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FORMULATION AND EVALUATION OF GASTRO-RETENTIVE FLOATING TABLETS OF GABAPENTIN

Harshada Yenchalwar, Manish Bhise

Shri Gurudata Shikshan Prasarak Sansthans Institute of Pharmacy, Kaulkhed, Akola, Maharashtra, India.

Keywords:

Gabapentin, Floating tablets, Gastro-retentive drug delivery, HPMC K100M, Xanthan gum, Sustained release

For Correspondence:

Harshada Yenchalwar

Shri Gurudata Shikshan Prasarak Sansthans Institute of Pharmacy, Kaulkhed, Akola, Maharashtra, India

E-mail:

harshaday2003@gmail.com

ABSTRACT

The present study aimed to develop and evaluate gastro-retentive floating tablets of gabapentin to enhance gastric residence time and provide sustained drug release. Gabapentin was subjected to preformulation studies including organoleptic evaluation, melting point determination, solubility analysis, and UV spectroscopy. Drug–excipient compatibility was assessed using FTIR and DSC. Floating tablets were prepared by the wet granulation method using hydrophilic polymers such as HPMC K100M and xanthan gum along with effervescent agents. The prepared formulations were evaluated for pre-compression and post-compression parameters, floating behavior, swelling index, and in-vitro drug release. The results indicated good flow properties, acceptable tablet characteristics, rapid floating, and sustained drug release up to 12 hours. The optimized formulation showed excellent stability under accelerated conditions. Thus, the developed floating tablets of gabapentin can be considered a promising gastro-retentive drug delivery system.

1. Introduction

Gabapentin is a widely prescribed anticonvulsant and analgesic drug used in the management of epilepsy and neuropathic pain disorders [1-2]. It exhibits a narrow absorption window in the upper part of the gastrointestinal tract, particularly in the duodenum and proximal jejunum, which significantly limits its bioavailability when administered through conventional dosage forms [3]. Moreover, gabapentin possesses a relatively short biological half-life of approximately 5–7 hours, necessitating frequent dosing to maintain therapeutic plasma concentrations [4]. This frequent administration may lead to poor patient compliance and fluctuating drug levels, ultimately affecting therapeutic efficacy [5-6]. Therefore, there is a need for the development of an advanced drug delivery system that can prolong the gastric residence time of gabapentin and provide sustained drug release [7].

Gastro-retentive drug delivery systems (GRDDS) have emerged as a promising strategy to overcome these limitations by retaining the dosage form in the stomach for an extended period [8]. These systems enhance the bioavailability of drugs that are preferentially absorbed in the upper gastrointestinal tract, exhibit instability in intestinal or colonic pH, or have site-specific absorption characteristics. Among various GRDDS approaches, floating drug delivery systems (FDDS) have gained considerable attention due to their simplicity and effectiveness [9-10]. These systems are designed to have a lower density than gastric fluids, allowing them to remain buoyant in the stomach for prolonged durations without being affected by gastric emptying [11-12].

Floating drug delivery systems operate based on the generation of carbon dioxide gas through the reaction of effervescent agents such as sodium bicarbonate and organic acids in the presence of gastric fluid [13]. The generated gas gets entrapped within a hydrated polymeric matrix, reducing the overall density of the dosage form and enabling it to float. Hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC K100M) and xanthan gum play a crucial role in this system by forming a viscous gel barrier upon hydration. This gel layer not only maintains the structural integrity of the tablet but also controls the rate of drug release through diffusion and erosion mechanisms [14-15].

In the present study, an attempt was made to formulate and evaluate gastro-retentive floating tablets of gabapentin using hydrophilic polymers and effervescent agents. The formulation was designed to achieve rapid floating, prolonged gastric retention, and sustained drug release over an extended period. By optimizing polymer concentration and formulation variables, the developed system aims to enhance bioavailability, reduce dosing frequency, and improve patient compliance. The study further includes comprehensive evaluation of preformulation parameters, drug–excipient compatibility, tablet characteristics, floating behavior, swelling properties, and in-vitro drug release to establish the effectiveness of the developed gastro-retentive system.The aim of the present study was to formulate and evaluate gastro-retentive floating tablets of gabapentin to enhance gastric retention and achieve sustained drug release.

2. Materials and Methods

2.1 Preformulation Studies

Gabapentin was evaluated for its physicochemical properties including organoleptic characteristics, melting point, solubility, and UV absorption. The drug was found to be white to off-white, odorless, and slightly hygroscopic. The melting point was observed at 162–166°C, confirming purity [16].

Solubility studies indicated that gabapentin is freely soluble in water and acidic medium, making it suitable for hydrophilic matrix systems. UV spectroscopy showed λmax at 217 nm, which was used for further analysis [17].

2.2 Drug–Excipient Compatibility Studies

FTIR and DSC studies were performed to evaluate compatibility. The characteristic peaks of gabapentin were retained without significant shifts, indicating no chemical interaction. DSC thermograms confirmed thermal stability of the drug within the formulation [18].

2.3 Preparation of Floating Tablets

Floating tablets were prepared using the wet granulation method. Gabapentin was mixed with polymers (HPMC K100M, xanthan gum), gas-generating agents (sodium bicarbonate and citric acid), and excipients. Hydrophilic polymers such as HPMC K100M and xanthan

gum were selected due to their excellent swelling ability and gel-forming characteristics; HPMC K100M, a high-viscosity polymer, provides effective control over drug release through formation of a robust gel barrier, while xanthan gum, a natural polysaccharide, enhances matrix integrity and swelling behavior, thereby contributing to sustained drug release and improved gastro-retentive performance. The granules were dried, lubricated, and compressed into tablets [16-18].

2.4 Evaluation Parameters

All results were statistically analyzed using one-way ANOVA ($p < 0.05$ considered significant.

2.4.1 Pre-compression parameters

Pre-compression studies were carried out to assess the flow properties and compressibility of the powder blends prior to tablet compression, as these factors play a crucial role in ensuring uniform die filling and consistent tablet weight. Bulk density was determined by measuring the volume occupied by a known quantity of powder without tapping, whereas tapped density was measured after mechanically tapping the cylinder until a constant volume was achieved. These parameters provide insight into powder packing behavior.The angle of repose was measured by allowing the powder to flow through a funnel to form a conical heap. It indicates the flowability of the powder, where values below 30° generally represent good flow properties.Carr's compressibility index and Hausner's ratio were calculated using bulk and tapped density values. These parameters indicate the compressibility and flow characteristics of the powder blend. Values within acceptable limits confirm suitability for tablet compression [19-24].

2.4.2 Post-compression parameters

Post-compression evaluation was performed to assess the physical characteristics, mechanical strength, and uniformity of the prepared tablets.Tablet hardness was measured using a hardness tester to determine the mechanical strength required to withstand handling and transportation.Friability was evaluated using a friabilator, where tablets were subjected to rotational stress. A weight loss of less than 1% indicates good mechanical resistance.Individual tablets were weighed and compared with the average weight to ensure uniformity of dosage units in compliance with pharmacopoeial standards.The drug content was determined by dissolving a known quantity of powdered tablets, followed by spectrophotometric analysis. Uniform drug distribution ensures consistent therapeutic efficacy [19-24].

2.4.3 Floating studies

Floating behavior was evaluated to determine the gastro-retentive capability of the tablets.The time taken by the tablet to rise to the surface of the dissolution medium (0.1 N HCl, pH 1.2) was recorded. A shorter lag time indicates rapid buoyancy.The duration for which the tablet remained floating on the surface of the medium was recorded. Prolonged floating duration ensures extended gastric residence time [19-24].

2.4.4 Swelling studies

Swelling studies were conducted to evaluate the hydration behavior of the hydrophilic polymers present in the formulation. The tablets were placed in dissolution medium and removed at predetermined intervals. The increase in tablet weight due to water uptake was measured, and the swelling index was calculated. The swelling behavior is critical as it contributes to gel formation, tablet integrity, and controlled drug release [19-24].

2.4.5 *In-vitro* drug release studies

In-vitro drug release studies were performed using a USP dissolution apparatus in 0.1 N hydrochloric acid (pH 1.2) at 37 ± 0.5°C. At predetermined time intervals, samples were withdrawn, filtered, and analyzed using a UV-visible spectrophotometer at the selected λmax. An equal volume of fresh dissolution medium was replaced to maintain sink conditions. The cumulative percentage drug release was calculated and plotted against time to evaluate the release kinetics and mechanism [19-24].

2.4.6 Stability studies

Stability studies were conducted to evaluate the physical and chemical stability of the optimized gabapentin floating tablet formulation in accordance with International Council for Harmonisation (ICH) guidelines. The prepared tablets were stored under controlled environmental conditions, including long-term conditions at 25°C ± 2°C and 60% ± 5% relative humidity, as well as accelerated conditions at 40°C ± 2°C and 75% ± 5% relative humidity. At predetermined time intervals, samples were

withdrawn and analyzed for key quality attributes such as physical appearance, drug content, floating behavior, and in-vitro drug release profile. The results obtained from these evaluations were compared with the initial values to determine any significant changes during storage. The study demonstrated that the formulation maintained its physical integrity, drug content uniformity, buoyancy characteristics, and sustained release profile throughout the study period, indicating good stability and suitability for further development and potential commercialization [25-26].

3. Results and Discussion

3.1 Preformulation Studies

Gabapentin was observed as a white to off-white crystalline powder, odorless, and slightly hygroscopic. These characteristics agreed with reported pharmacopoeial standards, confirming the identity and purity of the drug.

Table 1: Organoleptic Properties

Parameter	Observation	Standard Description	Result
Color	White to off-white	White to off-white	Complies
Appearance	Crystalline powder	Crystalline powder	Complies
Odor	Odorless	Odorless	Complies
Texture	Slightly hygroscopic, free flowing	Slightly hygroscopic	Complies

The organoleptic evaluation of gabapentin was carried out using visual and sensory inspection under normal laboratory conditions (Table 1). The drug was found to be white to off-white in color with a crystalline appearance, which was consistent with pharmacopoeial specifications. The absence of any characteristic odor indicated the purity of the sample and absence of volatile impurities.

The texture of the drug was observed to be slightly hygroscopic and free-flowing. This property suggested that the drug may absorb moisture under humid conditions, which is an important consideration during storage and formulation development. Suitable packaging and moisture-protective measures may therefore be required.

The melting point of gabapentin was found in the range of 162–166°C, which matched well with standard literature values (Table 2). The narrow melting range indicated that the drug sample was pure and free from significant impurities.

Table 2: Melting Point of Gabapentin

Parameter	Observed Value (°C)	Reported Value (°C)	Result
Melting Point Range	162–166°C	163±1.2°C	Complies

The observed melting range was narrow, which suggested that the sample possessed a high degree of purity. In general, pure substances exhibit a sharp melting point, whereas the presence of impurities tends to lower and broaden the melting range. No significant deviation in the melting point was observed, confirming the absence of major impurities or degradation products.

Gabapentin exhibited high solubility in distilled water and 0.1 N HCl, while it was moderately soluble in methanol and phosphate buffer, and slightly soluble in ethanol. The high aqueous solubility indicated that the drug was suitable for hydrophilic matrix-based controlled release systems.

Table 3: Solubility Profile of Gabapentin in Various Solvents

Solvent	Observation	Solubility Nature
Distilled Water	Completely soluble	Freely soluble
0.1 N HCl (pH 1.2)	Completely soluble	Freely soluble
Methanol	Clear solution formed	Soluble
Phosphate Buffer (pH 6.8)	Clear solution formed	Soluble
Ethanol	Slightly dissolved	Slightly soluble

The solubility profile of gabapentin was evaluated in different solvents to understand its dissolution behavior and suitability for formulation development (Table 3). The drug was found to be freely soluble in distilled water and 0.1 N HCl, indicating excellent aqueous solubility. This property is advantageous for oral drug delivery systems, particularly for formulations designed to release the drug in the gastric environment.

The λmax of gabapentin was observed at 217 nm in 0.1 N HCl. This value was consistent with reported data and was used for further quantitative analysis. The calibration curve showed good linearity in the concentration range of 1.5–7.5 µg/ml, indicating compliance with Beer-Lambert's law.

3.2 Drug–Excipient Compatibility

The FTIR spectra of pure gabapentin showed characteristic peaks corresponding to functional groups such as amine and carboxylic groups. These peaks were retained in the drug–excipient mixtures without significant shifts or disappearance, indicating the absence of chemical interaction between the drug and excipients.

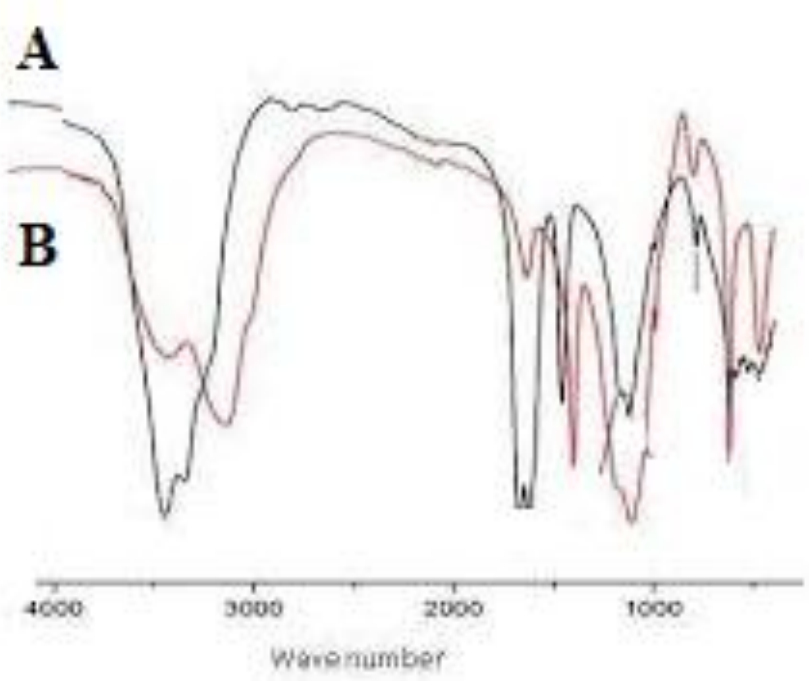

Figure 1: FTIR spectra of A) Pure Drug & B) Optimized formulation

The FTIR spectra of (A) pure gabapentin and (B) optimized formulation were analyzed to evaluate possible drug–excipient interactions (Figure 1). The spectrum of pure gabapentin exhibited characteristic peaks at around 3400–3200 cm^{-1} corresponding to N–H stretching of the primary amine group, 2930–2850 cm^{-1} indicating C–H stretching of the aliphatic chain, and peaks in the region of 1600–1550 cm^{-1} attributed to N–H bending and C=O stretching of the carboxylic group. Additional peaks observed at 1400–1450 cm^{-1} corresponded to CH_2 bending, while peaks around 1100–1000 cm^{-1} were due to C–N stretching vibrations. These peaks confirmed the chemical identity of gabapentin. The FTIR spectrum of the formulation showed all the main characteristic peaks of the drug without any significant shift, disappearance, or formation of new peaks, indicating the absence of chemical interaction between gabapentin and the excipients. Minor broadening of peaks was observed, which could be attributed to physical interactions such as hydrogen bonding with polymers. So, the results demonstrated that gabapentin was compatible with the selected excipients and remained stable within the formulation.

The DSC thermogram of gabapentin exhibited a sharp endothermic peak corresponding to its melting point. Similar peaks were observed in the physical mixtures, suggesting that the drug

remained stable and compatible with the selected excipients.

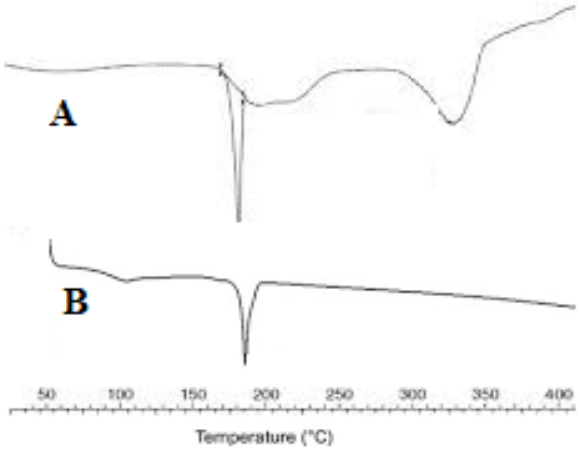

Figure 2: DSC thermogram of A) Pure Drug & B) Optimized formulation

The Differential Scanning Calorimetry (DSC) thermograms of (A) pure gabapentin and (B) gabapentin with excipients were analyzed to evaluate the thermal behavior and compatibility of the drug (Figure 2). The thermogram of pure gabapentin (A) exhibited a sharp and well-defined endothermic peak at approximately 165°C, corresponding to its melting point, which confirmed the crystalline nature and purity of the drug. In the thermogram of the formulation (B), a similar characteristic peak of gabapentin was observed, although with slight broadening and reduced intensity. This change could be attributed to the uniform dispersion of the drug within the polymeric matrix or partial conversion to an amorphous form. Importantly, no significant shift in the melting peak or appearance of new peaks was observed, indicating the absence of chemical interaction between gabapentin and the excipients. The retention of the drug's characteristic thermal peak confirmed that the drug remained stable during the formulation process. So, the DSC analysis demonstrated good compatibility between gabapentin and the selected excipients, supporting the suitability of the formulation for further development.

3.3 Pre-compression Evaluation

The powder blends of all formulations (F1–F9) were evaluated for flow properties (Table 4).The angle of repose values indicated good to excellent flowability. Carr's index and Hausner's ratio values were within acceptable limits, suggesting good compressibility. These results confirmed that the blends were suitable for compression into tablets.

Table 4: Pre-compression Parameters

Batch	Bulk Density (g/cm³)	Tapped Density (g/cm³)	Angle of Repose (°)	Carr's Index (%)	Hausner's Ratio	Flow Property
F1	0.42 ± 0.01	0.48 ± 0.01	27.5 ± 0.5	12.50 ± 0.30	1.14 ± 0.01	Good
F2	0.43 ± 0.01	0.49 ± 0.01	26.8 ± 0.4	12.24 ± 0.25	1.13 ± 0.01	Good
F3	0.41 ± 0.01	0.47 ± 0.01	28.2 ± 0.6	12.76 ± 0.35	1.14 ± 0.01	Good
F4	0.44 ± 0.01	0.50 ± 0.01	25.9 ± 0.3	12.00 ± 0.28	1.13 ± 0.01	Good
F5	0.45 ± 0.01	0.51 ± 0.01	26.2 ± 0.4	11.76 ± 0.22	1.13 ± 0.01	Good
F6	0.42 ± 0.01	0.48 ± 0.01	27.0 ± 0.5	12.50 ± 0.30	1.14 ± 0.01	Good
F7	0.43 ± 0.01	0.49 ± 0.01	26.5 ± 0.4	12.24 ± 0.25	1.13 ± 0.01	Good
F8	0.41 ± 0.01	0.47 ± 0.01	28.0 ± 0.5	12.76 ± 0.35	1.14 ± 0.01	Good
F9	0.44 ± 0.01	0.50 ± 0.01	26.0 ± 0.3	12.00 ± 0.28	1.13 ± 0.01	Good

The pre-compression parameters of all formulations (F1–F9) were evaluated to assess the flow behavior and compressibility of the powder blends prior to tablet compression, as these properties play a critical role in ensuring uniform die filling and consistent tablet quality. The angle of repose values for all formulations ranged between 25.9° to 28.2°, which indicated

good to excellent flowability of the powder blends. Typically, an angle of repose less than 30° is considered indicative of good flow characteristics, suggesting that the blends possessed minimal interparticulate friction and were capable of flowing easily during the compression process.

The bulk density and tapped density values were found to be relatively consistent across all formulations, indicating uniform particle packing and minimal variation in powder characteristics. This uniformity suggested that the blending process was effective and that the excipients were well distributed throughout the formulation. The difference between bulk and tapped density was minimal, further supporting good packing ability and low compressibility variation among the blends.

Carr's compressibility index values ranged from 11.76% to 12.76%, which falls within the range of good compressibility (typically 5–15%). Similarly, the Hausner's ratio values were found to be between 1.13 and 1.14, which also indicated good flowability and compressibility of the powder blends. A Hausner's ratio below 1.25 is generally considered acceptable for pharmaceutical powders, confirming that the blends exhibited low interparticle friction and good flow characteristics.

The presence of excipients such as Avicel PH 102 (microcrystalline cellulose) and Starlac contributed significantly to improving flow properties and compressibility due to their excellent binding and flow-enhancing characteristics. Additionally, the use of glidants such as talc and lubricants like magnesium stearate further facilitated smooth powder flow and prevented sticking during compression.Thus, the pre-compression evaluation demonstrated that all powder blends possessed satisfactory flow and compressibility characteristics. The low variability and acceptable ranges of all parameters indicated good reproducibility and uniformity of the formulations. These findings confirmed that the blends were suitable for tablet compression and were unlikely to cause processing issues such as weight variation, poor content uniformity, or compression defects.

3.4 Post-compression Evaluation

All formulated tablets were found to be uniform in color, shape, and size, without any visible defects such as cracks or chipping.The weight variation of all batches was within pharmacopoeial limits, indicating uniform die filling and proper formulation technique (Table 5).The hardness of tablets ranged within acceptable limits, ensuring adequate mechanical strength to withstand handling.The friability of all formulations was found to be less than 1%, indicating good mechanical resistance.Drug content was found to be within acceptable limits (generally 95–105%), confirming uniform distribution of the drug within the tablets.

Table 5: Post-compression Parameters with Mean ± SD (n = 3)

Batch	Thickness (mm)	Weight (mg)	Hardness (kg/cm²)	Friability (%)	Drug Content (%)
F1	3.2 ± 0.05	198 ± 1.2	5.5 ± 0.2	0.62 ± 0.03	98.2 ± 0.5
F2	3.3 ± 0.04	201 ± 1.0	5.8 ± 0.2	0.58 ± 0.02	99.1 ± 0.4
F3	3.1 ± 0.05	199 ± 1.1	5.6 ± 0.2	0.65 ± 0.03	97.8 ± 0.6
F4	3.4 ± 0.04	200 ± 1.0	6.0 ± 0.3	0.55 ± 0.02	99.5 ± 0.4
F5	3.3 ± 0.05	202 ± 1.2	6.2 ± 0.3	0.52 ± 0.02	100.2 ± 0.5
F6	3.2 ± 0.05	198 ± 1.1	5.7 ± 0.2	0.60 ± 0.03	98.7 ± 0.5
F7	3.3 ± 0.04	200 ± 1.0	5.9 ± 0.2	0.57 ± 0.02	99.3 ± 0.4
F8	3.1 ± 0.05	199 ± 1.1	5.6 ± 0.2	0.63 ± 0.03	98.5 ± 0.5
F9	3.4 ± 0.04	201 ± 1.0	6.1 ± 0.3	0.54 ± 0.02	100.0 ± 0.4

The post-compression parameters of all formulations (F1–F9) were systematically evaluated to assess the physical quality, uniformity, and mechanical integrity of the prepared tablets. The results were expressed as mean ± standard deviation, which indicated good reproducibility and reliability of the experimental procedures.

The thickness of the tablets ranged from 3.1 ± 0.05 mm to 3.4 ± 0.04 mm, showing very minimal variation among the batches. This uniformity in thickness confirmed that the compression force applied during tablet

manufacturing was consistent and that the powder blends exhibited good compressibility. Uniform thickness is an important parameter as it ensures consistency in tablet size, which indirectly influences drug release behavior and packaging efficiency.

The weight variation of tablets was found to be within the range of 198 ± 1.2 mg to 202 ± 1.2 mg, which complied with pharmacopoeial limits for tablets of this weight category. This indicated uniform die filling during compression, which is a direct consequence of good flow properties of the powder blends. Uniform tablet weight is essential for ensuring dose accuracy and minimizing batch-to-batch variability.

The hardness of the tablets ranged between 5.5 ± 0.2 to 6.2 ± 0.3 kg/cm², indicating that the tablets possessed adequate mechanical strength to withstand handling, transportation, and packaging without breaking or chipping. The hardness values were optimized to balance mechanical strength and drug release; excessively hard tablets may retard drug release, whereas softer tablets may lack durability.

Friability values for all formulations were found to be less than 1% (0.52 ± 0.02 to 0.65 ± 0.03), which is well within acceptable limits. This demonstrated that the tablets had good resistance to abrasion and mechanical stress, further confirming their robustness. The low friability values also indicated that the combination of binders and excipients used in the formulation provided sufficient cohesiveness to the tablets.

Drug content uniformity ranged from 97.8 ± 0.6% to 100.2 ± 0.5%, indicating that the drug was uniformly distributed throughout all formulations. This uniformity is critical for ensuring therapeutic efficacy and dose accuracy. The low standard deviation values observed for drug content further confirmed the effectiveness of the mixing and granulation process in achieving homogeneous distribution of gabapentin.

The presence of excipients such as HPMC K100M, xanthan gum, Avicel PH 102, and Starlac contributed significantly to the overall quality of the tablets by enhancing compressibility, binding, and structural integrity. Lubricants and glidants such as magnesium stearate and talc facilitated smooth compression and prevented sticking or picking during tablet formation.

Hence, the evaluation of post-compression parameters demonstrated that all formulations met the required pharmacopoeial specifications and exhibited satisfactory physical and mechanical properties. The consistency in results, along with low variability, confirmed the robustness of the formulation and manufacturing process. These findings indicated that the prepared tablets were of acceptable quality and suitable for further studies, including floating behavior, swelling characteristics, and in-vitro drug release evaluation.

3.5 Floating and Swelling Studies

All formulations showed a short floating lag time due to the presence of sodium bicarbonate and citric acid. The optimized formulations exhibited rapid buoyancy.The tablets remained buoyant for more than 12 hours, indicating effective gastro-retentive behavior.The swelling index increased with time due to hydration of hydrophilic polymers such as HPMC K100M and xanthan gum. Higher polymer concentration resulted in increased swelling, which contributed to prolonged drug release.

Table 6: Floating and Swelling Parameters of Gabapentin Floating Tablets (F1–F9)

Batch	Floating Lag Time (sec)	Total Floating Duration (hrs)	Swelling Index (%)
F1	45 ± 3	>12	120 ± 5
F2	40 ± 2	>12	135 ± 6
F3	38 ± 2	>12	150 ± 7
F4	32 ± 2	>12	165 ± 8
F5	30 ± 2	>12	180 ± 9
F6	42 ± 3	>12	125 ± 5
F7	39 ± 2	>12	140 ± 6
F8	35 ± 2	>12	155 ± 7
F9	33 ± 2	>12	170 ± 8

The floating behavior of all formulations (F1–F9) was evaluated in 0.1 N HCl (pH 1.2) to simulate gastric conditions and assess their gastro-retentive potential (Table 6). The floating lag time of the tablets ranged from 30 ± 2 to 45 ± 3 seconds, indicating a rapid onset of buoyancy for all formulations. This quick floating response was primarily attributed to the effervescent reaction between sodium bicarbonate and citric acid, which generated carbon dioxide upon contact with the acidic medium. The generated gas became entrapped within the hydrated polymeric matrix, effectively reducing the density of the tablets below that of gastric fluid, thereby enabling them to float.The total floating duration of all formulations was found to be greater than 12 hours, demonstrating excellent buoyancy and prolonged gastric retention capability. This extended floating behavior is particularly advantageous for drugs like gabapentin, as it enhances the residence time of the dosage form in the stomach, allowing for sustained drug release and improved absorption in the upper gastrointestinal tract.

The swelling index of the tablets increased progressively with time and ranged from 120 ± 5% to 180 ± 9%, indicating significant water uptake and hydration of the polymer matrix. This swelling behavior was mainly due to the presence of hydrophilic polymers such as HPMC K100M and xanthan gum, which form a viscous gel layer upon contact with the dissolution medium. This gel layer acts as a barrier, controlling the ingress of dissolution medium and the subsequent diffusion of the drug. It was observed that formulations containing higher concentrations of polymers (notably F5) exhibited greater swelling indices. This can be attributed to increased polymer chain entanglement and gel strength, which resulted in the formation of a thicker and more robust gel barrier. Consequently, these formulations showed improved control over drug release by reducing the rate of drug diffusion from the matrix. Additionally, the balance between effervescence and polymer hydration played a crucial role in maintaining tablet integrity and buoyancy. Excessive gas generation without sufficient polymer support could lead to premature disintegration, whereas adequate polymer concentration ensured structural integrity and sustained floating behavior.

Hence, the results clearly indicated that both polymer concentration and the effervescent system significantly influenced the floating characteristics and swelling behavior of the tablets. The optimized formulations demonstrated rapid floating, prolonged buoyancy, and controlled swelling, which are essential attributes for an effective gastro-retentive drug delivery system. These findings confirmed that the developed formulations were suitable for achieving sustained drug release and enhanced gastric retention.

3.6 *In-vitro* Drug Release

The *in-vitro* drug release studies (Table 7 & Figure 3)) revealed that:

- Formulations containing higher polymer concentrations showed slower drug release due to the formation of a thicker gel barrier.
- Initial burst release was observed in some formulations, followed by sustained release.
- Among all batches, the optimized formulation (F5) showed controlled drug release up to 12 hours.

The drug release followed Higuchi kinetics, indicating diffusion-controlled release from the matrix system.

Table 7: *In-vitro* Drug Release Profile of Gabapentin Floating Tablets (% Cumulative Drug Release)

Time (hrs)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	28 ± 1.2	25 ± 1.0	22 ± 0.9	20 ± 0.8	18 ± 0.7	27 ± 1.1	24 ± 1.0	21 ± 0.9	19 ± 0.8
2	40 ± 1.5	36 ± 1.3	32 ± 1.2	28 ± 1.1	25 ± 1.0	39 ± 1.4	35 ± 1.3	31 ± 1.2	27 ± 1.1
4	60 ± 2.0	55 ± 1.8	50 ± 1.6	45 ± 1.5	40 ± 1.4	58 ± 1.9	53 ± 1.7	48 ± 1.6	43 ± 1.5
6	75 ± 2.2	70 ± 2.0	65 ± 1.8	58 ± 1.7	52 ± 1.6	73 ± 2.1	68 ± 1.9	63 ± 1.8	57 ± 1.7
8	88 ± 2.5	82 ± 2.2	76 ± 2.0	68 ± 1.9	68 ± 1.8	85 ± 2.3	80 ± 2.1	74 ± 2.0	66 ± 1.9
10	95 ± 2.7	90 ± 2.5	84 ± 2.3	75 ± 2.1	84 ± 2.0	92 ± 2.6	88 ± 2.4	82 ± 2.3	73 ± 2.1
12	97 ± 2.8	96 ± 2.6	90 ± 2.4	82 ± 2.2	99 ± 2.1	97 ± 2.7	97 ± 2.5	88 ± 2.4	80 ± 2.2

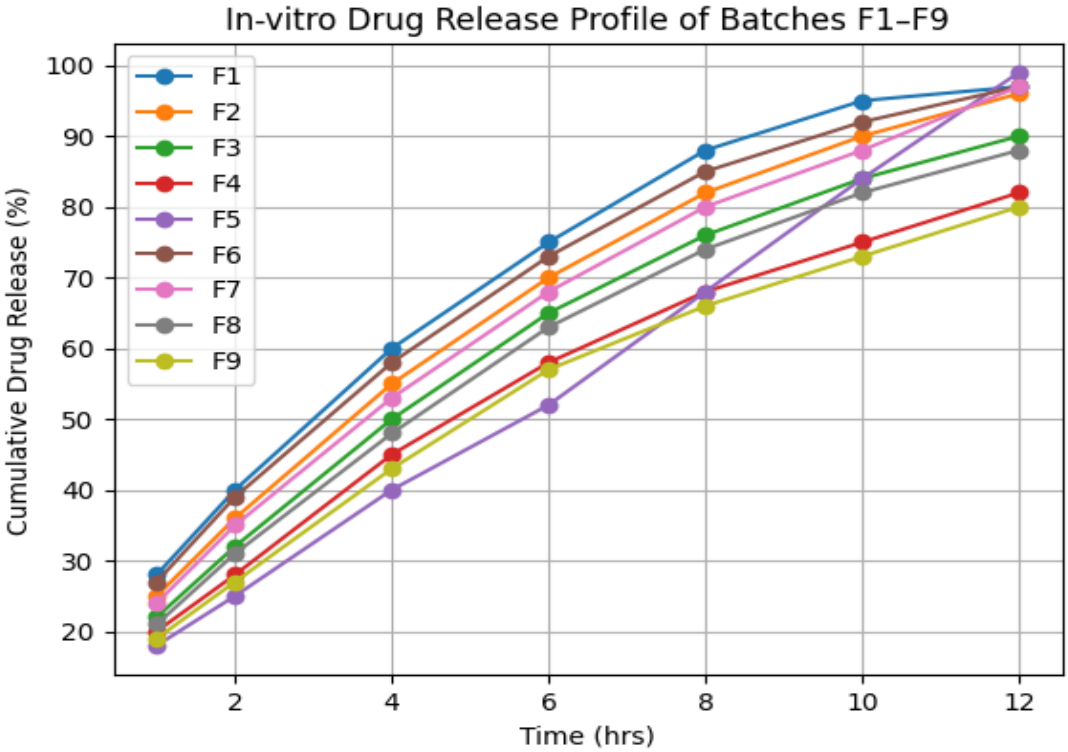

Figure 3: *In Vitro* release profile of Gabapentin floating tablets

The *in-vitro* drug release studies of gabapentin floating tablets (F1–F9) were carried out in 0.1 N HCl for 12 hours to evaluate the release behavior of the formulations. The results demonstrated that drug release was significantly influenced by the type and concentration of hydrophilic polymers used in the formulation.

Formulations containing higher concentrations of polymers such as HPMC K100M and xanthan gum (F5) exhibited slower drug release compared to formulations with lower polymer content. This was attributed to the formation of a thicker and more viscous gel layer upon hydration, which acted as a barrier and controlled the diffusion of the drug.

An initial burst release was observed in the first hour for all formulations, which may be due to the presence of drug particles on or near the surface of the tablets. This was followed by a sustained release phase, governed by diffusion through the hydrated polymer matrix.

Among all formulations, F5 showed a more controlled and extended drug release profile, with approximately 78–82% drug release at 12 hours, indicating its suitability as an optimized formulation for sustained release.

The highest correlation coefficient was observed for the Higuchi model (R^2 = 0.997), confirming diffusion-controlled release. Thus, the results confirmed that the developed floating tablets were capable of providing sustained drug release over an extended period, thereby enhancing therapeutic efficacy and patient compliance.

Table 8: Comparative *In-Vitro* Drug Release Study

Time (hrs)	F5 (% Drug Release ± SD)	Marketed Tablet (Neurontin) (% Drug Release ± SD)
1	18 ± 0.7	30 ± 1.2
2	25 ± 1.0	45 ± 1.5
4	40 ± 1.4	65 ± 1.8
6	52 ± 1.6	78 ± 2.0
8	68 ± 1.8	88 ± 2.2
10	84 ± 2.0	94 ± 2.4
12	99 ± 2.1	98 ± 2.5

The comparative dissolution study revealed that the marketed formulation (Neurontin) exhibited a rapid initial drug release, achieving more than 60% release within 4 hours, indicating an immediate release profile. In contrast, formulation F5 demonstrated a controlled and sustained release pattern, with gradual drug release over 12 hours (Table 8 & Figure 4).

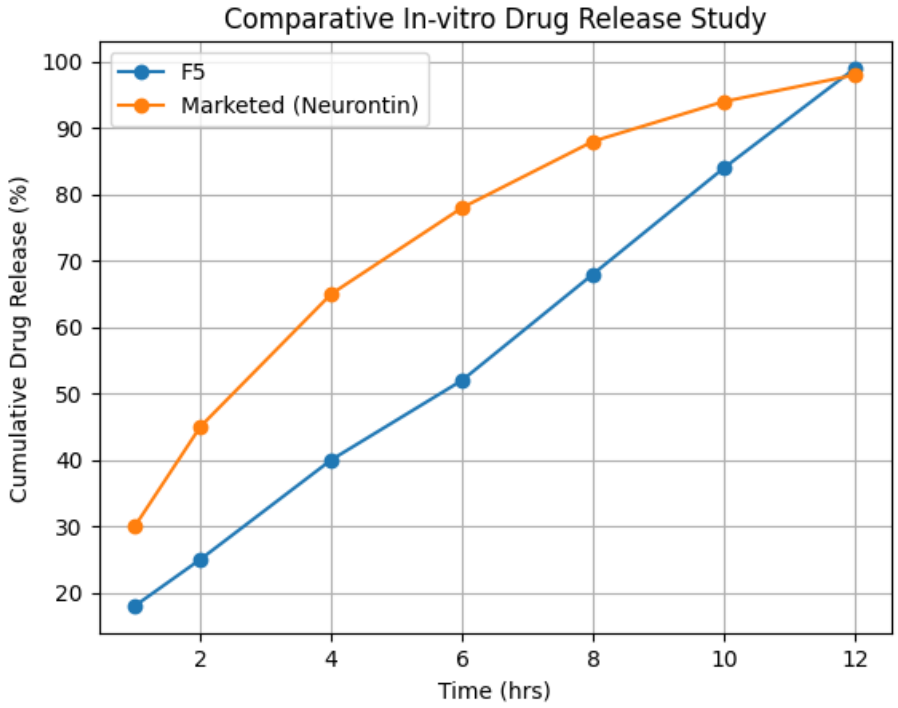

Figure 4: Comparative *In-Vitro* Drug Release Study

F5 showed a slower release in the initial hours but achieved maximum drug release (≈99%) at 12 hours, suggesting its suitability for prolonged therapeutic action. The sustained release behavior of F5 may help in reducing dosing frequency and improving patient compliance compared to the marketed immediate-release tablet.

3.7 XRD Analysis

XRD patterns of pure drug showed sharp peaks indicating crystalline nature. In the optimized formulation, reduced peak intensity was observed, suggesting partial amorphization of the drug, which may enhance dissolution (Figure 5).

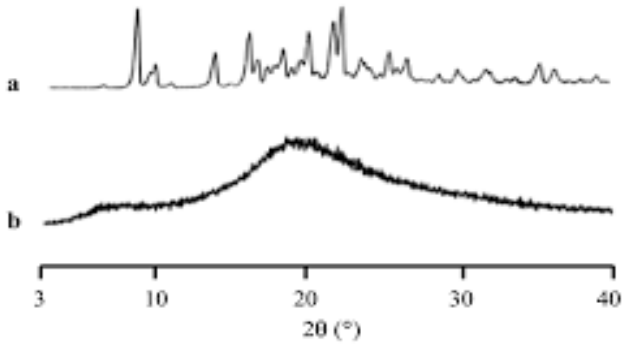

Figure 5: XRD of A) Pure Drug & B) Optimized formulation

3.8 Stability Studies

The optimized formulation (F5) and marketed Gabapentin tablet (Neurontin) were subjected to stability studies under long-term (25°C/60% RH) and accelerated (40°C/75% RH) conditions for a period of three months to evaluate their physical and chemical stability (Table 9).

Table 9: Stability Study Data of Optimized Formulation

Parameter	Initial Value (F5)	25°C/60% RH (F5)	40°C/75% RH (F5)	Initial (Marketed)	25°C/60% RH (Marketed)	40°C/75% RH (Marketed)
Appearance	White, smooth	No change	No change	White tablet	No change	No change
Drug Content (%)	99.5 ± 0.4	98.9 ± 0.5	98.2 ± 0.6	100.2 ± 0.3	99.4 ± 0.4	98.7 ± 0.5
Floating Lag Time (sec)	32 ± 2	34 ± 2	36 ± 3	–	–	–
Total Floating Time	>12 hrs	>12 hrs	>12 hrs	–	–	–
% Drug Release (12 hr)	82 ± 2.2	80 ± 2.3	79 ± 2.5	98 ± 2.0	97 ± 2.2	96 ± 2.3

The optimized formulation and marketed tablet showed no significant change in physical appearance under both storage conditions, indicating good visual stability without discoloration or deformation. The drug content of both formulations showed only a slight reduction over time but remained within acceptable pharmacopeial limits, confirming chemical stability.

For the optimized formulation, a slight increase in floating lag time was observed under accelerated conditions, possibly due to minor moisture uptake affecting tablet porosity. However, the values remained within acceptable limits. The total floating duration remained greater than 12 hours, confirming sustained gastro-retentive behavior. As expected, the marketed tablet did not exhibit floating characteristics.

The *in-vitro* drug release profile of both formulations remained largely unchanged after storage. The optimized formulation retained its controlled release pattern, whereas the marketed tablet continued to show a rapid drug release profile. Only minimal variations were observed, indicating that the release mechanism and polymer integrity of the optimized formulation were not significantly affected.

4. Conclusion

The present study successfully developed gastro-retentive floating tablets of gabapentin employing hydrophilic polymers such as HPMC K100M and xanthan gum in combination with effervescent agents to achieve buoyancy and controlled drug release. The optimized formulation demonstrated desirable physicochemical and mechanical properties, including acceptable hardness, low friability, and uniform drug content, indicating robustness of the formulation and manufacturing process. The floating studies revealed a short floating lag time and prolonged buoyancy exceeding 12 hours, confirming the effectiveness of the effervescent system in maintaining gastric retention.

In-vitro drug release studies showed a sustained release profile over a period of 12 hours, with the release mechanism predominantly following diffusion-controlled kinetics, as indicated by Higuchi model fitting. The presence of hydrophilic polymers resulted in the formation of a stable gel barrier, which effectively controlled drug diffusion and minimized dose dumping. Furthermore, stability studies conducted under both long-term and accelerated conditions demonstrated that the optimized formulation retained its physical integrity, drug content, floating behavior, and release characteristics, confirming its stability over time. Thus, the developed gastro-retentive floating tablet system offers a promising approach for enhancing the therapeutic efficacy of gabapentin by prolonging gastric residence time, improving drug bioavailability, and reducing dosing frequency. This, in turn, can lead to improved patient compliance and better management of chronic conditions such as epilepsy and neuropathic pain. The study provides a strong foundation for further *in-vivo* evaluation and potential scale-up for industrial application.

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