RESEARCH PAPER

Formulation and Evaluation of Gastro-Retentive Floating Tablets of Tegoprazan

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ABSTRACT

The present research work was undertaken to develop and optimize a gastro-retentive floating drug delivery system of Tegoprazan for the effective management of gastroesophageal reflux disease (GERD). GERD is a prevalent chronic gastrointestinal disorder characterized by reflux of gastric contents, leading to mucosal damage and reduced quality of life, necessitating prolonged and effective acid suppression therapy. Tegoprazan, a novel potassium-competitive acid blocker (P-CAB), exhibits rapid onset of action and potent acid suppression but possesses a relatively short half-life (3–5 hours), which may require frequent dosing. Therefore, a gastro-retentive floating tablet was designed to prolong gastric residence time and achieve sustained drug release. Preformulation studies confirmed the identity and purity of the drug. The melting point was found in the range of 118–122 °C, and UV spectrophotometric analysis showed a λmax at 261 nm with excellent linearity (R^2 = 0.9993). FTIR studies confirmed characteristic functional groups and indicated no drug–excipient interaction. Floating tablets were prepared using polymers such as Carbopol 934P and Sodium Alginate. Pre- and post-compression parameters were within acceptable limits, indicating good flowability and tablet integrity. Floating studies demonstrated prolonged buoyancy, and in vitro dissolution studies showed sustained drug release up to 24 hours. The optimized formulation (TF9) exhibited 98.86% drug release with excellent floating duration (~24.64 h) and stable performance under accelerated conditions. Thus, the developed gastro-retentive floating system of Tegoprazan offers a promising approach for sustained drug delivery, improved therapeutic efficacy, and enhanced patient compliance.

Keywords: Tegoprazan; Gastro-retentive Floating Tablet; Controlled Release; Carbopol 934P; Sodium Alginate.

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INTRODUCTION:

Gastric acid–related disorders such as gastroesophageal reflux disease (GERD), peptic ulcer disease, and functional dyspepsia continue to pose a significant clinical burden, with patients often experiencing recurrent symptoms despite the widespread use of proton pump inhibitors (PPIs). Although PPIs remain the mainstay of therapy, their delayed onset of action, variable response, and limitations in controlling nocturnal acid secretion highlight the need for improved therapeutic strategies. In this context, there is a growing demand for drug delivery systems that can provide rapid onset, consistent acid suppression, and better patient adherence, particularly for individuals requiring on-demand symptom relief. From a public health perspective, achieving more effective acid control can reduce complications such as erosive esophagitis and bleeding ulcers, while also minimizing repeated healthcare interventions.[1]

Tegoprazan, a potassium-competitive acid blocker (P-CAB), represents a promising alternative to conventional PPIs due to its distinct pharmacological mechanism. Unlike PPIs, it directly and reversibly inhibits the H^+/K^+-ATPase enzyme without requiring prior activation in an acidic

environment, resulting in a faster onset of action. Pharmacokinetic studies have demonstrated rapid absorption (Tmax ≈ 0.5–1 hour) and a relatively short elimination half-life of approximately 3.5–6 hours, with dose-proportional exposure observed in clinical trials. While these characteristics make Tegoprazan highly effective for rapid symptom relief, its short half-life may lead to fluctuations in plasma drug levels, necessitating multiple dosing to maintain sustained acid suppression over 24 hours.[2-3]

To address these limitations, the development of a gastro-retentive drug delivery system presents a rational and innovative approach. Gastro-retentive floating matrix tablets are specifically designed to remain buoyant in the stomach for prolonged periods, allowing controlled and sustained drug release within the gastric environment. This strategy is particularly advantageous for Tegoprazan, as it is primarily absorbed in the upper gastrointestinal tract. Prolonging gastric residence time can therefore enhance the drug's absorption window and maintain consistent therapeutic levels. Additionally, sustained release in the stomach may help maintain optimal intragastric pH, which is crucial for effective acid suppression and may also support combination therapies where pH modulation is beneficial.[3]

Furthermore, a floating matrix system can minimize variability caused by gastric emptying and food intake, leading to more predictable drug performance. By converting the rapid systemic exposure of Tegoprazan into a controlled-release profile, it is possible to reduce peak-related adverse effects, decrease dosing frequency, and improve patient compliance.[4]

From a formulation standpoint, an effervescent floating matrix system incorporating hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC) and Kollidon SR, along with gas-generating agents, offers a robust and scalable design. Techniques such as direct compression or wet granulation can be employed to ensure uniformity, reproducibility, and ease of large-scale manufacturing. Overall, this approach provides a scientifically sound and practically feasible strategy to optimize the therapeutic performance of Tegoprazan in the management of acid-related disorders.[5-6]

MATERIALS AND METHOD

Materials: Excipients like HPMC K4M and HPMC K15M, Carbopol 934P, Sodium Alginate, Sodium Bicarbonate, Citric Acid, Microcrystalline Cellulose (MCC), Magnesium Stearate, Talc were obtained from Chemdyes Corporation, Rajkot, Gujarat.

Method: Floating tablets of Tegoprazan were prepared using the wet granulation method. All ingredients were accurately weighed and passed through sieve #30 to ensure uniform particle size. The drug and excipients, excluding talc and magnesium stearate, were thoroughly blended to obtain a homogeneous mixture. Granulation was carried out using isopropyl alcohol (IPA), and the wet mass was passed through sieve #16 to form granules. The prepared granules were dried in a hot air oven at 50–60°C for 30 minutes, followed by sizing through sieve #24 to achieve uniformity. The dried granules were then lubricated with talc and magnesium stearate to improve flow properties and prevent sticking during compression. Finally, the lubricated blend was compressed into tablets using a 12 mm punch. This method provided good flowability, uniform granule formation, and reproducible tablet characteristics suitable for gastro-retentive floating drug delivery.[7-8]

Statistical analysis: A 3^2 factorial design was employed to systematically evaluate the combined effect of two formulation variables Carbopol 934P (X_1) and Sodium Alginate (X_2) on key performance parameters of the formulation. Each variable was studied at three levels (−1, 0, +1), allowing detailed assessment of both individual and interaction effects, formulation of different batches are shown in table 1. The selected dependent responses included floating lag time, total floating time, and percentage drug release at 24 hours (Y_1, Y_2, and Y_3). Experimental data obtained from nine formulations were analysed using ANOVA with Design-Expert software to determine the significance of variables and optimize the formulation. The relationship between variables was described using a quadratic polynomial equation: $\mathbf{Y= B_0 + B_1X_1 + B_2X_2 + B_{12}X_1X_2 + B_{11}X_1^2 + B_{22}X_2^2 + E.}$ The design demonstrated that varying the concentrations of Carbopol 934P (50–100 mg) and Sodium Alginate (50–100 mg) significantly influenced the formulation characteristics. Overall, this approach enabled efficient optimization and identification of an ideal formulation with desirable floating behaviour and controlled drug release.[9-10]

Table 1: Formulation of Floating Tablet by using 3^2 Factorial Design

Ingredients (mg)	TF1	TF2	TF3	TF4	TF5	TF6	TF7	TF8	TF9

Tegoprazan	50	50	50	50	50	50	50	50	50
Carbopol 934P	50	75	100	50	75	100	50	75	100
Sodium Alginate	50	50	50	75	75	75	100	100	100
Sodium Bicarbonate	30	30	30	30	35	35	35	40	40
Citric Acid	15	15	15	15	20	20	20	20	20
MCC	140	115	90	115	80	55	80	50	25
Magnesium Stearate	5	5	5	5	5	5	5	5	5
Talc	10	10	10	10	10	10	10	10	10
Total Weight (mg)	350	350	350	350	350	350	350	350	350

Determination of Melting Point of Tegoprazan: The melting point of Tegoprazan was determined using a digital melting point apparatus. A small quantity of the drug was filled into a thin-walled capillary tube sealed at one end. The capillary tube was then placed in the melting point apparatus alongside a calibrated thermometer. The temperature range at which the drug sample melted was recorded. All measurements were performed in triplicate to ensure accuracy and reproducibility, and the average value was reported.[11]

Estimation of Tegoprazan by UV spectroscopy method: 10 mg Tegoprazan was dissolved in in 0.1 N HCl in 100 ml of volumetric flask and diluted quantitatively with 0.1 N HCl to obtain a solution having a known concentration of 100 µg/ml. The standard solution of Tegoprazan was subsequently diluted with 0.1 N HCl to obtain a series of dilutions containing 10, 20, 30, 40 and 50 µg/ml solution of Tegoprazan. The absorbance of these solutions was measured in analytical technologies Limited, UV-Visible Spectrophotometer at 261 nm using 0.1 N HCl as blank.[12]

Determination of drug by FTIR and Compatibility Study of Drug and Excipients: FTIR was performed for determination of Tegoprazan and was estimated for standard FTIR peaks. And FTIR spectroscopy was employed to identify the drug and excipients and assess their compatibility.[12]

PRE-COMPRESSION PARAMETERS: Pre-compression parameters of the powder blend were evaluated to assess the flow characteristics and compressibility of the formulation prior to tablet compression.

Bulk Density[13,14]: Bulk density was determined by gently transferring a known mass of the powder blend into a graduated measuring cylinder without compacting the material. The volume occupied by the powder was recorded, and bulk density was calculated using the following equation:

$$\textbf{Bulk Density} = \frac{\textbf{Mass of powder (gm)}}{\textbf{Bulk volume of powder (ml)}}$$

Tapped Density[13,14]: Tapped density was measured using a mechanical tapping apparatus. A graduated cylinder containing a known quantity of powder blend was tapped repeatedly until a constant volume was obtained. The tapped density was then calculated using the following formula:

$$\textbf{Tapped Density} = \frac{\textbf{Mass of powder (gm)}}{\textbf{Tapped volume of powder (ml)}}$$

Compressibility Index (Carr's Index)[15]: The compressibility index indicates the flow properties of a powder blend and was calculated from the bulk and tapped densities using the following equation:

$$\textbf{Carr's index} = \frac{\textbf{Tapped Density} - \textbf{Bulk Density}}{\textbf{Tapped Density}} \boldsymbol{X\ 100}$$

Hausner's Ratio[15]: Hausner's ratio was calculated as the ratio of tapped density to bulk density and provides an indication of powder flowability. A Hausner's ratio value of ≤ 1.25 indicates good flow properties, whereas values greater than 1.25 indicate poor flow characteristics.

$$\textbf{Hausner's Ratio} = \frac{\textbf{Tapped Density}}{\textbf{Tapped Density}}$$

Angle of Repose[16]: The angle of repose was determined using the funnel method to evaluate the flowability of the powder blend. The powder was allowed to flow through a funnel positioned at a fixed height to form a conical heap on a flat surface. The height (h) and radius (r) of the powder cone were measured, and the angle of repose (θ) was calculated using the following equation:

$$\tan \emptyset = \frac{\textbf{Height of pile (h)}}{\textbf{radius of pile (r)}}$$

POST COMPRESSION PARAMETERS

Thickness[17]: The thickness of the tablets were

gauged using Digimatic Vernier calipers. Five tablets were selected at random, and their thickness were measured by positioning them between the two arms of the Vernier calipers.

Hardness[17]: Tablet hardness is characterized as the force needed to fracture a tablet in a diametric compression examination. The crushing strength of tablets was assessed using a Monsanto-type hardness tester.

Weight variation[18]: Twenty tablets were individually weighed using a calibrated analytical balance, and the mean weight was calculated. Since the tablet weight was 350 mg (≥ 250 mg), the permissible deviation limit of ± 5% was applied. Not more than two tablets were allowed to deviate beyond ± 5%, and no tablet exceeded ± 10%. Results were expressed as mean ± SD.

Friability test[18]: The friability of tablets was assessed using a Roche-type friabilator. Initially, twenty tablets were weighed, and subsequently, they were placed in the friabilator, operated at 25 rpm for 4 minutes. Afterward, the tablets were removed and weighed again. The loss in weight should not exceed 1%. The percentage of friability was determined using the following equation.

$$\% \textbf{ Friabiliy} = \frac{\textbf{Initial weight} - \textbf{Final weight}}{\textbf{Initial weight}} \times \mathbf{100}$$

Drug content[19]: 10 tablets were weighed, and their average weight was computed. Subsequently, all 10 tablets were crushed in a mortar. The resulting powder, equivalent to 50 mg of Tegoprazan, was dissolved in a small quantity of acetic acid and then adjusted to 10 ml with 0.1 N HCl. The drug solution was filtered through Whatman filter paper. The sample was examined for drug content using UV Spectrophotometry at 261 nm after appropriate dilutions.

Floating lag time[20]: The randomly selected tablets from each formulation were kept in a 250 ml beaker containing 150 ml simulated gastric fluid, pH 1.2 as per USP. The time taken for the tablet to rise to the surface and float was taken as floating lag time. The time interval between the introduction of the tablet into the dissolution medium and its buoyancy to the top of dissolution medium was taken as floating lag time.

Total floating time[20]: The floating behavior of the formulated floating controlled release tablet of Tegoprazanwas studied. The floating time was determined using a USP XXIV type II (paddle) apparatus at 37 ± 0.5 ^{0}C containing 900 ml of 0.1N HCl and at 50 rpm. The time for which the tablet flo7788on the surface of the medium was measured as total floating time.

***In vitro* drug release**[21]: The release rate of Tegoprazan from floating tablets was determined using USP dissolution testing apparatus II (paddle type). The dissolution test was performed using 900 ml at 37±0.5 ^{0}C at 50 rpm in 0.1 N HCl. Aliquot 10 ml was withdrawn from the dissolution apparatus at the time intervals of 1 to 24 h and the samples were replaced with fresh dissolution medium. After filtration, the amount of drug released was determined from the standard calibration curve of pure drug.

Stability study of optimized batch[22]: In this study, the stability of the optimized batch was assessed under accelerated conditions of 40°C ± 2°C and 75% ± 5% relative humidity (RH) for a duration of one month. The formulation was wrapped in aluminum foil to shield it from light exposure as per ICH guidelines. After the 30-day period, tablets were analyzed for various parameters.

RESULTS AND DISCUSSION

Melting point of Tegoprazan: Melting point determination is one of the popular techniques used to identify drug using melting point apparatus and melting point of Tegoprazan was found in the range of 118 – 122 $^\circ$C. Reported melting point of Tegoprazan is ≈ 120 $^\circ$C and is thus similar to the melting point of Tegoprazan.

Estimation of drug by UV overlay spectra: The UV–visible spectrophotometric analysis of Tegoprazan in 0.1 N HCl showed a clear and well-defined absorption maximum (λ_{max}) at 261 nm, which was selected for further analysis as shown in figure 1. A calibration curve shown in figure 2 was constructed over the concentration range of 10–50 µg/mL, and a strong linear relationship between absorbance and concentration was observed as show in table 2. The regression equation ($y=0.0188x-0.0861$) with a high correlation coefficient ($R^2=0.9991$) confirms excellent linearity of the method within the studied range. The absorbance values at each concentration were consistent, with very low standard deviation, indicating good precision and reproducibility. Overall, the method was found to be simple, reliable, and suitable for the quantitative estimation of Tegoprazan in further studies.

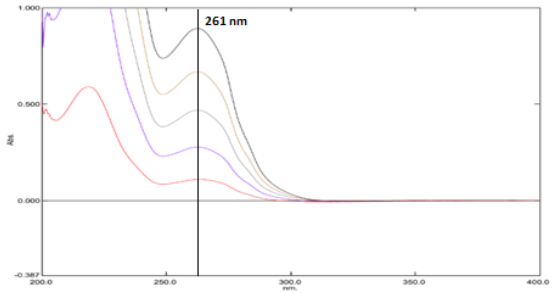

Figure 1: Overlay Spectra of Tegoprazan

Table 2: Absorbance of different concentrations of Tegoprazan in 0.1 N HCl

Sr. No.	Concentration (ppm)	Absorbance			Mean Absorbance ±SD
		I	II	III	
1.	10	0.114	0.114	0.112	0.113±0.001
2.	20	0.280	0.279	0.282	0.280±0.002
3.	30	0.470	0.470	0.471	0.470±0.001
4.	40	0.667	0.667	0.669	0.668±0.001
5.	50	0.860	0.860	0.862	0.861±0.001

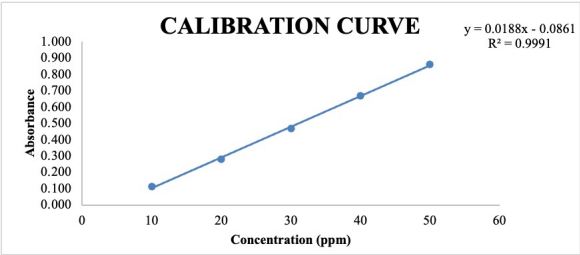

Figure 2: Calibration curve of Tegoprazan in 0.1 N HCl

Identification & Drug Excipients Compatibility Study by FTIR: The FTIR spectrum of Tegoprazan displayed well-defined characteristic absorption bands corresponding to its functional groups, which were consistent with reported reference spectra, thereby confirming the identity and purity of the drug substance. No additional peaks or significant spectral distortions were observed, indicating the absence of detectable impurities or degradation products. Furthermore, the FTIR spectra of Tegoprazan in combination with the selected excipients demonstrated retention of all principal drug-specific peaks without any meaningful shift in wavenumber, loss of intensity, or emergence of new bands. This spectral consistency suggests that no chemical interactions occurred between Tegoprazan and the excipients under the conditions studied. Collectively, these findings confirm the physicochemical compatibility of the drug with the formulation components, supporting its suitability for the development of floating tablet dosage forms.

DISCUSSION OF TRIAL BATCH RESULTS

A series of preliminary trial batches of Tegoprazan floating tablets were formulated using hydrophilic polymers, namely HPMC K4M, HPMC K100M, Carbopol 934P, and sodium alginate, via the wet granulation method. Among the evaluated formulations, those containing Carbopol 934P and sodium alginate exhibited comparatively prolonged drug release, extending up to 14 h, along with superior floating characteristics relative to the other polymeric systems. Based on these observations, it was hypothesized that a combination of these two polymers could further modulate the release profile and potentially achieve extended drug release up to 24 h. Accordingly, Carbopol 934P and sodium alginate were selected as independent formulation variables, and a 3^2 full factorial design was employed to systematically investigate their individual and interactive effects on critical response parameters, including total floating time and percentage cumulative drug release.

RESULTS OF TEGOPRAZAN FLOATING TABLET FORMULATED BY USING 3^2 FACTORIAL DESIGN

PRE-COMPRESSION PARAMETERS: Pre-compression evaluation was carried out for factorial design batches TF1–TF9 to assess their powder flow and packing characteristics, which are critical for achieving uniform die filling and reproducible tablet compression. The parameters evaluated included bulk density, tapped density, Hausner's ratio, Carr's compressibility index, and angle of repose, and the results demonstrated distinct formulation-dependent variations as shown in table 3.

Table 3: Bulk density, Tapped density, Carr's index, Hausner's ratio and Angle of Repose data

Batch	Bulk density (gm/ml) (n=3)	Tapped density (gm/ml) (n=3)	Hausner's ratio (n=3)	Carr's ndex (%) (n=3)	Angle of repose (°θ) (n=3)
TF1	0.50 ± 0.01	0.56 ± 0.00	1.09 ± 0.02	10.59 ± 1.02	27.16 ± 0.60
TF2	0.50 ± 0.00	0.93 ± 0.03	1.11 ± 0.00	10.00 ± 0.00	28.83 ± 0.38

TF3	0.86 ± 0.00	0.94 ± 0.05	1.09 ± 0.06	8.05 ± 5.27	29.05 ± 0.00
TF4	0.89 ± 0.03	1.14 ± 0.05	1.28 ± 0.10	21.28 ± 6.39	31.48 ± 0.45
TF5	0.85 ± 0.02	0.56 ± 0.00	1.09 ± 0.02	7.97 ± 2.06	28.83 ± 0.38
TF6	0.85 ± 0.02	0.93 ± 0.03	1.12 ± 0.01	9.08 ± 1.90	26.95 ± 0.34
TF7	0.50 ± 0.00	0.56 ± 0.00	1.11 ± 0.00	10.00 ± 0.00	27.16 ± 0.60
TF8	0.85 ± 0.02	0.94 ± 0.02	1.10 ± 0.02	7.97 ± 2.06	28.61 ± 0.38
TF9	0.89 ± 0.03	1.15 ± 0.03	1.29 ± 0.08	22.51 ± 4.63	32.02 ± 0.81

The pre-compression evaluation of batches (TF1–TF9) revealed clear differences in powder flow and packing behavior, mainly influenced by formulation composition.

Bulk density ranged from 0.50 to 0.89 g/ml, while **tapped density** varied from 0.56 to 1.15 g/ml. Batches TF1, TF2, and TF7 showed lower density values, indicating loosely packed particles with higher porosity. In contrast, TF4 and TF9 exhibited higher densities, suggesting better particle packing. The low variability across batches reflects good consistency in the blending process.

Hausner's ratio (1.09–1.29) indicated that batches TF3, TF5, TF6, and TF8 had excellent flow properties, while TF1, TF2, and TF7 showed good flow. However, TF4 and TF9 displayed poor flow due to higher cohesiveness.

Carr's index (7.97%–22.51%) supported these findings. TF3, TF5, TF6, and TF8 showed excellent compressibility, whereas TF1, TF2, and TF7 were in the good range. TF4 and TF9 again showed poor compressibility, confirming their inferior flow behaviour.

The **angle of repose** (26.95°–32.02°) further validated these results, with most batches showing good flow (<30°), except TF4 and TF9, which indicated poor flow.

Overall, optimized formulations demonstrated better flow and packing characteristics. Among all batches, TF3 showed the most balanced and desirable properties, making it the best candidate for further compression and evaluation.

POST COMPRESSION PARAMETER: The post-compression evaluation of factorial batches (TF1–TF9) highlighted how formulation variables influenced tablet quality, strength, and floating performance key requirements for gastroretentive systems as shown in table 4 and 5.

Table 4: Weight variation, Thickness, Hardness and Friability (%) Data

Batch	Weight variation (mg) (n=3)	Thickness (mm) (n=3)	Hardness (kg/cm^2) (n=3)	Friability (%)
TF1	350.30 ± 1.45	5.43 ± 0.12	4.00 ± 0.87	0.63
TF2	349.60 ± 1.43	5.43 ± 0.06	4.67 ± 0.29	0.49
TF3	350.35 ± 1.09	5.37 ± 0.12	5.17 ± 0.76	0.38
TF4	349.10 ± 1.25	4.97 ± 0.38	4.17 ± 0.29	0.62
TF5	350.75 ± 1.37	5.53 ± 0.06	4.83 ± 0.29	0.45
TF6	350.15 ± 1.27	5.50 ± 0.00	5.50 ± 0.87	0.32
TF7	349.85 ± 1.39	4.87 ± 0.06	4.33 ± 0.29	0.55
TF8	351.10 ± 1.17	4.90 ± 0.00	5.33 ± 0.76	0.35
TF9	343.95 ± 26.87	5.07 ± 0.15	5.67 ± 0.58	0.29

Table 5: Drug Content, Floating time and Total Floating Time Data

Batch	% Drug Content (n=3)	Floating lag time (sec.) (n=3)	Total Floating time (hrs) (n=3)
TF1	99.04 ± 0.57	39.87 ± 13.65	17.58 ± 0.49
TF2	99.08 ± 0.54	46.58 ± 14.17	20.68 ± 0.18
TF3	99.12 ± 0.52	64.31 ± 00.08	22.85 ± 0.55
TF4	98.83 ± 0.40	43.22 ± 13.91	18.36 ± 0.10
TF5	98.57 ± 0.58	51.68 ± 00.59	21.45 ± 0.16
TF6	98.64 ± 0.58	70.38 ± 00.14	24.15 ± 0.08
TF7	99.37 ± 0.37	45.22 ± 00.13	19.13 ± 0.23

TF8	99.18 ± 0.55	67.03 ± 00.37	23.76 ± 0.09
TF9	99.05 ± 0.53	73.74 ± 00.19	24.54 ± 0.08

All batches showed uniform **tablet weight** (349.10–351.10 mg) within pharmacopoeial limits, indicating consistent die filling and compression. Thickness (4.87–5.53 mm) also remained uniform, reflecting controlled manufacturing conditions and good reproducibility.

Drug content (%) across all batches (98.57–99.37%) was well within acceptable limits, confirming uniform drug distribution and no segregation during processing. This suggests that the selected formulation method and excipients were suitable.

Mechanical strength improved in several batches, with **hardness** ranging from 4.00 to 5.67 kg/cm². Batches TF3, TF6, TF8, and TF9 showed higher hardness, indicating stronger tablet structure. **Friability** values (0.29–0.63%) were well below the limit, with TF9 and TF6 showing the best resistance to breakage, confirming excellent mechanical integrity.

Floating behavior varied among batches. **Floating lag time** ranged from ~40 to 74 seconds, but all tablets achieved buoyancy successfully. **Total floating time** ranged from about 17.5 to 24.5 hours, showing effective gastroretentive performance, especially in optimized formulations.

Overall, formulation composition significantly affected tablet performance. Among all batches, TF9 showed the best overall profile with optimal hardness, lowest friability, consistent drug content, acceptable floating lag time, and the longest floating duration, making it the optimized batch for further studies.

In vitro* cumulative drug release (%) *at* 24 hrs.*: The *in vitro* dissolution study of factorial batches (TF1–TF9) showed a clear, formulation-dependent drug release pattern in simulated gastric conditions (0.1 N HCl). All batches exhibited controlled and time-dependent drug release up to 24 hours, confirming the effectiveness of the polymeric matrix in sustaining drug delivery as shown in table 6 and figure 3.

Table 6: *In vitro* cumulative drug release (%) at 24 hrs.

Time (hrs)	TF1	TF2	TF3	TF4	TF5	TF6	TF7	TF8	TF9
0	0	0	0	0	0	0	0	0	0
1	2.18	5.38	6.44	3.14	6.12	8.36	4.26	7.28	9.42
2	5.22	11.36	13.24	7.14	12.26	15.18	9.28	14.22	16.36
4	12.24	22.18	26.44	16.18	24.38	30.24	20.26	28.26	32.18
6	20.18	34.28	38.14	26.22	36.26	42.22	30.36	40.18	45.36
8	30.26	46.36	50.18	36.18	48.36	55.22	42.24	52.44	58.26
12	44.18	60.24	66.36	50.26	64.22	70.14	56.18	68.36	74.18
16	56.18	76.28	80.14	64.26	78.36	84.26	70.18	82.18	86.24
20	66.26	86.26	90.18	74.18	88.24	92.36	80.32	92.18	94.26
24	84.18	94.36	96.18	88.26	94.44	97.36	92.18	96.28	98.86

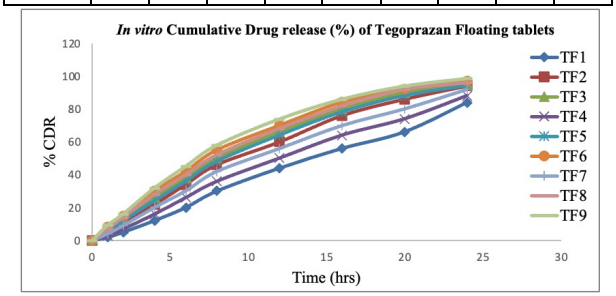

Figure 3: *In vitro* Cumulative Drug release (%) of Batch TF1 to TF9 in 0.1 N HCl

In the initial phase, drug release was slow across all batches, which is desirable to prevent burst release. At 1 hour, release ranged from about 2% (TF1) to 9% (TF9), and increased gradually by 2 hours. Lower release in TF1 and TF4 indicated stronger matrix resistance, while TF6, TF8, and TF9 showed slightly higher release due to better hydration and gel formation. During the mid-phase, a steady and sustained release was observed. By 6–8 hours, TF6, TF8, and TF9 showed higher drug release compared to other batches, suggesting an optimal balance between polymer swelling and diffusion. In contrast, TF1 and TF4 continued to show slower release due to higher diffusion resistance. In the later phase, most batches approached near-complete drug release. By 20 hours, TF6, TF8, and TF9 released over 90% of the drug, while TF1 showed slower

release. At 24 hours, drug release ranged from about 84% (TF1) to nearly 99% (TF9), with TF9 achieving the best sustained release without compromising matrix integrity. Overall, formulation variables significantly influenced drug release. Optimized batches, especially TF9, demonstrated controlled initial release, sustained drug delivery over 24 hours, and maximum drug release. Based on combined evaluation of all parameters, TF9 was identified as the optimized formulation.

Statistical analysis for Floating Lag Time (sec.) (Y_1): The influence of Carbopol 934 P (X_1) and Sodium Alginate (X_2) on floating lag time (Y_1) was investigated using a quadratic polynomial model, and the resulting equation $\mathbf{Y_1 = 54.41 + 13.35X_1 + 5.87X_2 + 1.02X_{12} + 1.03X_1^2 + 1.03X_2^2}$ clearly reflects how each polymer contributes to the response. The positive coefficient of X_1 (13.35) suggests that Carbopol 934 P plays a dominant role in extending the floating lag time, while Sodium Alginate (5.87) also contributes meaningfully, though to a lesser extent. As seen in the contour plot (figure 4a), floating lag time gradually increased from approximately 39.87 sec at lower polymer levels to around 73.74 sec when both concentrations were raised, highlighting a cooperative behavior between the two excipients. The 3D response surface plot (figure 4b) further supports this observation, showing a smoothly rising surface that confirms a steady and uniform increase in floating lag time across the experimental domain, with no unexpected fluctuations a characteristic of a well-behaved quadratic model. Finally, the predicted versus actual plot (figure 4c) brings confidence to these findings, as the experimental values aligned closely with model predictions along the line of identity, demonstrating that the developed model is not only statistically sound but also practically reliable for guiding the optimization of floating lag time in the formulated system.

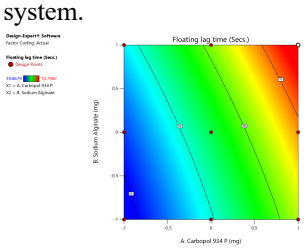

Figure 4a: Contour plot showing the effect Carbopol 934 P (X_1) and Sodium Alginate (X_2) on Floating Lag Time (Y_1)

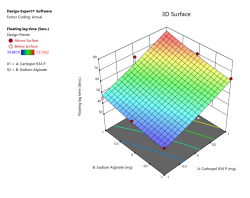

Figure 4b: 3D surface plot showing the effect of Carbopol 934 P (X_1) and Sodium Alginate (X_2) on Floating Lag Time (Y_1)

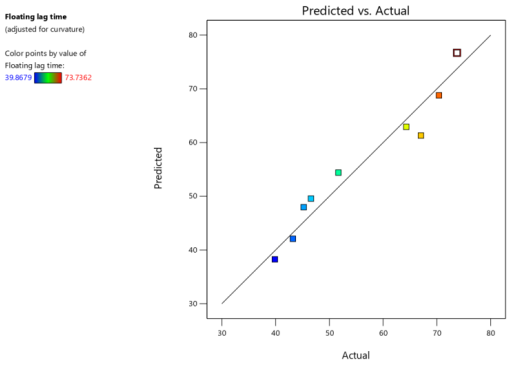

Figure 4c: Actual value vs predicted value of Floating Lag Time (Y_1)

Statistical analysis for Total Floating Time (hrs.) (Y_2): The impact of Carbopol 934 P (X_1) and Sodium Alginate (X_2) on total floating time (Y_2) was explored using a quadratic polynomial model, and the equation $\mathbf{Y_2 = 21.89 + 2.75X_1 + 1.05X_2 + 0.0317X_{12} - 0.8610X_1^2 + 0.1038X_2^2}$ tells an interesting story about how these two polymers work together to keep the tablets buoyant. The positive linear coefficients of X_1 (2.75) and X_2 (1.05) simply mean that adding more of either polymer helps the tablets float longer, which makes intuitive sense Carbopol 934 P, being a strong gel-forming agent, takes the lead in sustaining buoyancy, while Sodium Alginate plays a meaningful supporting role. Interestingly, the negative quadratic term of X_1 (−0.8610) hints that pushing Carbopol 934 P beyond a certain level does not continue to improve floating time proportionally, suggesting there is a sweet spot in its concentration that formulators should aim for. Looking at the contour plot (figure 5a), this behavior becomes visually apparent floating time rises progressively from around 17.58 hrs at lower polymer levels to nearly 24.54 hrs as concentrations increase, with the diagonal isolines reflecting the balanced contribution of both excipients. The 3D response surface plot (figure 5b) adds another layer of clarity, presenting a smoothly curved ascending surface that makes it easy to visualize how thoughtful adjustment of polymer concentrations can fine-tune the floating performance. To round it all off, the predicted versus actual plot (figure 5c) shows that the model predictions and real experimental values sit very close to each other along the line of identity, which is a reassuring sign that the quadratic model genuinely captures the system's behavior and can be trusted for practical optimization of total floating time in this formulation.

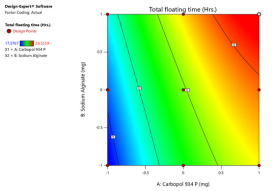

Figure 5a: Contour plot showing the effect Carbopol 934 P (X_1) and Sodium Alginate (X_2) on Total Floating Time (Y_2)

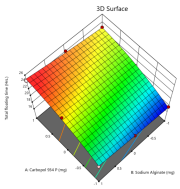

Figure 5b: 3D surface plot showing the effect of Carbopol 934 P (X_1) and Sodium Alginate (X_2) on Total Floating Time (Y_2)

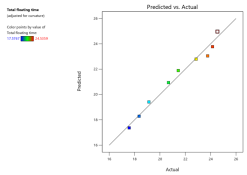

Figure 5c: Actual value vs predicted value of Total Floating Time (Y_2)

Statistical analysis for *In vitro* cumulative drug release (%) at 24 hrs. (Y_3): The relationship between Carbopol 934 P (X_1) and Sodium Alginate (X_2) on cumulative drug release (CDR) in 0.1 N HCl (Y_1) was explored using a quadratic polynomial model, and the equation $\mathbf{Y_1 = 94.81 + 4.63X_1 + 2.10X_2 - 1.33X_{12} - 2.19X_1^2 + 0.3200X_2^2}$ paints a clear picture of how these two polymers collectively govern drug release behavior in the acidic gastric environment. The positive linear coefficients of X_1 (4.63) and X_2 (2.10) indicate that raising the concentration of either polymer tends to enhance drug release, with Carbopol 934 P clearly taking the lead most likely because its swelling nature helps create a hydrated gel network that allows the drug to diffuse out steadily under acidic conditions. What makes this more interesting, however, is the negative quadratic term of X_1 (−2.19), which tells us that too much Carbopol 934 P can actually start working against drug release by building up a thick gel barrier that slows diffusion a timely reminder that more is not always better in formulation science. The contour plot (figure 6a) brings this to life quite well, showing CDR values climbing from around 84.18% at lower polymer concentrations to close to 98.86% as concentrations increase, with the curved isolines clearly reflecting the non-linear nature of the interaction between the two excipients. The 3D response surface plot (figure 6b) adds further depth to this story, presenting a broad, gently rolling surface that rises across the experimental space and makes it intuitive to see how even modest adjustments in polymer levels can meaningfully influence drug release outcomes. Finally, the predicted versus actual plot (figure 6c) wraps things up convincingly, with experimental data points hugging the line of identity closely across the full response range a strong indicator that the quadratic model is not just mathematically sound, but genuinely reliable for steering the optimization of drug release in 0.1 N HCl during formulation development.

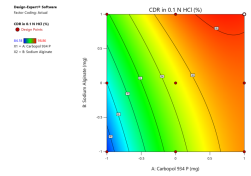

Figure 6a: Contour plot showing the effect Carbopol 934 P (X_1) and Sodium Alginate (X_2) on *In vitro* cumulative drug release (%) at 24 hrs. (Y_3)

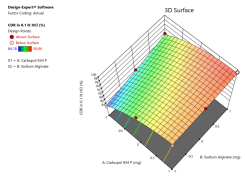

Figure 6b: 3D surface plot showing the effect of Carbopol 934 P (X_1) and Sodium Alginate (X_2) on *In vitro* cumulative drug release (%) at 24 hrs. (Y_3)

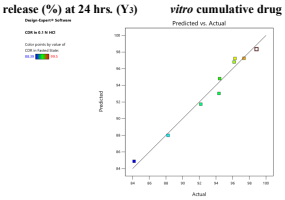

Figure 6c: Actual value vs predicted value of Total Floating Time (Y_3)

STABILITY STUDY: Upon evaluation of all factorial design batches, formulation TF9 was selected as the optimized batch owing to its desirable surface characteristics, sufficient mechanical strength, and uniform drug content. To further establish its stability, a short-term accelerated stability study was performed at 40°± 2 °C and 75 ± 5% RH relative humidity over a period of one month. At the end of the study, the formulation was re-evaluated for key quality attributes, including hardness, thickness, swelling index, drug content, and *in vitro* cumulative drug release (%). The findings, summarized in table 7 and table 8, revealed no appreciable changes in these parameters, indicating that the formulation remained stable under the applied conditions. In addition, a comparison of the *in vitro* drug release profiles before and after storage, as depicted in figure 6, further confirmed the consistency of the drug release behavior of the optimized formulation.

Table 7: Results for Stability study of Optimized batch (TF9)

Parameters	Optimized batch (TF9)	Optimized batch after 1 month
Hardness (kg/cm^2)	5.67 ± 0.58	5.83 ± 0.25
Floating lag time (sec)	73.74 ± 0.19	43.94 ± 0.67
Total Floating time (hrs)	24.64 ± 0.21	24.33 ± 0.45
Drug Content (%)	99.05 ± 0.54	99.19 ± 0.20

Table 8: Comparison of % CDR of batchTF9 Initially and after 1 month in 0.1 N HCl

Time (hrs)	% CDR of Optimized Batch TF9 Initially	% CDR of Optimized Batch TF9 After 1 Month

0	0	0
1	9.42	9.18
2	16.36	15.85
4	32.18	31.76
6	45.36	43.18
8	58.26	56.48
12	74.18	72.93
16	86.24	85.19
20	94.26	92.75
24	98.86	96.18

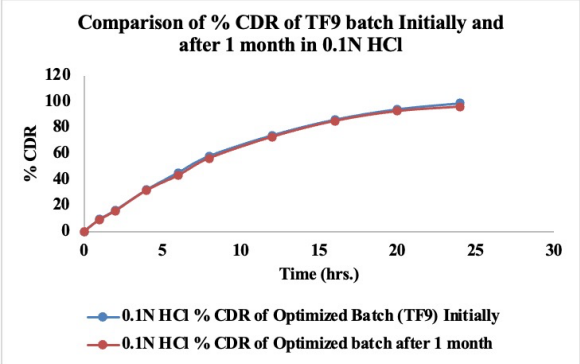

Figure 6: Comparison of % CDR of Optimized batch TF9 initially and after 1 month in 0.1 N HCl

CONCLUSION

The study focused on developing gastro-retentive floating tablets of Tegoprazan to improve its therapeutic effectiveness and reduce frequent dosing. The formulation used polymers like Carbopol 934P and Sodium Alginate to achieve sustained drug release and prolonged gastric retention. Pre-compression studies confirmed good flow properties for most batches, while post-compression results showed uniformity in weight, thickness, and drug content with adequate mechanical strength. Floating studies demonstrated successful buoyancy with extended floating time. *In vitro* dissolution studies revealed that optimized formulations provided controlled and sustained drug release up to 24 hours. The factorial design approach helped in understanding the effect of formulation variables, showing that polymer concentration significantly influenced floating behaviour and drug release. Among all batches, TF9 exhibited the best overall performance with prolonged floating, high drug release (~98%), and stable behaviour. The study successfully developed a stable and effective gastro-retentive floating tablet of Tegoprazan. The optimized formulation (TF9) demonstrated an ideal balance of mechanical strength, floating capability, and sustained drug release over 24 hours. The use of Response Surface Methodology enabled efficient optimization of polymer concentrations, ensuring controlled drug delivery. Overall, this formulation approach offers a promising strategy for improving the therapeutic efficacy, gastric retention, and patient compliance of Tegoprazan in the management of GERD.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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