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Formulation and Evaluation of Carbamazepine Floating Matrix Sustained-Release Tablets Using Psyllium Husk Approach for Sustained Immunosuppression in Rheumatoid Arthritis

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Abstract: The present study aimed to formulate and evaluate effervescent floating matrix sustained-release tablets of carbamazepine using Eudragit L-100 and psyllium husk as matrix-forming materials. Gastro-retentive floating systems are designed to remain buoyant in gastric contents and release drug over an extended period, potentially supporting delivery to the upper gastrointestinal tract. Five formulations (F1–F5) were prepared by direct compression. Sodium bicarbonate and citric acid were incorporated as gas-generating components, while microcrystalline cellulose, talc and magnesium stearate served as formulation auxiliaries. Powder blends were assessed for flow-related parameters, and the compressed tablets were evaluated for physical quality, drug content, buoyancy, swelling, in-vitro release and drug–excipient compatibility. The source study reports a carbamazepine absorption maximum (λmax) of 283 nm in 0.1 N hydrochloric acid and linearity over 5–20 µg/mL. Drug content across the formulations ranged from 97.18% to 100.4%. Formulation F4 showed a reported buoyancy lag time of 14 seconds, an 8-hour swelling index of 65.57%, and 97.86% drug release at 12 hours. FTIR and DSC observations were interpreted as indicating no significant interaction between carbamazepine and the selected polymers. Based on the reported in-vitro results, F4 was selected as the optimized formulation. Further confirmation, including reproducibility, stability and in-vivo evaluation, is needed before drawing clinical conclusions.

Keywords: Carbamazepine; gastro-retentive drug delivery; floating matrix tablet; sustained release; psyllium husk; Eudragit L-100; effervescence.

ABBREVIATIONS

FDDS, floating drug delivery system; GRDDS, gastro-retentive drug delivery system; GRT, gastric residence time; GIT, gastrointestinal tract; FTIR, Fourier-transform infrared spectroscopy; DSC, differential scanning calorimetry; λmax, wavelength of maximum absorption.

1. INTRODUCTION

Oral administration remains a widely used route for drug delivery because it is convenient and generally acceptable to patients. However, the performance of an oral dosage form depends on drug properties, gastrointestinal physiology, dissolution and the time for which the dosage form remains in the stomach. Rapid gastric emptying may limit the usefulness of conventional formulations for drugs that are preferentially absorbed in the upper gastrointestinal tract or require prolonged local exposure.

Gastro-retentive drug delivery systems (GRDDS) are designed to extend gastric residence and provide controlled release in the stomach or proximal small intestine. Common approaches include floating or low-density systems, high-density systems, expandable and swellable systems, mucoadhesive systems, superporous hydrogel systems and magnetic systems. Floating systems have a bulk density lower than gastric fluid and can remain buoyant while releasing the drug gradually. Effervescent systems generate gas through the reaction of an acid component with sodium bicarbonate; the gas becomes entrapped in the hydrated polymer matrix and reduces the apparent density of the tablet.

Floating formulations may offer sustained drug release, site-directed delivery and reduced dosing frequency. Their performance, however, can be affected by gastric contents, motility, posture, dosage-form size, polymer hydration and the amount of gas generated. A suitable formulation must therefore balance rapid buoyancy, matrix integrity, swelling and controlled drug release.

Carbamazepine is an anticonvulsant used in the management of seizure disorders and certain neuralgic and mood-related conditions. The project document describes carbamazepine as a candidate for a floating sustained-release matrix formulation. The formulation strategy combined Eudragit L-100 with psyllium husk and used an effervescent approach to promote buoyancy.

1.1 Rationale

A polymeric matrix can hydrate in gastric medium and form a gel-like barrier through which dissolved drug diffuses. Psyllium husk was investigated as a natural matrix component alongside Eudragit L-100. The intended outcome was a tablet that floats promptly, swells sufficiently to maintain matrix integrity and releases carbamazepine over a prolonged in-vitro period.

1.2 Aim and objectives

Aim: To formulate and evaluate floating matrix sustained-release tablets of carbamazepine using psyllium husk by direct compression and an effervescent technique.

Objectives: (i) review relevant literature on gastro-retentive delivery; (ii) perform preformulation and drug–polymer compatibility studies; (iii) prepare five formulations with varying polymer and effervescent-agent levels; and (iv) evaluate powder flow, tablet quality, drug content, buoyancy, swelling and in-vitro release.

2. REVIEW OF LITERATURE

Previous work summarized in the source thesis indicates that floating tablets have been explored with a range of drugs and polymer combinations. Studies of clarithromycin floating matrix tablets used hydroxypropyl methylcellulose (HPMC), ethyl cellulose and gas-generating agents, with reported floating durations exceeding 12 hours in the cited work. Pregabalin floating tablets have also been studied with natural gums and synthetic polymers, illustrating how polymer type and concentration can influence release.

Research on imatinib mesylate, troxipide, ranitidine hydrochloride and metronidazole has investigated gastro-floating or sustained-release systems using hydrophilic matrix polymers, sodium bicarbonate and, in some cases, citric acid. The literature summarized in the thesis reports that polymer composition can influence gel formation, buoyancy lag time and the rate of drug release.

The source also cites work on carbamazepine floating tablets using guar gum and sodium bicarbonate, with drug release described as prolonged and diffusion-controlled. Other cited studies investigated psyllium husk in floating formulations, providing a rationale for assessing a natural polysaccharide-containing matrix. These reports support the general formulation concept but do not independently validate the performance of the present batches.

2.1 Study rationale and formulation variables

In the present project, the carbamazepine dose was held constant at 10 mg per tablet. Psyllium husk was increased from 2 to 10 mg across F1–F5, while Eudragit L-100 was decreased from 140 to 100 mg. Sodium bicarbonate was increased from 20 to 40 mg. Citric acid, talc and magnesium stearate were kept constant, while microcrystalline cellulose was adjusted to maintain a nominal tablet weight of 200 mg.

This design allowed the project to examine the combined influence of matrix composition and gas-generating capacity on tablet buoyancy, swelling and release. Because several components changed simultaneously, the results should be interpreted as a comparison of complete formulations rather than as proof of the isolated effect of any single excipient.

2.2 Research question

Can a direct-compression effervescent matrix tablet containing carbamazepine, Eudragit L-100 and psyllium husk achieve acceptable tablet quality, rapid in-vitro buoyancy and sustained drug release, and which of the five trial formulations performs best under the reported test conditions?

3. MATERIALS AND METHODS

3.1 Materials

Carbamazepine was the active pharmaceutical ingredient. The formulation materials listed in the project document were Eudragit L-100, psyllium husk, sodium bicarbonate, citric acid, microcrystalline cellulose, talc and magnesium stearate. The thesis lists suppliers for these materials; supplier details should be verified against laboratory purchase records before submission to a journal.

Material	Function stated or implied in the study
Carbamazepine	Active pharmaceutical ingredient
Eudragit L-100	Matrix-forming / hydrophilic polymer as described in the source
Psyllium husk	Natural sustained-release matrix component
Sodium bicarbonate	Effervescent gas-generating agent
Citric acid	Acid component of the effervescent system
Microcrystalline cellulose	Binding / diluent component
Talc	Glidant
Magnesium stearate	Lubricant

3.2 Instruments

The source document lists an electronic balance, hot-air oven, single-punch tablet compression machine, vernier caliper, Monsanto hardness tester, friability tester, pH meter, disintegration apparatus, dissolution test apparatus, UV-visible spectrophotometer and FTIR instrument. Instrument model numbers and calibration status should be confirmed in the final manuscript where required by the target journal.

3.3 Analytical calibration

Carbamazepine was calibrated in 0.1 N hydrochloric acid. The reported wavelength of maximum absorption was 283 nm, and Beer's law was reported over 5–20 µg/mL. Samples from release testing were analysed by UV-visible spectrophotometry according to the study's stated method. The source document does not provide enough consistently formatted information in the extracted sections to reproduce every calibration equation or all absorbance readings; these should be inserted from the original laboratory records if requested by the journal.

3.4 Drug–polymer compatibility

FTIR spectra of pure carbamazepine and the drug–polymer mixture were compared for retention or meaningful shifts of characteristic functional-group bands. Differential scanning calorimetry was used to compare the thermal behaviour of the pure drug and the selected formulation. The source reports a prominent endothermic peak at approximately 103.4 °C and interprets the observations as showing no significant drug–polymer interaction.

3.5 Formulation of floating tablets

Five effervescent floating matrix tablet formulations (F1–F5) were prepared by direct compression. The nominal weight of each tablet was 200 mg. The ingredient quantities reproduced below are those stated in the source document.

Ingredient (mg/tablet)	F1	F2	F3	F4	F5
Carbamazepine	10	10	10	10	10
Psyllium husk	2	4	6	8	10
Eudragit L-100	140	130	120	110	100
Sodium bicarbonate	20	25	30	35	40
Citric acid	6	6	6	6	6

Talc	2	2	2	2	2
Magnesium stearate	4	4	4	4	4
Microcrystalline cellulose	16	19	22	25	28
Total tablet weight	200	200	200	200	200

3.6 Preparation procedure

The ingredients were weighed according to the formulation table and blended to obtain a uniform powder mixture. The effervescent components were included to generate carbon dioxide in acidic medium. The blend was compressed using a single-punch tablet compression machine. The project describes the process as direct compression. Details such as blending duration, order of addition, sieve size, compression force and environmental humidity were not consistently available in the extracted source text; these parameters should be added from the laboratory notebook for full reproducibility.

3.7 Pre-compression evaluation

Powder blends were evaluated using angle of repose, bulk density, tapped density, Carr's compressibility index and Hausner's ratio. These tests provide an indication of powder flow and packing behaviour, which are important for consistent die filling and tablet weight. Carr's index was calculated from bulk and tapped density, while Hausner's ratio was calculated as tapped density divided by bulk density.

3.8 Post-compression evaluation

The study describes evaluation of appearance, dimensions, hardness, friability, weight variation, drug content, buoyancy lag time, total floating time, swelling index and in-vitro drug release. Drug content was assessed to examine the uniformity of the active ingredient. Buoyancy was evaluated in acidic medium, while swelling was assessed by monitoring the increase in tablet weight after exposure to the test medium.

3.9 In-vitro buoyancy, swelling and drug-release studies

For effervescent floating systems, sodium bicarbonate reacts with the acidic medium to produce carbon dioxide. When gas is retained within the hydrated polymer matrix, the tablet's apparent density may decrease and buoyancy can develop. Buoyancy lag time is the time required for a tablet to rise to the medium surface; total floating time records how long the tablet remains afloat under the test conditions.

The source reports testing in acid buffer at pH 1.2 and describes the floating lag time and total floating time for the five formulations. The source text includes some inconsistencies between narrative statements and tabulated values; the main table values are therefore presented as reported, with the need for verification noted in the discussion.

Swelling index was assessed after exposure to medium. Hydration of the matrix produces a swollen layer that can influence both buoyancy and drug diffusion. A sufficient gel layer may help maintain tablet integrity and retard release, whereas differences in polymer levels and effervescent-agent content may change water uptake and release behaviour.

In-vitro release was followed over time, and release data were assessed using kinetic models. The source identifies zero-order kinetics for the selected formulation, with a reported coefficient of determination of $r^2 = 0.996$. This suggests that the observed profile was well fitted by the zero-order model among the models considered in the source study. However, the full model-comparison table and raw dissolution values should be checked before final publication.

3.10 Data handling

The reported numerical results were summarized descriptively. Where the thesis reports mean values with standard deviations, those values are retained in the relevant tables. No new statistical analysis was introduced in this article. The original raw data, replicate numbers and statistical procedures should be verified and added where required by the journal's reporting standards.

3.11 Ethical and safety considerations

The work described is an in-vitro formulation study. The source mentions in-vivo X-ray studies in the plan of work, but the extracted results do not establish that such studies were completed. Accordingly, no in-vivo findings or clinical efficacy claims are presented here. Any future animal or human investigation would require the applicable ethical approval and study-specific documentation.

4. RESULTS

4.1 Calibration and compatibility

The source reports a λmax of 283 nm for carbamazepine in 0.1 N hydrochloric acid and a linear working range of 5–20 μg/mL. These findings were used to support UV-based analysis of the drug during the study.

FTIR analysis of the pure drug and drug–polymer mixture was interpreted as showing retention of the characteristic bands. The reported peak positions included N–H stretching, aromatic C–H stretching, C=N stretching, N–H bending, C–H bending and C–N stretching. The source concluded that no significant chemical interaction was detected from the spectra. DSC was also reported to show a prominent endothermic peak near 103.4 °C, interpreted as evidence that the drug remained in its unchanged form in the selected mixture.

4.2 Pre-compression properties

The thesis reports an angle of repose range of approximately 30°–35°, bulk density values of approximately 1.08–1.12 g/mL and tapped density values of approximately 1.29–1.34 g/mL. Carr's index was described as approximately 15.58%–17.8%, supporting acceptable-to-good flow for compression according to the interpretation used in the source. The reported Hausner's ratio range was approximately 1.18–1.22, although one table entry for F1 appears inconsistent and should be checked against the original data.

Parameter	Reported range / observation	Interpretation in source
Angle of repose	Approximately 30°–35°	Good flow
Bulk density	Approximately 1.08–1.12 g/mL	Powder blends not excessively bulky
Tapped density	Approximately 1.29–1.34 g/mL	Packing after tapping
Carr's index	Approximately 15.58%–17.8%	Good flow/compressibility
Hausner's ratio	Approximately 1.18–1.22 in narrative	Good flow; verify anomalous table entry

4.3 Drug content

Drug content across formulations F1–F5 was reported to range from 97.18% to 100.4%. This range was interpreted in the source as indicating acceptable uniformity of drug content among the prepared formulations.

4.4 Buoyancy and swelling

Formulation	Buoyancy lag time	Total floating time	Swelling index at 8 h
F1	45 seconds	<12 h	60.91%
F2	37 seconds	<12 h	59.51%
F3	25 seconds	<12 h	60.82%
F4	14 seconds	<12 h	65.57%
F5	16 seconds	<12 h	59.56%

Among the tabulated values, F4 had the shortest reported buoyancy lag time (14 seconds) and the highest reported swelling index at 8 hours (65.57%). The thesis narrative states that F4 floated for up to 12 hours, although the table uses "<12 h" for all formulations. This discrepancy should be resolved using the original observations before submission.

4.5 In-vitro drug release

The source identifies F4 as the best formulation and reports 97.86% drug release at 12 hours. The release profile was described as following zero-order kinetics, with $r^2 = 0.996$. This supports the authors' selection of F4 based on the combined in-vitro findings. Because the extracted document does not provide a fully consistent numerical release table for every time point and all five batches, comparative release values for F1–F5 have not been reconstructed or estimated.

4.6 Summary of key findings

Evaluation	Key result reported for F4
Drug content	Overall formulation range: 97.18%–100.4%
Buoyancy lag time	14 seconds
Swelling index	65.57% at 8 hours
Drug release	97.86% at 12 hours
Release kinetics	Zero-order fit; $r^2 = 0.996$
FTIR / DSC	No significant interaction reported

5. DISCUSSION

The findings suggest that an effervescent matrix containing carbamazepine, Eudragit L-100 and psyllium husk can be manufactured by direct compression and can display in-vitro floating and sustained-release characteristics. The observed rapid buoyancy of F4 is consistent with gas generation and entrapment within the hydrated matrix. Its comparatively higher reported swelling index may reflect hydration and gel formation, which can support tablet buoyancy and influence diffusion of drug through the matrix.

5. DISCUSSION (CONTINUED)

F4 contained 8 mg psyllium husk, 110 mg Eudragit L-100 and 35 mg sodium bicarbonate per 200 mg tablet. Relative to F1–F3, the increased amount of gas-generating agent and the changed polymer balance may have contributed to its shorter lag time. F5 contained still more psyllium husk and sodium bicarbonate but showed a slightly longer lag time and a lower reported swelling index than F4. This indicates that the relationship between formulation composition and performance may not be linear; matrix structure, hydration and gas retention can interact.

The drug-content range of 97.18%–100.4% and the reported powder-flow indices suggest that the blends were suitable for further tablet evaluation under the conditions described. FTIR and DSC results were interpreted as showing no major incompatibility. Nevertheless, these techniques alone do not establish long-term chemical stability, and formal stability studies would be needed to support a shelf-life claim.

The reported 97.86% release at 12 hours and zero-order fit ($r^2 = 0.996$) are encouraging in-vitro findings. A high coefficient of determination for one kinetic model should not, by itself, be treated as proof of a particular release mechanism. Model comparison, residual analysis and complete time-point data are needed to assess the most appropriate kinetic description. In addition, in-vitro dissolution does not establish increased bioavailability or clinical benefit.

5.1 Study limitations

Several limitations should be considered. First, the article is based on the results available in the supplied project document, which contains occasional inconsistencies in the numerical tables and narrative. Second, the full raw data, replicate counts and detailed dissolution time points were not consistently available in the extracted text. Third, because psyllium husk, Eudragit L-100 and sodium bicarbonate levels changed together across batches, the contribution of each individual variable cannot be separated. Fourth, the source does not provide sufficiently complete evidence to confirm long-term stability or in-vivo gastric retention.

5.2 Further work

Future studies should repeat the formulation batches using a documented manufacturing protocol; report mean ± standard deviation with replicate numbers; provide complete dissolution profiles and model comparisons; conduct formal stability testing; and consider a suitable experimental design to isolate the effects of polymer and effervescent-agent concentration. In-vivo imaging or pharmacokinetic studies, if scientifically justified, would be needed to establish gastric retention or bioavailability effects.

6. CONCLUSION

Effervescent floating matrix tablets of carbamazepine were prepared by direct compression using Eudragit L-100 and psyllium husk. Among the five formulations, F4 was selected as the best-performing batch in the source study. It showed a reported buoyancy lag time of 14 seconds, a swelling index of 65.57% at 8 hours and 97.86% drug release at 12 hours; the release data were reported to fit zero-order kinetics with $r^2 = 0.996$. FTIR and DSC findings were interpreted as showing no significant drug–polymer interaction.

These results support further investigation of the formulation as an in-vitro sustained-release floating system. Confirmation through complete data verification, reproducibility and stability studies is required, and clinical or bioavailability advantages cannot be concluded from the in-vitro results alone.

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Editorial note: *This manuscript has been condensed from the supplied project document. Some source references are incomplete and selected source tables contain inconsistencies; verify bibliographic details and raw results against original records before journal submission. No external data or unreported experimental results have been added.*