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Development and Evaluation of Gastro Rententive Microspheres for Anticonvulsant Drugs

Mr. Bhagwan Madhukar Kale[1] and Dr. K Sarvanan[2]
Research Scholar, Bhagwant Global University, Kotdwar, Uttarakhand[1]
Research Guide, Bhagwant Global University, Kotdwar, Uttarakhand[2]

Abstract: ***Background:*** *Gastroretentive drug delivery systems are designed to prolong gastric residence time and improve drug bioavailability. Floating microspheres are particularly useful for drugs that require controlled release and extended gastric retention. The present study aimed to develop and evaluate floating gastroretentive microspheres containing* ***Gabapentin*** *and* ***Nortriptyline*** *for sustained drug delivery.* ***Objective:*** *The objective of this study was to formulate floating gastroretentive microspheres using different polymer concentrations and evaluate their physicochemical properties, buoyancy behavior, drug entrapment efficiency, swelling characteristics, and in-vitro drug release profile.* ***Methods:*** *Floating microspheres were prepared by the solvent evaporation technique using hydroxypropyl methylcellulose (HPMC K15M) and ethyl cellulose as polymeric carriers. Twelve formulations (F1–F12) were developed by varying polymer concentrations. The prepared microspheres were evaluated for micromeritic properties, particle size distribution, swelling index, drug loading, entrapment efficiency, in-vitro buoyancy, and drug release behavior. Drug release studies were performed in simulated gastric fluid for 12 hours. The optimized formulation was further subjected to stability studies for three months under accelerated conditions.* ***Results:*** *The microspheres exhibited satisfactory micromeritic properties with bulk density ranging from 0.37 to 0.49 g/mL and angle of repose between 26.8° and 31.2°, indicating good flow characteristics. Particle size ranged from 168.4 µm to 246.4 µm. Entrapment efficiency varied between 71.4% and 89.5%, while drug loading ranged from 18.6% to 26.2%. In-vitro buoyancy studies showed floating ability between 68.4% and 89.6%. The optimized formulation (F10) demonstrated sustained drug release up to 12 hours with nearly complete drug release and excellent buoyancy. Stability studies indicated no significant changes in physicochemical parameters during storage.* ***Conclusion:*** *The developed floating gastroretentive microspheres successfully provided sustained drug release and prolonged gastric retention. The optimized formulation exhibited desirable micromeritic properties, high entrapment efficiency, and excellent floating ability, suggesting its potential as an effective gastroretentive drug delivery system for controlled release therapy.*

Keywords: Floating gastroretentive microspheres, gastroretentive drug delivery system, Gabapentin, Nortriptyline, solvent evaporation method, controlled drug release, buoyancy, polymeric microspheres.

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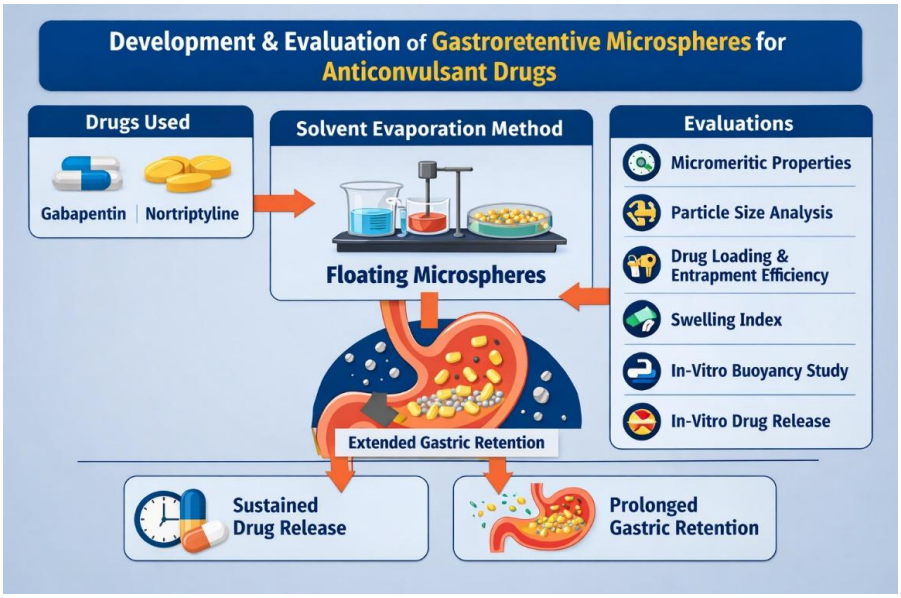
GRAPHICAL ABSTRACT:



I. INTRODUCTION

Oral drug delivery remains the most widely preferred route of administration due to its convenience, patient compliance, and cost-effectiveness. However, the conventional oral dosage forms often face limitations such as rapid gastric emptying and unpredictable gastrointestinal transit time, which can reduce drug absorption and therapeutic effectiveness. To overcome these limitations, gastroretentive drug delivery systems (GRDDS) have been developed to prolong the residence time of dosage forms in the stomach and enhance drug bioavailability.[1,2]

Floating drug delivery systems are among the most promising approaches within GRDDS. These systems are designed to have a lower density than gastric fluid, allowing them to remain buoyant in the stomach for extended periods. This prolonged gastric retention enables controlled and sustained drug release, improves drug absorption in the upper gastrointestinal tract, and reduces dosing frequency. Floating microspheres, in particular, have attracted considerable attention due to their advantages such as uniform drug distribution, reduced risk of dose dumping, and improved stability.[3,4]

Microspheres are multiparticulate drug delivery systems consisting of polymeric particles in the micrometer size range. These systems provide several benefits including controlled drug release, improved bioavailability, and enhanced therapeutic efficacy. When incorporated into floating systems, microspheres can remain suspended in gastric fluid while gradually releasing the drug over a prolonged period. The use of hydrophilic and hydrophobic polymers plays a critical role in controlling swelling, buoyancy, and drug release characteristics of these systems.[5,6]

In the present study, two drugs were selected for the development of floating gastroretentive microspheres: **Gabapentin** and **Nortriptyline**. Gabapentin is widely used for the management of epilepsy and neuropathic pain, while nortriptyline is commonly prescribed for neuropathic pain and depressive disorders. Both drugs require controlled drug delivery to maintain consistent plasma drug concentrations and improve therapeutic outcomes.

The preparation of floating microspheres using polymeric carriers such as hydroxypropyl methylcellulose and ethyl cellulose offers a promising strategy for achieving sustained drug release and improved gastric retention. The solvent evaporation technique is commonly employed for preparing such microspheres due to its simplicity and ability to produce uniform spherical particles.

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Therefore, the objective of the present study was to formulate and evaluate floating gastroretentive microspheres containing gabapentin and nortriptyline using suitable polymeric combinations. The prepared formulations were evaluated for micromeritic properties, particle size, swelling behavior, drug loading, entrapment efficiency, in-vitro buoyancy, and drug release characteristics in order to identify an optimized formulation capable of providing prolonged gastric retention and controlled drug release.

II. MATERIALS AND METHOD

Two anticonvulsant/neuropathic drugs were used in the formulation of floating gastroretentive microspheres: Gabapentin and Nortriptyline. Gabapentin was used in formulations F1–F6, while Nortriptyline was incorporated in formulations F7–F12 to evaluate the suitability of the floating gastroretentive microsphere system for different drugs with varying physicochemical properties. Hydroxypropyl methylcellulose (HPMC K15M) and ethyl cellulose were used as release-retarding polymers. Polyvinyl Alcohol served as an emulsifying agent, while Dichloromethane and Ethanol were used as volatile solvents during microsphere preparation. All reagents used were of analytical grade.

Table 1: Composition

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Drug	**Gabapentin**						**Nortriptyline**					
Drug (mg)	400	400	400	400	400	400	10	10	10	10	10	10
HPMC K15M (mg)	200	250	300	200	250	300	200	250	300	200	250	300
Ethyl Cellulose (mg)	100	100	100	150	150	150	100	100	100	150	150	150
Polyvinyl Alcohol (% w/v)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Dichloromethane: Ethanol (mL)	10:5	10:5	10:5	10:5	10:5	10:5	10:5	10:5	10:5	10:5	10:5	10:5

Preparation of Floating Gastroretentive Microspheres

Floating gastroretentive microspheres were prepared by the **solvent evaporation method**.

Accurately weighed quantities of the anticonvulsant drug and polymers (HPMC K15M and ethyl cellulose) were dissolved in a mixture of dichloromethane and ethanol to form a uniform polymeric solution. The drug was dispersed in this polymeric solution under continuous stirring to obtain a homogeneous mixture.

The resulting solution was slowly poured into an aqueous phase containing polyvinyl alcohol under continuous stirring using a mechanical stirrer at 800–1000 rpm. The stirring process facilitated the formation of emulsion droplets which subsequently solidified into microspheres as the organic solvents evaporated.

The stirring was continued for approximately 3 hours to ensure complete evaporation of the solvents and formation of solid floating microspheres. The formed microspheres were collected by filtration, washed several times with distilled water to remove residual stabilizer, and dried at room temperature for 24 hours.

Different formulations (F1–F12) were prepared by varying the concentration of polymers to study their influence on microsphere characteristics and drug release behavior.[7,8]

Characterization of Floating Gastroretentive Microspheres

Micromeritic Properties

The flow properties of the prepared microspheres were evaluated by determining **bulk density, tapped density, Carr's compressibility index, Hausner ratio, and angle of repose** using standard pharmacopeial methods.

Bulk density was determined by measuring the volume occupied by a known weight of microspheres. Tapped density was obtained by mechanically tapping the cylinder until a constant volume was achieved. Carr's index and Hausner ratio were calculated using the following equations:

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Carr's Index = (Tapped Density – Bulk Density) / Tapped Density × 100
Hausner Ratio = Tapped Density / Bulk Density
The angle of repose was measured using the fixed funnel method to evaluate the flow behavior of microspheres.

Particle Size Analysis

Particle size of the prepared microspheres was determined using optical microscopy. A small quantity of microspheres was dispersed on a glass slide and observed under a calibrated optical microscope. The diameters of approximately 100 microspheres were measured and the mean particle size was calculated.[9]

Determination of Drug Loading

Drug loading of the microspheres was determined by dissolving a known quantity of microspheres in a suitable solvent. The solution was filtered and analyzed spectrophotometrically using **UV–Visible Spectrophotometer** at the predetermined wavelength corresponding to the drug.
Drug loading (%) was calculated using the following equation:
Drug Loading (%) = (Amount of drug present in microspheres / Total weight of microspheres) × 100

Drug Entrapment Efficiency

Entrapment efficiency was determined by extracting the drug from a known quantity of microspheres and analyzing it using UV spectrophotometry.
Entrapment Efficiency (%) was calculated using the formula:
Entrapment Efficiency (%) = (Actual drug content / Theoretical drug content) × 100

Swelling Study

Swelling behavior of the microspheres was studied by placing a known weight of microspheres in simulated gastric fluid (pH 1.2). The swollen microspheres were periodically removed, blotted with filter paper, and weighed.
Swelling index was calculated using the formula:
Swelling Index (%) = (Weight of swollen microspheres – Initial weight) / Initial weight × 100

In-Vitro Buoyancy Study

Floating behavior of the microspheres was determined using simulated gastric fluid (0.1 N HCl, pH 1.2). A known quantity of microspheres was dispersed in the dissolution medium maintained at 37 ± 0.5°C and stirred at 100 rpm.
After a predetermined time interval, floating microspheres were separated from settled microspheres. Both fractions were dried and weighed.
Buoyancy percentage was calculated as:
Buoyancy (%) = Weight of floating microspheres / Total weight of microspheres × 100

In-Vitro Drug Release Study

Drug release studies were carried out using the **USP Dissolution Apparatus II**.
Microspheres equivalent to the required drug dose were placed in 900 mL of simulated gastric fluid (0.1 N HCl, pH 1.2) maintained at 37 ± 0.5°C and stirred at 100 rpm.
At predetermined time intervals, 5 mL samples were withdrawn and replaced with fresh dissolution medium to maintain sink conditions. The samples were filtered and analyzed using a UV-Visible spectrophotometer to determine cumulative drug release.

Stability Study

The optimized formulation (F10) was subjected to stability studies according to **International Council for Harmonisation**. Microspheres were stored at **40°C ± 2°C and 75% ± 5% relative humidity** for three months. Samples were withdrawn at 0, 1, 2, and 3 months and evaluated for physical appearance, drug content, entrapment efficiency, buoyancy, and drug release characteristics. [10-12]

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III. RESULTS AND DISCUSSION

Micromeritic Characterization of Floating Gastroretentive Microspheres

The micromeritic properties of the prepared floating gastroretentive microspheres containing **Gabapentin** (F1–F6) and **Nortriptyline** (F7–F12) were evaluated to determine their flow behavior and packing properties.

The bulk density of the formulations ranged from **0.37 ± 0.02 to 0.49 ± 0.01 g/mL**, while the tapped density varied from **0.44 ± 0.02 to 0.59 ± 0.02 g/mL**. The relatively small difference between bulk and tapped densities indicated good packing ability of the microspheres.

The Carr's compressibility index ranged from **15.91 ± 0.3 to 18.87 ± 0.5%**, suggesting **fair to good flow properties** of the microspheres. Similarly, the Hausner ratio values ranged from **1.19 ± 0.02 to 1.24 ± 0.02**, which further confirmed acceptable flow characteristics.

The angle of repose values ranged from **26.8° ± 0.5 to 31.2° ± 0.6**, indicating **good flowability of the microspheres**. These results suggest that the prepared formulations possess suitable micromeritic properties, which are important for uniform handling, processing, and filling during pharmaceutical manufacturing.

Particle Size Analysis

The particle size of the floating gastroretentive microspheres ranged from **168.4 ± 5.2 µm to 246.4 ± 7.0 µm**.

Formulations F1–F6 (containing Gabapentin) exhibited relatively smaller particle sizes compared to formulations F7–F12 containing Nortriptyline. An increase in polymer concentration resulted in a gradual increase in particle size. This increase can be attributed to the higher viscosity of the polymer solution, which leads to the formation of larger emulsion droplets during the solvent evaporation process.

Among all the formulations, **F10 showed the highest particle size (246.4 ± 7.0 µm)**, which could contribute to improved floating ability and sustained drug release behavior.

Swelling Behavior of Microspheres

The swelling index of the microspheres ranged from **128.6 ± 3.4% to 186.8 ± 4.5%**.

An increase in swelling was observed with increasing polymer concentration. This can be attributed to the hydrophilic nature of HPMC, which absorbs gastric fluid and forms a gel layer around the microspheres. This gel barrier helps in controlling drug diffusion and maintaining buoyancy.

The optimized formulation **F10 showed the highest swelling index (186.8 ± 4.5%)**, indicating excellent hydration capacity and matrix formation, which contributes to prolonged gastric retention.

Drug Loading of Microspheres

The drug loading efficiency of the microspheres ranged from **18.6 ± 0.7% to 26.2 ± 0.6%**.

The increase in polymer concentration slightly improved drug loading due to better entrapment of drug molecules within the polymer matrix. Formulations containing Nortriptyline generally showed slightly higher drug loading compared to Gabapentin formulations, which may be related to differences in drug solubility and polymer interaction.

The highest drug loading was observed in **formulation F10 (26.2 ± 0.6%)**, indicating efficient incorporation of the drug into the microsphere matrix.

Drug Entrapment Efficiency

The entrapment efficiency of the microspheres ranged from **71.4 ± 1.9% to 89.5 ± 1.7%**.

The entrapment efficiency increased with increasing polymer concentration. Higher polymer content improves the viscosity of the dispersed phase and reduces drug diffusion into the external aqueous phase during microsphere formation.

Among all formulations, **F10 exhibited the highest entrapment efficiency (89.5 ± 1.7%)**, suggesting that the polymer combination effectively encapsulated the drug.

Swelling Measurement

Swelling measurements showed values ranging from **129.4 ± 3.5% to 188.3 ± 4.4%**.

The swelling behavior is important for maintaining the buoyancy of microspheres in gastric fluid. Increased polymer concentration leads to greater hydration and swelling, which enhances the floating ability of the microspheres.

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Formulation **F10 again demonstrated the highest swelling index**, indicating the formation of a strong polymeric matrix.

In-Vitro Buoyancy Study

The floating ability of the microspheres ranged from **68.4 ± 1.8% to 89.6 ± 1.7%**.

Formulations with higher polymer content showed improved buoyancy due to the formation of a low-density polymeric matrix that traps air within the microspheres.

The optimized formulation **F10 exhibited the highest buoyancy (89.6 ± 1.7%)**, indicating excellent floating ability and prolonged gastric residence time. The increased buoyancy ensures that the microspheres remain in the gastric environment for an extended period, improving drug absorption

In-Vitro Drug Release Study

The cumulative drug release of the microspheres was evaluated for **12 hours** in simulated gastric fluid.

Formulations containing lower polymer concentrations showed relatively faster drug release, while higher polymer concentrations resulted in sustained release profiles.

At the end of 12 hours:

F1 released 88.1% of drug

F10 released nearly 100% of drug

The sustained drug release observed in formulations with higher polymer content is attributed to the formation of a thicker gel barrier around the microspheres, which slows down drug diffusion.

Among all the formulations, **F10 showed the most controlled and sustained drug release profile**, making it the optimized formulation.

Stability Study of Optimized Formulation (F10)

The optimized formulation F10 was subjected to accelerated stability studies for **3 months**.

No significant changes were observed in the **appearance, drug content, entrapment efficiency, buoyancy, or drug release profile** during the storage period.

Drug content decreased slightly from **100.3 ± 0.9% to 98.6 ± 1.0%**, which remained within acceptable pharmaceutical limits. Similarly, entrapment efficiency and buoyancy showed only minor variations.

These results indicate that the optimized microsphere formulation remained **physically and chemically stable during the storage period**.

Micromeritic Characterization of Floating Gastroprotective Microspheres

Table 2: Micromeritic Characterization of Floating Gastroprotective Microspheres

Formulation	Bulk Density (g/mL)	Tapped Density (g/mL)	Carr's Compressibility Index (%)	Hausner Ratio	Angle of Repose (°)
F1	0.37 ± 0.02	0.44 ± 0.02	15.91 ± 0.3	1.19 ± 0.02	26.8 ± 0.5
F2	0.39 ± 0.01	0.47 ± 0.02	17.02 ± 0.4	1.21 ± 0.02	27.3 ± 0.6
F3	0.40 ± 0.02	0.48 ± 0.02	16.67 ± 0.5	1.20 ± 0.02	27.9 ± 0.5
F4	0.42 ± 0.01	0.51 ± 0.02	17.65 ± 0.4	1.22 ± 0.02	28.7 ± 0.6
F5	0.44 ± 0.02	0.54 ± 0.02	18.52 ± 0.3	1.23 ± 0.02	29.4 ± 0.5
F6	0.41 ± 0.01	0.50 ± 0.02	18.00 ± 0.4	1.22 ± 0.02	28.3 ± 0.6
F7	0.43 ± 0.02	0.53 ± 0.02	18.87 ± 0.5	1.24 ± 0.02	29.8 ± 0.5
F8	0.45 ± 0.01	0.55 ± 0.02	18.18 ± 0.4	1.22 ± 0.02	30.3 ± 0.6
F9	0.47 ± 0.02	0.57 ± 0.02	17.54 ± 0.3	1.21 ± 0.02	30.9 ± 0.5
F10	0.49 ± 0.01	0.59 ± 0.02	16.95 ± 0.4	1.20 ± 0.02	31.2 ± 0.6
F11	0.46 ± 0.02	0.56 ± 0.02	17.86 ± 0.5	1.22 ± 0.02	30.4 ± 0.5
F12	0.48 ± 0.01	0.58 ± 0.02	17.24 ± 0.4	1.21 ± 0.02	30.7 ± 0.6

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of Floating Gastroprotective Microspheres

Table 3: Particle Size Analysis

Formulation	Particle Size (µm) (Mean ± S.D.)
F1	168.4 ± 5.2
F2	175.7 ± 4.9
F3	182.6 ± 5.4
F4	191.3 ± 5.1
F5	204.8 ± 6.2
F6	187.5 ± 5.6
F7	212.7 ± 6.4
F8	225.9 ± 6.1
F9	238.6 ± 6.8
F10	246.4 ± 7.0
F11	232.1 ± 6.3
F12	241.8 ± 6.5

Measurement of Microspheres Hydration (Swelling Index)

Table 4: Swelling Index

Formulation	Swelling Index (%) (Mean ± S.D.)
F1	128.6 ± 3.4
F2	134.2 ± 3.7
F3	139.8 ± 4.1
F4	147.5 ± 3.9
F5	156.3 ± 4.2
F6	142.7 ± 3.6
F7	163.9 ± 4.4
F8	171.6 ± 4.0
F9	179.4 ± 4.3
F10	186.8 ± 4.5
F11	174.1 ± 4.2
F12	181.5 ± 4.1

Determination of Drug Loading of Microspheres

Table 5: Drug Loading of Microspheres

Formulation	Drug Loading (%) (Mean ± S.D.)
F1	18.6 ± 0.7
F2	19.4 ± 0.6
F3	20.3 ± 0.8
F4	21.5 ± 0.7
F5	22.7 ± 0.6
F6	20.9 ± 0.7
F7	23.8 ± 0.8
F8	24.6 ± 0.7
F9	25.4 ± 0.8
F10	26.2 ± 0.6

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F11	24.9 ± 0.7
F12	25.7 ± 0.8

Drug Entrapment Efficiency of Microspheres

Table 6: Drug Entrapment Efficiency of Microspheres

Formulation	Entrapment Efficiency (%) (Mean ± S.D.)
F1	71.4 ± 1.9
F2	73.2 ± 2.0
F3	75.6 ± 1.8
F4	78.1 ± 2.1
F5	80.7 ± 1.7
F6	77.3 ± 1.9
F7	82.4 ± 2.0
F8	84.8 ± 1.8
F9	87.1 ± 2.1
F10	89.5 ± 1.7
F11	86.3 ± 1.9
F12	88.2 ± 2.0

of Microspheres

Table 7: **Swelling Index (%)**

Formulation	Swelling (Mean ± S.D.)
F1	129.4 ± 3.5
F2	134.7 ± 3.6
F3	141.2 ± 3.9
F4	148.6 ± 4.1
F5	157.4 ± 4.0
F6	144.3 ± 3.8
F7	165.2 ± 4.3
F8	172.8 ± 4.2
F9	180.6 ± 4.5
F10	188.3 ± 4.4
F11	176.5 ± 4.1
F12	183.9 ± 4.3

In-vitro Buoyancy of Floating Microspheres

Table 8: In-vitro Buoyancy of Floating Microspheres

Formulation	Floating Microspheres (%)	Settled Microspheres (%)
F1	68.4 ± 1.8	31.6 ± 1.8
F2	70.7 ± 1.9	29.3 ± 1.9
F3	73.5 ± 2.0	26.5 ± 2.0
F4	76.2 ± 2.1	23.8 ± 2.1
F5	79.6 ± 1.7	20.4 ± 1.7
F6	74.8 ± 1.9	25.2 ± 1.9
F7	82.1 ± 2.2	17.9 ± 2.2

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F8	84.7 ± 2.0	15.3 ± 2.0
F9	87.3 ± 1.8	12.7 ± 1.8
F10	89.6 ± 1.7	10.4 ± 1.7
F11	85.4 ± 1.9	14.6 ± 1.9
F12	88.1 ± 2.1	11.9 ± 2.1

In-vitro Drug Release of Floating Microspheres (% Cumulative Drug Release)

Table 9: In-vitro Drug Release of Floating Microspheres

Time (hr)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
1	11.6	12.4	13.8	14.7	15.5	14.1	16.4	17.6	18.9	19.7	18.1	19.2
2	19.8	21.2	23.5	24.9	26.4	24.1	28.2	29.6	31.8	33.4	30.9	32.2
3	29.4	31.1	33.7	35.8	38.2	34.5	40.1	42.7	45.3	47.1	43.8	45.9
4	38.6	41.3	44.9	47.8	50.6	46.2	53.7	56.4	59.2	61.8	57.5	59.8
5	47.9	50.8	54.3	57.6	60.9	55.4	64.2	67.3	70.1	72.8	68.6	71.0
6	56.7	60.1	63.9	67.5	71.4	65.2	74.3	77.8	80.6	83.1	78.4	80.9
8	70.2	73.4	77.6	81.5	85.3	79.1	88.6	91.4	94.1	96.2	92.7	94.3
10	80.4	83.6	87.5	90.8	93.7	88.6	95.8	97.3	98.4	99.1	97.6	98.5
12	88.1	90.6	93.8	96.4	98.2	94.9	98.7	99.2	99.6	100	99.1	99.4

Stability Study of Optimized Floating Microspheres (F10)

Table 10: Stability Study of Optimized Floating Microspheres (F10)

Time (Months)	Appearance	Drug Content (%)	Entrapment Efficiency (%)	In-vitro Buoyancy (%)	% Drug Release (12 hr)
0	Creamish, free-flowing microspheres	100.3 ± 0.9	89.5 ± 1.7	89.6 ± 1.7	100
1	No visible change	99.7 ± 0.8	88.9 ± 1.6	88.8 ± 1.8	99.2
2	No visible change	99.1 ± 0.9	88.1 ± 1.8	88.0 ± 1.7	98.6
3	No visible change	98.6 ± 1.0	87.4 ± 1.9	87.2 ± 1.8	97.9

IV. CONCLUSION

The present study successfully developed floating gastroretentive microspheres containing Gabapentin and Nortriptyline using the solvent evaporation technique. The prepared microspheres exhibited satisfactory micromeritic properties, appropriate particle size distribution, and good flow characteristics. Increasing polymer concentration significantly influenced particle size, swelling behavior, drug entrapment efficiency, and drug release profile. Among all the formulations, formulation F10 demonstrated optimal characteristics including high entrapment efficiency, excellent buoyancy, and sustained drug release for up to 12 hours. The in-vitro drug release studies indicated a controlled diffusion-based release mechanism from the polymeric matrix. Stability studies confirmed that the optimized formulation remained stable without significant changes in drug content, buoyancy, or release profile. Overall, the developed floating gastroretentive microspheres represent a promising drug delivery approach for improving gastric retention and achieving sustained release of anticonvulsant drugs. This system may enhance therapeutic efficacy and patient compliance by reducing dosing frequency and maintaining prolonged drug availability in the gastrointestinal tract.

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