



Formulation and evaluation of floating tablets of *Aegle marmelos* (bael) fruit extract for sustained release

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ABSTRACT :

Background: The fruit pulp of *Aegle marmelos* (bael) protects the gastric mucosa in several animal models, but a conventional tablet of the extract would leave the stomach quickly and give the mucosa only a brief exposure. A floating, sustained-release tablet could hold the extract in the stomach for longer.

Objective: To formulate effervescent floating matrix tablets of bael fruit extract with sodium alginate as the release-controlling polymer, and to characterise their buoyancy, swelling and release behaviour.

Methods: Dried fruit pulp was defatted with *n*-hexane and extracted with ethanol in a Soxhlet apparatus. Five formulations (F1–F5) were prepared by wet granulation. The extract, PVP K30, citric acid and lubricants were kept constant, while sodium alginate was raised from 1.5 to 2.4 g per batch, with microcrystalline cellulose reduced correspondingly and sodium bicarbonate raised slightly (1.2 to 1.4 g). Blends and tablets were assessed for flow, hardness, friability, drug content, floating behaviour, swelling and *in vitro* release. Drug–excipient compatibility was examined by FTIR spectroscopy.

Results: All blends flowed well (angle of repose 24.3–28.9°; Carr's index 11.9–14.6%), and the tablets were mechanically sound (hardness 4.2–4.6 kg/cm²; friability 0.84–0.96%; drug content 97.4–99.8%). Floating lag time followed a U-shaped trend, falling from 2.50 min (F1) to 1.20 min (F3) and rising again to 5.56 min (F4) and 12.00 min (F5). Every tablet floated for more than 8 h, and F3 for more than 12 h. F3 also showed the greatest swelling (102% at 8 h) and the highest release (93.6% at 12 h), with no initial burst. Release from F3 was best described by the Korsmeyer–Peppas model ($n = 0.822$), which indicates anomalous (non-Fickian) transport. FTIR gave no evidence of extract–excipient interaction.

Conclusion: A moderate alginate level (F3) gave the best balance of rapid buoyancy, matrix integrity and 12-h release, which supports bael extract as a candidate for gastroretentive delivery. Marker-based standardisation, stability testing and *in vivo* gastric retention studies are still required.

Keywords: *Aegle marmelos*; bael; gastroretentive drug delivery; floating tablets; sodium alginate; sustained release; Korsmeyer–Peppas model

1. Introduction

Oral sustained-release tablets are designed to hold plasma concentrations within the therapeutic window and to cut dosing frequency, yet they still depend on how quickly the dosage form travels through the gastrointestinal tract. A non-disintegrating tablet usually leaves the stomach within a few hours. That can be too short for drugs absorbed mainly in the stomach or upper small intestine, for drugs that act locally on the gastric mucosa, and for drugs that are unstable or poorly soluble at intestinal pH.[1,2] Gastroretentive drug delivery systems (GRDDS) address the problem by prolonging the time the dosage form spends in the stomach. The main strategies are floating (low-density), high-density, mucoadhesive, expandable and raft-forming systems.[2,3]

Floating systems have attracted the most attention because they can be made with conventional tablet technology. In effervescent designs, a carbonate or bicarbonate is combined with an organic acid inside a gel-forming matrix. On contact with gastric fluid the pair releases carbon dioxide, which is trapped in the hydrating polymer and lowers the bulk density of the tablet below that of gastric contents (about 1.004 g/cm³).[3,4] Sodium alginate is a natural matrix former that suits this purpose. It is insoluble below about pH 3, where it converts to alginic acid and forms a gel layer around the tablet,[5] and gas-forming agents such as sodium bicarbonate have been shown to make alginate systems buoyant.[6] Alginate has also been evaluated as a release-modifying polymer in matrix tablets more generally.[7,8]

Bael (*Aegle marmelos* (L.) Corrêa, Rutaceae) is a sacred and widely cultivated tree of the Indian subcontinent. Its unripe and half-ripe fruit is used in Ayurveda, Siddha and Unani medicine for diarrhoea, dysentery and stomach complaints.[9] The pulp contains coumarins (marmelosin at roughly 0.5%), flavonoids such as rutin, phenolic acids, tannins, alkaloids and vitamins.[9–11] In rats, fruit extracts reduced gastric ulceration induced by *Helicobacter pylori* lipopolysaccharide or aspirin, restored mucosal antioxidant enzymes and lowered lipid peroxidation, with efficacy comparable to sucralfate and omeprazole in those models.[12,13] Comparable protection has been reported in experimental colitis and, for a leaf extract, in pylorus-ligated rats.[14,15]

These effects are exerted largely at the mucosal surface, so the time the extract stays in the stomach should matter as much as the dose. An immediate-release tablet or capsule would be emptied along with the meal, whereas a floating matrix could go on releasing the extract for many hours. Floating tablets of liquorice extract have already been developed for gastric ulcer and *H. pylori* infection,[16] and a recent review of the antiulcer action of bael specifically suggested a stomach-specific dosage form.[17] Reviews of the plant also note that its pharmacology has been studied far more than its formulation into standardised dosage forms.[18–20] We did not find a published report of a floating tablet that carries bael fruit extract as the active ingredient.

The aim of this work was therefore to develop effervescent floating matrix tablets of *A. marmelos* fruit extract with sodium alginate as the release-controlling polymer. We varied the alginate level across five formulations and evaluated flow properties, tablet quality, buoyancy, swelling and *in vitro* release. We then analysed the release kinetics of the best formulation and checked extract–excipient compatibility by FTIR.

2. Materials and methods

2.1 Materials

Sodium alginate, sodium bicarbonate, citric acid, microcrystalline cellulose, polyvinylpyrrolidone K30 (PVP K30), isopropyl alcohol, talc, magnesium stearate and ethanol were obtained from Molychem (India). The suppliers and roles of all materials are listed in Table 1. All chemicals were of analytical or pharmaceutical grade.

Table 1. Materials used and their function in the formulation.

Material	Function	Source
Sodium alginate	Gel-forming, release-retarding polymer	Molychem, India
Sodium bicarbonate	Gas-generating (effervescent) agent	Molychem, India
Citric acid	Acidulant; effervescent co-agent	Molychem, India
Microcrystalline cellulose	Diluent and dry binder	Molychem, India
PVP K30	Binder for wet granulation	Molychem, India
Isopropyl alcohol	Non-aqueous granulating solvent	Molychem, India
Talc	Glidant and anti-adherent	Molychem, India
Magnesium stearate	Lubricant	Molychem, India
Ethanol	Extraction solvent	Molychem, India

2.2 Plant material

The fruit pulp of *Aegle marmelos* (L.) Corrêa (family Rutaceae; known as bael, bilva or vilvam) was used.[21] Fresh, mature fruits were collected from [locality]. A fruit sample submitted by the authors was identified at the Siddha Central Research Institute (Central Council for Research in Siddha, Ministry of AYUSH, Government of India), Arumbakkam, Chennai, as *Aegle marmelos* (L.) Corrêa, part used: fruit (Authentication Certificate No. 1818.03072605, Form No. PCOG002-ACF, dated 3 July 2026; sample code A03072605M). The certificate carries the signatures of Dr K. N. Sunil Kumar, Research Officer (Pharmacognosy), and Dr A. Kanagarajan, Assistant Director (Siddha) in charge. Authentication was obtained so that the phytochemical and formulation data could be traced to the correct species.[22]

2.3 Preparation of the extract

The fruits were washed, the hard shell was cracked, and the pulp was separated from seeds and fibrous strands. The pulp was dried in the shade to protect heat- and light-labile constituents such as flavonoids and coumarins, then ground coarsely and sieved. The powder was stored in an airtight container away from light and moisture.

Five hundred grams of the powder were first defatted with *n*-hexane for 48 h to remove lipids and waxes. The marc was air-dried and extracted with ethanol (solvent-to-drug ratio 5:1) in a Soxhlet apparatus at about 60 °C for 8–10 h, until the siphoning solvent ran colourless or nearly so. The extract was filtered through Whatman filter paper and the solvent was removed in a rotary vacuum evaporator at a temperature not exceeding 50 °C. The concentrate was dried to constant weight in a vacuum desiccator over anhydrous calcium chloride or silica gel and stored at 4 °C in an airtight amber container.

2.4 Preliminary phytochemical screening

The ethanolic extract was tested for saponins, steroids and triterpenoids, tannins and phenolics, flavonoids, cardiac glycosides, alkaloids and terpenoids using standard colour reactions (foam, Liebermann–Burchard, ferric chloride, Shinoda, Keller–Kiliani, Dragendorff's and Salkowski tests).[23]

2.5 Preparation of floating tablets

Five formulations (F1–F5) were prepared by wet granulation. The extract quantity was fixed, and sodium alginate was increased from 1.5 to 2.4 g per batch while microcrystalline cellulose (MCC) was reduced correspondingly (Table 2). Sodium bicarbonate was raised slightly across the series, from 1.2 to 1.4 g. PVP K30, citric acid, talc and magnesium stearate were held constant.[24]

Table 2. Composition of the floating tablet formulations (g per batch).

Ingredient	F1	F2	F3	F4	F5
Bael fruit extract	5.0	5.0	5.0	5.0	5.0
Sodium alginate	1.5	1.8	2.0	2.2	2.4
Microcrystalline cellulose	0.7	0.6	0.5	0.3	0.1
Sodium bicarbonate	1.2	1.2	1.3	1.3	1.4
Citric acid	0.4	0.4	0.4	0.4	0.4
PVP K30	0.4	0.4	0.4	0.4	0.4
Talc	0.1	0.1	0.1	0.1	0.1
Magnesium stearate	0.07	0.07	0.07	0.07	0.07
Isopropyl alcohol	q.s.	q.s.	q.s.	q.s.	q.s.

q.s., quantity sufficient. F3 (shaded) was the optimised formulation.

The extract, sodium alginate and MCC were sieved and mixed thoroughly in a mortar. Sodium bicarbonate and citric acid were added gradually so that the gas-generating pair was evenly distributed. PVP K30 was dissolved in isopropyl alcohol and added slowly to the powder with continuous mixing, avoiding excess liquid. A non-aqueous binder vehicle was chosen deliberately, to prevent the bicarbonate and citric acid from reacting during granulation, a strategy also used for alginate-containing floating tablets prepared by wet granulation.[25] The wet mass was passed through a No. 16 sieve, and the granules were dried in a tray dryer at a controlled temperature until an appropriate moisture level was reached, and then cooled. Dried granules were resieved (No. 60) to break up lumps, then blended with talc and finally magnesium stearate; blending was kept short to avoid over-lubrication, which can slow hydration and release. The blend was compressed on a rotary tablet punching machine to produce round tablets with a central break line (Figure 1b).



Figure 1. (a) Dried bael fruit extract powder. (b) Compressed floating tablets. (c) Comparative appearance of the dissolution medium during the *in vitro* buoyancy study, with floating tablets at the surface.

2.6 Evaluation of granule blends

Angle of repose was measured by the fixed-funnel method from the height and radius of the powder heap. Bulk and tapped densities were determined in a graduated cylinder, and Carr's compressibility index and Hausner's ratio were calculated as $CI = [(tapped\ density - bulk\ density) / tapped\ density] \times 100$ and Hausner's ratio = $tapped\ density / bulk\ density$. [26,27] Measurements were made in triplicate.

2.7 Evaluation of tablets

Tablets were inspected for shape, colour, surface defects, cracking, chipping, sticking and picking. Weight variation was tested on 20 tablets, thickness (vernier caliper) and hardness (Monsanto tester) on five tablets each, and friability in a Roche friabilator at 25 rpm for 4 min (100 revolutions), with limits

taken from the Indian Pharmacopoeia.[28] Friability was calculated as $[(\text{initial weight} - \text{final weight})/\text{initial weight}] \times 100$. For drug content, tablets were weighed and powdered, a portion of the powder equivalent to the required amount of extract was extracted with a suitable solvent and filtered, and the concentration was determined by the validated analytical method selected for the extract. Results are reported as mean $\pm$ SD.

2.8 Buoyancy and swelling studies

Each tablet was placed in a 100 mL beaker containing the dissolution medium, which was kept at approximately physiological temperature. Floating lag time was the time taken for the tablet to rise to the surface, and total floating time was the period for which it stayed continuously afloat. Tablets were observed visually throughout. For the swelling study, tablets were weighed (W_0), immersed in the medium and removed at set intervals, blotted free of surface liquid and reweighed (W_t). The swelling index (%) was calculated as $[(W_t - W_0)/W_0] \times 100$ and reported at 8 h.

2.9 In vitro drug release

Release was studied in a DBK dissolution rate test apparatus. The selected dissolution medium was maintained at approximately 37 ± 0.5 °C, and the apparatus was operated at the selected rotation speed. Samples were withdrawn at 0.5, 1, 2, 3, 4, 6, 8, 10 and 12 h, replaced with an equal volume of fresh medium, filtered and analysed by the selected analytical method using a UV-visible spectrophotometer. The cumulative percentage released was calculated at each time point.

2.10 Release kinetics

Release data for the optimised formulation were fitted to zero-order ($Q = k_0t$), first-order ($\ln(100 - Q) = \ln 100 - k_1t$), Higuchi ($Q = k_{Ht}^{1/2}$) and Korsmeyer-Peppas ($M_t/M_\infty = kt^n$) models, where Q is the cumulative percentage released and t is time.[29–31] The Korsmeyer-Peppas equation is intended for the first 60% of release, so it was fitted to the points up to 4 h ($Q \leq 48.2\%$). To allow a like-for-like comparison, all four models were also fitted to this early window as well as to the full 12-h profile. The release exponent n was interpreted for a cylindrical tablet: $n \leq 0.45$, Fickian diffusion; $0.45 < n < 0.89$, anomalous (non-Fickian) transport; $n \approx 0.89$, Case II transport.[32–34] Regression was done on the linearised forms and the model with the highest coefficient of determination (R^2) was taken to describe the data best.[35]

2.11 FTIR compatibility study

FTIR spectra of the pure extract and of the F3 granule blend (extract with all excipients) were recorded over approximately $4000\text{--}400\text{ cm}^{-1}$. Spectra were compared for shifts, loss or appearance of characteristic bands.

3. Results and discussion

3.1 Extract characteristics and phytochemical screening

The ethanolic extract was a dark brown to reddish-brown, sticky semisolid on concentration and became a free-flowing, hygroscopic, amorphous powder after vacuum-desiccator drying (Figure 1a). It had a mildly aromatic odour and an astringent, slightly sour taste. Qualitative tests indicated saponins, steroids and triterpenoids, tannins and phenolics, flavonoids, cardiac glycosides, alkaloids and terpenoids (Table 3). These classes agree with those reported for bael pulp.[9,10,18] The tests are colour reactions, however. They show which classes are present but not how much, and some of them, such as Dragendorff's test, are not fully specific. Batch-to-batch standardisation will need a quantified marker such as marmelosin, rutin or total phenolics.[10,11]

Table 3. Preliminary phytochemical screening of the ethanolic extract of *A. marmelos* fruit.

Test	Reagents	Observation	Inference
Foam test	Extract + water, shaken	Persistent honeycomb foam	Saponins
Liebermann-Burchard	Chloroform + acetic anhydride + conc. H_2SO_4	Blue-green colour	Steroids / triterpenoids
Ferric chloride	Neutral 5% $FeCl_3$	Blue-black colour	Tannins and phenolics
Shinoda	Mg turnings + conc. HCl	Pink to red colour	Flavonoids
Keller-Kiliani	Glacial acetic acid + $FeCl_3$ + conc. H_2SO_4	Blue-green ring at interface	Cardiac glycosides
Dragendorff's	Dragendorff's reagent	Orange-red precipitate	Alkaloids
Salkowski	Chloroform + conc. H_2SO_4 (down the wall)	Reddish-brown colour at interface	Terpenoids / steroids

3.2 Flow properties of the granule blends

All five blends had angles of repose below 30° ($24.32\text{--}28.92^\circ$), Carr's indices between 11.92 and 14.60% and Hausner's ratios of 1.135–1.171 (Table 4, Figure 2). These values fall in the good-flow range, so the granules could be compressed without further flow aids beyond the talc already present.[26]

Flow worsened slightly but steadily from F1 to F5. As alginate replaced MCC the blends became a little more cohesive, which fits the fibrous, mildly hygroscopic nature of alginate and the freer flow of MCC.[5] The effect was small, and even F5 stayed within the good range.

Table 4. Pre-compression parameters of the granule blends (mean $\pm$ SD, $n = 3$).

Formulation	Angle of repose ($^{\circ}$)	Bulk density (g/mL)	Tapped density (g/mL)	Carr's index (%)	Hausner's ratio
F1	24.32 $\pm$ 0.21	0.421 $\pm$ 0.004	0.478 $\pm$ 0.006	11.92 $\pm$ 0.31	1.135 $\pm$ 0.010
F2	25.47 $\pm$ 0.18	0.432 $\pm$ 0.005	0.492 $\pm$ 0.005	12.20 $\pm$ 0.28	1.139 $\pm$ 0.009
F3	26.85 $\pm$ 0.24	0.445 $\pm$ 0.003	0.512 $\pm$ 0.004	13.09 $\pm$ 0.26	1.151 $\pm$ 0.011
F4	27.63 $\pm$ 0.20	0.451 $\pm$ 0.004	0.523 $\pm$ 0.005	13.77 $\pm$ 0.30	1.160 $\pm$ 0.008
F5	28.92 $\pm$ 0.22	0.462 $\pm$ 0.006	0.541 $\pm$ 0.006	14.60 $\pm$ 0.27	1.171 $\pm$ 0.010

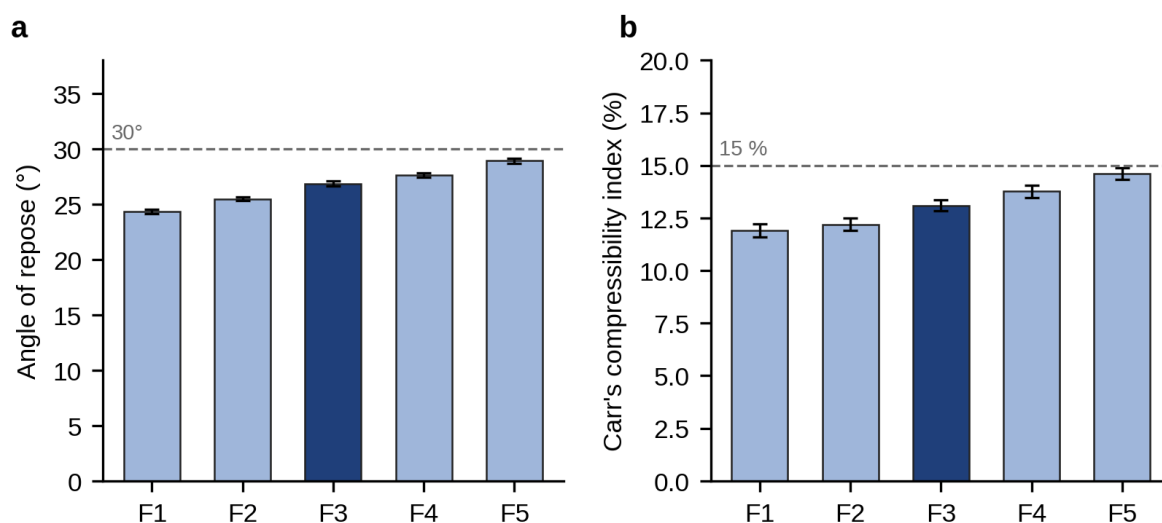


Figure 2. Flow properties of the granule blends. (a) Angle of repose, with the 30° limit shown as a dashed line. (b) Carr's compressibility index, with the 15% limit shown as a dashed line. Bars show mean $\pm$ SD ($n = 3$); F3 (dark blue) is the optimised formulation.

3.3 Tablet quality

The tablets were round with a central break line and a uniform brown surface, with no capping, chipping or sticking (Figure 1b). All batches complied with the Indian Pharmacopoeia limits for weight variation.[28] Thickness rose slightly, from 4.12 to 4.30 mm, as alginate content increased. Hardness ranged from 4.2 to 4.6 kg/cm² and friability from 0.84 to 0.96%, all below the 1% limit (Table 5, Figure 3).

Neither hardness nor friability changed steadily with alginate level. Hardness peaked at F4 (4.6 kg/cm²) and friability was lowest at F3 (0.84%), while F5 was slightly softer and more friable than F4. A likely reason is that alginate helps to bind the granules up to a point, beyond which the gummy, viscous mass at the highest level consolidates less evenly under compression. Drug content was 97.42–99.78%, which indicates good content uniformity. It rose slightly with alginate content, possibly because the more cohesive granules lost less of the sticky, hygroscopic extract during handling, but the differences are small and were not tested statistically.

Table 5. Post-compression parameters of the floating tablets (mean $\pm$ SD).

Formulation	Thickness (mm)	Hardness (kg/cm ²)	Friability (%)	Drug content (%)
F1	4.12 $\pm$ 0.03	4.2 $\pm$ 0.14	0.96 $\pm$ 0.04	97.42 $\pm$ 0.34
F2	4.18 $\pm$ 0.02	4.3 $\pm$ 0.16	0.91 $\pm$ 0.03	98.15 $\pm$ 0.29
F3	4.21 $\pm$ 0.03	4.5 $\pm$ 0.17	0.84 $\pm$ 0.03	98.87 $\pm$ 0.31
F4	4.26 $\pm$ 0.02	4.6 $\pm$ 0.18	0.87 $\pm$ 0.03	99.34 $\pm$ 0.27
F5	4.30 $\pm$ 0.03	4.4 $\pm$ 0.15	0.92 $\pm$ 0.04	99.78 $\pm$ 0.25

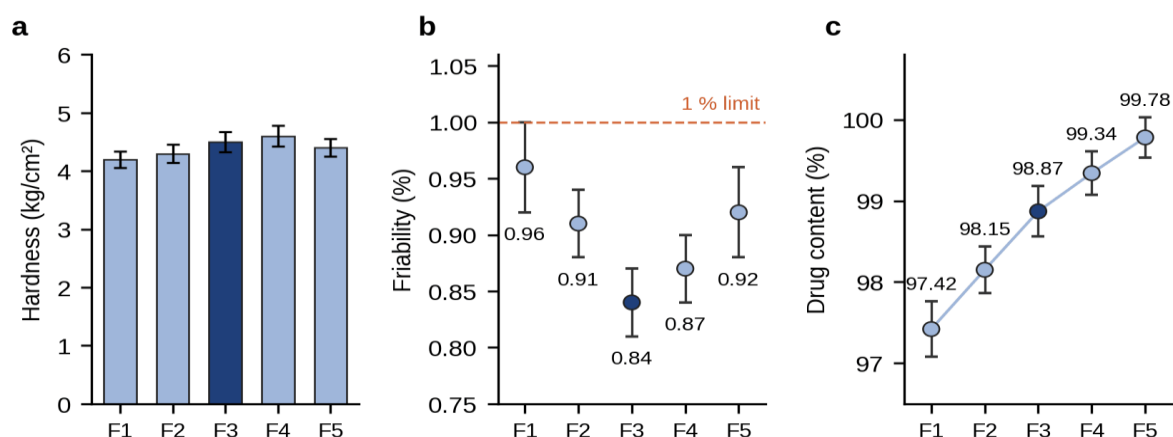


Figure 3. Mechanical properties and drug content of the tablets. (a) Hardness. (b) Friability, with the 1% pharmacopoeial limit as a dashed line. (c) Drug content. Values are mean $\pm$ SD; F3 is shown in dark blue.

3.4 Buoyancy

All tablets sank briefly on immersion and then rose as the effervescent reaction generated carbon dioxide inside the swelling gel. Floating lag time did not fall steadily with polymer level but followed a U-shaped pattern: 2.50 min for F1, 1.35 min for F2, 1.20 min for F3, then 5.56 min for F4 and 12.00 min for F5 (Table 6, Figure 4a). F2 was close behind F3, and the two are best regarded as similar. Total floating time, in contrast, increased with alginate content, from more than 8 h in F1 to more than 13 h in F5 (Figure 4b).

We interpret the U-shape in terms of gel-layer formation. In acidic, gastric-type medium alginate is converted to alginic acid, which gels around the tablet.[5] At the lowest alginate levels (F1, F2) the gel layer was too thin to hold the gas. Fine bubbles appeared only after a visible delay, small fragments were occasionally lost from the tablet edge, and stable buoyancy was established late. In F3 a thin but coherent gel skin formed quickly and evenly, a steady stream of fine bubbles appeared almost at once, and the tablet floated after about 72 s. The gel then eroded slowly and evenly from the periphery over the 12-h observation. At the highest levels (F4, F5) a thick, glassy gel skin formed within seconds and trapped bubbles beneath it, so buoyancy came later, although once afloat these tablets stayed up longest. F4 and F5 also contained slightly more sodium bicarbonate (1.3 and 1.4 g), yet had the longest lag times, which suggests that the dense gel skin, rather than a shortage of gas, limited early buoyancy. The pattern illustrates a general point about effervescent matrices: gas generation and gel strength must be balanced, because they jointly govern both lag time and floating duration.[4,6] The polymer chosen, and its level, likewise governed buoyancy and release in floating ranitidine tablets.[36]

3.5 Swelling

Water uptake at 8 h, expressed as the swelling index, was 82, 91, 102, 96 and 88% for F1–F5 (Table 6, Figure 4c). Up to F3, more alginate meant more polymer available to hydrate and build a gel network, so uptake increased. Beyond F3 it fell. We attribute this to the dense outer gel skin of F4 and F5, which limits how far the medium can penetrate into the core within 8 h even though the skin continues to support buoyancy. A swelling index of 102% means that the F3 tablet had roughly doubled in weight by 8 h. Because swelling was measured gravimetrically, the values reflect water uptake rather than dimensional change.

Table 6. Buoyancy, swelling and release characteristics of formulations F1–F5.

Formulation	Floating lag time (min)	Total floating time (h)	Swelling index at 8 h (%)	Cumulative release at 12 h (%)
F1	2.50 $\pm$ 0.08	>8	82 $\pm$ 2.1	87.8
F2	1.35 $\pm$ 0.06	>10	91 $\pm$ 2.4	90.5
F3	1.20 $\pm$ 0.05	>12	102 $\pm$ 2.8	93.6
F4	5.56 $\pm$ 0.18	>12	96 $\pm$ 2.5	91.8
F5	12.00 $\pm$ 0.32	>13	88 $\pm$ 2.2	89.7

Mean $\pm$ SD. Release values are means; SD was not recorded for these data.

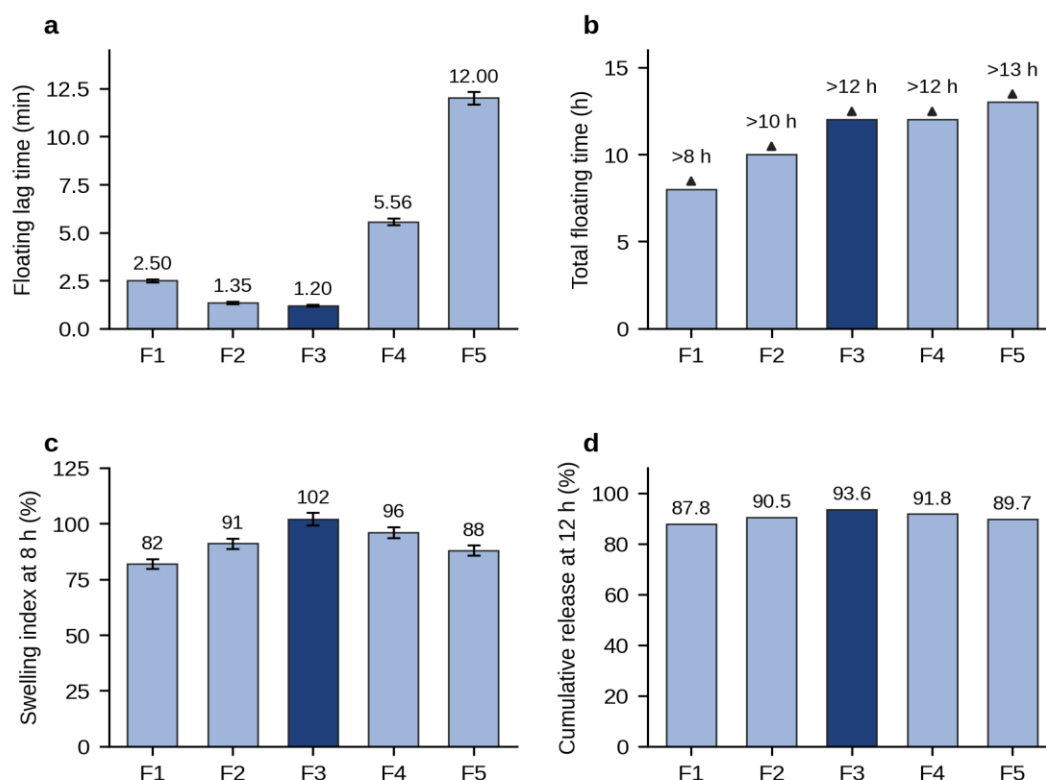


Figure 4. Effect of sodium alginate level on tablet performance. (a) Floating lag time (mean $\pm$ SD). (b) Total floating time; arrows indicate that floating continued beyond the stated value. (c) Swelling index at 8 h (mean $\pm$ SD). (d) Cumulative drug release at 12 h. F3 is shown in dark blue.

3.6 In vitro release and choice of the optimised formulation

Cumulative release at 12 h was 87.8, 90.5, 93.6, 91.8 and 89.7% for F1–F5 (Table 6, Figure 4d). No formulation released more than 94%, and the spread among them was modest, about six percentage points. The highest release, in F3, coincided with its coherent gel layer, which allowed a balance between diffusion of the extract through the gel and slow erosion of the surface. In F4 and F5 the denser gel appeared to slow both processes, leaving 8.2% and 10.3% of the extract unreleased at 12 h. The reason for the lowest release in F1 is less clear. Its weak matrix fragmented early and, in our reading, allowed uneven penetration of the medium, but we did not test this directly. Because replicate variability was not recorded for the release data, the ranking of formulations that lie close together should be read as indicative rather than conclusive.

Taking lag time, floating duration, swelling and release together, F3 gave the best overall balance and was selected as the optimised formulation. It had the shortest lag time (1.20 min), floated for more than 12 h, showed the highest swelling index and the highest 12-h release, and had the lowest friability. It was not the hardest tablet (F4, 4.6 kg/cm²), but its hardness of 4.5 kg/cm² was well within the acceptable range for uncoated tablets.

3.7 Release kinetics of the optimised formulation

Release from F3 was gradual and free of an initial burst: 8.7% at 0.5 h, 15.0% at 1 h, 48.2% at 4 h, 80.3% at 8 h and 93.6% at 12 h (Table 7, Figure 5a). By interpolation between sampling points, 50%, 80% and 90% of the extract had been released at about 4.2, 8.0 and 10.7 h. The average release rate fell from about 14% per hour over the first 2 h to under 3% per hour between 10 and 12 h.

Table 7. Cumulative release profile of the optimised formulation F3.

Time (h)	0.5	1	2	3	4	6	8	10	12
Cumulative release (%)	8.7	15.0	27.3	36.9	48.2	64.8	80.3	88.1	93.6

Mean values; SD was not recorded.

Over the full 12-h profile the Korsmeyer–Peppas model gave the highest correlation ($R^2 = 0.9949$), followed by Higuchi (0.9934), first-order (0.9861) and zero-order (0.9617) (Table 8, Figure 5c). When the models were refitted to the first five points (0.5–4 h), Korsmeyer–Peppas was again best ($R^2 = 0.9995$), but the margin over zero-order (0.9980) and first-order (0.9962) was very small. The ranking of the simpler models therefore depends on the fitting window, and R^2 alone should not be over-interpreted.

Table 8. Kinetic model fitting of the release data of F3 (recalculated from the mean release values in Table 7).

Model	Linearised equation	R ² (0.5–12 h, 9 points)	R ² (0.5–4 h, 5 points)	Constant or exponent
Zero-order	$Q = k_0 t$	0.9617	0.9980	$k_0 = 7.62 \% h^{-1}$ (full profile)
First-order	$\ln(100 - Q) = \ln 100 - k_1 t$	0.9861	0.9962	$k_1 = 0.229 h^{-1}$ (full profile)
Higuchi	$Q = k_H t^{1/2}$	0.9934	0.9900	$k_H = 32.95 \% h^{-1/2}$ (full profile)
Korsmeyer–Peppas	$\log Q = \log k + n \log t$	0.9949	0.9995	$n = 0.822, k = 15.24 (0.5–4 h); n = 0.770 (0.5–12 h)$

Q, cumulative % released; t, time in hours.

The release exponent was $n = 0.822$ in the 0.5–4 h window and 0.770 when every point was used. For a cylindrical tablet, values between 0.45 and 0.89 indicate anomalous (non-Fickian) transport, in which diffusion through the hydrated gel and relaxation or erosion of the polymer both contribute.[32–34] Both estimates fall in this range. The value of 0.822 lies nearer the upper limit, which suggests that polymer relaxation and erosion carry substantial weight, while the good Higuchi fit points to a diffusional component as well. This mixed mechanism is what is generally described for swellable hydrophilic matrices.[30,34]

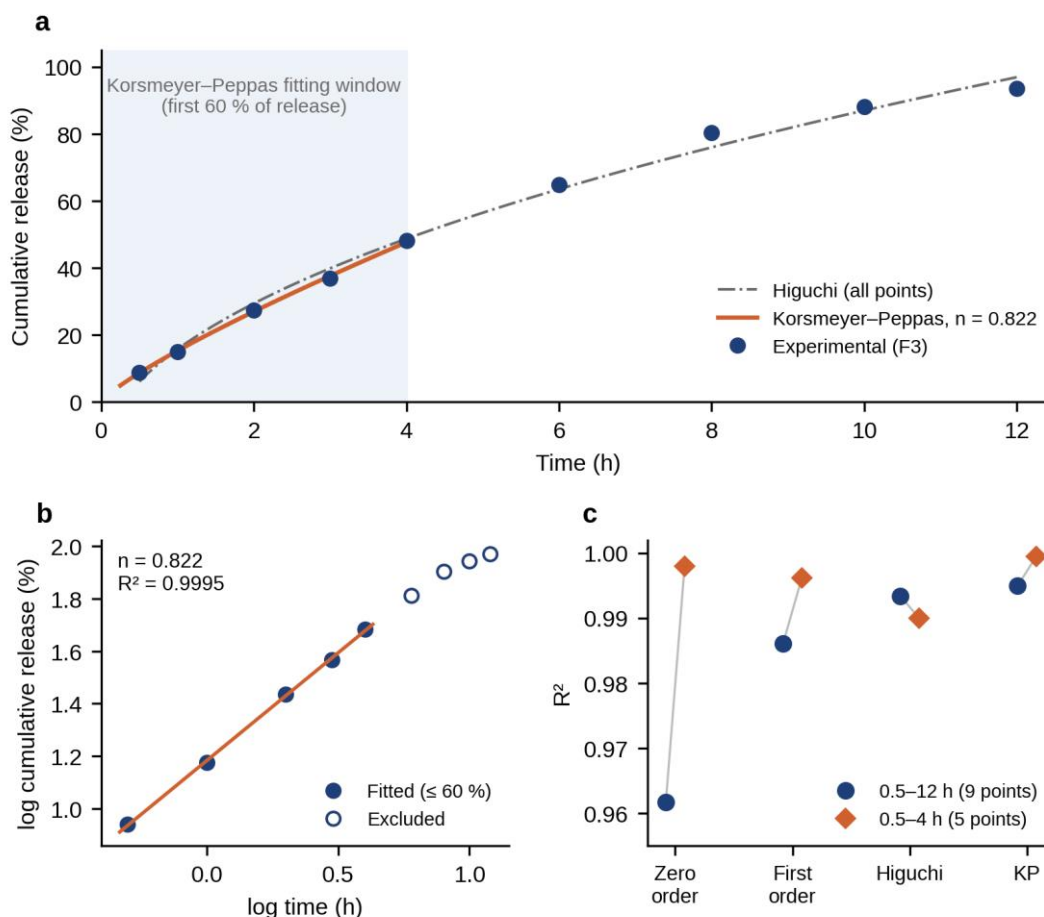


Figure 5. Release kinetics of the optimised formulation F3. (a) Experimental release profile with fitted Higuchi (all points) and Korsmeyer–Peppas (0.5–4 h) curves; the shaded band marks the Korsmeyer–Peppas fitting window. (b) Korsmeyer–Peppas plot; filled points were fitted, open points were excluded. (c) Coefficient of determination (R^2) of the four models over the full profile and over the 0.5–4 h window.

3.8 Drug–excipient compatibility (FTIR)

The spectrum of the pure extract showed a broad O–H stretching band at 3422.70 cm^{-1} , aliphatic C–H stretching at 2926.97 cm^{-1} , bands at 1614.04 and 1518.54 cm^{-1} from aromatic or conjugated C=C, a band at 1384.18 cm^{-1} , a C–O–C band at 1079.36 cm^{-1} and fingerprint bands at 835.31 , 618.22 and 443.62 cm^{-1} (Figure 6a, Table 9). In the F3 granule blend the same bands appeared at 3421.68 , 2918.58 , 1619.15 , 1517.76 , 1384.15 , 1077.71 , 836.38 , 613.85 and 443.00 cm^{-1} (Figure 6b), within a few wavenumbers of their original positions, and none had disappeared.

Three differences were explained by the excipients rather than by interaction: a shoulder at 2851.87 cm^{-1} (aliphatic C–H of magnesium stearate and PVP K30), an extra C–O–C component at 1020.14 cm^{-1} (sodium alginate), and a new band at 1716.25 cm^{-1} assigned to C=O stretching of citric acid and/or PVP K30. Some weaker fingerprint bands were not resolved in the blend, probably through broadening and overlap with excipient bands. The weak band at 2375 cm^{-1} in the pure extract comes from atmospheric CO_2 and was disregarded. Overall, the principal functional groups of the extract survived wet granulation, and we found no sign of a major chemical interaction. This conclusion has limits. The blend contained all excipients at once, and the extract is itself a complex mixture, so FTIR can exclude gross interactions but not subtle changes in individual constituents.

Table 9. Principal FTIR bands (cm^{-1}) of the pure extract and the F3 granule blend.

Assignment	Pure extract	F3 granule blend	Remark
O–H stretching	3422.70	3421.68	Retained
Aliphatic C–H stretching	2926.97	2918.58; 2851.87 (shoulder)	Shoulder from Mg stearate / PVP K30
C=O stretching	—	1716.25	New; citric acid and/or PVP K30
Aromatic / conjugated C=C	1614.04	1619.15	Retained
Aromatic / conjugated C=C	1518.54	1517.76	Retained
C–H bending	1384.18	1384.15	Unchanged
C–O–C stretching	1079.36	1077.71; 1020.14	Extra band from alginate
Fingerprint region	835.31	836.38	Retained
Fingerprint region	618.22	613.85	Retained
Fingerprint region	443.62	443.00	Retained

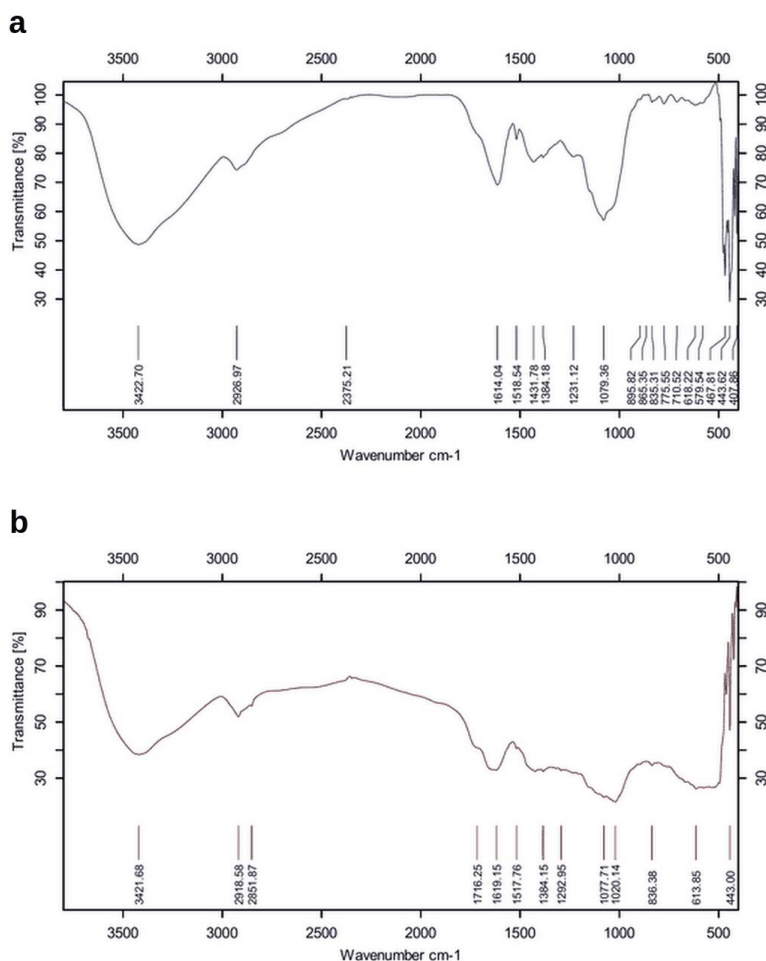


Figure 6. FTIR spectra of (a) the pure *A. marmelos* extract and (b) the optimised F3 granule blend (extract with all excipients).

3.9 Comparison with earlier work

Direct comparison with earlier studies is limited because the polymer, drug, medium and test set-up all differ. With that caveat, the 1.20-min lag time and more than 12 h of floating for F3 compare well with HPMC-based liquorice extract tablets, which floated in under 5 min and stayed afloat for the 8-h study period.[16] Wet granulation with isopropyl alcohol, used here to keep water away from the bicarbonate–citric acid pair, has been applied before to floating matrix tablets containing sodium alginate.[25] The anomalous release we observed for an alginate matrix is consistent with the mixed diffusion–erosion behaviour described for hydrophilic matrix tablets in general.[34]

3.10 Limitations

This was a single-batch, laboratory-scale study, and several limits should be kept in mind. Standard deviations are given for most tests but were not recorded for the release data, and no formal statistical comparison was made between formulations. Drug content and release were followed for the extract as a whole rather than for a named marker compound, so standardisation against marmelosin, rutin or total phenolics is needed. Buoyancy was tested in a fixed volume of acid; real gastric retention depends on the fed or fasted state, gastric volume and motility, and floating tablets generally work best when taken with food and a full glass of water.[2,3] Imaging studies in animals or volunteers are needed to confirm retention. No stability data were generated. Finally, the formulations differed mainly in alginate level (with MCC compensating), but sodium bicarbonate also rose slightly from F1 to F5, so the effects of alginate and bicarbonate cannot be fully separated; a factorial or response-surface design that varies the alginate level and the bicarbonate to citric acid ratio independently would show how these factors interact, as has been done for metformin and ranitidine floating tablets.[36,37]

4. Conclusion

Effervescent floating matrix tablets of *Aegle marmelos* fruit extract were prepared by wet granulation with sodium alginate as the release-controlling polymer. The alginate level, which changed together with a small increase in sodium bicarbonate (1.2 to 1.4 g), had a marked, non-linear effect on buoyancy and release. A moderate level (F3) gave the shortest floating lag time (1.20 min), floating for more than 12 h, the greatest swelling (102% at 8 h) and the highest release at 12 h (93.6%), with no initial burst. Release followed anomalous (non-Fickian) kinetics, and FTIR showed no evidence of extract–excipient interaction. These results support the feasibility of a gastroretentive, sustained-release dosage form of bael extract. Before further development, the extract should be standardised against a chemical marker, the tablets tested for stability, and gastric retention and pharmacological activity confirmed *in vivo*.

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Author contribution:

Ashwin roshan raj.M,Atchaya.M,Balaji.P,Bharath.V had principal responsibility for the conception, design of the study and drafting of manuscript. S.Hemavathy was responsible for the revision of the manuscript for important intellectual content, Dr. J. Karthi, Dr. S. Swarnalatha contributed towards reviewing of the literature. All authors agreed on the final version of manuscript

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