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Review On Floating Microspheres: A Novel Approach

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ABSTRACT

The purpose of floating microsphere's is to improve gastric retention time. Floating drug delivery is considered as the most effective amongst the several approaches of gastro retentive drug delivery systems. The short gastric residence times (GRT) and unpredictable gastric emptying times (GET) are the two most important parameters that play a vital role in improving the bioavailability of drugs those are having an absorption window at the stomach. The purpose of writing this review on floating microspheres is to compile the recent literature with special focus on the principle mechanism of floatation to achieve gastric retention. Recent advances indicate that floating microspheres are especially suitable for achieving sustained or delayed release oral formulations with flexibility of blending to attain different release patterns, low risk of dose dumping as well as reproducible and short gastric retention time. The floating drug delivery approach is a low-density system that may be effervescent or Non - Effervescent type with sufficient buoyancy to flow over the gastric contents and remain buoyant in the stomach without affecting the stomachic emptying rate for a prolonged duration. Floating dosage forms include tablets, granules, capsules, microspheres, microparticle, etc. are few formulations available commercially. A comprehensive summary of different floating drug delivery and its present status has been highlighted in this review.

Keywords: Floating microsphere, Gastric retention time, Bioavailability, Sustained release, Delayed release, Absorption, Microsphere, Drug delivery.

1. INTRODUCTION FLOATING SYSTEM:

Davis was the first to use floating medication delivery in 1968. The moniker "floating medication delivery" was suggested based on the microspheres' properties. Floating drug delivery systems (FDDS) is one, amongst the several approaches that are likely used in prolongation of the gastric residence times (GRT)¹. This characteristic of the floating system allows it to maintain buoyancy in the belly for an extended length of time without affecting the pace of gastric emptying². During the GRT, the medication floats on the stomach content and then delays its release at the appropriate pace from the system. The drug plasma core improves as a result of this technique, and the stomach residence duration increases³. Floating microspheres have been gaining attention due to the uniform distribution of these multiple-unit dosage forms in the stomach, which results in more reproducible drug absorption and reduced risk of local irritation. Such systems have more advantages over the single-unit dosage forms.⁴ The Floating drug delivery is intended to hold drug in the stomach and ideal for drugs with poor solubility and low intestinal fluid stability on basis that FDDS makes the dosage type less dense than the gastric fluid to allow it swim on them. Without impacting rate of gastric emptying.⁵ The drugs with shorter half-lives that are readily absorbed in GIT are highly removed from circulation of the serum. To resolve these difficulties, oral managed drug delivery mechanism has been risen as they release the drug into the GIT for longer periods of time and retain a steady concentration of the medication in

the serum.⁶ In the gastric area, gastro retentive dosage type may last for few hours and thus significantly increase drug GRT to improve bioavailability, minimize the drug waste and improve the solubility of drugs with the low solubility⁷. Floating microspheres are gaining popularity due to their wide range of applications in drug delivery to the stomach, where they experience activity and are distributed uniformly over the gastric fluid to prevent gastric emptying fluctuations and increase drug liberation⁸. The creation of novel controlled and delayed-release oral formulations is also made possible by this system, which furthers the advancements in pharmaceutical expansion⁹. Floating microspheres were formulated to prolong the gastric retention and enhancement of bioavailability of the drug candidate¹⁰.

GASTRO RETENTIVE DRUG DELIVERY SYSTEM (GRDDS)

Gastric emptying of dosage forms is an extremely inconstant process and the ability to prolong and control emptying time is a valued asset for dosage forms that reside in the stomach for a longer period of time than conventional dosage forms ¹¹. Gastro retentive dosage forms have potential for use as controlled- release drug delivery systems. Gastro retentive floating drug delivery systems have a bulk density lower than that of gastric fluids and thus increase residence time of drug in stomach and provide controlled delivery of many drugs¹².

Hence one of the most feasible approaches for achieving a prolonged and predictable drug delivery in the GIT is to regulate the gastric residence time by using gastro-retentive dosage forms (GRDFs)¹³. Gastro-retentive drug delivery system offers several advantages besides providing better bioavailability to poorly absorbed drugs and a required release profile thus attracting interest of pharmaceutical formulation scientists¹⁴. GRDD is an approach to increase the gastric residence time, therefore targeting site-specific drug release in the upper GIT for local or systemic effects¹⁵. It remains in the gastric region for several hours and thereby prolongs the gastric residence time of drugs¹⁶. It has several advantages over immediate release dosage form including the minimization of fluctuations in plasma drug concentration and at the site of action over prolonged periods of time, resulting in optimized therapeutic effectiveness and reduced the side effects, reduction of total dose administered and reduction of administration frequency leading to greater patient compliances and bioavailability, reduces drug waste and number of dosage regimen and improves solubility for drugs that are less soluble in high pH environment ¹⁷. Gastric retention also helps to provide better availability of innovative products with new therapeutic potentials and substantial benefits for patients. The self-controlled gastric retaining of dosage forms may be managed by the appliance of floatation, mucoadhesion, expansion, sedimentation, modified shape systems etc¹⁸. Based on this, different approaches have been proposed to retain the dosage form in the stomach which comprises bloadhesive systems, floating systems, swelling and expandable systems but floating and bioadhesive system are extensively researched 19. GRDDS is one of the novel approaches in pharmaceutical industry as a means to achieve better therapeutic benefits such as easy to dosage administration, patient compliance and formulation flexibility²⁰.

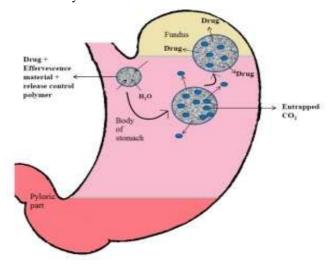


Fig 1: Gastro- Retentive drug delivery system

Advantages of floating microspheres

- Enhanced bioavailability
- Enhanced first-pass biotransformation
- Sustained drug delivery/reduced frequency of dosing
- Targeted therapy for local ailments in the upper GIT
- Reduced fluctuations of drug concentration

- Improved receptor activation selectivity
- Reduced counter-activity of the body
- Extended time over critical (effective) concentration

Disadvantages of floating microspheres

- Drugs that have issues with gastric fluid stability and solubility are not suitable for floating microspheres.
- Some factors, such as gastric motility, the presence of food, and pH, influence the drug retention of the floating system.
- Drugs that irritate the gastric mucosa are not permitted in this type of drug delivery system.
- High variability in gastric emptying time due to its all or non-emptying process.

CLASSIFICATION OF FLOATING DELIVERY OF DRUGS²¹:

Floating drug delivery has been classified into two types: -

- 1. Effervescent system
- 2. Non-effervescent system

I EFFERVESCENT SYSTEM

Effervescent medication delivery systems are made up of a matrix and a swellable polymer like methylcellulose or chitosan, as well as effervescent chemicals like sodium bicarbonate that react with the natural acid (HCl) present in the GIT when it comes into contact, resulting in the formation of carbon dioxide and the bouncy of the drug. Effervescent FDDS employs gas-generating components, such as sodium bicarbonate, in combination with organic acids like citric acid or tartaric acid. Upon contact with gastric fluid, these ingredients react to produce carbon dioxide (CO₂), reducing the system's density and enabling it to float on the stomach's contents.

The effervescent system is further classified as

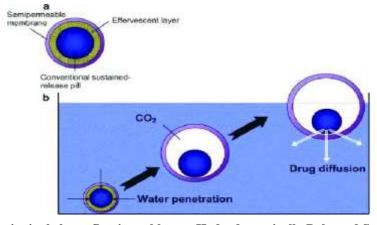
- A: Volatile liquid containing system
- B: Gas generating system

A. Volatile liquid containing system:

Within this drug delivery system, there are two chambers. The first chamber holds the medication, while the second chamber contains a volatile liquid, such as ether or cyclopentane. This system is a deformable unit that expands from its collapsed state and then returns to its original position to extend the duration of medication administration.

B. Gas generating system:

Because the matrix contains bicarbonate material, when it reacts to an acidic environment, it contributes to the production of carbon dioxide, lowering their bulk thickness or specific gravity and assisting them in swimming over the GI fluid (Chyme)



a. Intra gastric single layer floating tablets or Hydrodynamically Balanced System (HBS)

These are prepared by mixing the CO2 generating agents and the drug with in the matrix tablet. These have a bulk density lesser than gastric fluids and thus remain floating in the stomach unflattering the gastric emptying rate for a prolonged period. The drug is released gradually at a desired rate from the buoyant system and after the complete release the residual system is expelled from the stomach.

b. Intra gastric bilayered floating tablets

These are also compressed tablet and contains two layer i.e., i) Immediate release layer and ii) Sustained release layer

II NON-EFFERVESCENT SYSTEM:

The non-effervescent FDDS relies on the swelling properties of polymers or their bioadhesive interactions with the gastrointestinal (GI) mucosa to achieve gastric retention²¹. After the medication is taken, it interacts with gastric fluids in the GIT and expands, reducing its bulk density and preventing it from passing through the stomach. These systems are sometimes referred to as "plug-type" systems because they have a tendency to stay in the GIT for a long period and not cross the pyloric sphincter, therefore extending the amount of time they spend in the stomach.

The FDDS belonging to this class are usually prepared from gel-forming or highly swell able cellulose type hydrocolloids, polysaccharide or matrix forming polymers like polyacrylate, polycarbonate, polystyrene, and poly-methacrylate. The drug in the dosage form dissolves in and diffuses out with the diffusing solvent forming a 'receding boundary' within the gel structure. The various types of this system are as:

- Single Layer Floating Tablets
- > Bi-layer Floating Tablets
- Alginate Beads
- Hollow Microspheres
 - **Single Layer Floating Tablets**: They are formulated by intimate mixing of drug with a gel-forming hydrocolloid, which swells in contact with gastric fluid and maintains bulk density of less than unity.
 - **Bi-layer Floating Tablets:** A bi-layer tablet contains two layers one immediate release layer which releases initial dose from a system while another sustained release layer absorbs gastric fluid, forming an impermeable colloidal gel barrier on its surface, and maintain a bulk density of less than unity and thereby it remains buoyant in the stomach.
 - **Alginate Beads:** Spherical beads of approximately 2.5 mm diameter can be prepared by dropping a sodium alginate solution into the aqueous solution of calcium chloride, causing precipitation of calcium alginate leading to the formation of the porous system, which can maintain a floating force for over 12 hours.
 - Hollow Microspheres: Hollow microspheres (micro balloons), loaded with a drug in their outer polymer shells were prepared by a novel emulsion-solvent diffusion method. The micro balloons floated continuously over the surface of acidic dissolution media containing the surfactant for more than 12 hours in vitro.

MECHANISM OF FLOATING MICROSPHERE²²

Floating drug delivery systems (FDDS) have a bulk density less than gastric fluids and so remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. While the system is floating on the gastric contents, the drug is released slowly at the desired rate from the system. However, besides a minimal gastric content needed to allow the proper achievement of the buoyancy retention principle, a minimal level of floating force (F) is also required to keep the dosage form reliably buoyant on the surface of the eal. Because the outer layer of the floating microballoons includes polysaccharides and polymer hydrates to form a colloidal gel barrier that controls the movement of gastric fluid in and out after administration of the dosage type, low-density microspheres communicate with the gastric fluid (acid) in the stomach, resulting in increased gastric retention with reduced fluctuations in plasma drug concentration. The air molecule is trapped inside the inflated polymer. It helps to decrease its bulk density below that of the gastric fluid, allowing it to swim over the gastric fluid surface. For maximal cases, a lesser volume of stomach fluid is required for floation of the floating dose type.

Unique and innovative equipment for determining resultant weight has been published in the literature to quantify the floating force kinetics.

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F = F buoyancy - F gravity = (Df - Ds) gv
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Where,

F= total vertical force;

Df = fluid density;

Ds = object density;

v = volume;

g = acceleration due to gravity

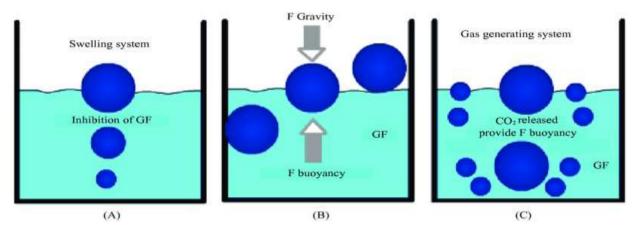


Fig 3: Mechanism of floating microsphere

POLYMERS USED IN FLOATING DRUG DELIVERY SYSTEM:

Table 1: List of polymer used in different dosage forms²³

S. No.	Polymer	Dosage Form
1	Xanthan Gum, Karaya Gum, Guar Gum, Carrageenan,	Tablets
	Hydroxypropyl Methylcellulose (HPMC K4M, HPMC K100M) HPMC E15LV, HPMC E50LV, HPMC K100LV, Polyvinyl Pyrrolidone (PVP K30) HPMC K15M, Carbopol, Sodium Carboxymethyl Cellulose, PVP K30 Psyllium Husk, Crospovidone	
2	Ethylcellulose,Eudragit RL100, Cellulose Acetate	Microspheres
3	HPMC K4M, HPMC K15M, HPMC K100K, Ethyl Cellulose	Matrix Tablet
4	HPMC, Carbopol 934P,Ethyl Cellulose, Chitosan, Sodium Carboxymethyl Cellulose	Superporous Hydrogel
5	HPMC K4M, Ethyl Cellulose	Microballoons

1.Natural Polymers

Chitosan: Biodegradable, biocompatible, and forms a gel in acidic pH, promoting sustained medicine release and buoyancy.

Guar gum: Provides gel- forming capability and helps sustain medicine release.

Xanthan gum: Used as a thickening agent and stabilizer, promoting floating and controlled release.

Alginates: Form hydrogels that swell in the stomach, enabling floatation and controlled medicine delivery.

Hydroxypropyl Methylcellulose (HPMC): A extensively used polymer for controlled release phrasings due to its gelforming capability. Different grades (e.g. HPMC K4M, K15M) can conform medicine release rates.

Methylcellulose: Provides buoyancy and a prolonged floating effect due to its high water immersion capacity.

Ethylcellulose: frequently used in combination with other polymers to modify medicine release and enhance floatation.

2. Synthetic Polymers²⁴

Eudragit (Methacrylic acid copolymers):

- a. Eudragit RL and RS give controlled medicine release and help maintain buoyancy.
- b. Eudragit NE 30D used in coatings for floatable phrasings.

Polyvinyl Alcohol (PVA): Biocompatible, forms stable hydrogels, and aids in floatation.

Polyethylene Oxide (PEO): Offers high lump capacity, perfecting the floatation and release profile.

Polylactic-co-Glycolic Acid (PLGA): Used in advanced FDDS to achieve sustained release.

2. METHODS OF PREPARATION

METHODS USED FOR PREPRATION OF FLOATING MICROSPHERES²⁵

- Spray Drying
- 2. Ionic gelation method
- 3. Double emulsion technique
- 4. Phase separation co-acervation technique
- 5. Single emulsion technique
- 6. Quasi emulsion solvent diffusion

1. Spray Drying:

In the Spray Drying technique, polymer is first dissolved in a suitable volatile organic solvent. The drug in solid form is then dispersed in polymer solution with high-speed homogenization. This dispersion is then atomized in the stream of hot air. The atomization leads to formation of the small droplets or fine mist from which the solvent evaporates instantaneously leading formation of the microspheres in a size range 1-1 00µm.

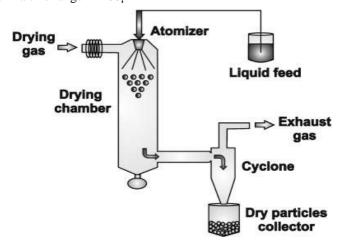


Fig 4: Spray drying process

2. Ionic gelation method:

Ionotropic gelation is based ability of poly electrolytes to cross link in presence of the counter ions to form beads. Since, use of alginates, gellan gum, chitosan and the carboxymethyl cellulose for encapsulation of drug and even cells, ionotropic gelation technique has been used for this purpose^{26.}

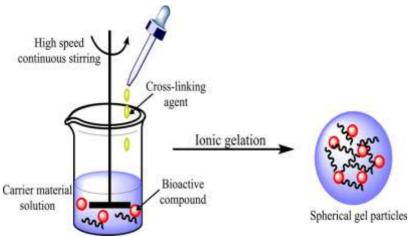


Fig 5: Ionotropic gelation method

3. Double emulsion technique:

The double-emulsion method used for preparation of microspheres involves formation of the double or multiple emulsions of water and oil. This method can be used with both natural and the synthetic polymers. The aqueous drug solution is dispersed in the lipophilic organic continuous phase.

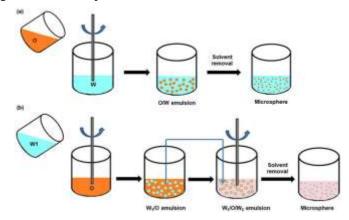


Fig 6: Double-emulsion Method

4. Phase separation co-acervation technique²⁷

In this method, drug particles are dispersed in the solution of polymer and an incompatible polymer is added to system which makes first polymer to phase separate and engulf the drug particles. Addition of non-solvent results in solidification of a polymer. The agglomeration must be avoided by stirring suspension using a suitable speed stirrer since as process of microspheres formation begins the formed polymerize globules start to stick and form the agg.

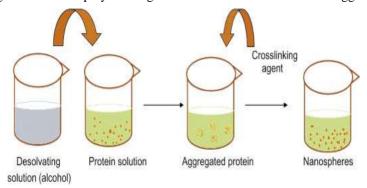


Fig 7: Phase separation technique

5. Single emulsion technique²⁸:

In this method, the micro particulate carriers of the natural polymers i.e. those of proteins and the carbohydrates are prepared by single emulsion technique. The natural polymers are dissolved or dispersed in the aqueous medium followed by dispersion in non-aqueous medium like oil with help of cross linking agent.

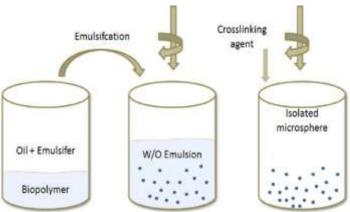


Fig 8: Single emulsion method

6. Quasi emulsion solvent diffusion:

Microsponges can be manufactured by a quasi emulsion solvent diffusion method using the external phase containing distilled water and polyvinyl alcohol. The internal phase consists of drug, ethanol, and the polymer. At first, internal phase is manufactured at 60°C and then added to external phase at room temperature.

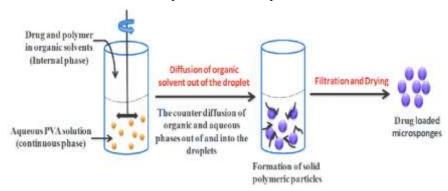


Fig 9: Quasi emulsion solvent method

FACTORS AFFECTING GASTRIC RETENTION²⁹

The gastric retention time (GRT) of capsule form is controlled by several factors that affect their effectiveness as a gastroretentive system.

Density – GRT is a function of capsule form buoyancy that is dependent on the density.

Size – capsule form units with a fringe of further than 9.5 mm are reported to have an increased GRT.

Shape of dosage form – Tetrahedron and ring- shaped bias with a flexural modulus of 48 and 22.5 kilopounds per square inch (KSI) are reported to have better GRT. 90 to 100 retentions at 24 hours compared with other shapes.

Single or multiple unit formulation – Multiple-unit formulations offer more predictable release profiles, reduce the risk of dose dumping, enable co-administration of incompatible substances, and provide greater safety compared to single-unit forms.

Gender – Mean ambulatory GRT in males $(3.4 \pm 0.6 \text{ hours})$ is less compared with their age and race- matched womanish counterparts $(4.6 \pm 1.2 \text{ hours})$, anyhow of the weight, height and body face.

Age – Elderly people, especially those over 70, have a significantly longer GRT.

Posture – GRT can vary between supine and upright ambulatory countries of the case.

Biological factors – Diabetes and Crohn's complaint.

APPLICATION OF FLOATING DRUG DELIVERY SYSTEM³⁰.

- 1. **Sustained Drug Delivery**: Floating systems prolong gastric residence, enabling controlled drug release over time. E.g., sustained-release floating capsules of nicardipine showed effective in vivo performance.
- 2. **Site-Specific Delivery**: Ideal for drugs absorbed in the stomach or upper intestine, like diuretics and vitamin B2, enhancing bioavailability significantly.²⁹
- 3. **Absorption Enhancement**: Improves bioavailability for drugs with site-specific absorption in the upper GI tract. E.g., floating formulations showed superior absorption compared to conventional forms.³⁰
- 4. **Constant Blood Levels**: Ensures steady drug release, maintaining consistent blood levels, with easy administration and better patient compliance.

FORMULATION OF FLOATING TABLETS³¹

1. Active Pharmaceutical Ingredient (API): The drug intended for controlled or sustained release.

Example: Metformin, Ciprofloxacin.

- 2. Polymers:
- 3. **Hydrophilic Polymers:** Control drug release and form the matrix.

Examples: Hydroxypropyl methylcellulose (HPMC), Carbopol.

b. **Effervescent Agents:** Generate gas for buoyancy.

Examples: Sodium bicarbonate, citric acid.

3. **Buoyancy Enhancers:** Provide low density.

Examples: Low-density materials like polyethylene oxide or ethyl cellulose.

4. **Binders:** Ensure tablet integrity.

Examples: Polyvinylpyrrolidone (PVP), starch.

5. Lubricants and Glidants: Facilitate manufacturing.

Examples: Magnesium stearate, talc.

6. **Gas-Generating System:** Sodium bicarbonate and organic acids (e.g., citric acid) react in the gastric medium to release CO₂.

EVALUATION OF FLOATING MICROSPHERE³²:

1) Particle Size and Shape

Optical microscopy was used to assess or determine particle size with the assistance of a calibrated eyepiece micrometer and a stage micrometer. The average particle size of microspheres is obtained by multiplying the size of 100 microspheres.

D mean = $\sum n d / \sum n$

Where

n = number of microspheres checked;

d = Mean size

2) Determination of encapsulation efficiency

By precisely weighing 50mg of microspheres and smashing them appropriately with the assistance of a glass mortar and pestle, drug entrapment efficiency was achieved. The microspheres were then suspended and dissolved in 50mL of hydrochloric acid buffer (pH 1.2) and set aside for 24 hours. content in the filtrate was measured spectrophotometrically at 232nm using a UV spectrophotometer after appropriate dilution³³.

[Drug Entrapment efficiency = Actual weight of microspheres/Theoretical weight of drug and polymer × 100]

3) Tapped density

Accurately weighed 10g of microballoon powder sample, which was put in a 25ml measuring cylinder. The cylinder was dropped 100 times from a height of one inch onto a hard hardwood surface at 2-second intervals. The final volume is measured after 100 taps, and the tapped density is computed using the equation (values in gm/cm3).

Tapped Density = Sample Weight /Volume Tapped

4) The angle of repose (θ)

The funnel was placed in a burette stand with the stem of the funnel 2.5cm above the horizontal surface. The microspheres sample powder was allowed to flow out the funnel until the pile's height just touched the funnel's tip. The pile radius was then calculated by drawing a border around the pile's circle and averaging the radius of the circumference across three attempts. The connection between flowability and the angle of repose³⁴.

A formula is used to compute the angle of repose.

 $\theta = \tan - 1 \text{ h/r}$

Where θ is the angle of repose, h is the height of the pile; r is the radius of the pile.

Table 2 : Relationship between the angle of repose (θ) and flowability

The angle of repose(θ)	Flowability
<20	Excellent
25–30	Good
30–40	Passable
>40	Very poor

5) Percentage Yield

It's determined by multiplying the weight of microspheres obtained from each batch by the total weight of all non-volatile ingredients (drug and polymer) used to make that batch by 100^{35} .

The following formula is used to express it.

% Yield = (Actual weight of floating microspheres/Weight of drug taken + Total polymer weight) ×100

6) Swelling Index

It's calculated by measuring how much microspheres swell in a specific solvent. For the Swelling examination of the material, dissolution equipment, optical microscopy, and other advanced methods are employed. Swelling of 5mg of dried microspheres poured in 5ml of buffer solution overnight in a measuring cylinder determines the equilibrium swelling degree of microspheres³⁶.

It has been computed.

Swelling Ratio = Wet Formulation Weight/ Formulation Weight

7) Buoyancy determination

The microspheres were weighed and distributed across the surface of a USP dissolving type II device filled with 900 ml of 0.1 N HCl containing 0.02 percent Tween 80. A paddle spinning at 100 rpm was used to stir the medium. Separately, the floating and settling parts of microspheres were collected. The microspheres were weighed after drying³⁷. The ratio of the mass of the microspheres that stayed floating to the overall mass of the microspheres was used to determine buoyancy percentage.

Percentage buoyancy = Wf/Wf+Ws x 100

Where,

Wf- Floating Weight,

Ws-Settled Microsphere, respectively

8) Surface Morphological Study using SEM

The exterior and interior morphology of the microspheres, as well as the surface degradation of biodegradable microspheres, were determined using scanning electron microscopy (SEM)³⁸.

9) In vitro drug release of microbaloons

In vitro dissolution tests were carried out per the United States Pharmacopoeia (USP) I basket type dissolving apparatus at a specified speed. A sample of floating microspheres equal to the medication dosage is introduced to 900ml of 0.1N HCL dissolving media and agitated at 100rpm at 370.5°C³⁹. After a predetermined period, samples are removed and examined using any appropriate analytical method, such as UV spectroscopy.

10) Evaluation In-Vivo

In vivo investigations are often conducted by giving floating microspheres to healthy albino rabbits weighing about 2-2.5kg. The animals fast for 24 hours before the trials, but food and water are supplied to the rats throughout the experiments, and a radiological technique is used for monitoring. Blood samples of 2ml are taken. In-vivo investigations employ X-ray photography to study the floating behavior and location of microspheres in GIT

11) Stability Studies

Sealing was done with aluminum packing. Inside is a polyethylene coating that has been

optimized. For three months, samples were stored at 40°C and 75 percent RH in the stability chamber. Samples were examined for physical appearance and drug content after the experiments⁴⁰.

3. CONCLUSION

Floating drug delivery systems, particularly floating tablets, represent a promising approach in the field of pharmaceutical science for enhancing the bioavailability of drugs with narrow therapeutic windows or those affected by gastric emptying times. These systems offer significant advantages, including prolonged gastric retention, localized drug release, and improved patient compliance. The design and formulation of floating tablets depend on various factors, such as the choice of excipients, polymers, and the method of preparation, which can significantly influence their performance. Despite the progress made in this field, challenges remain, including the variability in gastric conditions, the need for precise control over drug release, and the stability of the dosage form over time. Future research should focus on optimizing formulation strategies, exploring new material s for better floating properties, and conducting clinical studies to validate the efficacy of

floating tablets in diverse therapeutic areas. Overall, floating tablets continue to offer exciting potential in advancing oral drug delivery systems and improving patient outcomes.

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