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Gastroretentive Microballoons for Oral Drug Delivery: Formulation Strategies, Mechanistic Insights, Evaluation, Clinical Translation, and Future Perspectives

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Abstract

Microballons are the hollow sphere usually used as oral doses form which in turn used with proper polymer which enhances the bioavailability of drug as drug is entrapped within the hollow sphere which increases the drug retention in the stomach which results into the increase in the drug absorption in the stomach lining for the prolong time and controlled release. It improves the drug action along with proper doses suitable for various stomach illness. While there is still limitation to this drug delivery system yet it shows impressive therapeutic outcomes, particular with those drugs who are difficult to absorb or have little absorption windows. With the outburst of nano-technology and nano-particles in drug delivery system we can expect more effective and more site oriented microballons in future with enhance bioavailability and targeted results. This detailed review allows all the topic with respect to its concept, classification and use as gastroretentive drug delivery systems in the modern pharmaceutical advancement in doses form and enhance the process of drug delivery of drug which have low bioavailability in oral dosage form or those who can't withstand fast pass metabolism.

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1. Introduction

People prefer taking medicines orally because it's convenient and they're more likely to adhere to the prescribed dosage. Additionally, it's generally more affordable. However, there are some challenges associated with the conventional method of drug administration. Sometimes, the medicine passes through the stomach too quickly, leading to poor absorption or ineffective utilisation by the body. In this review we broadly explain the dosage form which reduce the challenge i.e. Microballons which comes under GRDDS (Gastro retentive drug delivery system) which overcome all negative points associated with oral drug delivery. The oral delivery of drugs has little absorption window in the GIT and it is also restricted by poor bioavailability with respect to drug absorption (Kumar *et al.* 2026) ^[1].

• Micro-balloons

Micro-balloons also known as hollow microsphere are those system that tends to be one the most suitable approach for gastric retention micro balloons drug delivery system can be explained as it is containing empty particles of spherical shape without core identically having a size than 200micrometers.

The floating micro balloons showed a mechanism in which drug is floating in the gastric fluid which in turns increases its bioavailability. Micro-balloons are one of the most like approving floating systems with the unique advantage of multiple unit's system as well as better floating properties, because there is a central hollow space within the microsphere (Nilkhumbang *et al.* 2009) ^[2]. Hollow microspheres of acrylic resins, eudragit, hydromellose, polyethylene oxide, cellulose acetate, polycarbonate floating balloons and glucire floating granules are the current advancements.

2. Concept and Principle of Floating Microspheres

The basic concept of these delivery system is that it makes drug to stay in the gastric fluids for a longer timeframe so that it can sustain released and it also do not leave the stomach for long duration that makes them to release drug at a constant rate for a long time and these drug particles are buoyant for 4-5 hours which directly increase the therapeutic effect of drug and its bioavailability.

• Principal of Micro-balloons

When micro balloons come in contact with gastric fluid, it makes sure that the drug is slowly released from the microballons at desirable rate to ensure its maximum gastric retention with condensed fluctuation in plasma drug concentration. However there required a minimum gastric content to make sure proper attainment of buoyancy (Jain *et al.* 2007) ^[3].

3. Classification of Floating Microspheres

Classification of Floating microspheres can be done on the bases of their structural traits, polymer buildup, their drug release nature. This classification set to understand various formulation design, to maximise performance, and make sure appropriate systems are used for specific therapeutic effects.

3.1. Classification Based on Structure

• Hollow Microspheres (Micro-balloons)

Hollow microspheres, that is micro-balloons, have a core internal cavity which is filled with gas & air. Their exceptional buoyancy is mostly due to their special structure. Key Features of Hollow Microspheres is that due to their hollow core, they have a low density as compare to gastric fluids. They are able to float over extended periods of time which can extend from 12-24 hours.

Hollow microspheres are usually made by emulsion solvent diffusion or evaporation techniques, which in turns makes the drug being dispersed inside the polymeric shell (Shah *et al.* 2009) ^[4].

• Mechanism of Floating

The polymer shell preserves structural integrity while the hollow chamber lowers overall density. Because of air trapping, the system stays buoyant and gets activated by contacting gastric fluids present in the stomach

Advantages

- Better retention in the stomach
- Drug release that is regulated and prolonged
- large surface area for the diffusion of drugs

Limitations

- Intricate methods of preparation
- Structural collapse risk while processing

Applications

- Perfect for medications that need to be present in the stomach and stay there for a long time, like antibiotics that target
- H. pylori and anti-ulcer medications (Awasthi *et al.* 2013) ^[5].

• Solid Microspheres

Dense, matrix-like structures without a hollow interior chamber are known as solid microspheres. The medication is evenly distributed throughout the matrix of polymers.

Key Features of Solid Microspheres as these have greater density in contrast to hollow microspheres and have Insufficient or nonexistent natural capacity to float. They also act as buoyancy enhancers, like gas-forming chemicals if required (Gattani *et al.* 2009) ^[6].

Floating Conduct

Internal void is absent, buoyancy depends on various parameters.

- Depends on Gastric fluid's Surface adsorption
- Low-density excipient incorporation

Benefits

- Simpler to create
- It also increases the mechanical strength and stability
- Distributing drugs uniformly

Restrictions

- It tends to diminish floating effect to very much extend.
- Gastric residence duration is reduced

Uses

- It is mainly used in situation when controlled release is given priority over floating.

3.2. Classification Based on Polymer Type

Polymer selection plays a great role which influence biocompatibility, it's stability, drug release which tends to increase the effectiveness of microballons.

• Microspheres Made of Natural Polymers

Biodegradable and biocompatible polymers from natural sources are used in these systems.

Typical Polymers like Alginate, chitosan, gelatin, and guar gum

Important Features of these natural polymers are as these are hydrophilic in nature and have ability to swell in stomach fluid. These molecules are non-toxic and biodegradable in nature (Sarkar *et al.* 2012) ^[7].

• Mechanism

Water is absorbed by natural polymers, creating a gel-like structure which promotes the distribution of drugs and improves mucoadhesion in certain situations.

Benefits

- Outstanding biocompatibility
- Safe for the environment
- Ideal for medications that are sensitive

Restrictions

- Variability from batch to batch
- Reduced mechanical power
- Quicker deterioration

Uses

- Drug distribution under control
- Mucoadhesive floating structures

- **Synthetic Polymer-Based Microspheres**

Because of their controlled release characteristics, stability, and reproducibility, synthetic polymers are employed extensively (Sarkar *et al.* 2012) (Mali *et al.* 2012) ^{[7] [8]}.

Typical Polymers

- Ethyl Cellulose
- Eudragit (types RL, RS, S, and L)
- PLGA, polyvinyl alcohol (PVA), and polylactic acid (PLA)

Important Features

- Semi-permeable or hydrophobic
- Improve medication release kinetics control
- Strong mechanical properties

Mechanism

The following factors primarily control drug release:

- Diffusion through the polymer matrix
- Restricted swelling (in the case of hydrophobic polymers)

Benefits

- Predictable and regulated release
- Strong stability
- Simple scalability

Restrictions

- Organic solvents might be needed.
- Possible toxicity issues (if improperly chosen)

Uses:

- Formulations for sustained release
- Systems of production on an industrial scale

3.3. Classification Based on Drug Release Characteristics

Drug release characteristics, which are essential for therapeutic efficacy, can also be used to classify floating microspheres (Rani *et al.* 2012) ^[9].

- **Microspheres with Instant Release**

These microspheres are made to quickly release the medication after being administered. Qualities:

- Low polymer barrier
- Quick drug dissolution
- Brief duration of action

Mechanism

- Rapid diffusion and dissolution cause the drug to be released fast.

Uses

- Medications with a rapid start of action
- Acute conditions or pain alleviation

Restrictions

- No long-term therapeutic benefit
- Regular dosage is necessary

- **Microspheres with Sustained Release**

In order to maintain therapeutic levels for prolonged periods of time, sustained release microspheres are designed to release medication over a long-extended length of duration (Kalyan *et al.* 2010) ^[10].

Qualities

- Diffusion control via a polymer matrix
- decreased frequency of dosage
- Enhanced adherence to treatment

Mechanism

- Diffusion and polymer swelling combined
- keeps the medication release constant over time.

Uses

- Chronic conditions (such as diabetes and hypertension)
- Short-half-life medications

- **Controlled Release Microspheres**

In order to guarantee constant plasma drug levels, controlled release devices are made to give medications at a set rate (Mathur *et al.* 2010) ^[11].

Qualities

- Accurate regulation of release kinetics
- reduction of peak-trough variations
- frequently adhere to zero-order or almost zero-order kinetics

Mechanism

- controlled by the thickness, content, and rate of breakdown of the polymer
- may use coated or multi-layered structures.

Benefits

- Enhanced effectiveness of treatment
- Diminished adverse effects
- Improved adherence to treatment

Uses

- Prolonged treatment
- Systems for targeted medication delivery

Table 1

Classification	Type	Key Feature	Examples of Drugs
Structure	Hollow microspheres	Air-filled cavity, high buoyancy	Famotidine, Metronidazole
Solid microspheres	Dense matrix	low buoyancy	Ibuprofen, Diclofenac
Polymer Type	Natural polymers	Biodegradable, hydrophilic	Amoxicillin, Curcumin
Synthetic polymers	Controlled release	stable	Propranolol, Omeprazole
Drug Release	Immediate release	Rapid action	Paracetamol, Caffeine
Sustained release	Prolonged effect		Metformin, Atenolol
Controlled release	Constant release rate		Nifedipine, Diltiazem

4. Components of Formulation

Several essential elements are involved in the creation of floating microspheres:

- **Polymers:** Control drug release and maintain structural integrity. Eudragit and ethyl cellulose are two polymers that are frequently utilized.
- **Solvents:** Used to dissolve medications and polymers (such as ethanol and dichloromethane).
- During preparation, surfactants and emulsifiers help to stabilize the emulsion system.
- The medication to be administered is known as the active pharmaceutical ingredient (API).

The shape, buoyancy, and drug release profile of the microspheres are strongly influenced by the choice of polymer and solvent solution (Negi *et al.* 2014) ^[12].

5. Preparation Techniques

• Method of Emulsion Solvent Diffusion

The most popular method is this one. A volatile organic solvent is used to dissolve the medication and polymer, which are then emulsified into an aqueous phase with a stabilizer. Hollow microspheres are created as the solvent evaporates and diffuses (Sharma *et al.* 2014) ^[13].

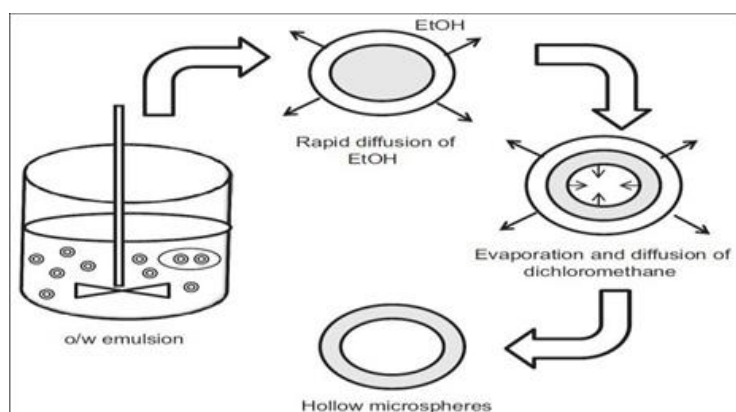


Fig 1

• Method of Solvent Evaporation

The polymer solution is distributed in an immiscible phase

using this technique. Solid or hollow microspheres are produced as the solvent evaporates (Nivesh *et al.* 2026) ^[14].

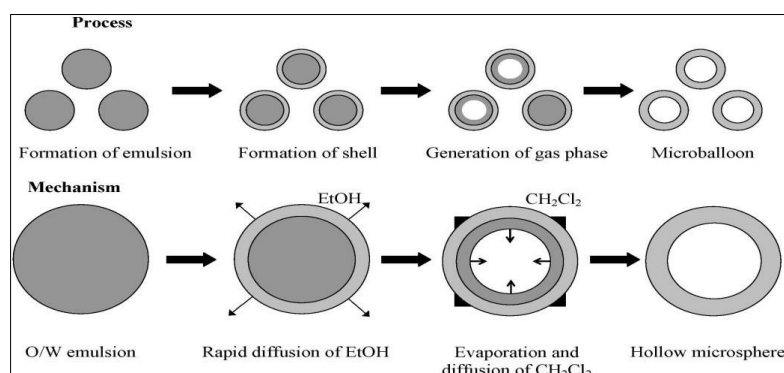


Fig 2

• Drying Using Spray

A quick and scalable method that creates microspheres by

atomizing the polymer-drug solution into a heated air chamber.

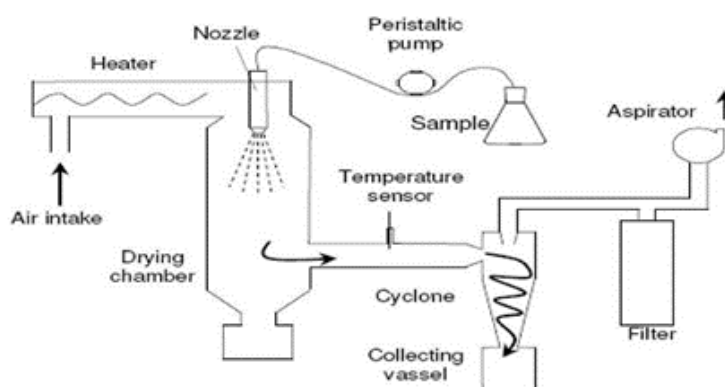


Fig 3

• Ionic Gelation Technique

This technique, which is mostly applied to natural polymers, entails cross-linking polymer chains in the presence of multivalent ions (Negi *et al.* 2014) ^[15].

6. Floating and Drug Release Mechanisms

Because of their hollow interior structure and low apparent density, which set them apart from traditional microspheres, microballoons are able to float. Gastric fluid typically has a density of 1.004 g/cm³; for a system to float, its density must be less than this (Kumar *et al.* 2012)(Jani *et al.* 2012) ^{[16] [17]}.

• Hollow Structure Formation

The center chamber of microballoons, which are created during solvent evaporation or diffusion processes, is filled with gas or air. A hollow core is created when volatile organic solvents (such as ethanol and dichloromethane) seep out of the polymer matrix during production, leaving behind void spaces. The microsphere's density is greatly decreased by this interior vacuum.

• Gastric Fluid Interaction

When microballoons are taken orally, they come into contact with stomach fluid, which starts the following process:

1. Gastric fluid is absorbed by hydrophilic or semi-permeable polymers during polymer hydration.
2. This results into formation of a gel barrier all around the microsphere's surface, which is hydrated.
3. Hollow cavity within the microsphere traps air, preventing it from sinking.
4. The total density of microballons remains lower than stomach fluid with the help of air which is trapped in microballons and swelling of polymer used in the formation of the same.
5. This results as microballoons remain buoyant for long duration, which even exceed over 12 hours, allowing its occupancy in the stomach for sustained release.

• Elements Influencing Floating Behavior

1. Polymers like ethyl cellulose which are hydrophobic in nature tends to it improve buoyancy.
2. Due to presence of increased void volume, Larger particles sizes float effectively.
3. High porosity gives better air entrapment.
4. The viscosity of stomach fluid influences the floating lag time, while surface tension affects stability and initial buoyancy.

6.1. Drug Release Mechanism

The drug release from microballoons is a complex process which involves many reoccurring mechanisms. It mainly revolves around that various properties of polymer used its configurations and matrix and the stomach's sensitivity and its environment (Singh *et al.* 2010)(Abhijeet *et al.* 2012) ^{[18] [19]}.

1. Mechanism of Diffusion

Diffusion plays a vital role

- Concentration gradient make drug molecules move from polymer matrix to the external media.
- First, if the medication is on or close to the surface, a burst release could happen.

- A regulated diffusion phase then takes over.

Fick's law of diffusion, which states that- release rate is directly dependent on:

- Drug diffusion coefficient
- Polymer barrier thickness & drug solubility

2. Mechanism of Polymer Swelling

When stomach fluid comes into contact with microballoons:

- Water is absorbed by hydrophilic polymers, causing them to swell.
- A gel-like diffusion barrier is created as a result of this swelling.
- The medication diffuses through channels created by the inflated polymer network.

Drug release is improved by swelling by

- Increasing the mobility of polymer chains
- Enabling the penetration of solvents
- Diffusion resistance reduction

3. Mechanism of Erosion

Particularly in hydrophilic or biodegradable environments, polymer erosion has a major role.

- In stomach fluid, the polymer matrix eventually breaks down or dissolves.
- The substance that is trapped is gradually released as a result. Erosion may be:
 - Drug release layer by layer due to surface degradation
 - **Bulk erosion:** The matrix as a whole deteriorates at once

In particular, erosion-controlled release is crucial in:

- Chitosan and Alginate are one of the natural polymers in these release
- Polymers which are synthetic in nature tends to decompose naturally

4. Combined Mechanism (Erosion + Diffusion + Swelling)

Drug release in the majority of practical formulations is controlled by multiple mechanisms rather than just one.

First stage → Diffusion-controlled

Phase intermediate → Swelling-controlled Last stage → Erosion-controlled

Drug release profiles are maintained and predictable as a result of this overlapping tendency.

6.2. Modeling and Drug Release Kinetics

Mathematical models are frequently used to examine the release behavior of microballoons:

1. Higuchi Diffusion Model

The Higuchi model describes drug release from a homogeneous matrix system where diffusion is the primary mechanism of release (Mukati *et al.* 2026) ^[20].

$$Q = KH$$

Where:

- Q = cumulative amount of drug released at time t
- KH = Higuchi dissolution constant

- t = time of drug release

This model indicates that drug release is proportional to the square root of time, suggesting a diffusion-controlled release mechanism.

2. Korsmeyer–Peppas Release Model

The Korsmeyer–Peppas model is employed to analyze the mechanism and kinetics of drug release from polymeric delivery systems (Naimuddin *et al.* 2010) ^[21].

$$M_t = k t^n M_\infty$$

Where:

- M_t / M_∞ = fraction of drug released at time t
- k = Constant(kinetic release constant)
- n = release exponent indicating the mechanism of drug release
- t = release time

Interpretation of the release exponent (n):

- $n < 0.45 \rightarrow$ Fickian diffusion
- $0.45 < n < 0.89 \rightarrow$ Non-Fickian (anomalous) transport
- $n = 0.89 \rightarrow$ Case-II transport (swelling-controlled release)

6.3. Transport That Is Non-Fickian (Anomalous)

Drug release in microballoons is frequently referred to as non-Fickian or anomalous transport, that means:

- Diffusion and polymer relaxation/swelling both regulate drug release.
- Neither process is entirely dominant on its own.
- As a result, the release profile is balanced and sustained.

This practice is especially beneficial because:

- Rapid drug release (burst effect) is avoided.
- sustains long-term therapeutic medication levels.
- increases bioavailability (Nivesh *et al.* 2025) ^[22].

7. Assessment Criteria

Various assessment criteria are used ensure the effectiveness of microballons:

9. Relevant SDGs for Pharmaceutical Micro-balloons

Table 2

S D G No.	SDG Title	Relation to Microballoons
SDG 3	Good Health and Well-Being	Improved drug delivery, better therapeutic efficacy, reduced side effects
SDG 9	Industry, Innovation and Infrastructure	Advanced novel drug delivery system development
SDG 12	Responsible Consumption and Production	Reduced drug wastage & efficient dosage utilization
SDG 6	Clean Water and Sanitation	Eco-friendly solvents and reduced pharmaceutical pollution
SDG 13	Climate Action	Sustainable pharmaceutical manufacturing practice

10. Current Developments

Recent developments in floating microsphere:

Targeted Cancer Therapy: Biodegradable and drug-loaded microspheres (e.g., loaded with doxorubicin) now offer precise tumor targeting and sustained release, reducing systemic toxicity and improving efficacy.

Small-Sized Embolization: The use of smaller microspheres has been extensively studied to enhance the effectiveness of TACE procedures in liver cancer, overcoming limitations of

- **Size and Morphology of Particles**
measured with scanning electron microscopy (SEM) and optical microscopy.
- **Research on Buoyancy**
calculated by calculating the proportion of microspheres in simulated stomach fluid that stay afloat throughout time.
- **Effectiveness of Drug Entrapment**
shows the percentage of medication that was successfully incorporated into the microspheres.
- **Drug Release Studies in Vitro**
carried out to assess release kinetics utilizing dissolving equipment.
- **Measurement of Density**
makes sure the density of the microspheres is less with compare for the fluid content of the stomach so that they can easily float (Barhate *et al.* 2009) ^[23] (Sarode *et al.* 2011) ^[24].

8. Floating Microspheres' Benefits, Restrictions & Uses.

It has been noticed that Microspheres have many benefits like they induce extended retention in stomach, increased bioavailability of the drug, and tends to decreased frequency of dosage which helps in enhanced adherence to treatment with respect to disease.

There are many restrictions with respect to doses forms as microballons are inhibited to couple with drugs formulations which makes the stomach hostile place by incresing the acidic environment which makes the drug unstable therefore, they are very much dependable on stomach fluid volume along with stomach empty time variability for the drug to act.

Microballons are very much useful to cure helicobacter pylori and other stomach problems, it also back as a anti-ulcer medications with extended stomach action.

It ensures a pivtol key role to play in the absorption of antihypertensive drugs and these drugs bioavailability is increased with little absorption duration (Shwetha *et al.* 2012)(Nivesh *et al.* 2025) ^[25] ^[26].

older, larger particles. Stimuli-Responsive Systems: New, smart microspheres have been developed that are sensitive to glucose (for insulin delivery) or pH changes (for targeted drug release) to enhance precision in therapeutic action.

Bioactive Hydrogel Microspheres: Advanced hydrogels are increasingly used to mimic the 3D microenvironment for tissue repair, cell scaffolding, and improved biological sensing. Diabetes Management: Advanced, surface-modified microspheres are being used to deliver anti-diabetic

medications, offering improved bioavailability and sustained glucose regulation. Non-Medical Applications: Beyond drug delivery, advancements in ceramic and glass hollow

microspheres have enhanced their use in specialized coatings for thermal insulation and fire protection

Table 3: Current Marketed Formulation of Microballons

S.No.	Brand Name	Drug	Dosage Form	Company	Type/ Application	Key Feature
1	Madopar HBS	Levodopa + Benserazide	Floating Capsule	Roche	Parkinson disease	Gastro-retentive controlled release
2	Valreleas e	Diazepam	Floating Capsule	Roche	Anxiety disorders	Prolonged gastric residence
3	Topalkan	Alginic Acid + Antacid	Floating Liquid System	Pierre Fabre	Gastroesophageal reflux disease	Floating raft/ microballoon approach
4	Liquid Gaviscon	Sodium Alginate + Sodium Bicarbonate	Floating Suspension	Reckitt Benckiser	Acid reflux	Floating drug delivery concept
5	Cifran OD	Ciprofloxacin	Extended Release Tablet	Sun Pharma	Bacterial infections	Gastro-retentive release technology
6	Glumetz a	Metformin HCl	Floating Tablet	Salix Pharmaceuticals	Type 2 Diabetes	Gastric retention technology
7	Proquin XR	Ciprofloxacin	Extended Release Tablet	Depomed	Urinary tract infections	Swellable/ floating delivery
8	Conviron	Ferrous Sulfate	Floating Capsule	Various manufacturers	Iron deficiency anemia	Sustained gastric delivery
9	Cytotec	Misoprostol	Gastro-retentive Tablet	Pfizer	Gastric ulcer prevention	Controlled gastric release
10	Nifedical XL	Nifedipine	Controlled Release Tablet	Pfizer	Hypertension	Extended gastric retention

11. Future Prospects

Nanotechnology Integration: Leveraging nanotechnology to enhance the precision and functional capabilities of microspheres.

Biodegradable Polymers: Shift toward advanced biodegradable polymers (like PLA) to improve bio-

compatibility, control release rates, and eliminate the need for surgical removal.

Improved Manufacturing: Advanced techniques like microfluidics and large-scale manufacturing are being refined to ensure consistent, controllable, and high-quality production of microspheres.

12. Present Clinical Challenges of Gastroretentive Microballoons

Table 4

S. No.	Clinical Challenge	Description	Clinical/ Industrial Impact	Possible Solutions
1	Variability in gastric emptying time	Gastric retention varies with food, age, posture, and disease conditions	Unpredictable drug release and bioavailability	Mucoadhesive and expandable systems
2	Difficulty maintaining buoyancy	Loss of hollow structure and density increase over time	Premature sinking and reduced gastric retention	Low-density polymers and optimized cavity formation
3	Limited drug loading capacity	Poor encapsulation of high-dose or water-soluble drugs	Low therapeutic efficiency	Nanocarrier integration and polymer optimization
4	Burst drug release	Rapid initial release of drug from surface	Dose dumping and side effects	Multi-polymer coating systems
5	Poor in vitro/in vivo correlation (IVIVC)	Laboratory results may not match human gastric conditions	Difficulty predicting clinical performance	Advanced in vivo imaging and simulation models
6	Reproducibility issues	Batch-to-batch variation during manufacturing	Dose inconsistency and regulatory problems	Standardized manufacturing protocols
7	Scale-up challenges	Difficulty converting lab formulations to industrial production	Commercialization limitations	Continuous manufacturing technologies
8	Use of toxic organic solvents	Use of chloroform, dichloromethane, etc.	Toxicity and environmental concerns	Green solvent systems and solvent-free methods
9	Stability problems	Moisture uptake, polymer degradation, cavity collapse	Reduced shelf life and altered release	Lyophilization and protective packaging
10	Patient-to-patient variability	Differences in gastric pH and motility among patients	Variable therapeutic response	Personalized drug delivery approaches

13. Conclusion

In this review, we came to conclusion that the floating microspheres effectively known as floating microspheres which showed gastro retentive controlled release delivery system, promises to be a potential approach for gastric retention. These formulations which are low-density system that has sufficient buoyancy to float over gastric contents and remain in stomach for much longer period, which marks them as suitable candidates for high bioavailability of various

medications and drug molecules which tends to lose their bioavailability when given in oral doses form. The drug in the formulation is released slowly at required rate which floats in the stomach over gastric contents that results into reduced fluctuations in plasma drug concentration. It enhances the bioavailability. Ongoing research and further advancements in microballons are expected to overcome current challenges and their use in pharmaceutical applications in modern pharmaceuticals doses forms, despite few drawbacks

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