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## Formulation, Optimization, and Characterization of Gastroretentive Floating Matrix Tablets of Vonoprazan Using Natural and Synthetic Polymers

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*Vonoprazan; Gastroretentive drug delivery system; Floating matrix tablets; Box–Behnken Design; Sustained release; HPMC K15M; Buoyancy performance.*

## ABSTRACT

**Background:** Vonoprazan, a potent potassium-competitive acid blocker, requires localized gastric delivery due to its narrow absorption window and short elimination half-life. Gastroretentive drug delivery systems (GRDDS) present an effective approach to enhance gastric residence time and sustain drug release, improving therapeutic outcomes in acid-related disorders. **Objective:** This study aimed to formulate, optimize, and characterize gastroretentive floating matrix tablets of Vonoprazan utilizing natural and synthetic hydrophilic polymers. **Methods:** A Box–Behnken Design (BBD) was employed to evaluate the influence of HPMC K15M (A), Xanthan gum (B), and sodium bicarbonate (C) on floating behaviour and drug release. Seventeen experimental formulations were prepared by direct compression. Floating lag time (FLT), total floating duration (TFD), and cumulative drug release at 12 h were recorded as response variables. Optimization was performed using a desirability-based statistical model, followed by comprehensive physicochemical and in-vitro performance evaluation of the optimized batch. **Results:** All formulations showed acceptable buoyancy and sustained release patterns. The optimized formulation demonstrated rapid floatation ( $94.1 \pm 1.5$  sec), prolonged gastric retention ( $>13$  h), excellent matrix integrity, and controlled drug release ( $87.21 \pm 0.6\%$  over 12 h). ANOVA confirmed significant effects of all formulation factors ( $p < 0.0001$ ) with non-significant lack-of-fit, validating the predictive model reliability. **Conclusion:** The developed gastroretentive floating tablets of Vonoprazan provide a robust and controlled delivery platform capable of enhancing gastric residence and improving therapeutic efficacy. The formulation strategy offers strong potential for clinical translation following further in vivo and stability investigations.

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## 1. INTRODUCTION:

Oral drug delivery remains the most preferred route of administration due to its convenience, patient compliance, and cost-effectiveness<sup>1</sup>. However, drugs with narrow absorption windows, instability in intestinal pH, or a requirement for localized gastric action exhibit reduced bioavailability when delivered through conventional dosage forms<sup>2</sup>. Gastroretentive Drug Delivery Systems (GRDDS) offer a promising approach to overcome these limitations by prolonging gastric residence time, enhancing absorption, and improving therapeutic efficacy<sup>3</sup>. Floating drug delivery systems, based on

buoyancy over gastric fluids, sustain drug release while maintaining dosage form integrity in the stomach for an extended duration. Vonoprazan, a novel potassium-competitive acid blocker (P-CAB), exhibits potent and rapid acid suppression but has a relatively short elimination half-life and absorption predominantly in the upper gastrointestinal tract<sup>4</sup>. Therefore, a gastroretentive formulation of Vonoprazan is advantageous to improve drug retention at the site of absorption, extend therapeutic action, reduce dosing frequency, and enhance patient convenience<sup>5</sup>. Hydrophilic polymers such as Hydroxypropyl Methylcellulose (HPMC K15M) and natural gums like Xanthan gum contribute to swelling and gel-matrix formation, whereas sodium bicarbonate promotes buoyancy by generating carbon dioxide in acidic medium<sup>6</sup>. In the present study, gastroretentive floating matrix tablets of Vonoprazan were developed and optimized using a Box–Behnken experimental design to achieve rapid buoyancy, prolonged gastric retention, and sustained drug release. The optimized formulation was evaluated for physicochemical characteristics, floating performance, swelling behaviour, and drug release kinetics to ensure effective therapeutic delivery in gastric environments.

## MATERIALS AND METHODS:

### Materials:

Vonoprazan fumarate was obtained as a gift sample from a reputed pharmaceutical manufacturer. Hydroxypropyl Methylcellulose (HPMC K15M), Xanthan gum, and Sodium bicarbonate were procured from authorized suppliers. Microcrystalline cellulose (MCC), magnesium stearate, talc, and all other excipients and solvents used were of analytical grade and utilized without further purification.

### Experimental Design and Optimization:

A Box–Behnken Design (BBD) was utilized to investigate the effect of formulation variables on floating behaviour and drug release using Design-

Expert® software. Three formulation factors HPMC K15M (A), Xanthan gum (B), and Sodium bicarbonate (C) were evaluated at three levels each, as shown in Table 1A. A total of 17 experimental runs, including center points to estimate experimental error, were generated. Floating Lag Time (R1) was minimized, Total Floating Time (R2) was maximized, and Cumulative Drug Release at 12 hours (R3) was targeted in the range of 90–95%<sup>7-9</sup>. The coded and actual levels of the independent variables are provided in Table 1A, while the formulation composition and measured responses are presented in Table 1B.

### Preparation of Gastroretentive Floating Tablets of Vonoprazan:

Floating matrix tablets were prepared by direct compression. Accurately weighed quantities of drug, polymers, and sodium bicarbonate (as per Table 1B) were sifted through #40 mesh and blended uniformly using geometric dilution. Lubricants (talc and magnesium stearate) were added in the final stage and gently mixed. The blend was compressed using an 8 mm flat-faced punch on a rotary tablet compression machine. Tablets were stored in airtight containers for further evaluation<sup>10</sup>.

**Table 1A. Independent variables and their experimental levels in Box–Behnken Design**

Run	A (% w/w)	B (% w/w)	C (% w/w)
1	5	1.5	3
2	8	1.5	1
3	2	2.5	3
4	5	1.5	3
5	8	1.5	5
6	5	2.5	1
7	2	1.5	1
8	2	1.5	5
9	5	2.5	5
10	5	0.5	1
11	2	0.5	3
12	5	1.5	3
13	5	1.5	3
14	5	0.5	5
15	8	2.5	3
16	5	1.5	3
17	8	0.5	3

**Table 1B. Formulation composition for all Batches (mg/tablet)**

Run	Vonoprazan (mg)	HPMC K15M (mg)	Xanthan gum (mg)	Sodium bicarbonate (mg)	MCC (mg)	Talc (mg)	Magnesium stearate (mg)	Total weight (mg)
1	20	10	3	6	157	2	2	200
2	20	16	3	2	155	2	2	200
3	20	4	5	6	161	2	2	200
4	20	10	3	6	157	2	2	200
5	20	16	3	10	147	2	2	200
6	20	10	5	2	159	2	2	200
7	20	4	3	2	167	2	2	200
8	20	4	3	10	159	2	2	200
9	20	10	5	10	151	2	2	200
10	20	10	1	2	163	2	2	200
11	20	4	1	6	165	2	2	200
12	20	10	3	6	157	2	2	200
13	20	10	3	6	157	2	2	200

14	20	10	1	10	155	2	2	200
15	20	16	5	6	149	2	2	200
16	20	10	3	6	157	2	2	200
17	20	16	1	6	153	2	2	200

### Characterization of Gastroretentive Floating Tablets

#### Floating Lag Time (FLT):

Floating lag time was measured by placing each tablet in 500 mL of 0.1 N HCl (pH 1.2) maintained at  $37 \pm 0.5^\circ\text{C}$  using USP Dissolution Apparatus II (paddle method). The time taken for the tablet to rise to the surface and remain afloat was recorded in seconds as FLT. The test was performed in triplicate and mean values were reported<sup>11-13</sup>.

#### Total Floating Duration (TFD):

To evaluate TFD, the tablets used in the FLT test were continuously monitored in the same medium (0.1 N HCl at  $37 \pm 0.5^\circ\text{C}$ ). The time for which the tablet remained buoyant without sinking or disintegrating was recorded as total floating time in hours. Observations were made up to 12–14 hours depending on the tablet integrity<sup>14,15</sup>.

#### In-Vitro Drug Release Study:

In-vitro drug release of Vonoprazan from floating tablets was evaluated using USP Type II Paddle Apparatus operated at 50 rpm in 900 mL of 0.1 N HCl (pH 1.2) at  $37 \pm 0.5^\circ\text{C}$ . Samples (5 mL) were withdrawn at predetermined time intervals up to 12 hours and immediately replaced with fresh medium to maintain sink conditions. Samples were filtered and analyzed UV-spectrophotometrically at 286 nm to determine the cumulative percentage drug release<sup>16</sup>.

#### Statistical Analysis:

All evaluations were performed in triplicate (mean  $\pm$  SD). Data were analyzed using Design-Expert® software through regression analysis, ANOVA, response surface plots, and desirability function optimization. A **p-value** < 0.05 was considered statistically significant.

### Evaluation of Optimized Vonoprazan Gastroretentive Floating Tablets:

Evaluation of the optimized batch included weight variation test (20 tablets), hardness (six tablets) using a Monsanto hardness tester, and thickness/diameter determined using a digital Vernier calliper. Friability testing was performed in a Roche friabilator at 25 rpm for 4 minutes. Drug content was determined by spectrophotometric analysis after dissolving powder equivalent to 20 mg of drug in 0.1 N HCl. Floating behaviour was assessed in 0.1 N HCl ( $37 \pm 0.5^\circ\text{C}$ ), recording FLT as the time to onset of buoyancy and TFD as the duration of floatation. Swelling index was determined after 6 hours in acidic medium. In vitro

drug release was measured for 12 hours using USP Type II apparatus, and cumulative release was calculated based on absorbance values at 286 nm<sup>17-19</sup>.

## RESULTS AND DISCUSSION:

### Evaluation of Vonoprazan Gastroretentive Floating Matrix Tablets:

Vonoprazan floating matrix tablets were successfully formulated using hydrophilic polymers (HPMC K15M and Xanthan gum) and a gas-generating agent (sodium bicarbonate). The influence of formulation factors on floating behaviour and drug release was investigated using Box–Behnken Design. The coded factor levels and measured responses for the 17 experimental batches are presented in **Table 2**.

**Table 2: Observed Responses for Gastroretentive Floating Matrix Tablets**

Run	Floating Lag Time (sec)	Total Floating Time (h)	Cumulative Drug Release at 12 h (%)
1	116.8	10.91	90.04
2	113.1	11.31	85.42
3	121.3	10.54	91.62
4	114.7	11.03	90.16
5	93.3	12.70	88.92
6	118.0	11.63	87.73
7	135.5	9.22	91.28
8	114.8	10.42	95.01
9	99.8	12.18	90.16
10	128.9	9.23	90.70
11	126.8	8.59	94.31
12	116.4	10.74	89.47
13	115.8	10.62	90.60
14	109.3	9.70	93.24
15	103.9	12.90	85.41
16	117.0	10.45	90.24
17	106.9	11.07	89.07

#### Floating Behavior:

The floating lag time (FLT) of the formulations ranged from **93.3 to 135.5 seconds**, confirming rapid buoyancy initiation (Table 2). An increase in **sodium bicarbonate (Factor C)** significantly reduced FLT due to rapid CO<sub>2</sub> evolution and entrapment within the matrix. Higher **HPMC K15M (Factor A)** concentration also contributed to faster floatation by forming a cohesive gel structure. Xanthan gum (Factor B) slightly increased FLT as its viscous gel delayed CO<sub>2</sub> escape.

#### Total Floating Duration (TFD):

The total floating duration (TFD) varied between **8.59 and 12.90 hours**. Formulations with higher polymer concentrations (A and B) demonstrated

longer gastric retention due to enhanced swelling and stable gel barrier formation. Maximum buoyancy duration was observed in **Run 15 (12.90 h)** with high HPMC and Xanthan gum content, indicating strong matrix integrity necessary for gastroretentive action.

#### In Vitro Drug Release:

Cumulative drug release at 12 hours ranged 85.41–95.01%. Drug release decreased with increasing polymer levels due to restricted fluid penetration and diffusion pathways. Conversely, increasing sodium bicarbonate increased porosity and facilitated drug dissolution and diffusion. The highest release was observed in Run 8 (95.01%), while Run 15 (85.41%) exhibited slow diffusion-controlled release due to dense gel matrix formation.

#### Effect of Formulation Variables and ANOVA Analysis:

The influence of formulation components HPMC K15M (A), Xanthan gum (B), and Sodium

bicarbonate (C) on the floating performance and drug release behaviour of Vonoprazan gastroretentive tablets was systematically evaluated using Design-Expert® software. ANOVA results confirmed that all three formulation variables significantly affected Floating Lag Time (R1), Total Floating Time (R2), and % Cumulative Drug Release at 12 h (R3), with each model showing high F-values and  $p < 0.0001$ , indicating strong statistical significance (Table 3). To further visualize the interactions and optimize formulation attributes, contour plots were generated for all three responses. The influence trends and optimal regions for minimizing floating lag time, maximizing buoyancy duration, and achieving a targeted drug release profile are depicted in Figure 1 (R1 contour plot), Figure 2 (R2 contour plot), and Figure 3 (R3 contour plot). These graphical illustrations support the ANOVA findings by demonstrating clear interaction between polymers and effervescent level, confirming the robustness and suitability of the developed formulation design.

Table 3. ANOVA for responses

Source	Floating Lag Time (R1)	p-value	Total Floating Time (R2)	p-value	Cumulative Drug Release (R3)	p-value
Model	171.45	<0.0001	113.75	<0.0001	234.40	<0.0001
A – HPMC K15M	250.11	<0.0001	167.46	<0.0001	452.91	<0.0001
B – Xanthan gum	31.68	0.0001	148.06	<0.0001	127.18	<0.0001
C – Sodium bicarbonate	232.56	<0.0001	25.73	0.0002	123.11	<0.0001
Lack of Fit	5.10	0.066 (NS)	1.29	0.432 (NS)	0.85	0.616 (NS)
Significance	Significant	—	Significant	—	Significant	—

\*Significant at  $p < 0.05$  (NS: Not Significant)

#### Optimized Formulation Batch (DoE Prediction)

The desirability function approach of Box–Behnken Design was applied to obtain the optimal formulation of Vonoprazan gastroretentive floating matrix tablets. Based on the criteria of minimizing floating lag time, maximizing total floating duration, and achieving sustained drug release, Solution No. 1 with the highest desirability of 0.944 was selected as the optimized batch. The optimized formulation composition exhibited excellent gastroretentive behaviour with rapid buoyancy (93.30 sec), prolonged floating duration (>13 hours), and controlled drug release (86.94%) within the targeted therapeutic window. The close agreement between predicted and observed responses confirmed the reliability and accuracy of the developed statistical model. Details are summarized in Table 4 A and Table 4 B.

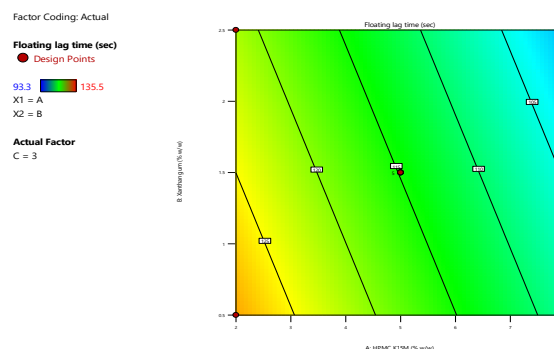


Figure 1. Contour plot illustrating the effect of HPMC K15M (A) and Xanthan Gum (B) on Floating Lag Time (R1)



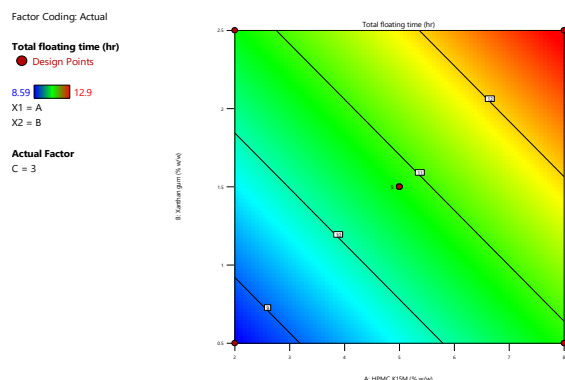


Figure 2. Contour plot showing the influence of HPMC K15M (A) and Xanthan Gum (B) on Total Floating Time (R2)

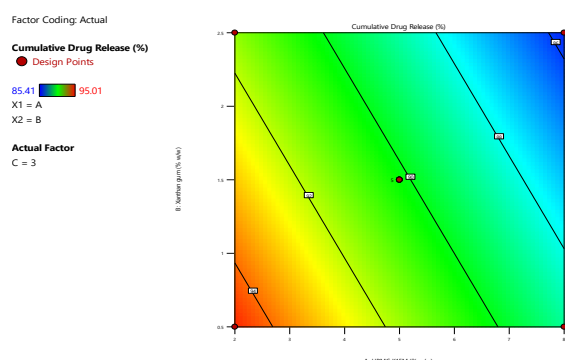


Figure 3. Contour plot representing the interaction between HPMC K15M (A) and Xanthan Gum (B) on % Cumulative Drug Release at 12 hours (R3).

Table 4. Experimental Results of the optimized batch F-18

Component	Quantity (mg/tablet)
HPMC K15M (Factor A)	16 mg
Xanthan gum (Factor B)	5 mg
Sodium bicarbonate (Factor C)	9.18 mg
Vonoprazan	20 mg
MCC (Diluent, q.s.)	147.82 mg
Talc	1 mg
Magnesium stearate	1 mg
Total tablet weight	200 mg

Table 4 B. Experimental vs. Predicted Response Values

Response Parameter	Predicted Value	Experimental Value*
Floating Lag Time (sec)	93.30	94.1 ± 1.5
Total Floating Time (hr)	13.37	13.40 ± 0.3
Cumulative Drug Release (12h, %)	86.94	87.21 ± 0.6

### Evaluation Results of Optimized Batch:

The optimized formulation F-18 (HPMC K15M 8% w/w, Xanthan gum 2.5% w/w, Sodium bicarbonate 4.59% w/w) was subjected to comprehensive physicochemical, mechanical, buoyancy, and in vitro release evaluations. Results confirmed excellent floating performance, controlled release profile, and quality compliance as per Pharmacopeial specifications. Findings are summarized in Table 5.

Table 5. Evaluation parameters of the optimized

formulation

Parameter	Result
Weight variation (mg)	198.6 ± 1.8
Hardness (kg/cm <sup>2</sup> )	5.3 ± 0.4
Thickness (mm)	4.21 ± 0.06
Diameter (mm)	8.02 ± 0.04
Friability (%)	0.38%
Drug Content (%)	99.12 ± 0.5
Floating Lag Time (sec)	94.1 ± 1.5
Total Floating Time (hr)	13.40 ± 0.3
Swelling Index (%) (after 6h)	216.82 ± 2.2
Cumulative Drug Release (12 hr)	87.21 ± 0.6

### CONCLUSION:

A gastroretentive floating matrix tablet of Vonoprazan was successfully designed and optimized using a Box–Behnken statistical approach to achieve enhanced gastric residence and controlled drug release. The systematic DoE-based investigation revealed that hydrophilic polymer concentrations (HPMC K15M and Xanthan gum) and the effervescent agent (sodium bicarbonate) exerted significant and interactive effects on buoyancy and drug dissolution behaviour. The optimized formulation exhibited rapid floatation (94.1 ± 1.5 sec), extended buoyancy (>13 h), excellent matrix stability in acidic medium, and sustained release up to 12 hours, while meeting all Pharmacopeial quality benchmarks. The synergistic interplay between gel-forming polymers and in situ carbon dioxide generation facilitated prolonged gastric retention with predictable diffusion-controlled release. The high statistical desirability score, coupled with close agreement between predicted and experimental results, confirms robustness and industrial scalability of the developed formulation. Given Vonoprazan absorption window in the upper gastrointestinal tract and short elimination half-life, this gastroretentive platform offers a rational strategy to improve local therapeutic exposure, reduce dosing frequency, and potentially enhance clinical outcomes in acid-related disorders, this work establishes a promising and economically viable gastroretentive delivery system for Vonoprazan using a combination of natural and synthetic polymers. Future studies involving in vivo radiographic confirmation, comparative pharmacokinetic assessments, and long-term stability evaluation are warranted to further substantiate its translational suitability for clinical development and regulatory approval.

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