Formulation and Evaluation of a Gastroretentive Floating In Situ Gel of Vonoprazan Fumarate

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Abstract

The present study aimed to formulate and evaluate a gastroretentive floating in situ gel system of Vonoprazan fumarate for prolonged gastric retention and sustained drug release. Vonoprazan fumarate, a new potassium-competitive acid blocker, exhibits powerful acid inhibition but may have a short gastric residence time in conventional dosage forms. To address this limitation, ion sensitive floating in situ gel was developed using sodium alginate as the main gelling polymer, guar gum and HPMC as release retarding agents, calcium carbonate as gas generating and cross linking agent and sodium citrate as calcium ion complexing agent.

Nine formulations (F1-F9) were prepared and evaluated for physicochemical characteristics like pH, density, drug content, floating lag time and in vitro drug release. The pH of the formulations ranged from 7.53 to 8.50, which is suitable for oral administration. Density values were in the range 0.81–0.97 g/cm³ confirming good floating characteristics. The content of drug was found to be varying from 88.74% to 95.30% indicating uniform distribution of drug. Floating lag time was between 20 and 95 sec showing rapid buoyancy. Results: Formulation F5 showed optimum performance in vitro drug release studies showed sustained drug release over a long period. The drug release kinetics studies revealed the release pattern to follow Korsmeyer-Peppas and zero-order models. Stability studies confirmed the stability of the formulation during storage.

The prepared gastroretentive floating in situ gel of Vonoprazan fumarate was achieved to improve gastric retention and sustained drug release and can be regarded as an effective delivery system for the management of acid related gastrointestinal disorders.

Keywords:

Vonoprazan fumarate, Gastroretentive drug delivery system, Floating in situ gel, Sodium alginate, Sustained release, Gastric retention

1.Introduction :-

Gastroretentive drug delivery systems have emerged as an advanced approach for improving the oral bioavailability and therapeutic efficacy of drugs with a narrow absorption window in the upper gastrointestinal tract, poor stability at intestinal pH, or short gastric residence time (Tripathi et al., 2019; Vrettos et al., 2021). These novel systems are specifically designed to prolong gastric residence time, thereby enhancing drug absorption, reducing dosing frequency, and improving patient compliance (C, 2025; Kasani et al., 2025; Kashyap et al., 2024; Vrettos et al., 2021). Conventional oral dosage forms often pass rapidly through the stomach, resulting in incomplete drug absorption and reduced therapeutic effectiveness; thus, the development of sophisticated delivery platforms remains a priority in pharmaceutical research (C, 2025; Kashyap et al., 2024).

Among various GRDDS approaches, floating in situ gelling systems have attracted considerable attention due to their ease of administration, enhanced gastric retention, and sustained drug release characteristics (Jagtap, 2024; K.1, 2026; Dutta et al., 2026; Warang et ai., n.d.). In situ gels are liquid formulations that undergo a "sol-to-gel" transition upon exposure to physiological conditions such as pH changes, temperature fluctuations, or ionic interactions (Dhanya et al., 2022; K.1, 2026; Makwana et al., 2015; Vigani et al., 2020). Floating in situ gel systems combine the advantages of floating drug delivery and controlled release systems (Shah et al., 2012; Mokashi et al., 2024). Upon contact with gastric fluid, the formulation forms a buoyant gel that remains floating over the gastric contents for a prolonged period, thereby increasing gastric retention and maintaining drug release at the desired site (Bachhar et al., 2026; Jagtap, 2024).

Ion-sensitive in situ gel systems are widely investigated because of their simplicity and excellent gelling properties (Ahmed et al., 2025; Dhanya et al., 2022). Sodium alginate is a preferred ion-sensitive polymer due to its biocompatibility, biodegradability, non-toxicity, and ability to form a gel in the presence of divalent cations such as calcium ions (Lynch et al., 2020; Makwana et al., 2015; Sahu, 2023). In the acidic gastric medium, calcium carbonate reacts with hydrochloric acid to release calcium ions and carbon dioxide (K.1, 2026; Makwana et al., 2015). Released calcium ions induce the gelation of sodium alginate, while carbon dioxide remains entrapped within the gel matrix to provide buoyancy (K.1, 2026). Additional polymers, such as guar gum and HPMC K4M, are incorporated to enhance viscosity, strengthen the gel structure, and sustain drug release (Lynch et al., 2020; Xianxi, 2008; Xin, 2011).

Vonoprazan fumarate is a novel potassium-competitive acid blocker utilized for the treatment of acid-related gastrointestinal disorders, including gastroesophageal reflux disease, gastric ulcers, peptic ulcers, and *Helicobacter pylori* infection (Savarino et al., 2016). Unlike conventional proton pump inhibitors, Vonoprazan produces rapid, potent, and prolonged inhibition of gastric acid secretion by competitively blocking the H+/K+-ATPase enzyme in gastric parietal cells without requiring pre-activation (E. Savarino et al., 2016; V. Savarino et al., 2023). It exhibits a faster onset of action and superior acid stability compared to traditional agents; however, conventional dosage forms may exhibit limited gastric residence time, leading to reduced site-specific availability (Savarino et al., 2016). To overcome these limitations, the present study aimed to develop and evaluate a gastroretentive floating in situ gel of Vonoprazan fumarate for sustained gastric retention and controlled drug delivery.

2. Materials and methods:-

Dhamtec Pharma and Consultant, Taloja , Navi Mumbai , India provided Vonoprazan fumarate as a sample . Sodium alginate (New Neeta Chemicals, PCMC) , Guar gum (New Neeta Chemicals, PCMC), HPMC (New Neeta Chemicals, PCMC), Calcium carbonate (New Neeta Chemicals, PCMC), Sodium citrate (New Neeta Chemicals, PCMC) , Methyl paraben (New Neeta Chemicals, PCMC) . All the other chemical , reagents and solvents were of analytical grade.

2.1 Pre-formulation Studies:

The purpose of the preformulation study was to ensure the accuracy of the drug sample and to determine various parameters for the formulation of In-situ gel.

2.1.1Organoleptic properties:

Vonoprazan fumarate's physical appearance was evaluated based on a number of organoleptic characteristics, including colour, state, odour, and taste.

2.1.2 Determination of melting point:

The capillary fusion method was used to estimate the melting point of the vonoprazan fumarate. A little amount of medication was placed inside a capillary that was sealed at one end, and the capillary was then positioned with the sealed end facing down into the melting point device.

2.1.3 Cllibration curve of Vonoprazan Fumarate:

100 mg of crude drug (Vonoprazan fumarate) were weighed and dissolved in 100 ml of 0.1N HC1 and concentration of the stock solution was found to be 1mg/ml i.e 1000 µg/ml from the stock solution 10 ml is taken and diluted 100 ml with 0.1N HCI and the concentration of second stock solution was found to be 100 µg/ml. 2ml,4ml,6ml,8ml&10ml are taken from the second stock solution and diluted to 10ml with 0.1N HCI respectively and concentration of the solution was found to be 20,40,60,80,100 respectively and the standard graph was plotted by taking concentration on X-axis and absorbance on Y-axis at 272nm.

2.1.4 Fourier Transform Infrared Spectral Analysis:

The material was analyzed by FTIR for qualitative compound identification using IR spectra. The infrared spectrum of Vonoprazan Fumarate was obtained on Fourier Transform Infra-red Spectrophotometer by scanning between 4000 and 400cm-1.

2.1.5 Drug Polymer Interaction Study :-

During the in-situ gel system development, it was key to check that the drug and polymers were compatible. So, we recorded the infrared absorption spectra of the drug, Sodium Alginate, and HPMC K100M, and their mixture, in the range of 4000 to 400 cm^{-1}. Then we looked at the spectra to see if there were any interactions between the drug and the polymers in the formulation.

2.2 Formulation:

The in situ gel was prepared by dissolving sodium alginate in deionized water with thorough stirring at an elevated temperature (Shendge et al., 2020).Upon cooling, xanthan gum (pre-hydrated) and HPMC K100M were incorporated. The drug was dissolved in water and added to the polymeric mixture. An ion-control solution was prepared by combining sodium citrate and calcium carbonate with water. Methylparaben was dissolved in warm water and added as a preservative (Chang et al., 2015). The ion-control solution was added gradually to the main polymeric solution under continuous stirring, ensuring the temperature remained below 40 °C. The use of triggerable and tough hydrogel components ensures the formation of a robust gastric resident dosage form capable of withstanding physiological pressures (G. W. Liu et al., 2024; J. Liu et al., 2017).

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Vonoprazan Fumarate	20mg	20mg	20mg	20mg	20mg	20mg	20mg	20mg	20mg
Sodium alginate	50mg	50mg	50mg	100mg	100mg	100mg	150mg	150mg	150mg
Guar gum	50mg	100mg	150mg	50mg	100mg	150mg	50mg	100mg	150mg
HPMC	50mg	50mg	50mg	50mg	50mg	50mg	50mg	50mg	50mg
Calcium carbonate	200mg	200mg	200mg	200mg	200mg	200mg	200mg	200mg	200mg
Sodium citrate	10mg	10mg	10mg	10mg	10mg	10mg	10mg	10mg	10mg
Methyl paraben	18mg	18mg	18mg	18mg	18mg	18mg	18mg	18mg	18mg
Distilled Water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

Table No.1: Composition of Vonoprazam Fumarate Insitu Gel

2.3 Characterization of Insitu Gel:

2.3.1 Determination of pH of insitu gel:-

The pH of the in situ gel formulations was measured with a calibrated digital pH meter. Prior to the analysis, the pH meter was calibrated with standard buffer solutions of pH 4.0 and pH 7.0. About 10 mL of each formulation batch (F1–F9) was placed in a clean beaker, and the electrode was immersed in the sample. The pH was noted once the reading stabilized. Measurements were taken at room temperature, and the averages were reported. (Nasra et al., 2017)

2.3.2 Determination of Density:

The density of the in situ gel formulation was determined using a clean and dry density bottle. The empty density bottle was weighed accurately and recorded as W_1. The bottle was then filled completely with the in situ gel formulation (sol state) without entrapping air bubbles. After wiping off excess liquid from the outer surface, the filled bottle was weighed and recorded as W_2. The volume (V) of the density bottle was noted (10 mL). The density of the formulation was calculated using the following equation: (Shabaraya et al., 2023)

Density:-W2-W1/V

2.3.3 Determination of Drug Content:

In a volumetric flask with 0.1 N HCl, a specific amount of the gastroretentive in situ gel formulation was added. To make sure all the drug was extracted, we mixed it well and sonicated it for about 15-20 minutes. We then topped off the volume with more solvent and filtered it through Whatman filter paper. After preparing the right dilution, we used spectrophotometry to analyze it at 272 nm. The drug content was figured out using this formula:

Drug Content (%) = (Practical Drug Content / Theoretical Drug Content) × 100.

2.3.4 In Vitro Drug Release Study:

For the in vitro drug release study of the gastroretentive in situ gel formulation, researchers used a USP dissolution apparatus. They placed the formulation in a medium of 900 mL of 0.1 N HCl (pH 1.2), kept at 37 ± 0.5°C and stirred at 50 rpm. After introducing the formulation, it was left to gel. At set intervals, samples were collected and substituted with fresh medium to keep sink conditions. Next, the gathered samples got filtered through Whatman filter paper, appropriately diluted, and analyzed with a UV-visible spectrophotometer at 272 nm. Finally, they figured out the cumulative percentage of drug released. (Talaviya et al., 2026)

2.3.5 Floating lag Time:-

Take 100 mL of 0.1N HCl (with a pH of 1.2) and pour it into a beaker. Make sure to keep the temp at 37±0.5°C. Slowly add 1 mL of the in-situ gel formulation using a syringe or pipette and start the stopwatch right after adding it. Watch closely for when the gel forms and floats to the surface, noting how long it takes to get there. (Nasra et al., 2017)

2.3.6 Stability Studies:-

Formulation code F5 was stored in an amber colored bottle at room temperature. The in-situ gel was then tested for dissolution profile after 30 and 60 days, respectively.

3.RESULTS

3.1 Pre-formulation Studies

3.1.1 Determination of physicochemical properties:

The physicochemical properties of vonoprazan fumarate were found to be –

Sr.No	Physical Parameter	Interpretation
1	Colour	White
2	Odour	Odourless
3	Taste	Bitter
4	State	Crystalline Powder

Table 2: Interpretation of physicochemical properties of Vonoprazan fumarate.

3.1.2 Determination of Melting point:

The melting point of a substance is the temperature at which it changes from the solid to the liquid phase under a pressure of one atmosphere. Determination of the melting point is indicative of the purity of the drug. The melting point of Vonoprazan fumarate was determined by capillary fusion method and found to be very close to the reported melting point given in table no.3.

Method Empolyed	Literuture Value	Experimental Value
Capillary Fusion method	203°c to 205°c	205°c to 207°c

Table 3: Melting Point Of Vonoprazan Fumarate.

3.1.3 Calibration Curve of Vonoprazan Fumarate:

The yield characteristics curve of vonoprazan fumarate in a previously prepared diluent is observed when scanned in the UV spectrum from 200 to 400 nm. Vonoprazan fumarate has a lamda max of 272 nm. The absorbance of Vonoprazan fumarate at different concentrations ranging from 20 to 100 µg/ml was measured using spectrophotometry.

The calibration curve of the drug follows Beer's Lambert law.

The calibration curve was shown in fig.No. 1

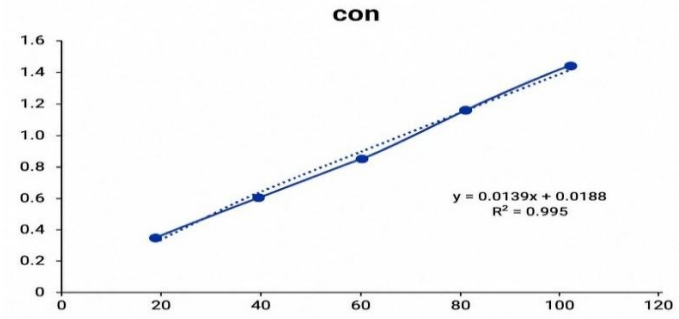

Fig No.1 Callibration Curve of Vonoprazam Fumarate

Sr. No	Concentration (µ g/mL)	Absorbance
1	24	0.333
2	40	0.552
3	60	0.814
4	80	1.135
5	100	1.432

Table No. 4 Cllibration Curve of Vonoprazam Fumarate

Sr.No	**Parameter**	**Value**
1	**Regresion Coefficient**	**0.995**
2	**Intercept**	**0.0188**
3	**Equation of Line**	**Y=0.0139x +0.0188**

Table No. 5 Statistical Parameter related to Cllibration curve

3.1.2 Fourier Transform Infra-red Spectral Analysis:

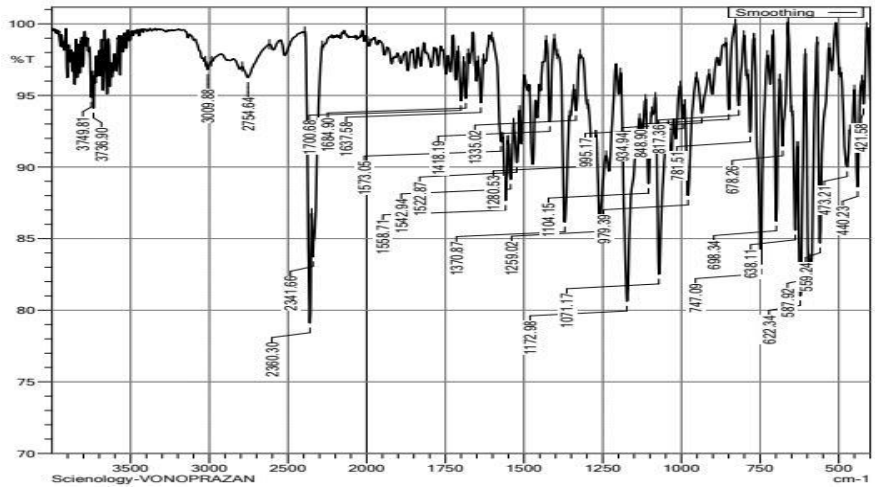

Fig.No. 2: FTIR Spectra Of Drug Vonoprazan Fumarate.

3.1.3 Drug- Polymer Interaction Study:

The characteristic peak of the drug in the IR spectra was not physically altered in the mixture as a result of the drug-excipient interaction under investigation. This indicates compatibility between the drug and the excipient.

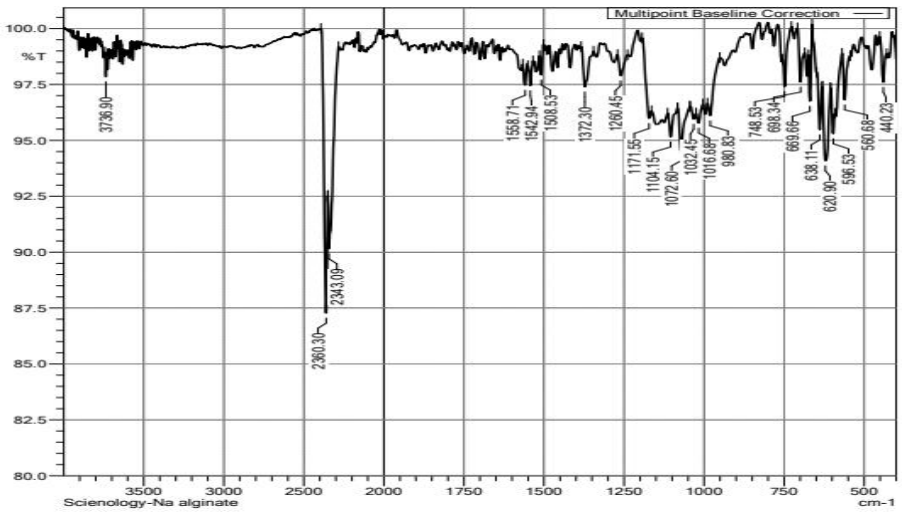

Fig.No 3: FTIR spectra of Drug Vonoprazan fumarate + Sodium alginate

3.2 Evaluation of vonoprazan fumarate in Situ Gel:

3.2.1 Determination of pH of in situ gel:

Sr.No	Formulation Code	pH
1	F1	7.53
2	F2	7.60
3	F3	7.69
4	F4	7.98
5	F5	7.92
6	F6	7.94
7	F7	8.07
8	F8	8.50
9	F9	8.30

Table No.6 : pH Levels of In Situ Gel Formulations.

The pH of the in situ gel formulations we prepared ranged from 7.53 ± 0.02 to 8.50 ± 0.03, which shows that the formulations are slightly alkaline. The pH values recorded were within the acceptable limits for oral in situ gel systems and are deemed appropriate for gastric administration. To ensure formulation stability, drug

solubility, and gelation behavior, maintaining the appropriate pH is crucial. The findings indicate that the formulations made have a favorable pH, which could aid in effective drug release and be more acceptable to patients.

3.2.2 Determination of Density:-

The density of all formulations (F1–F9) ranged between 0.81 and 0.97 g/cm³. Since the measured values were below the density of gastric fluid (around 1.004 g/cm³), this suggests that the formulations are appropriate for a gastroretentive floating behavior. With a density of 0.97 g/cm³, formulation F5 was the densest, while formulation F3 had the lowest density at 0.81 g/cm³. Lower density values aid in buoyancy and allow the in situ gel formulations to be retained in the stomach for longer periods.

Sr No.	Formulation Codes	Density (g/cm³.)
1	F1	0.94
2	F2	0.90
3	F3	0.81
4	F4	0.92
5	F5	0.97
6	F6	0.95
7	F7	0.93
8	F8	0.85
9	F9	0.94

Table No.7 : Density of Formulations After Optimization

The findings show that every formulation had density characteristics that are acceptable for floating in situ gel systems, and they are likely to stay buoyant in the gastric environment, which would improve gastric residence time and allow for sustained drug release.

3.2.4Determination of drug content:-

Sr.No	Formulation Code	Drug Content(%)
1	F1	95.10%
2	F2	92.18%
3	F3	88.74%
4	F4	93.53%
5	F5	95.30%
6	F6	92.35%
7	F7	91.47%
8	F8	90.68%
9	F9	90.29%

Table No. 8: Drug content of Formulated Insitu Gel

Each sample's drug content was determined using the standard callibration curve ranging from 88.74-95.53%.

3.2.5 In vitro Drug Release Studies:-

The in vitro drug release studies was carried out on F1 to F9 formulations by adding 900 mL of pH-1.2, 0.IN HCI to the vessel, the USP apparatus type II (Paddle Method) was assembled. The medium was equilibrated at a temperature of 37 °C ± 0.5 °C. The in situ gel was placed in the vessel and allowed to float and spun at 50 rpm for 12 hours. After removing 5 ml of the receptor fluid, this was filtered and re-added at pre-determined intervals. Samples were diluted in the dilution media as appropriate. and subsequently spectrophotometrically analyzed at 272 nm.

Sr. No.	Time (hrs)	% Drug Release								
		F 1	F 2	F 3	F 4	F 5	F 6	F 7	F 8	F 9
1	0	0	0	0	0	0	0	0	0	0
2	2	8.92	10.8	14.2	7.6	9.51	16.2	5.8	9.23	10.3
3	4	27.2	25.91	28.6	19.2	20.45	26.8	22.35	22.89	28.4
4	6	55.16	38.20	36.2	29.1	41.43	38.3	42.30	37.98	31.2
5	8	63.44	50.12	48.50	37.5	54.22	47.2	50.87	52.34	43.3
6	10	74.88	79.72	80.1	67.0	79.87	76.9	75.7	77.56	78.3
7	12	82.68	82.25	82.45	80.20	84.93	84.12	83.52	84.81	81.7

Table No 9: In vitro release profile of F1 to F9 in situ gel Formulations.

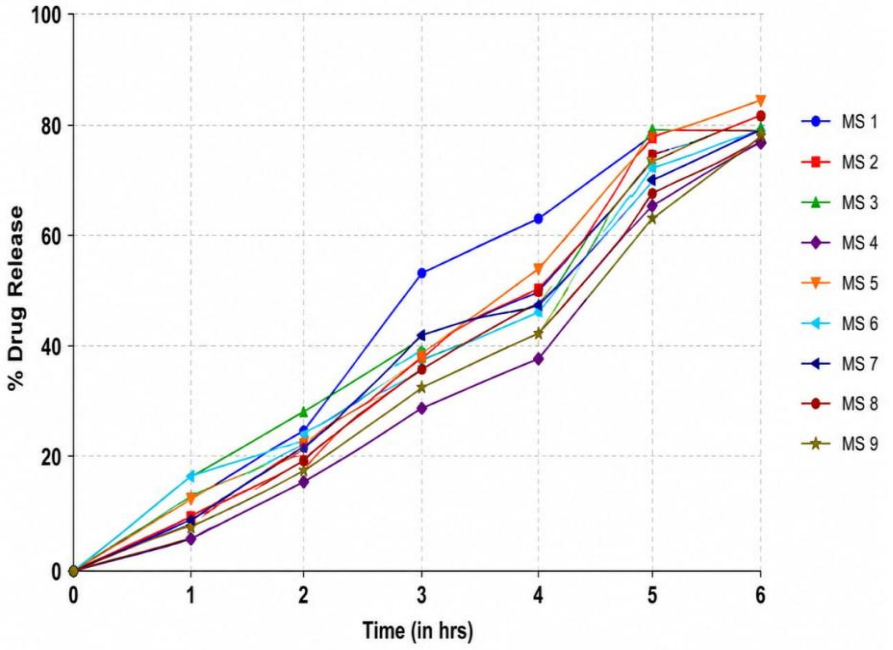

Fig No 4 :% Drug Release Graph for F1 to F9 in situ gel Formulations.

3.2.3 Drug Release Kinetics Table :

Sr. No	Formulation Code R^2	Zero order R^2	First Order R^2	Kors Peppas R^2	Higuchi R^2	Hixson Crowel R^2
1	F1	0.948	0.992	0.958	0.948	0.988
2	F2	0.969	0.91	0.99	0.949	0.935
3	F3	0.952	0.885	0.974	0.92	0.91
4	F4	0.958	0.881	0.986	0.909	0.912
5	F5	0.981	0.938	0.991	0.965	0.916
6	F6	0.962	0.894	0.97	0.922	0.921
7	F7	0.986	0.949	0.977	0.079	0.971
8	F8	0.987	0.934	0.977	0.966	0.96
9	F9	0.932	0.868	0.957	0.896	0.892

Table No.10 :Drug Release Kinetics of F1 to F9 Insitu Formulation

3.2.4 Floating Lag Time:

The floating lag time of the formulation was found to be in the range of 20-95 sec. The formulation displayed rapid floating behavior owing to carbon dioxide evolution and suitable gelation. The floating lag time obtained showed good buoyancy characteristics, which may help in prolonged gastric retention and sustained drug release from the in situ gel formulation.

Sr.No	Formulation Code	Floating Lag Time
1	F1	30
2	F2	90
3	F3	20
4	F4	30
5	F5	90
6	F6	45
7	F7	90
8	F8	70
9	F9	95

Table No 11 : floating lag time

3.2.5 Stability Studies:

Formulation code F5 was packed in Amber colored glass bottle at room temperature. Capsules were checked for dissolution profile testing at 30, 60 days. For stability studies, three parameters i.e. Physical appearance, drug content and percentage drug release were considered.

Sr. No.	Parameters	F5 (30 Day)	F5 (60 Day)
1	Physical Appearance	Positive	Positive
2	Drug Content	95.30	95.02
3	% Drug Release	84.92	83.99

Table 12: Stability Studies of F5 in situ gel Formulation

Discussion

The objective of this study was to formulate and evaluate a gastroretentive floating in situ gel of Vonoprazan fumarate. The selection of sodium alginate as the primary ion-sensitive polymer allowed for effective gelation in the presence of calcium ions, while guar gum and HPMC successfully modulated viscosity and drug release (Xianxi, 2008; Xin, 2011). This strategy aligns with findings for other gastroretentive agents like Omeprazole, Meloxicam, and Lafutidine, which benefit from similar in situ gelling matrices to overcome pharmacokinetic constraints (Soni & Kataria, 2021). The formulations exhibited suitable physicochemical properties, with pH values (7.53–8.50) within the acceptable range for oral administration. Density values

(0.81–0.97 g/cm³) were consistently lower than that of gastric fluid (~1.004 g/cm³), which is essential for buoyancy (Jadhav1, 2025; K.1, 2026).

Drug content analysis confirmed a uniform distribution of Vonoprazan fumarate (88.74%–95.30%) across all formulations. Floating lag times (20–95 sec) indicated rapid gelation and buoyancy triggered by generation from calcium carbonate (K.1, 2026). This behavior is critical for maintaining the system in the stomach to prevent premature gastric emptying (Bachhar et al., 2026). Kinetic analysis indicated that drug release followed the Korsmeyer–Peppas and zero-order models, suggesting a combination of diffusion and polymer relaxation mechanisms controlled by the pH-sensitive swelling of the hydrogel (Rizwan et al., 2017; Xianxi, 2008; Xin, 2011). Such controlled release patterns are vital for ensuring steady plasma concentrations of potassium-competitive acid blockers. Stability studies of the optimized formulation (F5) showed no significant changes in drug content or release profiles over 60 days.

Conclusion:

The present investigation was successfully formulated and evaluated gastroretentive floating in situ gel of Vonoprazan fumarate using sodium alginate, guar gum and HPMC as a polymeric matrix. The prepared in situ gel showed good physicochemical properties, fast floating ability, good density, acceptable drug content and sustained drug release behaviour.

Of the formulations developed, F5 showed the best performance with optimal floating properties, high drug content and controlled drug release. The drug release kinetic studies indicated that the release mechanism followed the diffusion-controlled and polymer relaxation pathways. Stability studies indicated that the formulation was stable under storage conditions.

So the developed gastroretentive floating in situ gel of Vonoprazan fumarate can be a promising strategy to increase gastric retention, improve drug bioavailability, sustain therapeutic action and improve patient compliance in treatment of acid related gastrointestinal disorders.

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