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Formulation and Evaluation of Gastroretentive Non-Effervescent Floating Tablet of Gabapentin by Sublimation Technique

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ABSTRACT

Gabapentin is a hydrophilic anticonvulsant and neuropathic-pain agent whose oral bioavailability is limited by a narrow, saturable absorption window confined to the stomach and proximal small intestine, making it a rational candidate for gastroretentive drug delivery. The present study aimed to formulate and evaluate non-effervescent gastroretentive floating tablets of gabapentin using the sublimation technique, with camphor as the pore-forming (sublimating) agent, thereby avoiding the erratic buoyancy associated with gas-generating effervescent systems. Nine formulations (F1–F9) were prepared by wet granulation using HPMC K100 and guar gum as matrix-forming polymers and camphor at graded concentrations, followed by post-compression sublimation of camphor in a hot-air oven. Pre-compression powder blends and post-compression tablets were evaluated for flow properties, physical parameters, floating behaviour, swelling index, drug content, and in-vitro drug release over 12 hours. All formulations showed a floating lag time of 0 seconds. Formulation F5 (HPMC K100 130 mg, guar gum 30 mg, camphor 50 mg) was selected as optimized, exhibiting a floating duration exceeding 24 hours, drug content of 99.5%, a swelling index of 190% at 8 hours, and a cumulative drug release of 96.8% at 12 hours. Release-kinetic modelling showed the best fit to the Korsmeyer–Peppas model (R^2 = 0.995) with a release exponent (n) of 0.67, indicating non-Fickian (anomalous) transport governed jointly by diffusion and polymer relaxation. One-way ANOVA confirmed statistically significant differences among formulations for drug release, floating behaviour, and swelling ($p < 0.0001$). These findings demonstrate that the sublimation technique using camphor is a simple, reproducible, effervescent-free approach for achieving immediate and prolonged gastric buoyancy, and that the optimized formulation represents a technically feasible strategy for prolonging the gastric residence and improving the site-specific absorption of gabapentin.

INTRODUCTION

Oral administration remains the most widely preferred route of drug delivery owing to its convenience, cost-effectiveness, and high patient compliance. However, conventional oral dosage forms are frequently limited by a short and unpredictable gastric residence time, which can compromise the bioavailability of drugs that are absorbed preferentially from the stomach or the upper small intestine. To extend the retention time of dosage forms within the stomach, gastroretentive drug delivery systems (GRDDS) have been developed. This mechanism facilitates sustained drug release at the primary absorption site, thereby enhancing the bioavailability of therapeutic agents with a narrow absorption window. [1].

Among the various gastroretentive approaches — including floating, swelling/expanding, bioadhesive, high-density, and raft-forming systems — floating drug delivery systems (FDDS) have received considerable attention because tablet density below that of gastric fluid (≈ 1.004 g/cm^3) can be achieved without complex fabrication [1,2]. Floating systems are broadly classified as effervescent (gas-generating) or non-effervescent. Effervescent systems rely on carbon dioxide generation from carbonates/bicarbonates in acidic media, which can produce variable and occasionally delayed onset of buoyancy [2,3]. Non-effervescent systems, by contrast, achieve low density through swellable hydrocolloids, hollow microspheres, or a porous matrix, and can offer more consistent and immediate floating behaviour [2].

The sublimation technique is a well-established, effervescent-free method for engineering a porous, low-density tablet matrix: a volatile pore-forming agent (subliming agent) is incorporated into the powder blend prior to compression and subsequently removed from the compressed tablet by controlled heating, leaving behind a network of micropores that lowers apparent tablet density and confers rapid, sustained buoyancy [4–6]. Camphor is a naturally occurring bicyclic ketone with a low sublimation temperature and has been widely used as a subliming agent in gastroretentive and orodispersible tablet formulations because of its favourable sublimation

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kinetics and compatibility with common tableting excipients [4,7].

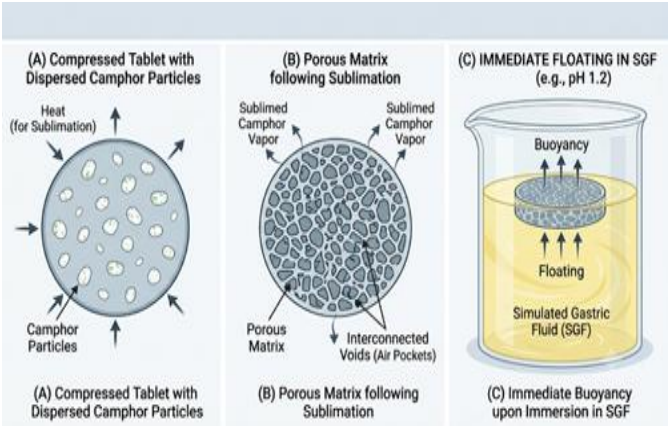

Figure 1. Sequential illustration of the sublimation-based floating mechanism: (A) compressed tablet with dispersed camphor particles, (B) porous matrix following sublimation, (C) immediate buoyancy of the porous tablet in simulated gastric fluid.

Gabapentin, a structural analogue of γ-aminobutyric acid (GABA), is used extensively in the management of epilepsy and neuropathic pain [8,9]. Its clinical utility is constrained by a saturable, carrier-mediated (L-amino acid transporter) absorption mechanism confined to the proximal small intestine, such that a disproportionate reduction in bioavailability occurs with increasing dose and with increasing gastrointestinal transit rate [10]. Prolonging gastric residence and delivering the drug in a controlled manner to its absorption window is therefore a rational formulation strategy for improving and stabilising gabapentin bioavailability, and has direct clinical relevance given the once- to multiple-daily dosing burden associated with conventional immediate-release gabapentin therapy [11,12].

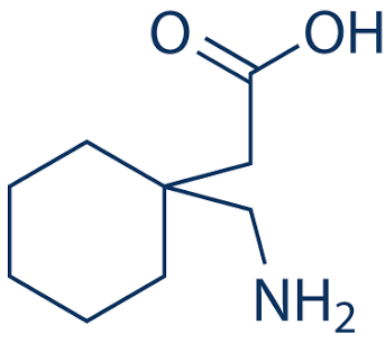

Figure 2. Chemical structure of Gabapentin.

Building on this rationale, the present investigation was undertaken to formulate non-effervescent gastroretentive floating tablets of gabapentin by the sublimation technique, using camphor as the sublimating agent and HPMC K100 with guar gum as matrix-forming polymers, and to systematically evaluate the influence of polymer and camphor concentration on the pre- and post-compression properties, floating behaviour, swelling, and in-vitro release kinetics of the developed tablets, with a view to identifying an optimized formulation.

Materials and Methods

Materials

Gabapentin was used as the model active pharmaceutical ingredient. Hydroxypropyl methylcellulose (HPMC K100) and guar gum were used as hydrophilic matrix-forming polymers; camphor was used as the sublimating (pore-forming) agent; polyvinylpyrrolidone K30 (PVP K30) was used as the granulating binder; microcrystalline cellulose (MCC) was used as the diluent; sodium starch glycolate was used as a channel-forming/wetting agent; talc and magnesium stearate were used as glidant and lubricant, respectively; and ethanol was used as the granulating solvent. All materials used were of pharmaceutical/analytical grade.

Preformulation Studies of Gabapentin

The supplied gabapentin was subjected to preformulation characterization prior to formulation development. Organoleptic properties (colour, odour, taste, appearance) were recorded. Equilibrium solubility was determined in distilled water, 0.1 N HCl (pH 1.2), phosphate buffer (pH 6.8), and ethanol by the shake-flask method, with quantification by UV spectrophotometry after appropriate dilution. Melting point was determined in triplicate by the capillary method using a digital melting-point apparatus and compared with the pharmacopoeial reference value. Drug identification was confirmed by melting point and FTIR spectral matching. For UV spectrophotometric analysis, a standard stock solution of gabapentin in 0.1 N HCl was scanned between 200–400 nm to determine λmax, and a calibration curve was constructed over the concentration range 2–14 µg/mL. Drug–excipient compatibility was assessed by FTIR spectroscopy (KBr disc method, 4000–400 cm^{-1}) by comparing the spectrum of pure gabapentin with that of a 1:1 (w/w) physical mixture of gabapentin with the combined excipient blend, both before and after the post-compression thermal (sublimation) treatment.

Formulation of gastroretentive floating tablets

Nine formulations (F1–F9) of gabapentin non-effervescent floating tablets were prepared by wet granulation, with the concentrations of HPMC K100, guar gum, camphor, and MCC varied across batches while gabapentin dose (100 mg/tablet), PVP K30, sodium starch glycolate, talc, and magnesium stearate were held constant, and the nominal pre-sublimation tablet weight fixed at 400 mg (Table 1).

Gabapentin, HPMC K100, guar gum, and camphor were dry-blended, and a granulating solution of PVP K30 in ethanol (used in preference to an aqueous solvent to minimise premature loss of camphor) was added to obtain a coherent wet mass. The wet mass was sieved into granules and dried under mild conditions sufficient to remove residual ethanol while avoiding premature sublimation of camphor. The dried granules were blended sequentially with MCC, sodium starch glycolate, and talc, and finally lubricated with magnesium stearate. The lubricated blend was evaluated for pre-compression flow

properties and compressed into tablets of the target weight. The compressed tablets were then placed in a hot-air oven at 60 °C for 24 hours to sublime the incorporated camphor, generating an internal porous network responsible for the reduced tablet density and buoyancy of the finished tablets.

Table 1. Composition of gabapentin gastroretentive non-effervescent floating tablets (mg/tablet)

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9
Gabapentin	100	100	100	100	100	100	100	100	100
HPMC K100	90	100	110	120	130	140	150	160	170
Guar gum	20	25	25	30	30	35	35	40	40
Camphor	80	70	65	55	50	40	35	25	20
PVP K30	20	20	20	20	20	20	20	20	20
MCC	70	65	60	55	50	45	40	35	30
Sodium starch glycolate	8	8	8	8	8	8	8	8	8
Talc	6	6	6	6	6	6	6	6	6
Magnesium stearate	6	6	6	6	6	6	6	6	6
Ethanol	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Total weight (mg)	400	400	400	400	400	400	400	400	400

Evaluation of Pre-Compression Parameters

The lubricated granule blends of F1–F9 were evaluated for angle of repose (fixed-funnel/free-standing cone method), bulk and tapped density, Carr's index, and Hausner ratio, using standard pharmacopoeial procedures, to confirm suitability for compression [13].

Evaluation of Post-Compression Parameters

Tablets from each batch were evaluated, before and/or after the sublimation step as appropriate, for general appearance, thickness and diameter, weight variation, hardness, drug content (by UV spectrophotometry at 271 nm after extraction), tablet density and porosity, floating lag time and total floating duration (250 ml volumetric flask containing 0.1 N HCl), and swelling index (weight-gain method in 0.1 N HCl over 8 hours).

In-vitro drug release studies

In-vitro release was carried out using a USP dissolution apparatus. To simulate the gastric-to-intestinal transit, tablets were first placed in 0.1 N HCl (pH 1.2) for 2 hours, after which the medium was replaced with phosphate buffer (pH 6.8) and the study continued up to 12 hours. Samples were withdrawn at predetermined intervals, filtered, suitably diluted, and analysed spectrophotometrically at 271 nm; an equal volume of fresh medium was replaced after each withdrawal.

Drug release kinetics

The cumulative release data of the optimized formulation were fitted to the Zero-order, First-order, Higuchi [14], and Korsmeyer–Peppas [15] models. The model giving the highest regression coefficient (R^2) was taken as best describing the release mechanism, and the release exponent (n) from the Korsmeyer–Peppas model was used to characterise the transport mechanism.

Statistical analysis

Data are expressed as mean ± standard deviation. Differences among formulations for drug release, floating lag time, and swelling index were analysed by one-way ANOVA, with $p < 0.05$ considered statistically significant.

RESULTS AND DISCUSSION

Preformulation studies

Gabapentin showed the highest solubility in 0.1 N HCl (pH 1.2), followed by distilled water and phosphate buffer pH 6.8, with markedly lower solubility in ethanol (Table 2), consistent with its zwitterionic, BCS Class I/III behaviour. The favourable solubility across gastric and intestinal pH supported the choice of gabapentin for a gastroretentive matrix system and the use of pH 1.2/6.8 media for the release study.

Table 2. Solubility of gabapentin in various media

Medium	Solubility (mg/mL)	Observation
Distilled water	48.6 ± 1.2	Freely soluble
0.1 N HCl, pH 1.2	52.8 ± 1.5	Freely soluble
Phosphate buffer, pH 6.8	46.3 ± 1.1	Freely soluble
Ethanol	8.4 ± 0.6	Slightly soluble

The melting range of the gabapentin sample (162–165 °C) matched that of the reference standard, confirming drug identity and acceptable crystalline purity. UV scanning showed λmax at 271 nm, and the calibration curve over 2–14 µg/mL was linear ($Y = 0.0606X - 0.0006$, $R^2 = 0.9989$), validating the analytical method used for subsequent drug-content and dissolution estimations (Figure 3).

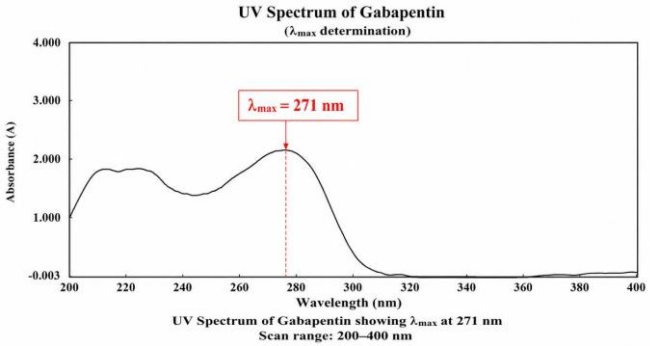

Figure 3. UV absorption spectrum of gabapentin in 0.1 N HCl, showing λmax at 271 nm (scan range 200–400 nm).

FTIR spectra of the standard, the pure drug, the physical mixture with excipients, and the tablet after sublimation (Figure 4) retained all principal characteristic absorption bands of gabapentin (notably the carboxylate and amine bands in the 1300–1620 cm^{-1} region) without the

appearance of new peaks or loss of existing ones beyond minor, explainable shifts; the camphor carbonyl marker band (≈ 1747 cm^{-1}), prominent before sublimation, was markedly diminished after the sublimation step, consistent with near-complete removal of camphor. These findings indicate the absence of a major drug–excipient incompatibility.

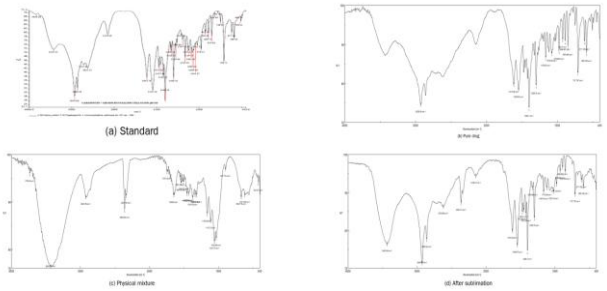

Figure 4. FTIR spectra of (a) standard, (b) pure gabapentin, (c) physical mixture with excipients, and (d) the tablet after sublimation.

Pre-compression evaluation

Table 3. Pre-compression (powder flow) properties of formulations F1–F9

Parameter	F1	F2	F3	F4	F5	F6	F7	F8	F9
Angle of repose (°)	30.8 ±0.4	29.6 ±0.3	28.9 ±0.5	28.2 ±0.3	27.4 ±0.2	27.9 ±0.4	28.3 ±0.3	29.1 ±0.2	29.8± 0.4
Bulk density (g/cm^3)	0.46	0.47	0.48	0.48	0.49	0.49	0.50	0.50	0.51
Tapped density (g/cm^3)	0.54	0.55	0.55	0.56	0.56	0.57	0.58	0.58	0.59
Carr's index (%)	14.8	14.5	13.6	14.2	12.5	14.0	13.8	13.7	13.6
Hauser ratio	1.17	1.17	1.16	1.16	1.14	1.16	1.16	1.16	1.15

All powder blends exhibited angles of repose between 27.4° and 30.8°, Carr's index of 12.5–14.8%, and Hausner ratio of 1.14–1.17, indicating good-to-excellent flow and compressibility. Formulation F5 consistently showed the most favourable flow indices, supporting uniform die filling and consistent compression during tableting.

Post-compression evaluation

Tablets of all batches were white, circular, flat-faced, and free of cracks, capping, or lamination, with a porous surface consistent with camphor removal. Thickness ranged from 5.48 to 5.57 mm and weight variation before sublimation from 399 to 401 mg, indicating uniform die filling; weight fell to 320–379 mg after sublimation, corresponding to loss of the incorporated camphor (Table 4).

Table 4. Post-compression physical parameters, hardness, and drug content of formulations F1–F9

Parameter	F1	F2	F3	F4	F5	F6	F7	F8	F9
Thickness (mm)	5.48±0.03	5.51±0.02	5.49±0.04	5.50±0.03	5.52±0.02	5.53±0.02	5.54±0.03	5.55±0.03	5.57±0.04
Weight before sublimation (mg)	399 ±3	401 ±2	400 ±3	401 ±2	400 ±2	399 ±2	401 ±3	400 ±2	401 ±2
Weight after sublimation (mg)	320 ±2	329 ±2	336 ±3	345 ±2	350 ±2	360 ±2	365 ±3	375 ±2	379 ±2
Hardness before sublimation (kg/cm^2)	4.2 ±0.15	4.3 ±0.15	4.3 ±0.20	4.2 ±0.10	4.4 ±0.10	4.3 ±0.10	4.2 ±0.10	4.4 ±0.10	4.3 ±0.10
Hardness after sublimation (kg/cm^2)	1.5 ±0.10	1.6 ±0.10	1.9 ±0.10	2.0 ±0.10	2.2 ±0.10	2.5 ±0.10	2.6 ±0.10	2.8 ±0.10	3.1 ±0.10
Drug content (%)	97.2	98.1	98.7	99.2	99.5	99.3	99.1	98.8	98.3
Tablet density (g/cm^3)	0.593	0.608	0.620	0.637	0.644	0.661	0.670	0.686	0.698

Tablet hardness decreased markedly after sublimation (from a pre-sublimation range of 4.2–4.4 kg/cm^2 to a post-sublimation range of 1.5–3.1 kg/cm^2), with the decrease inversely related to camphor content (80 mg in F1 to 20 mg in F9). This confirms that camphor removal generates internal micropores, with a higher camphor load producing greater porosity and correspondingly lower mechanical strength, while all formulations retained hardness within an acceptable range for oral tablets. Tablet density likewise increased progressively from F1 (0.593 g/cm^3) to F9 (0.698 g/cm^3) as camphor content decreased, and all values remained below the density of gastric fluid (≈ 1.004 g/cm^3), favouring buoyancy. Drug content across batches (97.2–99.5%) confirmed uniform distribution of gabapentin, with F5 showing the highest content (99.5%).

Floating behaviour and swelling index

Table 5. Floating lag time, total floating duration, and swelling index (8 h) of formulations F1–F9

Parameter	F1	F2	F3	F4	F5	F6	F7	F8	F9
Floating lag time (s)	0	0	0	0	**0**	0	0	0	0
Total floating time (h)	10	12	15	18	**24+**	24	24	24	24
Swelling index at 8 h (%)	149	159	168	181	**190**	195	200	204	208

All formulations showed a floating lag time of 0 seconds, and buoyancy improved progressively with increasing

polymer (HPMC K100/guar gum) content, from 10 hours for F1 (lowest polymer, highest camphor) to ≥24 hours for F5–F9. The immediate buoyancy reflects rapid generation of a low-density, porous matrix on camphor removal, while sustained floating for F5 and above resulted from the hydrated HPMC/guar gum gel layer, which limited medium penetration and preserved matrix integrity (Figure 6). Swelling index increased progressively with time for all batches, reaching 149–208% at 8 hours; F5 (190%) represented a balanced swelling profile, whereas F8/F9 showed excessive swelling from higher polymer loading, consistent with a thicker, more retardant gel barrier.

Figure 5. Photographs demonstrating in-vitro buoyancy of the optimized tablet (F5) in 0.1N HCl

In-vitro drug release

Release in 0.1 N HCl (pH 1.2, first 2 hours) decreased progressively with increasing polymer content, ranging from 42.1% (F1) to 17.8% (F9) at 2 hours; F5 released 24.8% at 2 hours (Table 6). This controlled initial release is desirable in a floating matrix system as it limits rapid drug loss during early gastric residence, reflecting formation of a hydrated HPMC–guar gum gel barrier immediately on contact with the acidic medium.

Table 6. Cumulative in-vitro drug release (%) of formulations F1–F9 in 0.1 N HCl, pH 1.2 (0–2 h acid stage)

Time (h)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	24.2	20.5	18.6	16.2	13.5	12.8	11.9	10.8	9.8
2	42.1	36.8	32.7	28.9	24.8	23.1	21.5	19.6	17.8

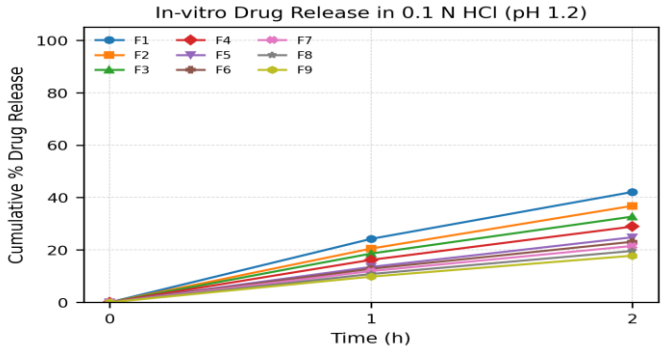

Figure 6. Cumulative in-vitro drug release profile of formulations F1–F9 in 0.1 N HCl, pH 1.2 (0–2 h).

After the medium change to phosphate buffer pH 6.8, cumulative release continued to rise steadily in all batches, reaching 90.1–100.0% by 12 hours (Table 7). F5 showed 47.1%, 64.2%, 78.0%, 89.3%, and 96.8% release at 4, 6, 8, 10, and 12 hours, respectively — a controlled, near-complete release profile without excessive initial burst or excessive retardation. The inverse relationship between polymer concentration and release rate across the series is consistent with a thicker, more viscous HPMC/guar gum gel layer at higher polymer loads, which lengthens the diffusional path and slows gabapentin release.

Table 7. Cumulative in-vitro drug release (%) of formulations F1–F9 in phosphate buffer, pH 6.8 (2–12h buffer stage)

Time (h)	F1	F2	F3	F4	F5	F6	F7	F8	F9
4	67.4	61.2	56.9	52.3	47.1	44.2	41.3	38.2	35.1
6	83.8	78.5	74.1	69.7	64.2	61.0	58.0	54.7	51.0
8	94.6	89.8	86.4	82.4	78.0	75.1	72.3	69.2	66.0
10	98.7	96.8	94.8	92.1	89.3	86.7	84.1	81.5	79.0
12	100.0	99.1	98.0	97.2	96.8	95.2	93.8	92.0	90.1

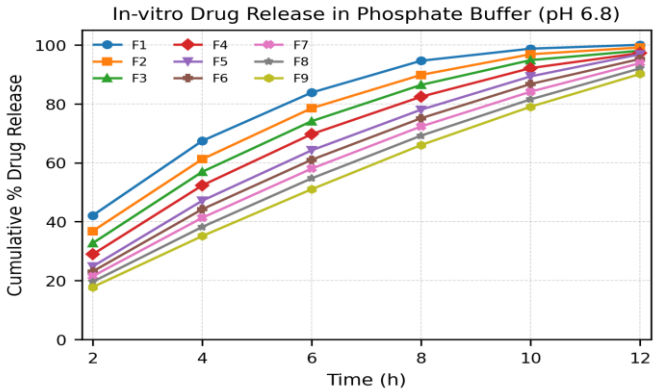

Figure 7. Cumulative in-vitro drug release profile of formulations F1–F9 in phosphate buffer, pH 6.8 (2–12 h)

Drug release kinetics

Table 8. Release-kinetic model fitting for the optimized formulation (F5)

Kinetic model	R^2 / parameter	Interpretation
Zero-order	R^2 = 0.976	Good linearity
First-order	R^2 = 0.916	Lower correlation
Higuchi	R^2 = 0.991	Diffusion-controlled release
Korsmeyer–Peppas	R^2 = 0.995	Best-fit model
Release exponent (n)	n = 0.67	Non-Fickian (anomalous) diffusion

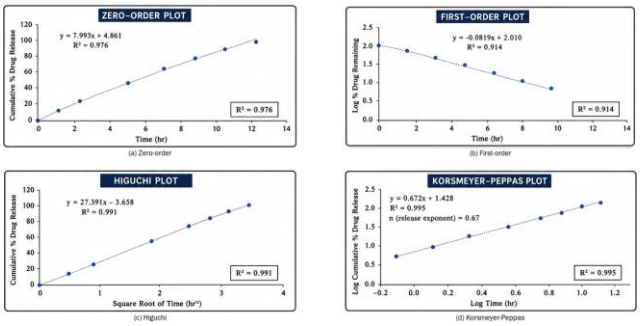

Figure 8. Release-kinetic model plots for the optimized formulation (F5): (a) zero-order, (b) first-order, (c) Higuchi, (d) Korsmeyer–Peppas.

The Korsmeyer–Peppas model gave the highest regression coefficient (R^2 = 0.995) among the models tested, with a release exponent of 0.67 (within the 0.65–0.89 range indicative of non-Fickian, anomalous transport), followed closely by the Higuchi model (R^2 = 0.991); the Zero-order (R^2 = 0.976) and First-order (R^2 = 0.916) fits were comparatively weaker [14,15]. This pattern indicates that gabapentin release from the optimized matrix was governed jointly by diffusion through the hydrated HPMC–guar gum gel layer and by relaxation/erosion of the swollen polymer chains, rather than by a single rate-controlling process.

Statistical analysis

Table 9. One-way ANOVA for drug release, floating lag time, and swelling index

Parameter	F-value	p-value
Drug release	56.21	< 0.0001
Floating lag time	0	< 0.0001
Swelling index	61.92	< 0.0001

One-way ANOVA confirmed statistically significant differences among formulations for drug release, floating behaviour, and swelling characteristics ($p < 0.0001$), indicating that variation in HPMC K100, guar gum, and camphor concentration had a direct and significant influence on the performance of the floating matrix tablets.

Selection of the optimized formulation

Formulation F5 (HPMC K100 130 mg, guar gum 30 mg, camphor 50 mg per tablet) was selected as the optimized formulation on the basis of its superior powder flow, uniform weight and thickness, hardness of 2.2 ± 0.10 kg/cm^2 with acceptable friability, the highest drug content (99.5%), immediate buoyancy (0 s lag) sustained beyond 24 hours, a balanced swelling index (190% at 8 h), controlled and near-complete 12-hour drug release (24.8% at 2 h in 0.1 N HCl; 96.8% at 12 h in pH 6.8 buffer), and the best fit to the Korsmeyer–Peppas kinetic model (R^2 = 0.995). Collectively, these results indicate that F5 achieved the most favourable balance of mechanical strength, buoyancy, swelling behaviour, and sustained release among the nine formulations investigated.

CONCLUSION

A gastroretentive non-effervescent floating tablet of gabapentin was successfully developed by the sublimation technique using camphor as the pore-forming agent. Post-compression sublimation of camphor generated sufficient internal porosity to reduce tablet density below that of gastric fluid, yielding tablets with negligible floating lag time and floating durations exceeding 24 hours, without recourse to gas-generating effervescent agents. The combination of HPMC K100 and guar gum effectively controlled gabapentin release through progressive hydration, gelation, and swelling of the tablet matrix while preserving structural integrity over the floating period. Among the nine formulations evaluated, F5 (HPMC K100 130 mg, guar gum 30 mg, camphor 50 mg) emerged as the optimized formulation, meeting all pre-defined evaluation criteria for mechanical strength, immediate and prolonged buoyancy, adequate swelling, and controlled, near-complete 12-hour release, with drug release best described by the Korsmeyer–Peppas model (non-Fickian transport, n = 0.67). These findings establish the sublimation technique with camphor as a simple, effervescent-free, and reproducible approach to achieving gastric retention, and support the developed system as a technically sound and pharmaceutically promising strategy for prolonging the gastric residence of gabapentin, warranting further in-vivo and stability evaluation, scale-up/process validation, and in-vitro–in-vivo correlation studies prior to clinical translation.

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