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Review

Formulation and Evaluation of Lacosamide Loaded Gastro-Retentive Drug Delivery System

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Abstract

Lacosamide, an antiepileptic drug, requires sustained release and gastroretentive delivery to improve therapeutic consistency. Floating tablets provide prolonged gastric residence and controlled drug release, enhancing bioavailability. To formulate and evaluate floating tablets of lacosamide using hydrophilic and rate-modifying polymers, optimizing buoyancy and drug release kinetics. Nine formulations (LGT1–LGT9) were prepared employing HPMC K15M and Kollidon SR, selected based on floating lag time and total floating duration results. HPMC K15M was chosen as the primary hydrophilic polymer in line with previous reports. All formulations were subjected to physicochemical evaluation including weight variation, hardness, friability, thickness, and drug content, which were within pharmacopeial limits. Floating parameters such as lag time and total floating time (>8 h) were assessed, and in vitro drug release was carried out in 0.1N HCl for 12 h. Optimized formulations exhibited rapid buoyancy with sustained floating for more than 8 h. The drug release extended up to 12 h, with most batches following zero-order kinetics and demonstrating non-Fickian diffusion. Among the tested formulations, the optimized batch showed desirable floating behavior and controlled release, making it suitable for sustained therapeutic action. Floating tablets of lacosamide formulated with HPMC K15M and Kollidon SR demonstrated robust physicochemical properties, prolonged gastric retention, and sustained drug release up to 12 h. The optimized formulation offers a promising gastroretentive system for enhancing lacosamide bioavailability and patient compliance.

Keywords: Floating tablets; HPMC K15M; Zero-order kinetics; Buoyancy; Antiepileptic drug.

Introduction:

Epilepsy is a long-term neurological disorder that causes seizures that happen again and again without any obvious cause. These seizures are caused by abnormal activity in the brain's neurons and affect millions of people around the world.[1] They greatly lower the quality of life. Long-term pharmacotherapy with antiepileptic drugs is the main way to treat epilepsy. This is because effective seizure control depends on keeping plasma drug levels steady within a narrow therapeutic window.[2] Nevertheless, traditional oral dosage forms frequently demonstrate constraints, including brief gastric residence time, inconsistent gastrointestinal transit, and erratic drug absorption affected by physiological and dietary variables, resulting in variable plasma drug concentrations. These changes can make the treatment less effective, cause breakthrough seizures, increase side effects, and require more frequent dosing, which makes it harder for patients to stick to their treatment plan.[3] So, we really need better ways to deliver drugs that can give patients with epilepsy long-lasting effects, make drugs more available, reduce changes in plasma levels, and improve long-term treatment outcomes.

Lacosamide is a third-generation antiepileptic drug that works by selectively speeding up the slow inactivation of voltage-gated sodium channels.[4] This helps stabilize hyperexcitable neuronal membranes without having a big effect on normal neuronal signaling. Because of this unique way of working, lacosamide is very effective at treating partial-onset seizures. It is often prescribed alone or with other antiepileptic drugs.[5] Clinically, lacosamide is valued for its favorable pharmacological and safety profile, including minimal drug–drug interactions and good tolerability. However, lacosamide has only moderate oral bioavailability and a short biological half-life, which means that it needs to be taken often to keep plasma concentrations high enough to be effective.[6] These kinds of dosing schedules could cause drug levels to change, which could make seizures harder to control or cause more side effects that are related to the dose. Also, the need for multiple doses each day can make it harder for patients to stick to their treatment, especially if they are on it for a long time. These limitations highlight the necessity of creating a modified or regulated drug delivery system for lacosamide that can maintain therapeutic drug concentrations, decrease dosing frequency, enhance patient adherence, and improve overall treatment effectiveness.[7]

Gastro-retentive drug delivery systems (GRDDS) have become a successful way to make drugs more available in the body that are better absorbed from the upper gastrointestinal tract or dissolve better in acidic environments.[8] By extending the duration of gastric residence time, GRDDS can facilitate sustained drug release, decrease dosing frequency, and enhance therapeutic efficacy. Floating drug delivery systems have gotten a lot of attention among different gastro-retentive methods because they are simple, safe, and can stay buoyant in stomach fluids without getting in the way of stomach emptying.[9]

The current study focuses on the development and thorough assessment of lacosamide-loaded gastro-retentive drug delivery systems intended to prolong gastric residence time and facilitate controlled drug release. We chose the right polymers to make formulations that could stay buoyant in the stomach, which would keep the drug in the stomach longer and make it work better. We used hydrophilic polymers like hydroxypropyl methylcellulose and other rate-controlling agents to make a low-density, swellable matrix system that helps tablets float and controls the release of lacosamide over a long period of time.[10] When these polymers come into contact with gastric fluid, they absorb water and form a gel barrier. This not only makes the tablet less dense, but it also changes how the drug diffuses and how the matrix erodes, which leads to a steady release of the drug.[11] The gastro-retentive systems that were made were carefully tested for a number of physicochemical properties, such as weight change, hardness, friability, and drug content uniformity. They were also tested for how they floated in vitro, including how long they floated and how long they stayed afloat. Furthermore, in vitro drug release and stability studies were performed to evaluate the release kinetics, formulation robustness, and long-term stability, thereby establishing the developed system's efficacy as a gastro-retentive delivery method for lacosamide.

Material:

Lacosamide was procured from Cipla Ltd., Hyderabad. Hydroxypropyl methylcellulose (HPMC K15M) was obtained from Colorcon Asia Pvt. Ltd., Hyderabad, and sodium bicarbonate was sourced through the Hyderabad distributor of Loba Chemie Pvt. Ltd. Citric acid (anhydrous) was supplied by S.D. Fine Chemicals (SDFCL), Hyderabad. Carbopol 934P was procured from Lubrizol Advanced Materials, Hyderabad, while polyvinylpyrrolidone (PVP K30) was obtained from BASF India Ltd., Hyderabad.

Methodology

Formulation of Floating Tablet of Lacosamide

The weighed amounts of Lacosamide, polymers (like HPMC K15M and Kollidon SR), diluent (MCC), and gas-generating agents (sodium bicarbonate and citric/tartaric acid) in a glass mortar and pestle until they were all the same. After that, the powder mixture was coated with 1% w/w magnesium stearate and 2% w/w talc (or aerosil).[12] The lubricated mixture was tested for

pre-compression factors like angle of repose, bulk density, tapped density, Carr's index, and Hausner ratio.Using a single-punch tablet compression machine (Cadmach, Ahmedabad, India), the final blend was compressed into tablets using the direct compression method. When flowability was low, wet granulation with PVP K-30 in isopropyl alcohol was used. This was followed by drying and sieving before lubrication. [13]

Table No: 1 Formulation table for Lacosamide Floating Tablet

Ingredients(mg)	**LGT1**	**LGT2**	**LGT3**	**LGT4**	**LGT 5**	**LGT6**	**LGT7**	**LGT8**	**LGT9**
Locosamide	100	100	100	100	100	100	100	100	100
MCC	90	65	40	80	55	60	70	75	50
Povidone K-30	15	15	15	15	15	15	15	15	15
(HPMC K 15M)	50	60	70	60	70	50	70	50	60
Kollidon SR	50	55	60	50	55	60	50	55	60
Sodium bicarbonate	35	45	55	35	45	55	35	45	55
Citric Acid	5	5	5	5	5	5	5	5	5
Magnesium Stearate	5	5	5	5	5	5	5	5	5
Total weight (mg)	**350**	**350**	**350**	**350**	**350**	**350**	**350**	**350**	**350**

LGT= Locosamide Gastroretentive Tablet

Evaluation of Gastro retentive Floating Tablet of Lacosamide

Post compression parameters:

The prepared tablets were evaluated for quality control tests like weight variation, hardness, thickness, friability and content uniformity.[14]

Weight variation:

Ten tablets were selected randomly from each batch and weighed individually, calculating the average weight and comparing the individual tablet weight to the average. From this; percentage weight difference was calculated and then checked for USP specifications.[15]

Hardness and friability:

Hardness of tablet was determined by Monsanto hardness Tester. Ten tablets were randomly picked from each batch and analyzed for hardness. The mean and standard deviation were also calculated. Friability test was done by Roche friabilator. Ten tablets were weighed and were subjected to the combined effect of attrition and shock by utilizing a plastic chamber that revolve at 25 rpm dropping the tablets at distance of 6 in. with each revolution. Operated for 100 revolutions, the tablets were de-dusted and reweighed. The percentage friability was calculated.[16]

In vitro buoyancy studies:

The in vitro buoyancy was evaluated by measuring the floating lag time (FLT), following the method described by Rosa et al. Tablets were placed in a 250 ml beaker containing 200 ml of 0.1 N HCl. The time required for the tablet to rise to the surface and float was recorded as the Floating Lag Time (FLT), while the duration the tablet remained buoyant was recorded as the Total Floating Time (TFT).[17]

In vitro Dissolution Studies:

For the in vitro dissolution studies, a United States Pharmacopeia (USP) type II (paddle) apparatus was used, set to a rotational speed of 100 rpm. The dissolution medium consisted of 900 ml of 0.1 N HCl, maintained at a temperature of 37°C ± 0.5°C. At specified intervals over a 12-hour period, 10 ml samples were withdrawn from the dissolution apparatus and replaced with pre-warmed fresh

dissolution medium. These samples were filtered using Whatman filter paper, diluted to an appropriate concentration with 0.1 N HCl, and their absorbance was measured with a UV spectrophotometer.[18]

Drug Release Kinetics:

To establish the order and mechanism of drug release, dissolution data of the optimized batches were fitted to four different kinetics models, namely, zero order model, first order model, Higuchi model and Korsmeyer peppas model. The model for best it was predicted from the value of R^2. For an ideal it, value of R^2 was 1. Hence, the model which gives the R^2 values nearest to 1 describe the order drug release. Zero order drug release and followed Higuchi model describing drug release from polymeric matrix.[19,20]

RESULTS & DISCUSSION

FTIR Pure Lacosamide

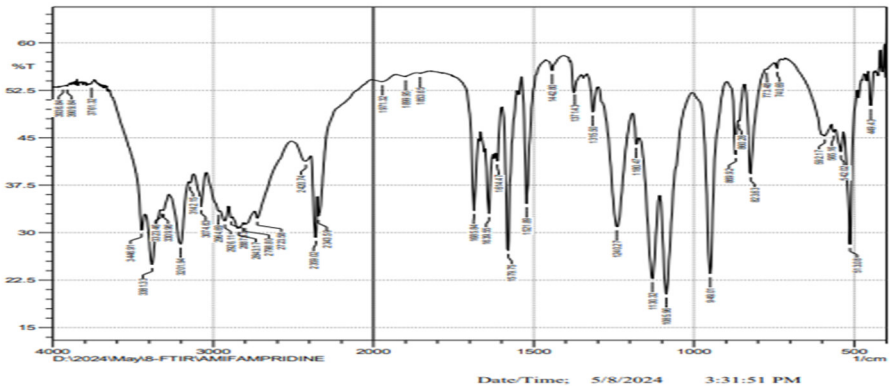

Figure No: 1 FTIR of Pure Lacosamide

The FTIR spectrum of lacosamide exhibited (**Fig: 1**) characteristic absorption bands confirming its structural integrity. A broad peak around 3300 cm^{-1} corresponds to N–H stretching vibrations of the primary amine group. A sharp band near 1650 cm^{-1} is attributed to the C=O stretching of the amide functionality, while peaks in the 1500–1600 cm^{-1} region indicate aromatic C=C stretching. Additional bands between 1200–1300 cm^{-1} and 700–900 cm^{-1} confirm C–N stretching and aromatic C–H bending, respectively. These spectral features collectively validate the presence of amide, amine, and aromatic groups, consistent with the molecular structure of lacosamide.

Table No: 2 Pre compression Results of Lacosamide Floating Tablet

Formulation	Carr's Index	Angle of Repose	Hausner Ratio
LGT1	11.6	23.8	1.16
LGT2	12.6	27.5	1.14
LGT3	12.5	28.0	1.13
LGT4	15.9	29.4	1.18
LGT5	12.4	28.5	1.14
LGT6	11.2	29.4	1.13
LGT7	15.7	28.4	1.12

LGT8	10.5	22.0	1.10
LGT9	14.6	27.5	1.15

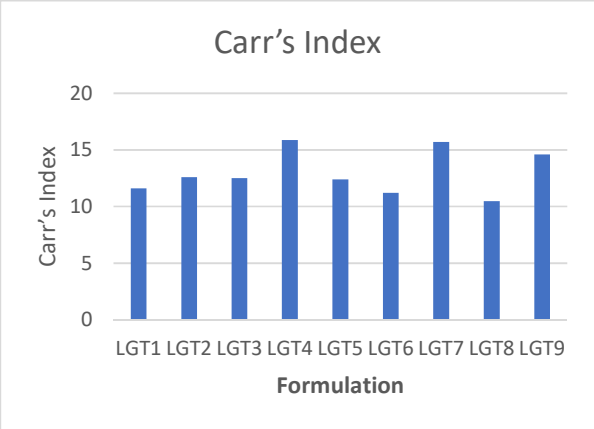

Figure No: 2a Carr's Index

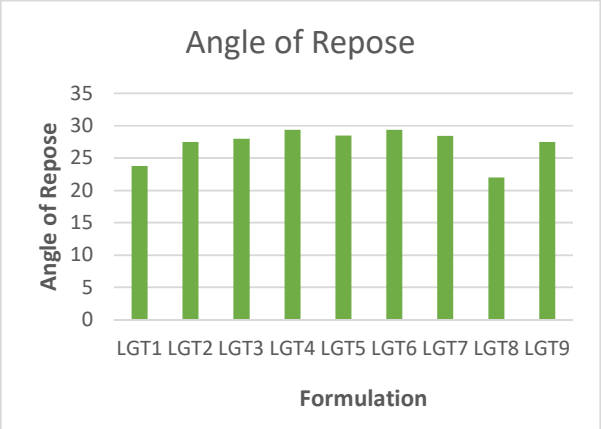

Figure No: 2b Angle of Repose

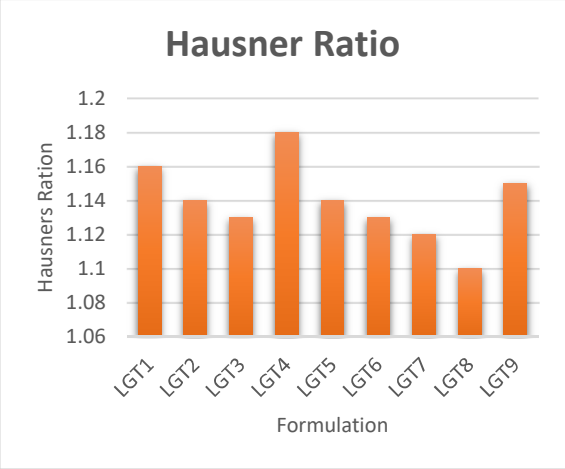

Figure No: 2c Hausner Ratio

The pre-compression parameters of all nine formulations (LGT1–LGT9) were systematically assessed (**Table:2**) to determine their suitability for direct compression and floating tablet manufacture. The evaluation focused on Carr's Index, Angle of Repose, and Hausner Ratio, which are widely recognized indicators of powder flowability, packing efficiency, and compressibility. Carr's Index values ranged between 10.5 and 15.9(**Fig.2a**) placing most formulations within the "good" to "fair" flowability category. A lower Carr's Index reflects better packing and compressibility. Among the formulations, LGT8 (10.5) exhibited the lowest value, suggesting excellent compressibility and minimal interparticle voids, which is advantageous for uniform tablet weight and mechanical strength. Angle of Repose values(**Fig.2b**) varied from 22.0° to 29.4°, all within acceptable pharmaceutical limits (LGT8 (22.0°) demonstrated the most favourable angle, confirming superior flow properties compared to other batches. This ensures consistent die filling during compression, reducing variability in tablet mass. Hausner Ratio values(**Fig.2c**) ranged between 1.10 and 1.18, further supporting acceptable flow characteristics across all formulations. A Hausner Ratio close to 1.00 indicates minimal interparticle friction and better flowability. LGT8

(1.10) again stood out as the most favorable, reflecting excellent powder handling and reduced risk of segregation during processing.

Table No: 3 Post Compression results of Lacosamide Floating Tablet

Formulation	Weight variation(mg)	Hardness(kg/cm^2	Friability(%)	Drug content (%)
LGT1	351	5.5	0.02	98.23
LGT2	352	5.2	0.02	97.83
LGT3	348	5.4	0.05	98.65
LGT4	352	4.8	0.03	93.33
LGT5	351	5.0	0.04	92.12
LGT6	348	4.9	0.07	96.64
LGT7	349	5.1	0.03	98.72
LGT8	350	4.6	0.01	99.45
LGT9	352	5.4	0.03	96.73

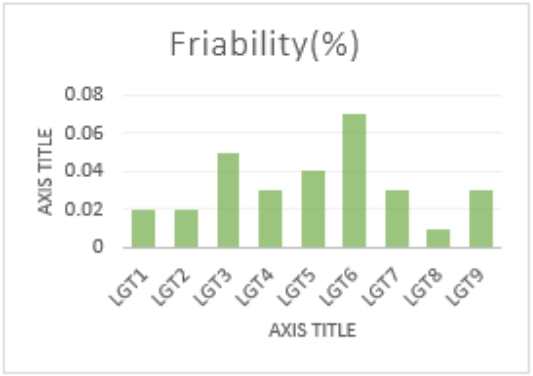

Figure No: 3a Weight variation(mg)

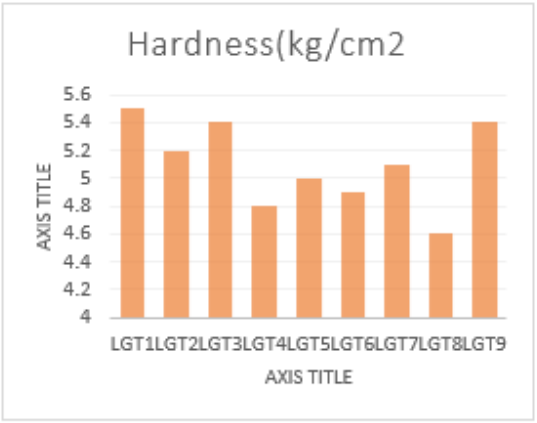

Figure No: 3b Hardness(kg/cm2)

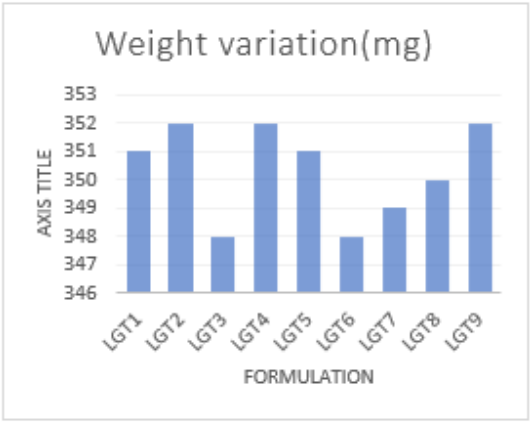

Figure No: 3c Friability (%)

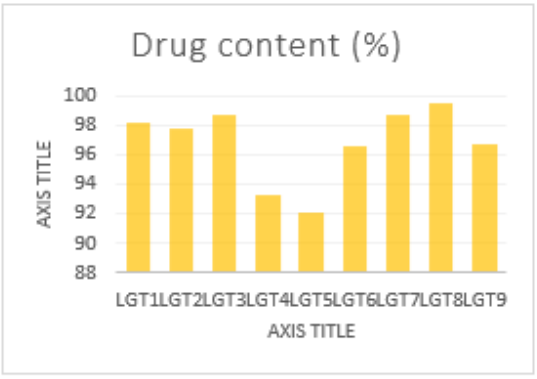

Figure No: 3d Drug content (%)

The post-compression evaluation of Lacosamide floating tablet formulations (LGT1–LGT9) revealed (**Table:3**) consistent weight variation(**Fig.3a**) within the acceptable range (348–352 mg), confirming uniform die filling. Hardness values (4.6–5.5 kg/cm²) indicated adequate mechanical strength(**Fig.3b**), with LGT1 showing the highest and LGT8 the lowest. Friability(**Fig.3c**) was remarkably low across all batches (0.01–0.07%), well below the pharmacopeial limit of 1%, demonstrating excellent resistance to mechanical stress. Drug content(**Fig.3d**) ranged from 92.12% to 99.45%, with most formulations falling within acceptable limits; however, LGT4 and LGT5 showed slightly lower values, suggesting the need for blending optimization. Overall, the tablets exhibited satisfactory pharmaceutical quality, with LGT8 standing out due to its optimal friability and highest drug content, despite slightly lower hardness.

Table No: 4 In-vitro buoyancy Results of Floating Tablets of Lacosamide

Formulation	Floating Lag time (seconds)	Total floating time (hours)
LGT1	16	>12
LGT2	19	>12
LGT3	10	>12
LGT4	22	>12
LGT5	15	>12
LGT6	14	>12
LGT7	15	>12
LGT8	8	>12
LGT9	11	>12

The in-vitro buoyancy evaluation of Lacosamide floating tablet formulations (LGT1–LGT9) demonstrated **(Table: 4)** that all batches exhibited excellent floating behavior, with total floating times exceeding 12 hours, confirming their suitability for sustained gastric retention. Floating lag times varied between 8 and 22 seconds, indicating rapid buoyancy initiation across formulations. Among them, LGT8 showed the shortest lag time (8 seconds), reflecting the most immediate buoyancy, while LGT4 exhibited the longest lag time (22 seconds), though still within acceptable limits. Overall, the results confirm that the formulations possess desirable buoyancy characteristics, ensuring prolonged gastric residence and potential enhancement of drug bioavailability.

Table No: 5 In vitro Release Profile for Lacosamide Floating Tablets(LGT1 to LGT5)

Time	LGT1	LGT2	LGT3	LGT4	LGT5
0	0	0	0	0	0
0.5	15.21	14.12	9.23	7.14	6.95
1	26.32	20.57	13.44	11.84	13.42
2	39.81	32.15	24.26	19.23	24.38
3	42.12	47.23	33.48	26.56	32.42

4	49.27	51.21	46.84	35.28	43.61
6	53.01	56.21	51.02	58.1	50.12
8	62.38	78.45	72.64	72.58	72.23
10	79.47	81.33	79.24	81.44	81.28
12	84.32	85.33	81.32	90.34	84.12

Table No: 6 In vitro Release Profile for Lacosamide Floating Tablets(LGT6 to LGT9)

Time	LGT6	LGT7	LGT8	LGT9
0	0	0	0	0
0.5	15.21	14.12	15.21	7.14
1	26.32	20.57	26.32	11.84
2	39.81	32.15	39.81	19.23
3	42.12	47.23	42.12	26.56
4	49.27	51.21	49.27	35.28
6	58.1	56.21	58.1	58.1
8	72.58	78.45	72.58	72.58
10	81.44	81.33	81.44	81.44
12	90.04	89.32	99.34	92.34

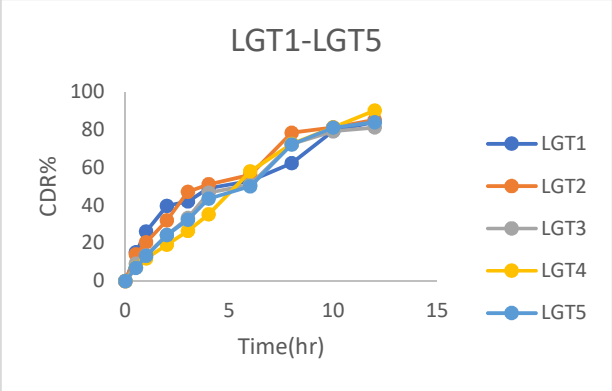

Figure No: 4a Drug release of LGT1-LGT5

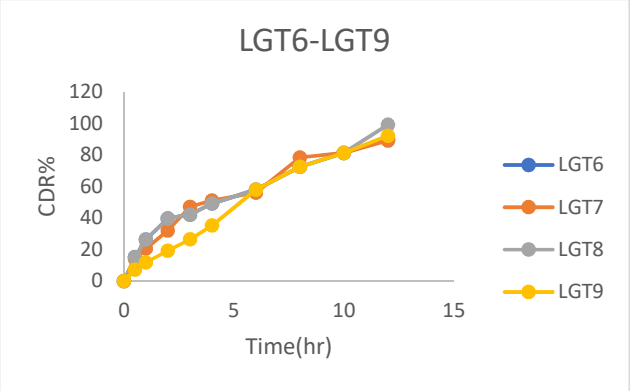

Figure No: 4b Drug release of LGT6-LGT9

All formulations showed a slow and steady release of the drug over 12 hours, which showed that they had controlled release behavior. (**Fig. 4a,4b**) The initial release at 0.5 h was low (6.95–15.21%), which means there was not much of a burst effect. By 2 hours, the release was between 19.23 and 39.81%, which showed steady progress. Values in the middle (4–6 h) showed a moderate release (35.28–58.10%), which made sure that delivery would last longer. Most formulations released more than 70% of their contents after 8 hours. LGT2, LGT7, and LGT8 had higher values (78–99%). The final release at 12 hours ranged from 81.32% (LGT3) to 99.34% (LGT8), showing that the product has a great ability to release over time. Overall, all batches had long-lasting drug release.

LGT8 had the highest cumulative release (99.34%), while LGT3 and LGT5 had slightly lower but still acceptable profiles.

Table No: 7 Release kinetics Study of Lacosamide Floating Tablets

Formulationcode	r^2			
	Zero	First	Higuchi	Korsmeyer& Peppas
LGT1	0.90	0.89	0.91	0.96
LGT2	0.93	0.92	0.94	0.92
LGT3	0.92	0.92	0.92	0.92
LGT4	0.91	0.94	0.95	0.97
LGT5	0.93	0.76	0.95	0.96
LGT6	0.89	0.91	0.95	0.93
LGT7	0.90	0.94	0.95	0.94
LGT8	0.99	0.91	0.96	0.92
LGT9	0.91	0.97	0.95	0.98

The kinetic analysis of Lacosamide floating tablets demonstrated (**Table: 7**) that the majority of formulations displayed a greater correlation with Zero order and Higuchi models, suggesting a controlled and diffusion-based release mechanism. Zero order fitting worked especially well for LGT8 ($r^2 = 0.99$), which showed that the drug would still be released even if the concentration changed. The Higuchi model values ($r^2 = 0.91–0.96$) for all formulations back up the idea that the matrix system controls the release of the drug through diffusion. The Korsmeyer–Peppas model exhibited a strong correlation ($r^2 = 0.92–0.98$), with LGT1, LGT4, LGT5, and LGT9 showing the highest values. This indicates unusual (non-Fickian) transport that involves both diffusion and erosion. LGT5 did not fit well with the First order model ($r^2 = 0.76$), which supports its Zero order release pattern. In general, the data show that the formulations mostly follow Zero order and Higuchi kinetics, with some contributions from strange transport as shown by the Korsmeyer–Peppas model. This makes sure that the drug is released steadily and in a controlled way.

Conclusion

HPMC K15M and Kollidon SR were selected for developing the optimized floating tablet based on floating lag time and total floating time. HPMC K15M was chosen as the hydrophilic rate-controlling polymer due to its proven controlled drug release properties. All formulations (LGT1–LGT9) met pharmacopeial limits for physicochemical parameters. The tablets showed satisfactory floating behavior with short lag times and total floating time exceeding 8 hours. In-vitro drug release studies in 0.1 N HCl indicated that most formulations followed zero-order kinetics. Among them, LGT8 was optimized, showing 99.34% drug release at 12 hours, minimal floating lag time (8 seconds), and acceptable drug content.

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