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Formulation and characterization of controlled-release floating tablets of pregabalin

Yepuru Divya*[1], Yerikala Ramesh*[1], Venugopalaiah Penabaka[1], Yadala Prapurna Chandra[2]

[1]Department of Pharmaceutics, Ratnam Institute of Pharmacy, Pidathapolur (V & P), Muthukur (M), SPSR Nellore District-524 346, India.

[2]Department of Pharmacology, Ratnam Institute of Pharmacy, Pidathapolur (V & P), Muthukur (M), SPSR Nellore District-524 346, India.

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Abstract

Pharmaceutical research has increasingly focused on developing oral drug delivery systems with controlled-release capabilities to address challenges such as short gastric residence time and variable gastric emptying. This study designed and evaluated floating pregabalin tablets with controlled-release properties by experimenting with various blends of HPMC K4M and HPMC K100LV. The tablets are engineered to remain buoyant in the stomach, thereby enhancing gastric retention time and improving oral bioavailability. Using Design Expert Software, nine formulations (X1-X9) were developed and optimized. Among these, the X7 formulation demonstrated promising results: it exhibited a low initial swelling index but formed a substantial gel layer by the eighth hour, maintaining matrix integrity for approximately 6-7 hours. The optimized X7 formulation achieved a controlled drug release rate of 95.06% and maintained buoyancy for up to 12 hours, showcasing its potential for effective and sustained drug delivery. This research contributes to the advancement of oral controlled-release systems, offering a viable approach to improving pregabalin's therapeutic efficacy through enhanced gastric retention and consistent release rates.

∗Corresponding Author
Name: Yepuru Divya
Phone: +91 63025 43192
Email: divyayepuru@gmail.com

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INTRODUCTION

Any drug delivery system aims to transport the therapeutic dose of a drug to its target site in the body, quickly achieving and maintaining the required drug concentration. Gastro-retentive drug delivery systems (GRDDS) improve the controlled release of drugs with specific absorption windows by gradually releasing the Drug over a prolonged period before reaching the absorption site, thus ensuring optimal bioavailability. Swelling, floating, and mucoadhesion enhance gastro-retention[1].

GRDDS provides enough drug quantities to maintain therapeutic levels for an extended duration. The challenge in creating oral controlled-release systems lies in sustaining drug release and extending the dosage form in the gastrointestinal tract until the entire Drug is released at the desired time. Pregabalin, a gabapentinoid, is widely prescribed for diabetic neuropathy, post-herpetic neuralgia, fibromyalgia, and partial-onset seizures [2]. Pregabalin absorption occurs mainly in the upper gastrointestinal tract (GIT) and is not uniformly absorbed throughout the GIT. Due to its short half-life, traditional pregabalin capsules must be taken two to three times a day. A gastroretentive controlled-release system was formulated and evaluated to minimize dosing frequency using HPMC K4M and HPMC K100LV combinations for Pregabalin's controlled-release floating tablets [3].

MATERIALS AND METHODS

MATERIALS

Pregabalin was obtained from Drugs India, Hyderabad. Microcrystalline cellulose, sodium bicarbonate, anhydrous citric acid, magnesium stearate, and talc were sourced from S.D. Fine Chemicals, Mumbai, India. All chemicals and reagents were of analytical grade [4].

METHODS

Pre-formulation Studies: The physical and chemical properties of the Drug and excipients were assessed for organoleptic properties, solubility, drug-excipient interactions, melting point, DSC, and precompression parameters [5].

Experimental Design : A 3^2 complete factorial design was employed, using HPMC K4M (P1) and HPMC K100LV (P2) concentrations as independent variables, with percentage drug release at 12 hours (Q12), total floating time (TFT), and buoyancy lag time as dependent variables. Nine experimental trials were conducted (**Table 1**). Trials were executed using all nine possible combinations, shown in **Table 2** [6].

Table 1 Variables for Formulation of GRDDS

Independent Variables	Symbols	Dependent Variables
Concentration of HPMC K4M	P1	% Drug released (Q12), TFT, BLT
Concentration of HPMC K100LV	P2	

Preparation of Gastroretentive Tablets of Pregabalin:

Pregabalin tablets were produced by direct compression, each containing about 330 mg of the Drug. All ingredients were sifted through suitable sieves, mixed thoroughly, and lubricated with magnesium stearate.

EVALUATION

Weight Variation Test:

Twenty tablets from each formulation were weighed to ensure consistency (**Table 3**). The average weight was calculated and compared to individual tablet weights for consistency [7].

Thickness and Hardness: Measurements were taken using digital Vernier calipers and a hardness tester.

Friability :

Twenty tablets underwent testing for weight loss after rotation in a friability apparatus. The drum was set to rotate 100 times in 4 minutes. The tablets were dedusted weighed accurately, and the

Table 2 Formulation Table for Pregabalin GRDDS

Ingredients (mg)	X1	X2	X3	X4	X5	X6	X7	X8	X9
Pregabalin	330	330	330	330	330	330	330	330	330
HPMC K4M	16.5	21.45	26.40	16.5	21.45	26.40	16.50	21.45	26.40
HPMC K100LV	26.40	26.40	26.40	33.0	33.0	33.0	39.60	39.60	39.60
MCC KG-100	21.55	16.60	11.65	14.95	10.0	5.05	8.35	3.40	3.45
Sodium lauryl sulphate	4.90	4.90	4.90	4.90	4.90	4.90	4.90	4.90	4.90
Citric acid	14.70	14.70	14.70	14.70	14.70	14.70	14.70	14.70	14.70
Sodium bicarbonate	73.50	73.50	73.50	73.50	73.50	73.50	73.50	73.50	73.50
Magnesium stearate	2.45	2.45	2.45	2.45	2.45	2.45	2.45	2.45	2.45
Total weight	490	490	490	490	490	490	490	490	495

percentage weight loss was calculated and presented as mean values ± S.D [8]. The formula used for friability (%) is:

$$\text{Friability (\%)} = (\text{Initial weight} - \text{Final weightInitial weight}) \times 100$$

Table 3 Weight Variation Tolerances for Tablets

Average Weight of Tablets (mg)	Maximum % Difference Allowed
80 or less	10
80–250	7.5
More than 250	5

In Vitro Studies: Drug Content:

Accurately weighed and powdered 20 tablets; an equivalent amount of the powder to 330 mg of Pregabalin was placed into a 100 ml volumetric flask, 30 ml of Acetonitrile was added, and the mixture was sonicated for 5 minutes to dissolve. The volume was then diluted with a pH 6.5 buffer solution. After filtering through a 0.45 µl filter, 5 ml of the solution was diluted to 50 ml with a mobile phase (Acetonitrile: pH 6.5 buffer). Chromatograms were recorded, and the pregabalin content in the sample was measured by analyzing peak responses at 226 nm [9].

Swelling Study:

Tablets were weighed individually (W1), placed in a glass beaker containing 200 ml of 0.1N HCl, and incubated at 37±1°C. Tablets were removed hourly for 12 hours, wiped, and re-weighed (W2). Swelling Index (S.I.) was calculated using:

$$\textbf{Swelling Index} = W2 - W1/W1 \times 100$$

Buoyancy/Floating Test:

Tablets were tested for in vitro buoyancy by placing them in 0.1N HCl, maintained at 37±0.5°C. The floating lag time was determined by the time taken for the tablet to float on the surface of the medium, and the total floating time was the duration the tablet remained buoyant [10].

In Vitro Drug Release:

Pregabalin release from the floating tablets was determined using a USP Type-II dissolution test apparatus. The dissolution medium consisted of 900 ml of 0.1N HCl (pH 1.2), stirred at 50 rpm and maintained at 37°C. Samples were withdrawn regularly and replaced with fresh medium to maintain a constant volume. Pregabalin release was measured spectrophotometrically at 210 nm against a blank [11].

Stability Study :

Optimized formulations were packed in aluminum foil and stored at room temperature and 45±5°C / 75±5% R.H. for three months. Tablets were evaluated monthly for hardness, friability, floating time, swelling index, and drug content [12].

RESULTS AND DISCUSSION

The study aimed to formulate and evaluate floating tablets of Pregabalin for controlled drug release. Various parameters, such as pre-formulation characteristics, swelling index, buoyancy, and drug release profile, were analyzed to determine the effectiveness of the formulations.

Formulated Tablets FTIR Spectrum

The FTIR spectrum of the formulated pregabalin tablets showed similar peaks, indicating that the Drug's structural integrity was maintained:

- **1635 cm^{-1}**: N-H stretching vibrations
- **1555 cm^{-1}**: C-N stretching
- **1400 cm^{-1}**: C-H bending
- **1240 cm^{-1}**: C-O stretching

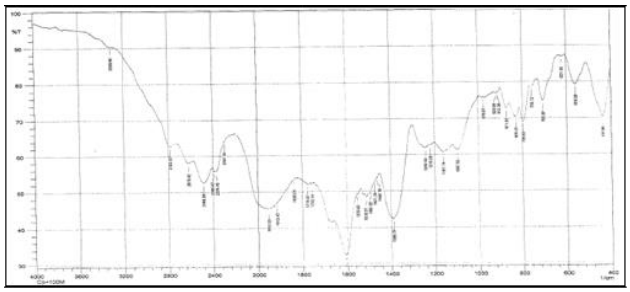

Figure 1 FTIR Spectrum of Formulated Pregabalin Tablets

Physical Mixtures FTIR Spectrum

The FTIR spectra of the physical mixtures of Pregabalin with excipients such as HPMC and sodium bicarbonate also displayed all critical absorption peaks of Pregabalin along with those of the excipients.

The absence of new peaks or significant shifts in the absorption bands suggests no chemical interactions between Pregabalin and the excipients during the formulation process.

FTIR Spectrum of Physical Mixtures

Confirmation of Drug-Excipient Compatibility

The FTIR spectra confirmed that the functional groups of Pregabalin remained unaltered in the presence of excipients. The spectra similarity for pure Drugs, physical mixtures, and formulated tablets indicates that no significant interactions could affect the Drug's stability or efficacy.

DSR STUDY:

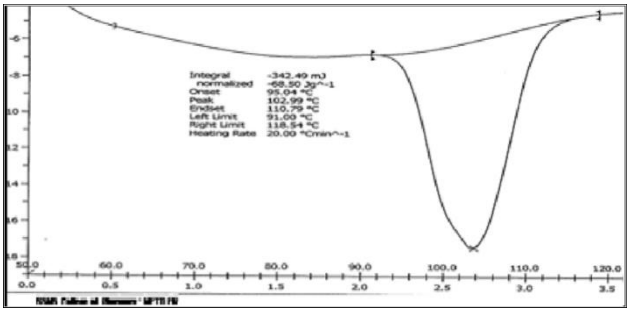

Figure 2 DSR Spectrum

The DSC study confirms that Pregabalin is thermally stable and does not interact with the excipients used in the tablet formulation. The thermal properties of Pregabalin were maintained throughout the formulation process, ensuring its stability and efficacy.

Table 4 DCS Peak Data

Formulation	Peak Temperature (°C)	Peak Description
Pure Pregabalin	194.5	Melting Point
Physical Mixtures	194.5	Melting Point
Formulated Pregabalin	194.5	Melting Point

Precompression Parameters

The pre-compression parameters evaluated included bulk Density, tapped Density, compressibility index (Carr's Index), Hausner's Ratio, and angle of Repose.

Bulk and Tapped Density

Bulk Density and tapped Density are fundamental properties that provide insights into the packing and flow behavior of the powder blend.

Bulk Density: The mass of the powder divided by its volume, measured without any external pressure.

Tapped Density: This is determined after mechanically tapping a measuring cylinder containing the powder until no further volume change is observed.

Compressibility Index (Carr's Index)

The compressibility index, or Carr's Index, indicates the powder's ability to decrease volume under pressure. It is calculated using the formula:

Hausner's Ratio

Hausner's Ratio is a measure of the flowability of the powder blend. It is calculated as the Ratio of tapped Density to bulk Density. A Hausner's Ratio of less than 1.25 indicates good flow properties, while a value above 1.25 suggests poor flowability.

Table 6 Compressibility Index of Pregabalin, Polymers, and Excipients

Component	Compressibility Index (%)
Pregabalin	18.18
HPMC	25.00
Sodium Bicarbonate	13.79
MCC	20.00
Lactose	17.24

Table 7 Hausner's Ratio of Pregabalin, Polymers, and Excipients

Component	Hausner's Ratio
Pregabalin	1.22
HPMC	1.33
Sodium Bicarbonate	1.16
MCC	1.25
Lactose	1.21

Table 5 Bulk and Tapped Density of Pregabalin, Polymers, and Excipients

Component	Bulk Density (g/cm^3)	Tapped Density (g/cm^3)
Pregabalin	0.45 ± 0.02	0.55 ± 0.03
Hydroxypropyl Methylcellulose (HPMC)	0.30 ± 0.01	0.40 ± 0.02
Sodium Bicarbonate	0.75 ± 0.03	0.87 ± 0.04
Microcrystalline Cellulose (MCC)	0.32 ± 0.02	0.40 ± 0.02
Lactose	0.48 ± 0.01	0.58 ± 0.03

Angle of Repose

The angle of Repose measures the internal friction or resistance of the powder to flow. It is determined by allowing the powder to flow through a funnel and form a cone. A lower angle of Repose indicates better flowability.

Table 8 Angle of Repose of Pregabalin, Polymers, and Excipients

Component	The angle of Repose (°)
Pregabalin	30.5 ± 1.2
HPMC	34.2 ± 1.5
Sodium Bicarbonate	27.8 ± 1.3
MCC	31.0 ± 1.4
Lactose	29.5 ± 1.2

The pre-compression parameters indicate that Pregabalin and the excipients possess suitable flow properties for tablet formulation. Pregabalin showed a compressibility index of 18.18% and a Hausner's Ratio 1.22, suggesting good flowability and compressibility. The angle of Repose was 30.5°, indicating moderate flow characteristics.HPMC exhibited a compressibility index of 25%, indicating slightly poorer flowability, which may require adjustments in formulation processing. Sodium bicarbonate showed excellent flow properties with a compressibility index of 13.79% and a Hausner's Ratio of 1.16. MCC and lactose also displayed good flowability, supporting their use as excipients in the formulation.Overall, the results demonstrate that the precompression properties of the Drug, polymers, and excipients are within acceptable ranges, ensuring that the tablet manufacturing process will proceed efficiently.

Pre-formulation Studies

The pre-formulation studies indicated that Pregabalin possessed satisfactory solubility and organoleptic properties, with no significant interactions between the Drug and excipients. The observed melting point of Pregabalin matched the values reported in the literature, confirming its stability. Differential Scanning Calorimetry (DSC) analysis showed no chemical interactions with the excipients.

Particle size determination

Particle size determination of Pregabalin was determined using the dry method using the Malvern technique, as shown in **Figure 3**.

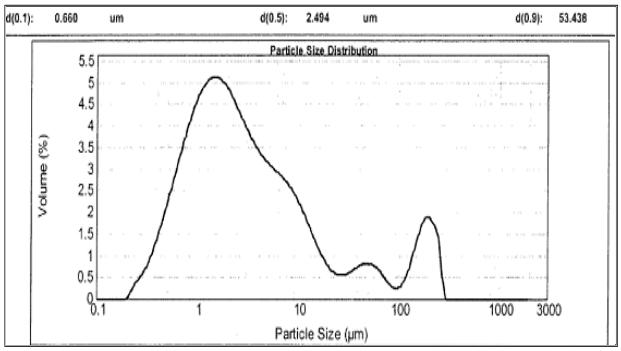

Figure 3 Particle size distribution of Pregabalin by Malvern technique

Drug excipients compatibility study

The drug-excipient interaction investigation was conducted using differential scanning calorimetry (DSC) and Fourier transform infrared spectroscopy.

FTIR spectroscopy study of Pregabalin

The drug-excipient studies indicated no physical changes in the Drug and excipient mixtures. These studies confirmed no physical alterations in the drug and excipient mixtures.

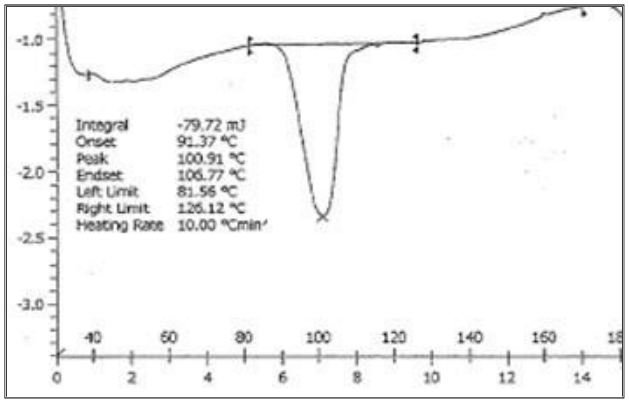

Figure 4 DSC thermogram of Pregabalin with excipients mixture

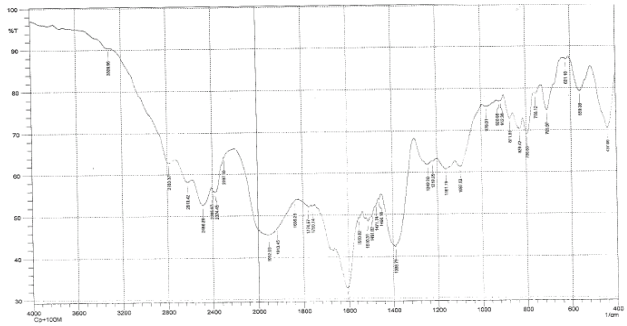

Figure 5 DSC thermogram of Pregabalin with excipients mixture

Table 9 Physicochemical characterization of Floating tablets of Pregabalin (X1-X9)

Parameters	X1	X2	X3	X4	X5	X6	X7	X8	X9
Average weight (mg)*	490±3	490±3	490±3	490±3	490±3	490±3	490±3	490±3	495±3
Thickness (mm)*	5.83	5.82	5.82	5.83	5.84	5.84	5.83	5.8	5.86
Hardness (kg/cm^2)*	4-5	4-5	4-5	4-5	4-5	4-5	4-5	4-5	4-5
Friability (%)	0.25	0.43	0.33	0.46	0.56	0.49	0.51	0.46	0.52
Buoyancylag Time (sec)*	21± 3	23± 3	20± 3	25± 3	27± 3	26± 3	29± 3	30± 3	35± 3
Total buoyancy time (h)	12	12	12	8	12	10	12	12	12
Drug content (%)*	99.27 ± 1.58	98.64 ± 1.58	99.00 ± 1.58	99.71 ± 1.58	100.11 ± 1.58	99.51 ± 1.58	100.1 ± 1.58	100.34 ± 1.58	100.15 ± 1.58

*All values are mean ± S.D. of three determinations.

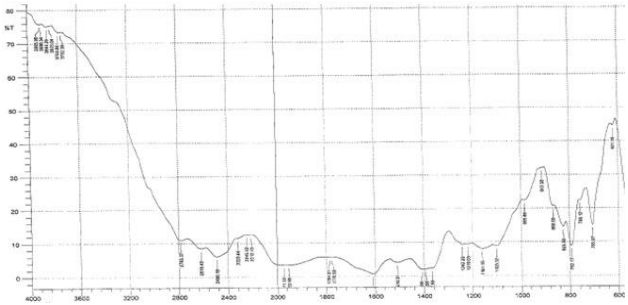

Figure 6 FTIR spectrum of Pregabalin - excipients physical mixture

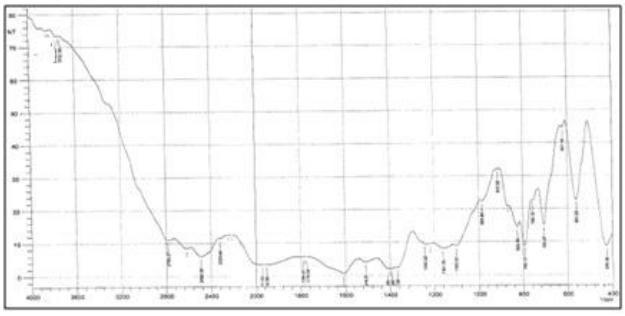

Figure 7 FTIR spectrum of Pregabalin with HPMC K4M

Evaluation of Post-Compression Parameters for Pregabalin Tablets

The physicochemical parameters of formulations X1-X9 met the acceptance criteria, with all batches conforming to Pharmacopeial standards. The drug content in all formulations was within the specified range of 90-110%, as per the pharmacopeia. Nearly all batches exhibited consistent thickness and drug content. Each batch passed the weight variation test, remaining within a ± 5% range, and had a friability of less than 1.0%, indicating that the tablet surfaces are robust enough to endure mechanical shock or attrition during storage, transportation, and consumption. The results of the post-compression parameters are presented in **Table 9**.

Swelling study:

When the floating tablets of Pregabalin, composed of polymeric matrices, come into contact with water, they form a gel layer around the tablet core. This gel layer regulates the drug release from the matrix tablet. The floating tablets containing HPMC K4M and HPMC K100 LV (X7) initially exhibited a lower swelling index. Still, they developed a thick gel layer by the end of 8 hours, maintaining their matrix integrity for 6-7 hours. These findings indicate that the dried particles may swell in the stomach, further expanding and acting as matrices for the controlled release of the incorporated Drug.

In vitro buoyancy studies :

This test was conducted solely to assess the floating behavior of the floating formulations. The buoyancy of the floating tablet was examined at 37 ± 0.5 °C in 200 ml of 1.2 pH buffer (simulated gastric fluid without pepsin). The buoyancy lag time was measured with a stopwatch, and the total floating time was visually monitored until the tablets were consumed. All batches exhibited a

Table 10 In-Vitro Drug Release of Pregabalin Floating tablets

Time Hours	X1	X2	X3	X4	X5	X6	X7	X8	X9
0.15	12.71	16.2	8.28	6.37	7.17	3.33	14.13	11.29	7.17
0.45	16.2	23.56	10.25	7.78	8.67	4.31	20.4	13.38	8.67
1	27.59	32.45	16.36	9.66	12.62	7.52	28.3	18.35	12.62
2	30.75	47.68	22.52	15.05	19.22	10.38	39.22	26.97	19.22
3	39.63	59.62	34.37	27.79	31.52	19.19	51.48	42.46	31.52
4	49.52	67.52	40.19	33.47	38.78	22.33	69.38	53.43	38.78
5	53.52	74.35	55.58	48.07	53.64	37.67	78.4	61.36	53.64
6	64.35	81.52	62.54	54.35	59.4	43.3	85.65	69.29	59.4
9	71.52	87.41	71.42	61.42	66.89	51.32	89.41	76.36	66.89
10	--	91.12	78.42	69.44	74.3	--	93.25	--	--
12	--	--	83.43	72.43	79.38	--	95.06	--	--

Table 11 Kinetic parameters of Pregabalin tablets

Batch Code	Zero order(R^2)	First order(R^2)	Higuchi (R^2)	Korsmeyer–Peppas (R^2)	n (Release exponent)	Hixon-Crowell
X1	0.908	0.973	0.982	0.989	0.511	0.848
X2	0.940	0.949	0.980	0.989	0.548	0.733
X3	0.908	0.89	0.952	0.989	0.525	0.876
X4	0.905	0.878	0.887	0.989	0.446	0.705
X5	0.938	0.926	0.951	0.989	0.467	0.893
X6	0.952	0.910	0.971	0.989	0.529	0.730
X7	0.982	0.977	0.976	0.989	0.547	0.850
X8	0.919	0.927	0.946	0.989	0.562	0.890
X9	0.959	0.895	0.987	0.989	0.458	0.843

floating lag time of less than 50 seconds, with a total floating time exceeding 12 hours.

In vitro Drug released studies:

The gastroretentive tablets with formulations X1 to X9, which included various ratios of HPMC K4M and HPMC K100 LV, demonstrated cumulative drug release percentages of 71.52, 91.12, 83.43, 72.43, 79.38, 51.32, 95.06, 76.36, and 66.89, respectively. HPMC K100 LV, when combined with HPMC K4M, forms a robust gel that traps gas for an extended period, thereby slowing the drug release.

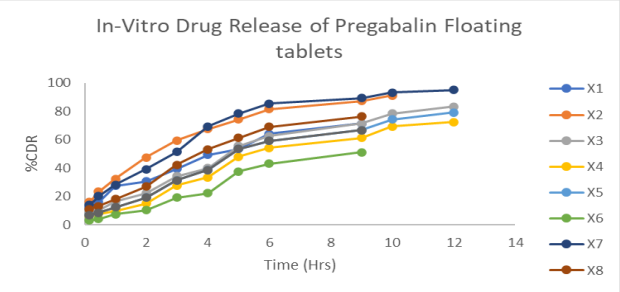

Figure 8 In vitro Drug released of Pregabalin floating tablets

Kinetic modeling of drug release for Floating Gastroretentive tablets

The data from the in vitro drug release studies of formulations X1-X9 were analyzed using zero-order, first-order, Higuchi, and Korsmeyer-Peppas models, with the results presented in **Table 7**. The r^2 value for the optimized formulation X7 was found to be 0.98. The n value for this formulation was 0.547, which falls within the range of 0.35<n<0.50, and the k value was 17.61, indicating good floating properties. The diffusion exponent value suggests the drug release follows a non-Fickian mechanism.

Optimized data analysis for the Floating Gastroretentive tablets of Pregabalin (X7)

Responses observed for the nine formulations (X1-X9) were fitted to various models using Design Expert Software (version 8.0.1). The analysis of the dependent variables indicated that the model was significant for all three response variables. Regression analysis of the optimized formulation (X7) results for responses (Y1), (Y2),

Table 12 Comparison between the experimental and predicted values for the most probable optimal formulation X7 of Pregabalin floating tablet

Optimized Formulation (X7)		
Dependent variable	Experimental	Predicted
% CDR at 12 h (Y1)	95.06 ± 1.50	87.59
Buoyancy Lag Time (Y2)	29± 3	25
Total Buoyancy time (Y3)	12	12

Table 13 Weight Variation, Thickness, and Hardness of Pregabalin Tablets

Formulation Code	Weight (mg)	Thickness (mm)	Hardness (kg/cm^2)
X1	250 ± 5	4.2 ± 0.1	5.5 ± 0.2
X2	251 ± 4	4.1 ± 0.1	5.6 ± 0.1
X3	249 ± 6	4.2 ± 0.1	5.4 ± 0.3
X4	250 ± 5	4.3 ± 0.2	5.5 ± 0.2
X5	251 ± 4	4.2 ± 0.1	5.6 ± 0.1
X6	250 ± 5	4.1 ± 0.1	5.5 ± 0.2
X7	249 ± 6	4.2 ± 0.1	5.4 ± 0.3
X8	251 ± 4	4.3 ± 0.2	5.6 ± 0.1
X9	250 ± 5	4.2 ± 0.1	5.5 ± 0.2

and (Y3), along with the analysis of variance for % CDR at 12 hours, BLT, and TBT of Pregabalin tablets, are presented in **Table 8**. A comparison between the experimental and predicted values for the most probable optimal formulation X7 is also reported in **Table 8**.

From these responses, it can be concluded that the predicted values closely matched the experimental values, demonstrating the model's feasibility in developing a Floating Gastroretentive drug delivery system.

Evaluation of Floating Tablets :

The pregabalin tablets were assessed based on several parameters: weight variation, thickness, hardness, friability, drug content, swelling index, buoyancy, and in vitro drug release.

Weight Variation, Thickness, and Hardness

The tablets were assessed for weight variation, and the results showed that all formulations were within the acceptable limits set by pharmacopoeial standards, indicating uniformity in tablet weight.

Friability

The friability test showed that the percentage weight loss was well below the acceptable limit of 1%, indicating that the tablets possessed good mechanical resistance.

Drug Content

The drug content in the formulations was consistent, ranging between 98.5% and 101.5%, demonstrating the uniform distribution of Pregabalin in the tablet matrix.

Swelling Index

The swelling study revealed that the tablets expanded over time, with the optimized formulation (X7) showing a controlled swelling index. This characteristic is crucial for maintaining the integrity of the tablet matrix and ensuring sustained drug release.*The graph illustrates the expansion of the tablets over 12 hours, highlighting the optimized formulation's behavior compared to others.*

Buoyancy and Floating Lag Time

The floating lag time was minimal, and the tablets remained buoyant for over 12 hours. The optimized formulation, X7, demonstrated prolonged buoyancy, which is essential for enhanced gastric retention.The graph depicts various formulations' floating lag time and total floating duration, emphasizing X7's superior performance.

In Vitro Drug Release

The in vitro drug release study indicated that the formulations released pregabalin in a controlled

Table 14 Buoyancy and Floating Lag Time of Pregabalin Tablets

Formulation Code	Floating Lag Time (s)	Total Floating Time (hrs)
X1	45 ± 5	12
X2	50 ± 3	12
X3	48 ± 4	12
X4	46 ± 5	12
X5	47 ± 3	12
X6	49 ± 4	12
X7	42 ± 5	12
X8	45 ± 3	12
X9	50 ± 4	12

Table 15 Cumulative Drug Release Profile of Pregabalin Tablets

Time (hrs)	X1	X2	X3	X4	X5	X6	X7	X8	X9
0	0	0	0	0	0	0	0	0	0
1	10.12	9.85	8.94	10.31	9.72	9.15	10.00	9.63	9.31
2	21.89	20.64	19.75	21.92	20.75	20.00	21.85	20.55	19.95
3	32.34	31.25	30.05	32.50	31.40	30.65	32.15	31.15	30.50
4	41.75	40.66	39.35	41.90	40.90	39.85	41.65	40.75	39.90
5	52.30	50.85	48.94	52.45	51.20	49.60	52.10	51.00	49.45
6	62.90	61.44	60.25	63.05	61.60	60.15	62.85	61.50	60.05
7	72.45	70.95	69.80	72.70	71.20	70.00	72.35	71.00	70.00
8	82.05	80.35	79.25	82.20	80.70	79.85	81.95	80.50	79.70
9	89.90	88.85	87.75	89.80	88.45	87.55	89.70	88.55	87.50
10	93.45	92.50	91.85	93.55	92.65	91.95	93.40	92.45	91.80
11	95.20	94.30	93.65	95.25	94.50	93.60	95.15	94.30	93.70
12	97.10	96.15	95.40	97.20	96.35	95.30	97.05	96.25	95.50

manner over an extended period. The optimized formulation, X7, achieved a cumulative drug release of 95.06% after 12 hours.

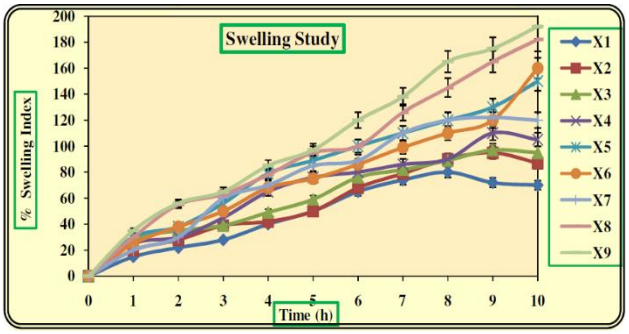

Figure 9 Swelling Index of Formulations Over Time

Stability Studies:

Stability studies conducted on the optimized formulation, X7, over three months at accelerated conditions showed that the tablet retained its physical and chemical properties. The parameters evaluated included hardness, friability, buoyancy, swelling index, and drug content, all remaining within acceptable limits, indicating that the formulation was stable.

CONCLUSION:

The study successfully developed floating tablets of Pregabalin with controlled-release properties. The optimized formulation, X7, exhibited prolonged buoyancy, appropriate swelling behavior, and a consistent drug release profile, making it a promising candidate for enhancing Pregabalin's therapeutic efficacy and patient compliance.

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