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Formulation and Characterization of Gastroretentive Floating Dosage Form of Vonoprazan.

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ABSTRACT

Background: The present study focuses on the development and optimization of a gastroretentive floating tablet of Vonoprazan aimed at improving gastric retention time and providing sustained drug release for enhanced therapeutic efficacy. **Methods:** Eight batches (F1–F8) were prepared by direct compression, varying concentrations of HPMC K15M and sodium bicarbonate. Evaluations included floating lag time, total floating duration, swelling index, hardness, friability, drug content, and in vitro drug release. Kinetic modeling and accelerated stability studies (40 °C/75% RH for 3 months) were also conducted. **Results:** Batch F6 emerged as the optimized formulation, showing floating lag time of 18.37 s, total floating duration of 12.47 h, swelling index of 82.34%, hardness of 5.81 kg/cm², friability of 0.52%, and drug content of 101.16%. In vitro dissolution demonstrated 95.14% drug release over 12 h. Release kinetics best fit the Korsmeyer–Peppas model ($R^2 = 0.992$; $n = 0.64$), indicating a non-Fickian (anomalous) release mechanism involving both diffusion and polymer erosion. Stability results confirmed no significant changes in physical properties or drug release profile. **Conclusion:** The optimized Batch F6 shows promise as a stable gastroretentive sustained-release formulation of Ranitidine Hydrochloride, potentially improving patient compliance and therapeutic outcomes in acid-related gastric disorders.

INTRODUCTION:

Vonoprazan, a novel potassium-competitive acid blocker (P-CAB), is increasingly prescribed for the treatment of acid-related gastrointestinal disorders such as gastroesophageal reflux disease (GERD), peptic ulcers, and Helicobacter pylori-associated gastritis [1]. Unlike traditional histamine H_2-receptor antagonists (H_2RAs), vonoprazan provides rapid, potent, and long-lasting suppression of gastric acid secretion by competitively inhibiting the potassium-binding site of the gastric H^+/K^+-ATPase enzyme. Despite its superior pharmacodynamics profile, the clinical performance of conventional vonoprazan dosage forms can be limited by its narrow absorption window, primarily located in the upper gastrointestinal tract, and the need to maintain adequate local drug concentration in the stomach for optimal acid suppression [2]. These factors highlight

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the potential benefit of sustained gastric retention to further enhance therapeutic efficacy [3]. To address these limitations, gastroretentive drug delivery systems (GRDDS) have been explored to prolong gastric residence time, thereby improving drug absorption and bioavailability [4]. Among various GRDDS approaches, floating drug delivery systems (FDDS) are particularly promising due to their formulation simplicity, cost-effectiveness, and ability to remain buoyant on gastric fluids without impeding normal gastric emptying. FDDS operate on the principle of reducing the dosage form's bulk density below that of gastric fluids, enabling it to float and release the drug in a controlled manner while in the stomach [5]. This buoyancy is typically achieved through incorporation of gas-generating agents such as sodium bicarbonate, which react with gastric acid to produce carbon dioxide. The gas becomes entrapped in a hydrated polymer matrix commonly hydrophilic polymers like Hydroxypropyl methylcellulose (HPMC) reducing the system's overall density. Such prolonged gastric retention allows for extended drug release at the absorption site, reduced dosing frequency, and improved patient adherence [6]. The unique pharmacokinetic and pharmacodynamics characteristics of vonoprazan make it an ideal candidate for an FDDS, as maintaining prolonged local availability in the stomach could enhance acid suppression and clinical outcomes [7]. This study aims to formulate and characterize a gastroretentive floating tablet of vonoprazan using suitable polymers and gas-generating agents, and to evaluate its in vitro floating behaviour, swelling index, and drug release kinetics. Optimization of formulation parameters is expected to yield a dosage form with ideal buoyancy, controlled release, and potentially improved therapeutic performance in the management of acid-related disorders [8].

MATERIALS AND METHODS:

Materials:

Vonoprazan was procured as a gift sample from Sun Pharmaceuticals Industries Ltd., Mumbai, India. Hydroxypropyl methylcellulose (HPMC K15M) was obtained from Colorcon Asia Pvt. Ltd., Goa, India. Sodium bicarbonate and citric acid were purchased from Loba Chemie Pvt. Ltd., Mumbai, India. Polyvinylpyrrolidone (PVP K30), lactose, magnesium stearate, and talc were obtained from SD Fine Chemicals, Mumbai, India. All chemicals and reagents used were of analytical grade.

Methodology:

Preparation of Gastroretentive Floating Tablets:

The gastroretentive floating tablets of Vonoprazan were prepared using the direct compression method. Eight different formulation batches were developed by varying the concentrations of HPMC K15M and sodium bicarbonate, as detailed in Table 1. Initially, the accurately weighed quantities of ranitidine hydrochloride, HPMC-K15M, lactose (used as a diluent), sodium bicarbonate, and citric acid were passed through a #60 sieve to ensure uniform particle size. The powders were then mixed thoroughly using geometric dilution for 15 minutes to achieve homogeneity. Subsequently, polyvinylpyrrolidone (PVP-K30) solution (5% w/v in isopropyl alcohol) was added as a binder to prepare wet granules. These granules were dried in a hot air oven at 40°C for 2 hours and passed again through a #60 sieve to obtain uniform granules. Finally, magnesium stearate and talc were incorporated as lubricant and glident, respectively, and the blend was mixed well before being compressed into tablets using a single punch tablet compression machine fitted with 10 mm flat-faced punches [9, 10].

Evaluation of Tablet:

The compressed tablets were tested for weight variation, hardness, friability, thickness, and drug content uniformity [11, 12].

***In-Vitro* Floating Studies:**

Floating lag time (time taken for tablet to float) and total floating time (duration the tablet remains buoyant) were determined in simulated gastric fluid (0.1 N HCl, pH 1.2) maintained at 37 ± 0.5°C [13].

Swelling Index:

The swelling behaviour of tablets was measured at predetermined time intervals by immersing pre-weighed tablets in 0.1 N HCl at 37 ± 0.5°C. At each time point, tablets were removed, blotted to remove surface moisture, and weighed [14]. Swelling index was calculated as:

$$\%\ \text{Swelling Index} = \frac{W_t - W_0}{W_0} \times 100$$

where W_t is the weight at time t, and W_0 is the initial weight.

***In-Vitro* Drug Release Study:**

Drug release studies were performed using USP dissolution apparatus II (paddle method) at 50 rpm in 900 mL of 0.1 N HCl maintained at 37 ± 0.5°C. Samples (5 mL) were withdrawn at specific intervals (0.5, 1, 2, 4, 6, 8, 10, 12 hours), filtered, and analyzed spectrophotometric ally at 348 nm. An equal volume of fresh medium was replaced after each sampling to maintain sink conditions [15, 16].

Drug Release Kinetics

The dissolution data were fitted to kinetic models including zero order, first order, Higuchi, and Korsmeyer-Peppas models to determine the mechanism of drug release [17, 18].

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Stability Studies:
The optimized formulation was subjected to accelerated stability testing at 40 ± 2°C and 75 ± 5% relative humidity for 3 months as per ICH guidelines. Samples were periodically evaluated for physical appearance, drug content, and in-vitro drug release profile [19, 20].

Table 1: Formulation Batches of Vonoprazan Floating Tablets

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8
Ranitidine HCl (mg)	150	150	150	150	150	150	150	150
HPMC K15M (mg)	36	45	54	45	45	54	60	60
Sodium Bicarbonate (mg)	30	30	30	36	45	45	36	45
Citric Acid (mg)	15	15	15	15	15	15	15	15
PVP K30 (mg)	15	15	15	15	15	15	15	15
Magnesium Stearate (mg)	6	6	6	6	6	6	6	6
Talc (mg)	6	6	6	6	6	6	6	6
Lactose (mg)	42	33	24	27	18	9	12	3
Total Weight (mg)	**300**	**300**	**300**	**300**	**300**	**300**	**300**	**300**

RESULTS AND DISCUSSION:

Pre-Compression Evaluation:
The pre-compression parameters of all powder blends were evaluated to assess their suitability for direct compression. The angle of repose values ranged from 27.31° ± 0.45 to 30.11° ± 0.38, indicating good flowability of the powder blends. Carr's index values varied between 12.46% ± 0.32 and 15.79% ± 0.29, while Hausner ratios ranged from 1.14 ± 0.02 to 1.18 ± 0.02 across batches F1 to F8. Table 2 values collectively suggest that the powder blends possess acceptable flow and compressibility characteristics suitable for tablet compression.

Table 2: Pre-Compression Evaluation Parameters of Powder Blends

Batch	Angle of Repose (°)	Carr's Index (%)	Hausner Ratio
F1	27.31 ± 0.45	12.46 ± 0.32	1.14 ± 0.02
F2	27.89 ± 0.52	13.10 ± 0.28	1.15 ± 0.01
F3	28.43 ± 0.48	13.75 ± 0.35	1.16 ± 0.03
F4	28.95 ± 0.39	14.20 ± 0.30	1.17 ± 0.02
F5	29.10 ± 0.41	14.55 ± 0.33	1.17 ± 0.01
F6	29.80 ± 0.36	15.25 ± 0.27	1.18 ± 0.02
F7	30.01 ± 0.40	15.70 ± 0.31	1.18 ± 0.01
F8	30.11 ± 0.38	15.79 ± 0.29	1.18 ± 0.02

Post-Compression Evaluation:
The formulated tablets from all batches exhibited satisfactory mechanical strength and content uniformity. Hardness values ranged from 4.52 ± 0.21 to 5.81 ± 0.16 kg/cm², indicating sufficient tablet hardness suitable for handling and packaging. Friability values were within acceptable limits, ranging from 0.52 ± 0.01% to 0.85 ± 0.03%, reflecting good resistance to abrasion. Drug content uniformity was consistent across all batches, ranging from 98.54 ± 0.49% to 101.16 ± 0.42%, confirming precise and homogeneous distribution of Vonoprazan in the tablets (Table 3).

Floating Behaviour:
The floating lag time (FLT) decreased with increasing concentrations of polymer and sodium bicarbonate. Batch F6 demonstrated the shortest FLT of 18.37 ± 1.89 seconds, indicating rapid tablet buoyancy essential for effective gastroretention. Moreover, the total floating time (TFT) was longest for Batch F6 at 12.47 ± 0.21 hours, ensuring prolonged gastric residence and sustained drug delivery. In contrast, Batch F1 showed a significantly longer floating lag time of 40.11 ± 2.94 seconds and a shorter total floating time of 9.52 ± 0.37 hours, indicating relatively reduced buoyancy and gastric retention (Table 3).

Swelling Index:
The swelling index showed a direct correlation with the polymer concentration in the formulation. Batch F6 exhibited the highest swelling index of 82.34 ± 3.18%, which facilitated the formation of a robust gel layer that supports prolonged floating and sustained drug release. In contrast, batches with lower polymer content, such as F1, showed a lower swelling index of 60.78 ± 2.91%, resulting in faster drug release due to weaker gel formation.

In-Vitro Drug Release:
The drug release profiles demonstrated a sustained release pattern that was dependent on the polymer concentration in the formulations. Batches F1 and F2 released 88.41 ± 2.87% and 90.32 ± 3.19% of the drug respectively at 12 hours, indicating relatively faster drug release. In comparison, batches F5 and F6 exhibited a more controlled and sustained release, with drug release percentages of 92.87 ± 2.33% and 95.14 ± 2.51% at 12 hours, respectively, attributed to the stronger gel matrix formation which effectively controlled drug diffusion.

Table 3: Evaluation Parameters of Vonoprazan Floating Tablets

Batch	Hardness (kg/cm²)	Friability (%)	Drug Content (%)	Floating Lag Time (sec)	Total Floating Time (hours)	Swelling Index at 8h (%)	% Drug Released at 12h
F1	4.52 ± 0.21	0.85 ± 0.03	98.54 ± 0.49	40.11 ± 2.94	9.52 ± 0.37	60.78 ± 2.91	88.41 ± 2.87

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F2	4.87 ± 0.29	0.78 ± 0.02	99.42 ± 0.43	38.25 ± 1.94	10.01 ± 0.51	64.72 ± 2.74	90.32 ± 3.19
F3	5.31 ± 0.13	0.65 ± 0.01	98.89 ± 0.56	35.49 ± 2.75	11.21 ± 0.28	75.89 ± 3.96	91.99 ± 2.96
F4	5.09 ± 0.22	0.60 ± 0.02	99.19 ± 0.34	32.41 ± 2.01	10.83 ± 0.44	68.37 ± 2.85	90.88 ± 3.11
F5	5.52 ± 0.27	0.58 ± 0.02	99.63 ± 0.21	22.35 ± 2.15	12.47 ± 0.29	70.45 ± 2.74	92.87 ± 2.33
F6	5.81 ± 0.16	0.52 ± 0.01	101.16 ± 0.4	18.37 ± 1.89	12.47 ± 0.21	82.34 ± 3.18	95.14 ± 2.51
F7	5.68 ± 0.20	0.55 ± 0.01	99.78 ± 0.48	25.48 ± 2.23	10.48 ± 0.46	78.12 ± 2.93	91.67 ± 2.88
F8	5.62 ± 0.12	0.54 ± 0.02	98.53 ± 0.29	20.59 ± 1.16	12.00 ± 0.37	79.68 ± 3.09	93.98 ± 2.65

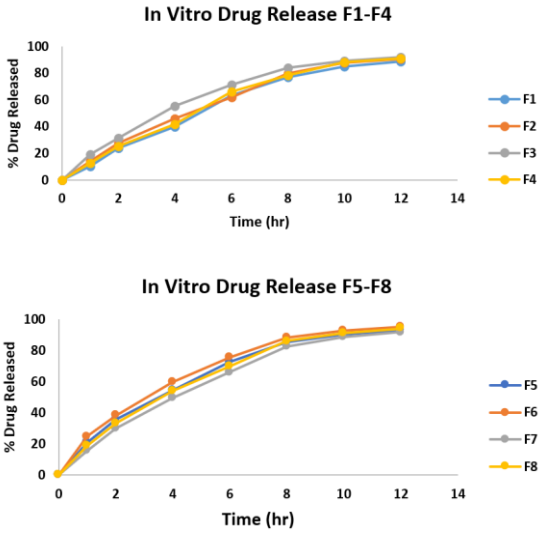

Figure 1. *In-Vitro* Drug Release Profiles of Gastroretentive Tablets

Optimization of Formulation:

Based on a multi-criteria assessment of floating behaviour, swelling, mechanical strength, drug content, and in-vitro release, Batch F6 was selected as the optimized formulation. It combined a short floating lag time (18.37 s) with prolonged buoyancy (12.47 h) and a high swelling index (82.34%), indicating formation of a robust gel layer that supports gastroretention. Mechanical properties were suitable for handling (hardness 5.81 kg/cm²; friability 0.52%), and drug content was close to label claim (101.16%). The cumulative drug release reached 95.14% at 12 h, demonstrating a sustained profile aligned with the formulation intent.

Kinetic Study of Optimized Batch F6

Release data for F6 were fitted to standard kinetic models to elucidate the mechanism of release. The Korsmeyer–Peppas model gave the best fit, indicating anomalous (non-Fickian) transport governed by both diffusions through the hydrated matrix and polymer relaxation/erosion (Table 4 and Figure 2).

Table 4. Drug-release kinetics for optimized batch (F6)

Model	Parameter / Metric
Korsmeyer–Peppas (n)	0.64
R² (Korsmeyer–Peppas)	0.9922
Zero-order R²	0.957
First-order R²	0.935
Higuchi R²	0.975

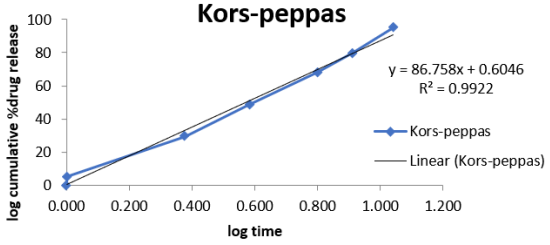

Figure 2. Korsmeyer–Peppas Model Plot for Optimized Batch

Stability Study of Optimized Batch F6:

Accelerated stability testing was conducted at 40 °C ± 2 °C / 75% RH ± 5% for 3 months. The formulation maintained physical integrity, buoyancy, and release behaviour with only minimal changes, indicating satisfactory stability (Table 5).

Table 5. Accelerated stability Study for F6

Parameter	Initial (0 month)	After 3 months
Appearance	Off-white, intact	No change
Hardness (kg/cm²)	5.81	5.74
Friability (%)	0.52	0.56
Drug content (%)	101.16	99.72
Floating lag time (s)	18.37	19.11
Total floating time (h)	12.47	12.32
Swelling index at 8 h (%)	82.34	80.91
% drug released at 12 h (%)	95.14	94.18

CONCLUSION:

The formulated gastroretentive system exhibited prolonged gastric retention with sustained drug release over a 12-hour period. Among all the developed batches, the optimized formulation showed a % drug release of 95.14% at 12 h, with favourable swelling index and mucoadhesive strength supporting prolonged gastric residence. In-vitro release data indicated a controlled release profile without an initial burst effect, fitting best to the Korsmeyer–Peppas model, suggesting anomalous (non-Fickian) transport. These results confirm the formulation's potential to enhance therapeutic efficacy and patient compliance for drugs requiring site-specific gastric delivery. Further *in-vivo* studies are recommended to validate the clinical performance of the optimized batch.

CONFLICT OF INTEREST:

None.

FUNDING: Nil.

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