablet is outlined in Table 1. To create a consistent tablet blend, all the components were thoroughly combined in a mortar and pestle. Then, the mixture was combined with talc and magnesium stearate. Next, using a single punch tablet machine and a distinct recipe, each tablet mix was individually weighed and compacted into a tablet (Upadhye et al., 2014).

Table 1. Formulation of floating tablets

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Amla extract (mg)	200	200	200	200	200	200	200	200	200
Ginger extract (mg)	150	150	150	150	150	150	150	150	150
HPMC K 100 (mg)	50	50	50	55	55	55	60	60	60
Sodium alginate (mg)	20	25	30	20	25	30	20	25	30
Sodium bicarbonate (mg)	50	50	50	50	50	50	50	50	50
Talc (mg)	2	2	2	2	2	2	2	2	2
Magnesium stearate (mg)	2	2	2	2	2	2	2	2	2

Factorial Design

A factorial design with three levels was created using Design-expert software. As a result, the experiment had to evaluate every possible combination of the three levels of each component that was being considered. HPMC K100 (X_1) and Sodium Alginate (X_2) that were used as independent variables. The independent factors were screened using a multilevel factorial design (3^2) and nine distinct formulations of floating tablets were created (Table 2). After all formulations were made using the direct compression method, the best formulation was determined by analyzing floating lag time (Y_1) and total floating time (Y_2) (Fatima & Shahidulla, 2023).

Table 2. Independent variables

Coded value level	Independent variables	
	X_1 HPMC K100 (mg)	X_2 Sodium Alginate (mg)
-1	50	20
0	55	25
+1	60	30

Pre-Compression Evaluations

Bulk Density: Bulk density (B) is the ratio of the total mass of powder (M) to the bulk volume (Vb) of powder (Nayak et al., 2010).

$$B = \frac{M}{Vb}$$

Tapped Density: Tapped density (T) is the ratio of the total mass of powder (M) to the tapped volume (Vt) of powder (Bhagat et al., 2019).

$$\mathrm{T} = \frac{M}{Vt}$$

Carr's Index: The flowability of powder can be assessed by comparing its bulk density and tapped density, along with the rate at which the powder settles. The compressibility index was calculated by the given formula (Baviskar et al., 2019).

$$\text{Carrs index (\%)} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \text{X100}$$

Hausner's Ratio: Hausner's ratio is evaluated by means of taking ratio of Tapped density (T) and it divided by Bulk density (B) by the usage of the following formula (Bhagat et al., 2019).

$$\text{Hausner's Ratio} = \frac{T}{B}$$

Angle of Repose: The frictional forces in a loose powder or granules can be assessed by measuring the angle of repose (θ). This is the steepest angle formed between the surface of a pile of powder or granules and the horizontal plane. The granules are permitted to flow through a funnel that is fixed at a set height. The angle of repose, then calculated by measuring the height (h) and radius (r) of the heap of granules formed (Baviskar et al., 2019).

$$\text{Tan } \theta = \frac{h}{r}$$

Post-compression evaluations

Evaluations of Floating Tablet: Each formulation's 20 Tablets were weighed, and the average weight of the group was found after that % variation of the prepared tablet was calculated. Vernier callipers were used to measure the thickness of the manufactured floating tablets. A Monsanto hardness tester was used to measure the tablets' hardness. Using a Roche friabilitor, the friability was determined as shown in Table 6 (Basak et al., 2004).

Floating Lag Time (FLT)**:** The time it takes for the dosage form to rise to the surface of the medium is referred to as the Floating lag time. Studies on floating behaviour were conducted to mimic in vivo conditions using a USP class II (paddle) apparatus, operated at 100 rpm in 900 mL of 0.1 N HCl maintained at 37 ± 0.2°C. The FLT was determined based on visual observation (Basak et al., 2004).

Total Floating Time (TFT): The floating time of a tablet is the duration for which the tablet remains buoyant in the stomach. This parameter is critical in the development of gastroretentive drug delivery systems (GRDDS), which are designed to sustain the gastric residence time of the dosage form. Total floating time of a tablet was calculated by using USP class II (paddle) apparatus at 50-100 rpm in 900 ml of 0.1 N HCl at 37 ± 0.2°C. Monitor and record the total floating time, which is the duration the tablet remains buoyant (Reddy & Murthy, 2002).

***In Vitro* Dissolution Studies:** The release of active ingredients from the tablets was studied using a USP dissolution apparatus II (paddle type) in 0.1 N HCl at 37±0.5°C. Samples were withdrawn at specified time intervals and analyzed using a UV-Vis spectrophotometer (Shimadzu Corporation, Japan) (Mulla et al., 2008).

Results

Table 3. Factors and Response of Herbal Floating Tablet

Formulation Batches	HPMC K100 (mg), X_1	Sodium Alginate (mg), X_2	Floating lag time (Sec)*, Y_1	Total Floating time (h)*, Y_2
F1	50	20	54.12±1.1	7.31±0.01
F2	50	25	48.22±0.98	7.58±0.05
F3	50	30	46.51±1.07	8.12±0.03
F4	55	20	42.31±1.31	9.23±0.02
F5	55	25	36.11±0.88	9.48±0.04
F6	55	30	34.15±1.4	10.12±0.06
F7	60	20	25.41±0.6	11.18±0.03
F8	60	25	21.3±1.7	11.51±0.02
F9	60	30	19.41±1.3	12.3±0.03

*n=3, ±SD

Floating Lag Time decreases as both HPMC K100 and Sodium Alginate concentrations increase, meaning the tablet begins floating sooner with higher polymer content. Total Floating Time increases with higher concentrations of these polymers, indicating that the tablet remains buoyant for a longer period. The optimal formulation would balance these components to achieve a rapid onset of floating (low Floating Lag Time) and prolonged floating duration (high Total Floating Time). For instance, F9 with 60 mg HPMC K100 and 30 mg Sodium Alginate would be optimal for a formulation requiring quick and sustained buoyancy which was outlined in Table 3.

ANOVA for Quadratic model of floating lag time

The Model F-value of 701.26 indicates that the model is significant. P-values less than 0.0500 signify that the model terms are significant. In this instance, X_1, X_2, X_1^2, and X_2^2 are significant model terms.

Table 4. Fit statistics for floating lag time

Std. Dev.	0.5929	**R^2**	0.9991
Mean	36.39	**Adjusted R^2**	0.9977
C.V. %	1.63	**Predicted R^2**	0.9900
		Adeq Precision	71.9598

The Predicted R^2 of 0.9900 is in good agreement with the Adjusted R^2 of 0.9977, as the difference is less than 0.2 (Table 4). Adeq Precision assesses the signal-to-noise ratio, with a ratio above 4 being desirable. In this case, a ratio of 71.960 indicates a sufficient signal. Therefore, this model is suitable for navigating the design space.

ANOVA for Quadratic model of total floating time

The Model F-value of 3070.47 implies the model is significant. P-values less than 0.0500 indicate model terms are significant. In this case X_1,X_2, X_1^2, X_2^2 are significant model terms.

Table 5. Fit statistics for total floating time

Std. Dev.	0.0406	**R^2**	0.9998
Mean	9.65	**Adjusted R^2**	0.9995
C.V. %	0.4211	**Predicted R^2**	0.9976
		Adeq Precision	148.7039

The Predicted R^2 of 0.9976 aligns well with the Adjusted R^2 of 0.9995, with a difference of less than 0.2 (Table 5). Adeq Precision evaluates the signal-to-noise ratio, and a ratio above 4 is preferred. In this case, a ratio of 148.704 indicates a strong signal. Thus, this model is suitable for exploring the design space.

Final Equation for Y_1 and Y_2

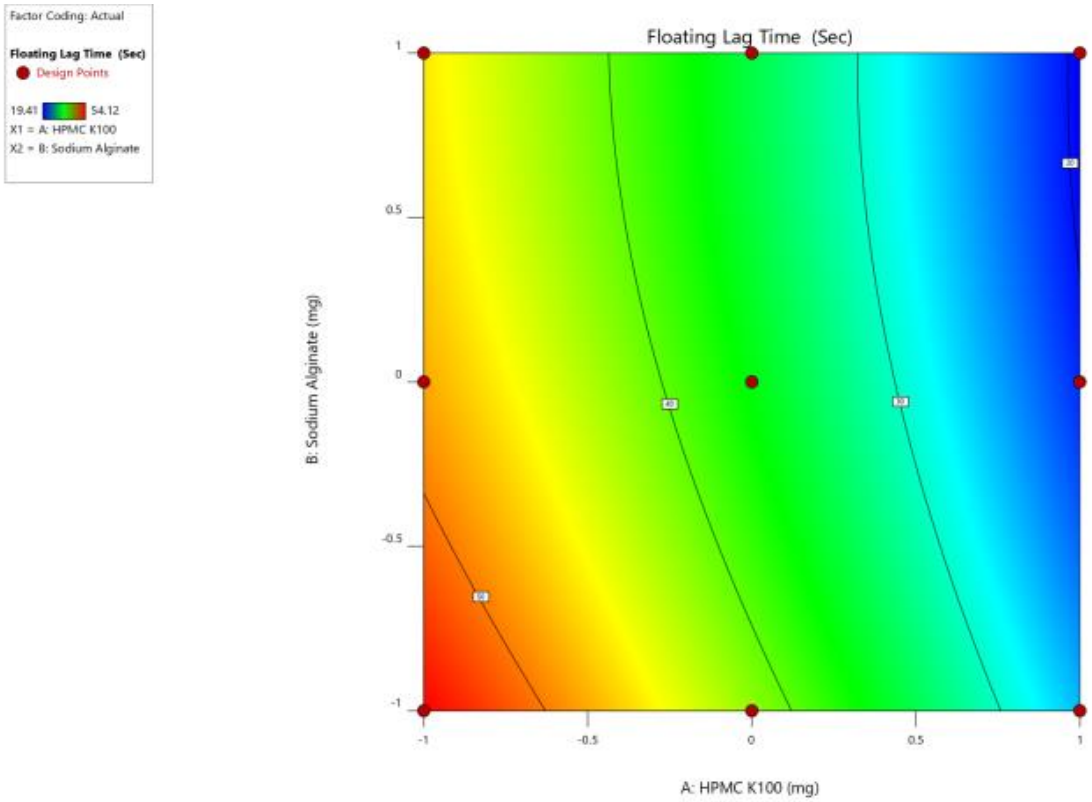
Response 1: Floating Lag Time, Y_1

$$Y_1 = 36.34-13.79X_1-3.63X_2+0.4025X_1X_2-1.69X_1^2+1.78X_2^2$$

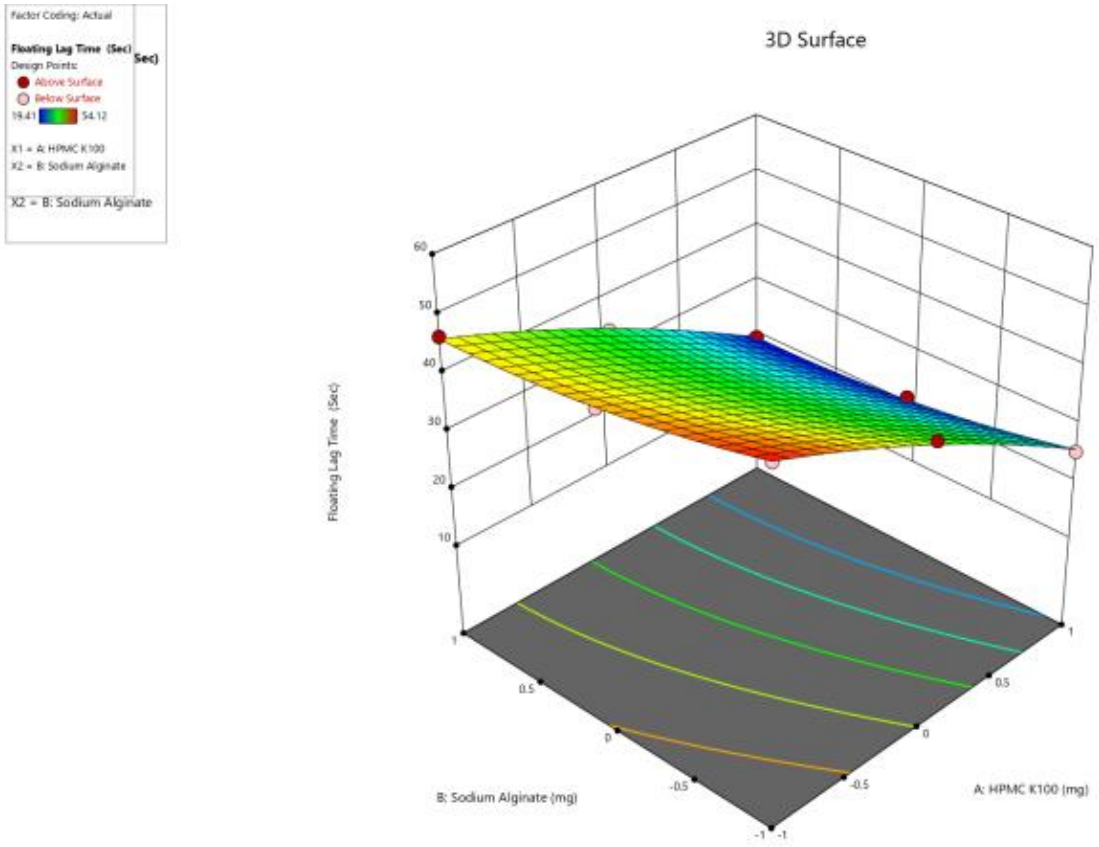
Response 2: Total Floating Time, Y_2

$$Y_2 = 9.49+2.00X_1+0.4700X_2+0.0775X_1X_2+0.0567X_1^2+0.1867X_2^2$$

The 3D surface is relatively flat, which suggests that the combination of HPMC K100 and Sodium Alginate does not drastically affect the Floating Lag Time. However, higher levels of both seem to slightly reduce the Floating Lag Time. (as shown in Figure 1)



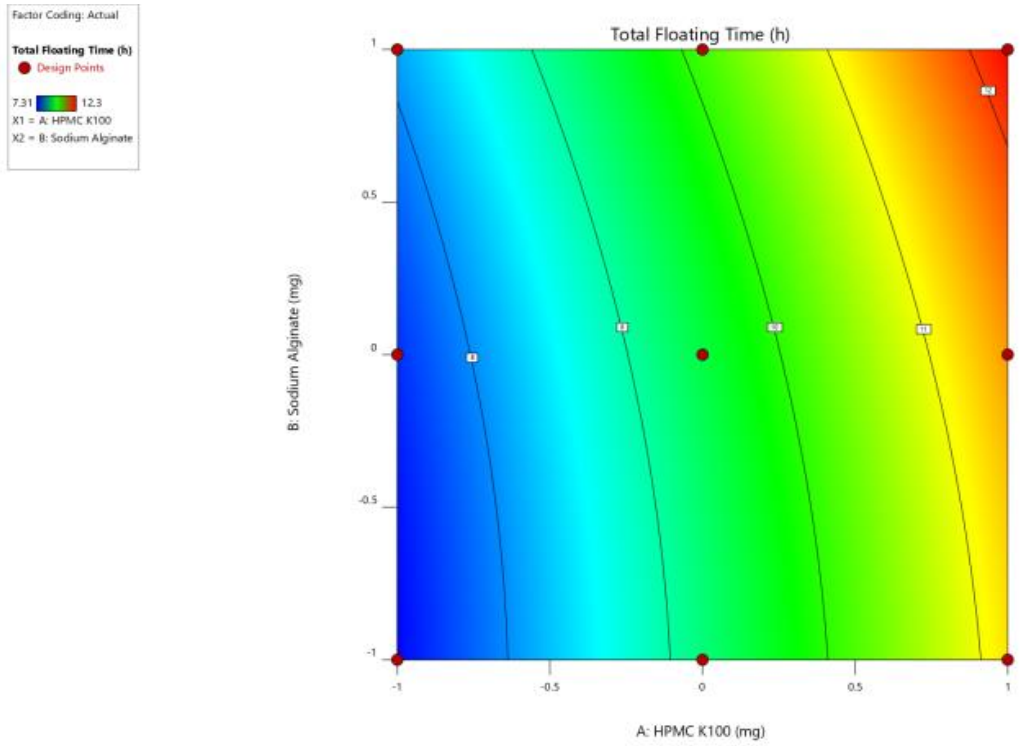
(a)



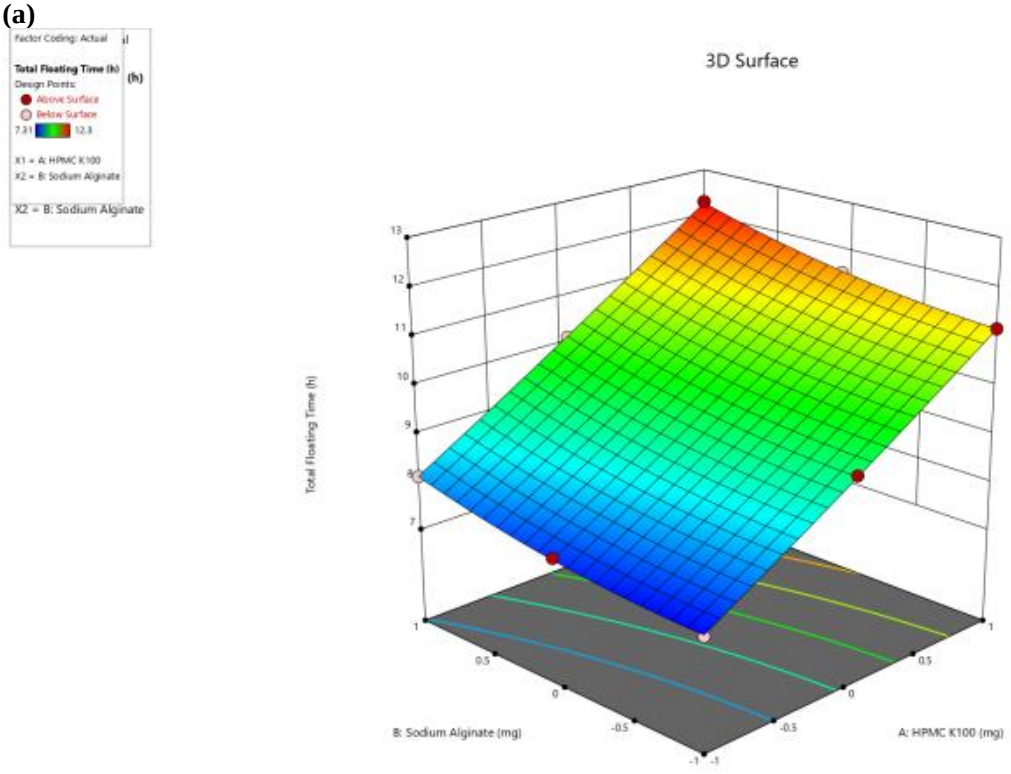
(b)

Figure 1. 2D Contour (a) and 3D Response surface plots (b) for evaluating influence of HPMC K100 (X1) and Sodium Algnate (X2) on Floating Lag Time (Y_1)

The steepness of the surface suggests that increasing concentrations of HPMC K100 and Sodium Alginate will increase the Total Floating Time. This indicates that the polymer matrix formed by these ingredients effectively controls the Total floating time of the tablet, leading to a longer floating duration. (as shown in figure 2)



(a)



(b)

Figure 2. 2D Contour (a) and 3D Response surface plots (b) for evaluating influence of HPMC K100 (X_1) and Sodium Algnate (X_2) on Total Floating Time (Y_2)

Pre-compression evaluations

Table 6. Pre-compression evaluations of floating tablet

Formulation	Bulk Density (gm/cm^3)*	Tapped ensity (gm/cm^3)*	Carr's Index (%)*	Housner's Ratio*	Angle of repose (θ)*
F1	0.47±0.0054	0.62±0.013	9.61±0.831	1.30±0.013	29.64±0.512
F2	0.50±0.0051	0.63±0.015	10.28±1.321	1.16±0.026	32.90±0.522
F3	0.46±0.021	0.60±0.018	11.53±0.983	1.23±0.041	25.81±0.623
F4	0.51±0.0042	0.59±0.011	10.43±1.534	1.13±0.014	25.3±0.6034
F5	0.53±0.0082	0.64±0.014	14.5±0.582	1.24±0.052	28.43±0.5324
F6	0.53±0.012	0.66±0.009	11.4±0.782	1.12±0.061	22.21±0.332
F7	0.49±0.0076	0.58±0016	17.5±1.453	1.32±0.056	28.5±0.435
F8	0.54±0.0092	0.68±0.012	14.2±0.835	1.42±0.044	26.3±0.4212
F9	0.56±0.015	0.66±0.017	16.7±1.32	1.21±0.016	31.7±0.4631

*n=3, ±SD

Post-compression evaluations

Table 7. Post-compression evaluations of floating tablet

Formulation Batches	Weight Variation (%)*	Tablet Thickness(mm)*	Hardness (kg/cm^3)*	Friability (%)*
F1	3.4± 0.15	4.19±0.2	3.8±0.2	0.32± 0.022
F2	3.7± 0.25	4.17±0.2	3.5±0.3	0.28±0.023
F3	4.3± 0.2	4.16±0.04	4.1±0.1	0.25±0.019
F4	3.9± 0.15	4.21±0.1	3.7±0.2	0.30±0.021
F5	4.2± 0.22	4.16±0.2	3.8±0.1	0.29±0.028
F6	3.8± 0.19	4.15±0.5	3.5± 0.2	0.31±0.023
F7	4.2± 0.17	4.18±0.2	3.9±0.1	0.27±0.022
F8	3.9± 0.31	4.14±0.4	3.6±0.2	0.28±0.020
F9	2.8± 0.34	4.20±0.1	3.8±0.1	0.24± 0.02

*n=3, ±SD

Floating lag time

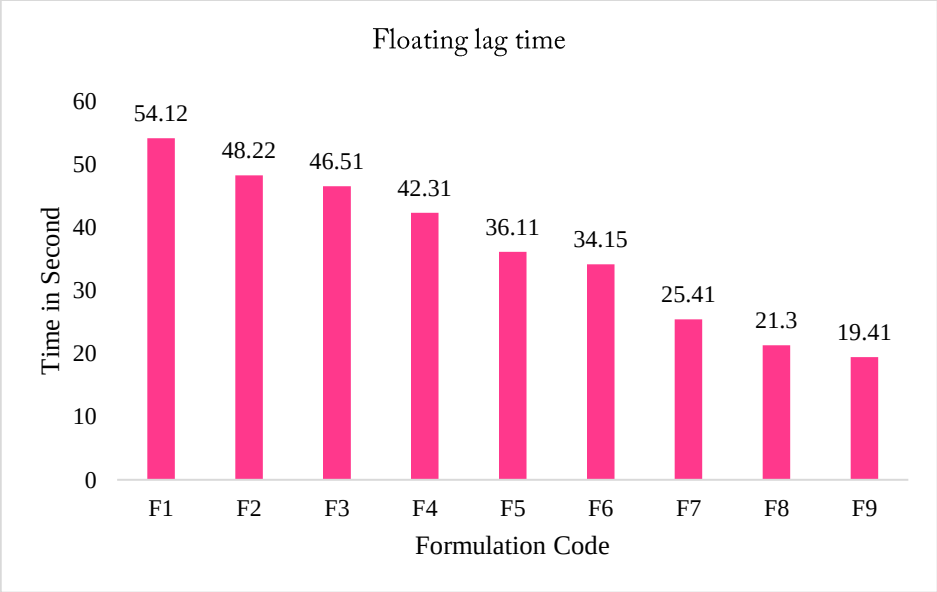


Figure 3. Floating lag time of herbal floating tablet

Total floating time

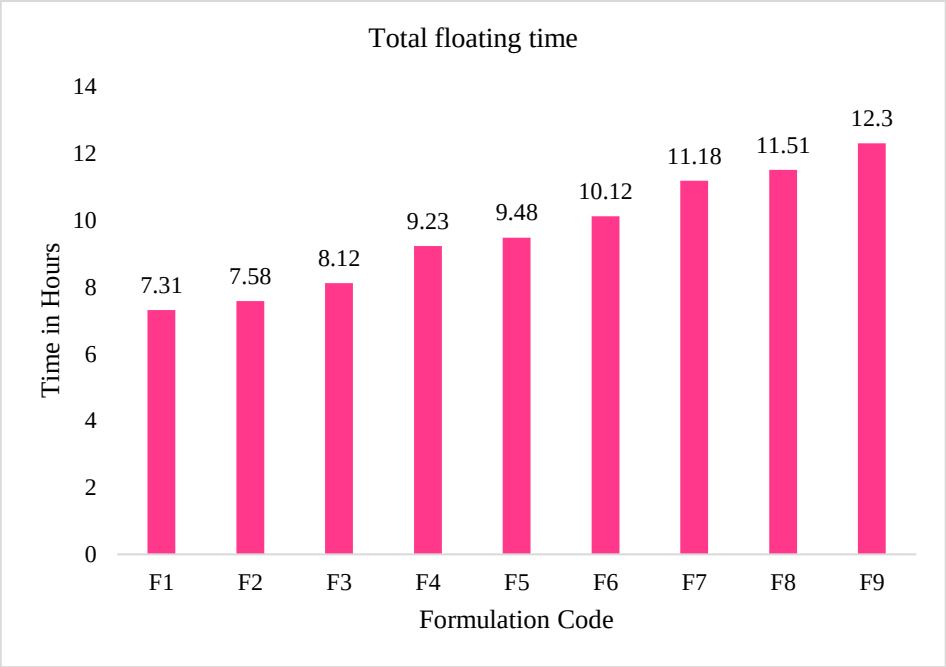


Figure 4. Total floating time of herbal floating tablet

***In Vitro* Dissolution studies:**

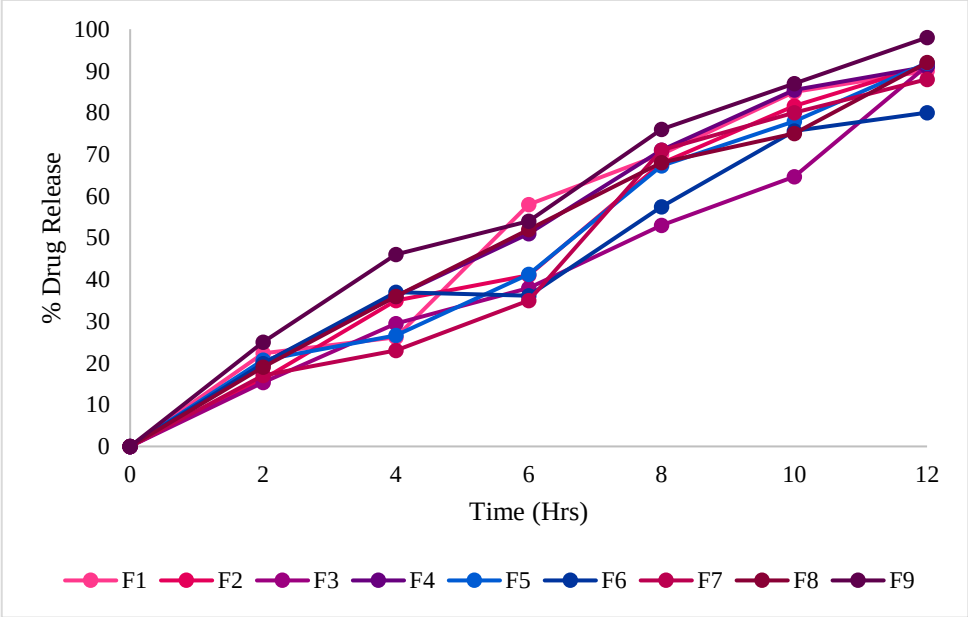


Figure 5. *In Vitro* Dissolution studies of herbal floating tablet

Discussion

The precompression parameters for the herbal floating tablet formulations are essential for understanding the flow properties and compressibility of the powder blends (as shown in Table 6). The precompression of floating tablet aligns with the previous studies conducted by Bhagat et al. (2019). The bulk density ranged from 0.46 to 0.56 g/cm³, and the tapped density ranged from 0.58 to 0.68 g/cm³ across formulations. These values indicate moderate compressibility and the potential for consistent tablet weight. Carr's Index values ranged from 9.61% to 17.5%. Formulations F1 (9.61%) and F4 (10.43%) show excellent flow properties (≤ 10%). Formulations F2, F3, F5, F6, and F9 fall within the range of 10-15%, indicating good flow properties. Hausner's Ratio values ranged from 1.12 to 1.42. Formulations F2, F4, F5, F6,

F8, and F9 with ratios close to or above 1.25 indicate passable flowability. Ratios below 1.25 for formulations F1 (1.30), F3 (1.23), F7 (1.32), and F8 (1.42) suggest better flow characteristics. The angle of repose ranged from 22.21° to 32.90°. Formulations F6 (22.21°) and F4 (25.3°) show excellent flowability (<30°). Formulations F3, F5, F7, and F8 exhibit good flowability with values between 25° and 30°. The provided 3D surface plot illustrates the relationship between two independent variables, HPMC K100 (A) and Sodium Alginate (B), and their effect on the response variable, Floating Lag Time (FLT) and Total Floating Time (TFT). 2^3 factorial design was demonstrated by Vummaneni et al. (2012) in there research article. As the concentration of HPMC K100 increases, the FLT generally decreases and TFT increases. This suggests that HPMC K100 positively influences the buoyancy of the tablets, allowing them to float faster and remain in buoyant condition for prolong time which was shown in (Fig 1) and (Fig 2). Increasing the concentration of Sodium Alginate also appears to reduce the FLT and increases the TFT, although its effect is less pronounced compared to HPMC K100. The post-compression parameters evaluated for the herbal floating tablet formulations include weight variation, tablet thickness, hardness, and friability as shown in Table 7. The study by Patel et al. (2023) demonstrated the post compression studies of floating tablet. These parameters are crucial for assessing the physical quality and mechanical integrity of the tablets. The weight variation for all formulations is within acceptable limits, indicating uniformity in tablet weight. Formulation F9 showed the least weight variation (2.8 ± 0.34%), suggesting excellent uniformity. The tablet thickness ranged from 4.14 to 4.21 mm, with minimal variation across different batches. This consistency in thickness ensures uniformity in tablet size and appearance. Tablet hardness ranged from 3.5 to 4.1 kg/cm².Formulation F3 exhibited the highest hardness (4.1 ± 0.1 kg/cm²), which is beneficial for handling and packaging. Friability values for all formulations were below 1%, indicating excellent mechanical integrity and resistance to abrasion. Formulation F9 had the lowest friability (0.24 ± 0.02%), while F1 had the highest (0.32 ± 0.022%), though still within acceptable limits. Form (Fig 3), (Fig 4) & (Table 3) Herbal floating tablet show the floating lag time in range from 54.12 to 19.41 second. F1 batch show highest floating lag time as compare to F9 batch. Therefore, F9 batch having excellent floating lag time as compare to other batches. Total floating time is ranged from 7.31 to 12.3 hours from which F9 batch tablets were float more than 12 hrs. It remains in buoyant condition for more than 12 hrs. The dissolution profiles of the herbal floating tablets indicate that all formulations are capable of providing extended drug release over a 12-hour period. Formulations F1, F2, F4, and F9 are particularly promising for rapid and sustained drug release, making them suitable candidates for further development. F6, with its slower release profile, may be advantageous for formulations requiring a more prolonged release. A research article published by Potekar et al. (2017) shows the significant finding of *in vitro* drug release. The variability in dissolution rates among the formulations provides options for tailoring the release profile to meet specific therapeutic needs. By 12 hours, most formulations had reached near-complete drug release (above 90%), with F9 achieving the highest release (98%) as shown in Fig 5.

Conclusion

The study successfully developed and evaluated floating herbal tablets containing extracts of amla (*Emblica officinalis*) and ginger (*Zingiber officinale*). The optimized formulation demonstrated excellent buoyancy characteristics, with a floating lag time of less than 20 second and a total floating duration exceeding 12 hours. These tablets exhibited satisfactory physical properties, adhering to pharmacopeial standards. *In vitro* release studies indicated a controlled and sustained release of the active constituents from the tablets over a period of 12 hours, with a significant release occurring in the initial 6 hours. The successful formulation of these floating herbal tablets presents a promising strategy for improving the delivery and efficacy of herbal medications. This novel approach could lead to better patient compliance and improved clinical outcomes, highlighting the potential of gastroretentive systems in herbal drug delivery.

Author contributions

V. S. Patil: methodology, investigation. J. A. S. Mulla: conceptualization, formal analysis, draft reviewing, supervision. M. V. Kapse: original draft writing, software.

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Conflict of interest

The author declares no conflict of interest. The manuscript has not been submitted for publication in another journal.

Ethics approval

Not applicable

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