Available online on 15.04.2026 at http://ajprd.com

Asian Journal of Pharmaceutical Research and Development

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Case Study

Floating Bilayered Tablets: A Novel Approach in Gastro-Retentive Drug Delivery System

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A B S T R A C T

Floating bilayered tablets represent an advanced gastro-retentive drug delivery approach designed to enhance the bioavailability of drugs that exhibit narrow absorption windows or poor solubility in alkaline environments. This review provides an in-depth overview of recent progress in the design, formulation, and evaluation of EFBTs. The effervescent mechanism relies on acid–base interactions, typically involving sodium bicarbonate and citric acid, which generate carbon dioxide to achieve rapid buoyancy and prolonged gastric residence. The bilayer configuration combines a floating or immediate-release layer with a sustained-release layer, ensuring controlled drug release and improved pharmacokinetic performance. Various studies have demonstrated floating lag times of less than one minute, sustained release over 12–24 hours, and marked enhancement in relative bioavailability and patient compliance. Drugs such as eplerenone, levofloxacin, nicotinamide, and clarithromycin have shown significant therapeutic benefits when formulated as FBTs. Key formulation aspects—including polymer selection, gas-generating agents, and matrix integrity—play vital roles in optimising drug release kinetics and buoyancy characteristics. Furthermore, the review discusses critical evaluation parameters, stability profiles, and regulatory considerations that influence the successful translation of laboratory findings into commercial dosage forms. Overall, effervescent floating bilayered tablets offer a versatile and patient-friendly platform for achieving sustained gastric retention, controlled release, and enhanced therapeutic efficacy in oral drug delivery.

Keywords: Floating bilayer tablets, Effervescent system, Sustained release, immediate release layer, Gastroretentive drug delivery system, Gas-generating agents, Buoyancy

A R T I C L E I N F O: Received 16 Dec.2025; Review Complete 29 Jan, 2026; Accepted 16 Feb. 2026; Available online 15 April. 2026

Cite this article as:
Bijore I, Wankhede V, Pande S, Mankar A, Bodke S, Virkhare S, Floating Bilayered Tablets: A Novel Approach In Gastro-Retentive Drug Delivery System, Asian Journal of Pharmaceutical Research and Development. 2026; 14(2):207-216,
DOI: http://dx.doi.org/10.22270/ajprd.v14i2.1746

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INTRODUCTION

For many decades, the treatment of various illnesses and disorders has required chronic medication, such as for hypertension, diabetes, and cardiovascular disease (1). These conditions are typically treated with conventional therapies, including tablets, capsules, solutions, suspensions, suppositories, liquids, and injectables (2). This indicates that this category of formulation is globally favoured, with research efforts predominantly directed towards its development. The primary aim of controlled drug administration is to decrease the number of required doses (3). Among various drug delivery systems, the bilayer tablet is regarded as one of the most effective formulations for delivering multiple pharmaceuticals (4). A bilayer tablet comprises an immediate-release layer for the initial dose and a sustained-release layer for the maintenance dose (5). Novel formulations, such as floating bilayer tablets with modified release rates, are being actively investigated to address current therapeutic requirements (6). Floating bilayer tablets provide a novel platform for sequential drug release, effective separation of incompatible agents, and sustained release, thereby enhancing therapeutic outcomes. Floating bilayer tablets are very useful for helping the formulation stay in the stomach and are useful for drugs that are unstable

or insoluble in intestinal fluid. They enable the sustained and regulated release of drugs over a prolonged duration while maintaining gastric buoyancy (7). Drugs suitable for this delivery system include antihypertensives, antihistamines, analgesics, antipyretics, and antiallergic medications (8-9).

Figure: 1 Formation of a bi-layered Tablet (10)

Description: This image depicts the formation of a bi-layer tablet, combining an immediate release layer (white) with a sustained release layer (blue) to create a single tablet for controlled drug delivery.This design is often used to ensure both a quick onset of action and prolonged drug levels in the body.

Anatomy of the Stomach

The stomach acts as a short-term storage site, processing ingested food and releasing it gradually into the small intestine. Stomach peristalsis mixes food with juices and turns it into a semi-liquid (11) . The stomach is divided into 3 regions: fundus, body, and pylorus

Fundus: It is the dome-shaped, upper portion of the stomach which forms a bulge above the level of the oesophageal opening.

Body: The body forms the central and largest portion of the stomach, responsible for most of the mixing and secretion activities.

Antrum: It acts as a mixing chamber and a gastric pump, propelling chyme into the duodenum during both fasting and fed conditions, causing gastric emptying (12)**.**

In the fasting state, a sequence of electrical activities passes through the stomach and intestine every 2-3 hours. This is known as the inter-digestive or migrating myoelectric complex (MMC). The cycle is classified into the following four phases:

Phase 1 (Basal Phase): This phase lasts approximately 30-60 minutes, with only occasional contractions.

Phase 2 (Pre-burst Phase) : Over 40-60 minutes, this phase involves intermittent action potentials with contractions that grow in both frequency and strength.

Phase 3 (Burst Phase) : This phase lasts for 4-6 minutes and is marked by regular contractions of short duration. As a result of this wave, all undigested material is cleared from the stomach into the intestine. It is also known as the housekeeper wave

Phase 4: It lasts for 0-5 minutes, and connects phase 3 with the next phase, 1. After eating, contractions change from the fasted pattern to the fed pattern. In this digestive motility pattern, continuous contractions occur, similar to phase 2, which reduces food particle size and drives them towards the pylorus. This transition delays MMC and reduces gastric emptying speed(13-14).

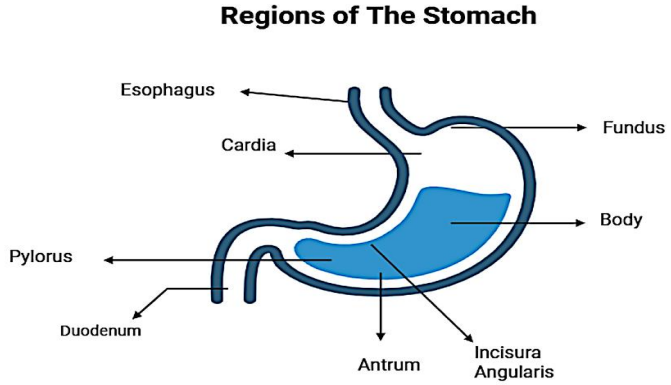


Figure 2: Anatomy of the Stomach (15)

Description: The image illustrates the major anatomy of the human stomach, including the oesophagus, cardia, fundus, body, incisura angularis, antrum, pylorus, and duodenum. Each region plays a distinct role in digestion, secretion, and gastric motility.

1. Floating Drug Delivery System (16)

These systems are designed with a bulk density less than that of gastric fluids, allowing them to stay buoyant on the stomach contents and prolong gastric residence time without interfering with normal gastric emptying. As the system floats over the gastric contents, the drug is released in a sustained, regulated manner. The buoyancy of the system is

attained through a floating chamber containing either a vacuum or an inert gas.

Classification of FloatingDrug Delivery System (17)

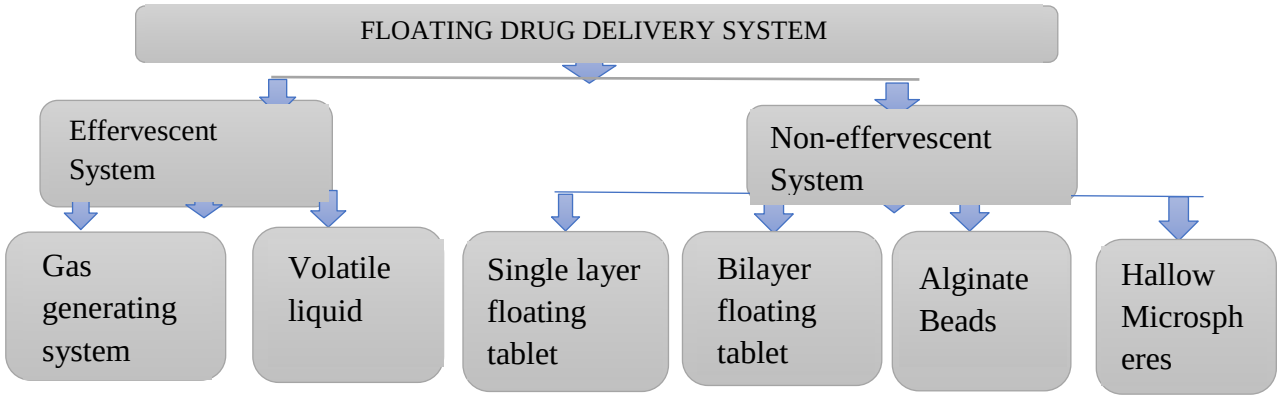


Figure: 3 Classification of Floating Drug Delivery Systems (FDDS)

Description: A flowchart categorizing Floating Drug Delivery Systems (FDDS) into two main types: Effervescent System (gas-generating) and Non-Effervescent System (polymer-based, including tablets, beads, and microspheres).

Effervescent System (18)

These systems are developed in a matrix form using swellable polymers such as methylcellulose combined with effervescent agents like sodium bicarbonate and tartaric acid. When they come in contact with the gastric fluids, the effervescent components react with the acidic medium to release carbon dioxide. The liberated gas gets trapped within the swollen polymer matrix, causing the dosage form to expand and reduce its density. This reduction in specific gravity enables the system to float on the stomach contents, helping it remains buoyant for a prolonged time.

Gas Generating Sytsem(19)

The system incorporates gas-generating agents responsible for the release of carbon dioxide. Commonly used effervescent components such as sodium bicarbonate, citric acid, tartaric acid, and chitosan facilitate the generation of carbon dioxide, resulting in reduced system density and enhanced buoyancy within the gastric environment. This floating behaviour enables prolonged gastric retention of the dosage form, thereby improving the residence time and overall drug absorption efficiency.

Volatile Liquid(19)

The osmotically controlled floating system operates by utilising volatile liquids such as ether and cyclopentane to achieve sustained gastric retention. This system is designed with an inflatable chamber that contains a volatile liquid and comprises two distinct compartments: one serving as the drug reservoir and the other containing the volatile liquid. Upon exposure to physiological temperature, the volatile component vaporises to form gas, which inflates the chamber and imparts buoyancy to the dosage form, thereby enabling it to float and maintain prolonged residence in the gastric environment.

Non-effervescent System (20)

The non-effervescent FDDS functions through polymer swelling or adhesion to the gastrointestinal mucosal lining. After administration, the system absorbs gastric fluids and swells, which prevents its passage through the stomach. The drug is incorporated into a gel-forming polymer that expands upon contact with gastric fluids while maintaining its integrity and shape. These formulations are often called plug-type systemsbecause they tend to stay lodged near the pyloric sphincter, thereby prolonging gastric retention.

2. Effervescent Floating Bilayered Tablets

The system is composed of two distinct layers: one containing the sustained-release polymer and drug (sustained-release layer), and the other consisting of effervescent components responsible for flotation (floating layer). The incorporation of an effervescent system in bilayer tablet formulations offers multiple therapeutic and formulation-related advantages(21). The key benefit lies in prolonged gastric retention, achieved through the generation of carbon dioxide gas from the effervescent layer, which decreases the tablet's density and enables it to remain buoyant in the gastric fluids. This extended gastric residence facilitates enhanced bioavailability, especially for drugs that are absorbed in the upper gastrointestinal tract. The bilayer design allows for independent modulation of drug release, wherein one layer ensures sustained or controlled release while the effervescent layer maintains floatation. Moreover, the separation of layers minimises drug-excipient interactions and enhances the stability of effervescent components that are otherwise sensitive to moisture. This system also offers formulation flexibility, making it suitable for combining multiple drugs or designing varied release profiles within a single dosage form. Additionally, sustained release contributes to reduced dosing frequency and improved patient adherence, while maintaining steady plasma concentrations and minimising potential side effects. Overall, bilayer effervescent systems provide a robust platform for achieving controlled drug delivery with improved therapeutic performance and formulation stability (22).

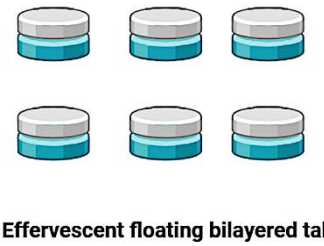


Figure: 4 Effervescent Gastro-Retentive Bilayer Tablets (23)

Description: The image illustratesEffervescent Gastro-Retentive Bilayer Tablets .Each tablet consists of two layers — an effervescent layer that generates gas for buoyancy and a sustained-release layer that controls drug release, enhancing gastric retention and improving bioavailability.

Advantages of Floating Bilayered Tablet(24)

- Improves the oral bioavailability of the drug.
- Minimises first-pass metabolism.
- Enables sustained drug release, reducing the need for frequent dosing.
- Lowers fluctuations in drug plasma levels.
- Enhances selectivity in receptor activation.
- Reduces opposing physiological responses.

Disadvantage of Floating Bilayered Tablet(25)

- Stability Concerns Due to Moisture Sensitivity
- May be difficult to swallow for children and unconscious patients.
- Possibility of contamination between tablet layers.
- Capping is a common manufacturing issue.
- Complex bilayer rotary presses are costly.
- Risk of layer separation during production.
- Achieving adequate tablet hardness can be challenging.
- Can improve patient compliance.
- Requires sufficient gastric fluid to maintain buoyancy

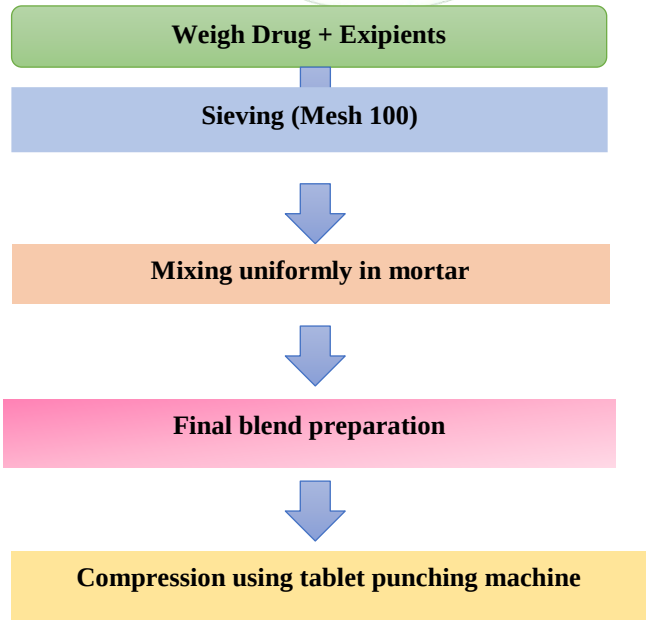
Selection of a Drug for a Floating Bilayered Tablet on its suitability (26)

- A drug having a narrow absorption window
- It should be basically absorbed from the upper GIT tract
- It should be unstable at intestinal pH.
- Drugs that together produce synergistic or additive effects
- The drugis absorbed rapidly from the stomach
- A drug that degradesthe colon

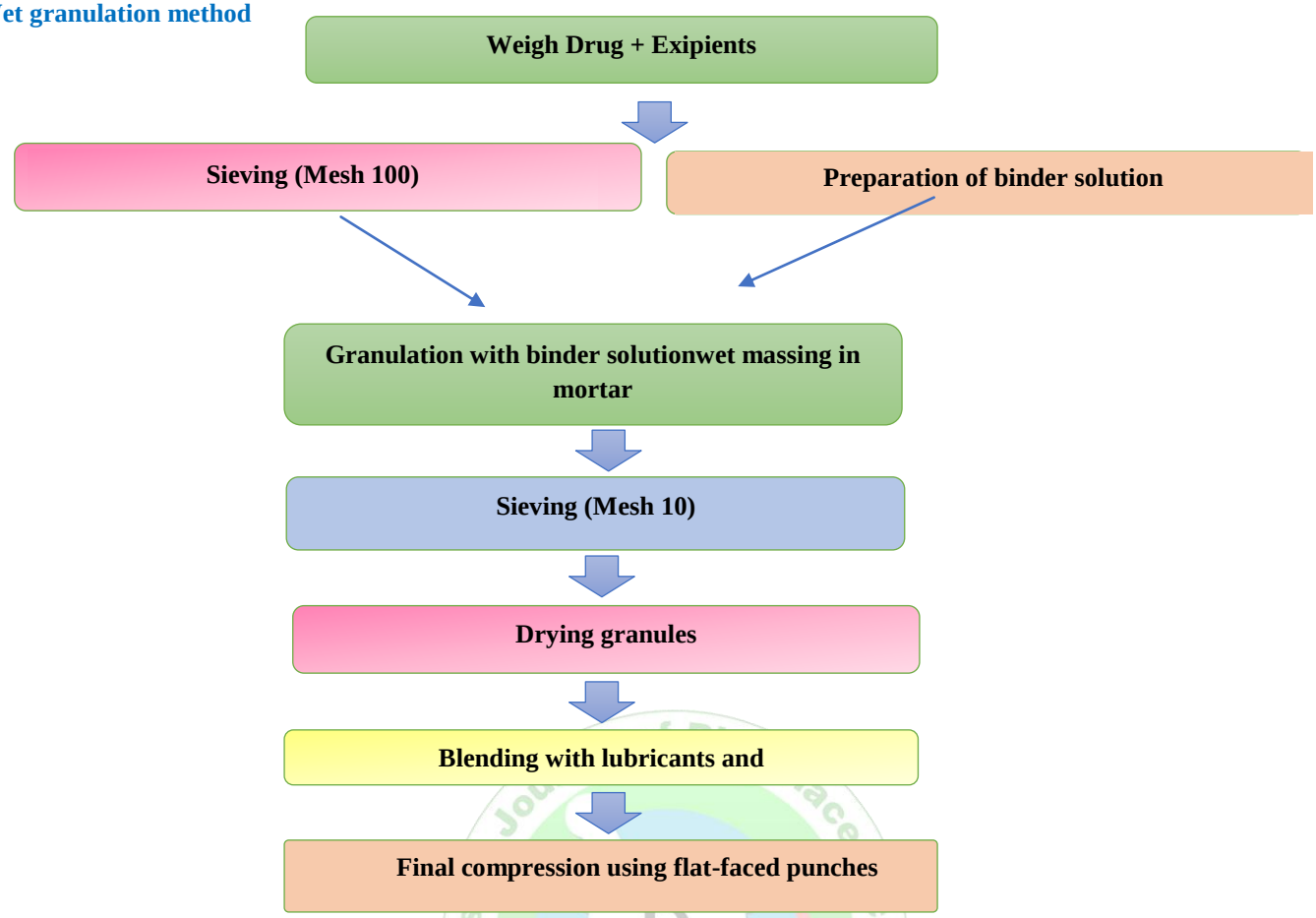
Preparation of Floating Bilayered Tablet(27)

A Floating Bilayer tablet is prepared by mainly two methods:-

Direct compression method



Wet granulation method



Types of BilayerTablet Press(28)

1. Single-sided tablet press
2. Double-sided tablet press
3. Bilayer tablet press with displacement monitoring

Single-sided tablet press

A single-sided press with a doublet feeder is the simplest setup for bilayer tablets. The feeders' two chambers deliver different powders, either by gravity or forced feed, to form separate layers in the die. Final compression is carried out in one or two steps.

Figure: 5 Single-Sided Tablet Press (29)

Description: The image depicts a single-sided tablet press machine used in pharmaceutical manufacturing for compressing powder blends into uniform tablets. It operates with one set of punches and dies, allowing precise control over tablet weight, hardness, and thickness, ensuring consistent quality and production efficiency.

Double-sided tablet press

In double-sided tablet presses, compression force is used to control tablet weight. The system measures the peak force during initial compression and uses this signal to reject faulty tablets and adjust die fill depth automatically.

Figure: 6 Double-Sided Tablet Press Machine (30)

Description: An image of a double-sided rotary tablet press (ACCURA B4), an industrial machine used in pharmaceutical manufacturing to efficiently compress powders into high-volume, uniform tablets.

Bilayer tablet press with displacement monitoring

The press design is based on displacement monitoring, which operates on a principle different from compression force measurement. This design is highly sensitive to displacement and depends on the applied pre-compression force rather than on tablet weight.

Figure: 7 Bi-layer Tablet Press with Displacement Monitoring (31)

Description: An image of a sophisticated rotary tablet press designed to manufacture bi-layer tablets, featuring an integrated displacement monitoring system to ensure accurate layer weight and thickness.

Evaluation Parametersfor FloatingBilayered Tablet

Pre-compression parameters

- Solubility of the drug
- Particle size determination
- Bulk density
- Tapped density
- Angle of repose
- Hausner ratio

Solubility of drug (32)

The Solubility of drugs intended for formulation as floating bilayer tablets should be evaluated in different media such as distilled water, 0.2 N HCL, 0.1 N NaOH, ethanol, methanol, and other relevant solvents.

Particle size determination (32)

Particle size can be measured by two methods, either using the laser diffraction method or by sieving method.

Bulk density (33)

It is expressed as the ratio of the mass of powder to its bulk volume. In this method, 50cm3 of powder is passed through sieve no. 20 and then transferred into a 100ml graduated cylinder.

Tapped density(33)

Tapped density is the increase in bulk density achieved after mechanically tapping the powder in a graduated cylinder.

Angle of repose(34).

Angle of repose represents the highest angle between the surface of accumulated powder and the horizontal plane.

Hausner ratio(34)

It is determined by using the formula,

Hausner ratio = Tapped Density/Bulk Density

Post-compression parameters(34-35)

- General appearance
- Thickness
- Weight Variation
- Hardness
- Friability test
- Disintegration test
- Dissolution test
- Floating lag time
- Floating time
- Drug content uniformity

General appearance (34)

Tablet appearance is evaluated based on its size, shape, colour, taste, surface characteristics, and the presence of any physical defects.

Thickness (35)

By using a vernier calliper or calibrated screw gauge, the thickness and diameter of three tablets selected at random were measured.

Weight variation (35)

Twenty tablets were selected and weighed individually. The average weight and standard deviation were then calculated. The test is considered acceptable if not more than two tablets deviate from the average weight. Since all formulations had tablet weights greater than 324mg, a maximum deviation of 5% permitted.

Hardness (35)

The hardness of the tablets was measured by using a Monsanto hardness tester by randomly selecting three tablets, and the results were expressed in kg/cm².

Friability test (35)

Friability was determined by weighing 26 tablets after removing any dust, then placing them in a Roche friabilator and rotating the drum vertically at 25 rpm for 4 minutes. After the run, the tablets were dusted and reweighed, and the percentage friability was calculated using the standard formula:

% Friability = initial wt. of tablet-final wt. of tablets/initial weight multiplied by 100

Disintegration test (35)

A single tablet was placed in the disintegration apparatus containing either 0.1 N HCL or phosphate buffer (pH 6.8), and the test was conducted at 37 +_ 0.5 0 C.

Dissolution test (35)

The study was performed using a USP paddle operated at a rotational speed of 50 rpm and maintained at 37 +- 0.5 0 C. At predetermined time intervals, 5 ml samples were withdrawn and replaced with an equal volume of fresh buffer.

Floating Lag time (35)

It represents the time taken by the tablet to begin floating, which should be less than 1 minute. This parameter is measured using a dissolution test apparatus containing 0.1 N HCL.

Floating time (35)

It denotes the total duration for which the tablet remains floating on the surface of the medium.

Drug content uniformity (35)

A quantity of powder equivalent to the drug dose from ten tablets was accurately weighed and transferred to a volumetric flask. Buffer solution was added, and the absorbance was determined using a UV spectrophotometer.

Summary of Invivo'ssuccess with GRDDS

Table 1: Invivo's success with GRDDS

Sr No	Scientist	Developed	Animal	Conclusion
1	Boorugu S., Radha G.V.(36)	Formulation and evaluation of eplerenone floating microspheres	Rabbits	Radiographic imaging showed clear gastric retention; PK profile improved vs plain drug.
2	Pande S.D. et al.(37)	Cefpodoxime proxetil floating microspheres as GRDDS	Male albino rats	Relative bioavailability increased 1.5× compared to suspension.
3	Khan F.N. & Dehghan M.H.G.(38)	Cephalexin floating tablets using HPMC K100M matrix	Albino rabbits	Floating lag time <15 s, floating duration >12 h; sustained in-vitro drug release 12 h.
5	Thakar et al.(39)	Floating tablets of baclofen using Polyox WSR 303 & HPMC K4M	Rabbits	Floating lag time 4–5 s, buoyancy >12 h; favourable GRDDS properties.

Summary of Human Study

Sr No	Scientist	Drug	Formulation	Conclusion
1	Chen et al.(40)	Losartan	gastro-retentive tablets based on swelling/effervescence mechanism	Optimised tablets achieved an enhanced bioavailability of approximately 164% relative to the immediate-release market formulation named Cozaar
2	Bomma and Veerabrahma(41)	cefuroxime	gastro-retentive tablets based on swelling/effervescence mechanism	An increase of 1.61-fold relative bioavailability.
3	Meijerink et al.(42)	nicotinamide	Hypromellose was used as a swelling agent in that formulation	An increase in nicotinamide plasma levels for a period of at least 8 h after ingestion
4	Ranade et al.(43)	ellagic acid and aloe vera gel	bilayer floating tablet	75% ulcer inhibition in comparison to 57% ulcer

Table 2. Human Study

Summary of Patent on FloatingBilayered Tablet (44)

Table 3. Patent on Floating BilayeredTablet

Sr No	Drug	Patent
1	Losartan and metformin	Indian Patent
2	Ciprofloxacin ,Acyclovir, Ofloxacin	US Patent
3	Acyclovir, Ganciclovir, Ritonavir, Minocycline, Cimetidine, Ranitidine, Captopril, Methyldopa, Selegiline, Fexofenadine, Bupropion, Orlistat & Metformin	US Patent
4	Heparin and Insulin	US Patent
5	Calcitriol, combined with the delayed release of a bisphosphonate calcium resorption inhibitor such as alendronic acid and its salts and hydrates	US Patent

Commercially available combination drug products with chemical compositions and manufacturers.(45)

Table: 4 Commercially available combination drug products

Sr No	Brand name	Chemical name	Manufacturer
1	ZOMELIS-MET	Vildagliptin+ Metformin HCl	Eris Lifesciences
2	TELMA-LN	Cilnidipine IP + Telmisartan IP	GlenmarkPharmaceuticals Ltd..,
3	LINAVON DM	Dapagliflozin + Linagliptin + Metformin	Ernst Pharmacia Pvt. Ltd.
4	VITARESP FX	Fexofenadine + Montelukast	Alembic Pharmaceuticals Ltd.
5	GLUXIT BETA	Dapagliflozin + Bisoprolol	Eris Lifesciences Pvt. Ltd.
6	VINGLYN TRIO	Dapagliflozin, Vildagliptin and Metformin	Zydus Lifesciences Ltd.
7	PIOKIND®-M15	Pioglitazone, Metformin hydrochloride	Psychotropics India Ltd.

Summary of recent research on Floating Bilayered Tablet

Table 5. Recent research on Floating BilayeredTablet

Sr No	Drug	Year	Category	Result
1	Sucralfate + Metoprolol Succinate(46)	2025	Anti-ulcer + Antihypertensive	Optimised tablet floating lag 22 sec, sustained release 18 hrs, stable formulation, suitable for ulcer protection and hypertension management.
2	Aceclofenac (47)	2024	NSAID	Formulation F5 (HPMC K15) showed floating lag <1 min, buoyancy >12 hrs, 97% drug release over 12 hrs, following the Korsmeyer-Peppas model. No drug-excipient interaction, stable formulation
3	Levofloxacin + Famotidine (48)	2024	Antibiotic + H2 Receptor Antagonist	Improved gastric retention, controlled release, and enhanced therapeutic efficacy against H. pylori infections.

4	Nifedipine (49)	2023	Antihypertensive	Bilayer floating tablets increased gastric residence time, bioavailability, and reduced dosing frequency.
5	Levofloxacin (50)	2023	Antibiotic	Floating tablets improved sustained release over 12 hours, enhancing bioavailability and reducing dosing frequency.
6	Eplerenone(51)	2022	Antihypertensive	Tablets demonstrated sustained release, enhancing efficacy in hypertension management.
7	Quinapril Hydrochloride(52)	2022	Antihypertensive	Sustained-release formulation improved therapeutic outcomes in hypertension treatment.
8	Clarithromycin + Famotidine(53)	2021	Antibiotic + H2 Receptor Antagonist	Effervescent bilayer tablets floated 14–20 sec, sustained release >12 hrs, non-Fickian diffusion; improved treatment for H. pylori.
9	Nicardipine(54)	2021	Antihypertensive	Optimised bilayer tablets provided extended release, enhancing blood pressure control.
10	Amoxicillin(55)	2020	Antibiotic	Developed bilayer floating tablets with short floating lag times; batch F2 exhibited a longer floating lag time of 23 minutes. The tablets exhibited an initial burst phase followed by limited drug release, suitable for targeted antibiotic therapy.
11	Dantrolene Sodium(56)	2020	Muscle Relaxant	Tablets remained buoyant for 12 hours, providing sustained release suitable for muscle spasm management.

CONCLUSION

Floating Bilayered Tablets (EFBTs) have gained prominence as a novel platform in oral controlled drug delivery, combining gas-generating buoyancy with prolonged drug release functionality. This dual-layered design extends gastric retention, facilitates better absorption of drugs confined to the upper gastrointestinal tract, and supports improved therapeutic consistency. Research findings consistently report enhanced bioavailability, optimised release kinetics, and superior patient adherence compared to traditional oral formulations.Future developments integrating EFBTs with responsive materials and advanced fabrication techniques could further broaden their clinical relevance, reinforcing their position as a next-generation approach for effective gastro-retentive drug delivery.

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