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A COMPREHENSIVE REVIEW ON: FLOATING MICROBEADS FOR GASTRORETENTIVE DRUG DELIVERY

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ABSTRACT

The purpose of floating microbeads is to enhance the duration of gastric retention. These floating drug delivery systems have a lower bulk density than gastric juice, allowing them to remain buoyant on the gastric fluid for extended periods without affecting the gastric-emptying rate, thereby improving bioavailability. Gastro-retentive microbeads are particularly advantageous for the sustained or delayed release of oral formulations, offering flexibility in blending to achieve different release profiles, minimizing dosage risks due to their consistent and brief gastric retention time. This review aims to explore the literature on floating devices, techniques, the selection of appropriate or unsuitable drug candidates for GRDDS, low-density polymers that enable flotation on gastric fluid, processes, and the evaluation and application of floating microbeads.

KEYWORDS: Gastro- retentive drug delivery system (GRDDS), Microbeads, Preparation methods, Polymers.

INTRODUCTION

The oral route is the most common way to administer medication. Traditional medicine delivery systems maintain drug concentrations within the therapeutic range only when taken multiple times a day, depending on the prescribed dosage schedule. This results in significant fluctuations in medication levels. Efforts to address these fluctuations have led to the development of various Novel Drug Delivery Systems (NDDS).

The goal of all drug delivery systems is to ensure that a therapeutic amount of medication reaches a specific site in the body at effective concentrations. Floating drug delivery systems are designed to keep the drug in the stomach, making

them ideal for drugs with low solubility and poor stability in intestinal fluids. These systems work by making the dosage form less dense than gastric fluids, allowing it to float without affecting the rate of gastric emptying. Drugs with short half-lives that are easily absorbed in the gastrointestinal tract are quickly eliminated from the bloodstream. To address these challenges, oral drug delivery systems have been developed to release medication in the gastrointestinal tract over extended periods, maintaining a consistent drug concentration in the bloodstream.

Gastro-retentive dosage forms can remain in the gastric region for several hours, significantly increasing gastric retention time (GRT) to enhance bioavailability, reduce drug waste, and improve the solubility of poorly soluble drugs. Floating microbeads are hollow spherical particles without a core, with free-flowing particles ranging in size from 1 to 1000μm. These solid and free-flowing particulate carriers, which contain dispersed drug particles in either solution or crystalline form, enable sustained or multiple release profiles of treatments with various active agents while minimizing significant side effects. Furthermore, these microbeads remain effective under physiological conditions and can incorporate drugs for localized delivery at high concentrations, ensuring therapeutic levels are achieved at the target site while minimizing side effects by maintaining low systemic concentrations.[1,2]

FLOATING SYSTEM

The floating drug delivery method is characterized by a bulk density lower than that of gastrointestinal (GI) fluids, allowing it to remain buoyant in the stomach for an extended period without affecting the gastric emptying rate. In this process, the material floats, delaying the release of the drug from the system at a critical rate, which increases the risk of bacterial invasion and ensures effective control of bacterial drug concentrations.

Classification of Floating Drug Delivery Systems

- **Effervescent System**

This system utilizes the production of carbon dioxide bubbles to enable the medication to float. It involves the use of carbonate or bicarbonate, which reacts with the stomach's natural acid or tartaric acid, leading to carbon dioxide formation.

1. Volatile Liquid Containing Device: This method includes a deformable device that expands from a collapsed state and then returns to its original form, maximizing the drug's delivery time.
2. Gas-Producing Device: In this system, a medium is added to bicarbonate material in an acidic environment, resulting in carbon dioxide formation, which reduces bulk density and aids in floating over GI fluids.

- **Non-effervescent System**

In this system, the drug reacts with gastric fluids upon ingestion, causing it to swell, reduce its bulk density, and float over gastric fluids.

1. Micro Porous Compartment System: Here, the medication is placed within a porous micro compartment with pores on its top and bottom walls. The floatation chamber traps air, allowing gastric fluids to float.
2. Micro-Balloon Floating: These are made of lightweight concrete or synthetic materials and have a hollow glass nature.
3. Colloidal Gel Barrier Device: This system features a hydro-colloidal gel form that keeps the medication floating on gastric material.
4. Alginate Beads: This involves the generation of calcium alginate precipitate by dropping sodium alginate into an aqueous calcium chloride solution, creating a porous system that floats over gastric fluid for more than 12 hours.

5. Raft Forming Method (in situ gel formation): A gel-forming polysaccharide polymer solution swells and forms a viscous gel trapped with CO2 bubbles, creating a raft layer on top of gastric fluid, allowing for the slow release of medication in the stomach.[3,4,5]

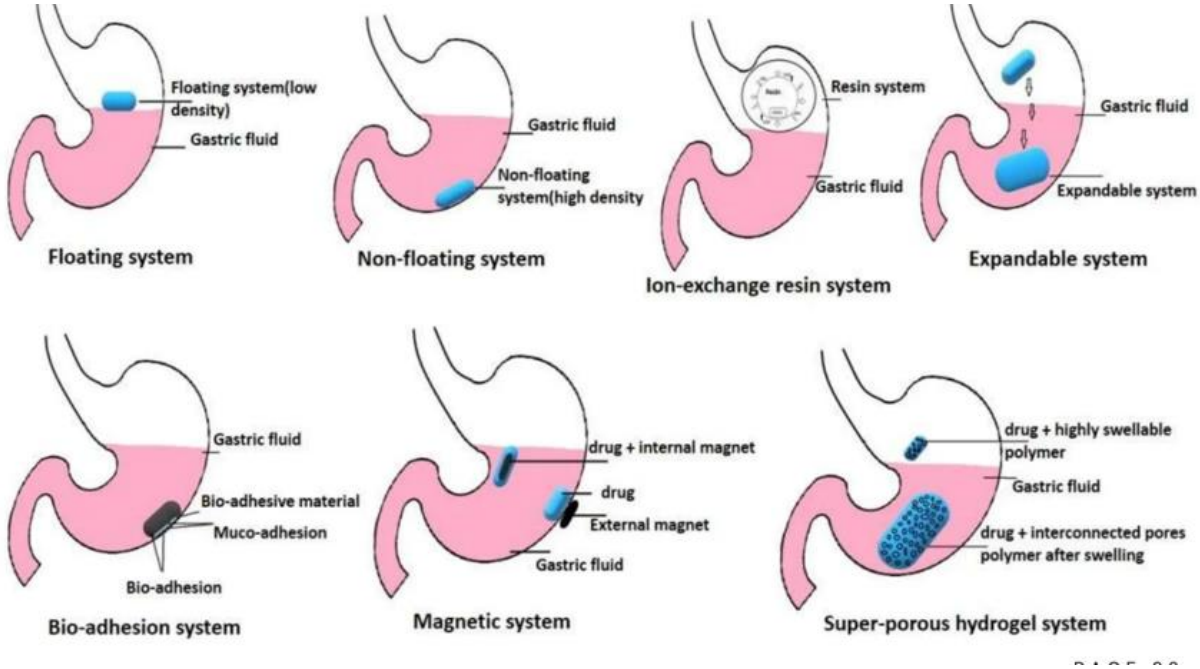

Fig. 1: Various Approaches to Gastro Gastric Retention.

➢ **The Advantages of microbeads include**

1. Minimizing fluctuations within the therapeutic range.
2. Reducing side effects.
3. Lowering the frequency of dosing.
4. Enhancing bioavailability.
5. Improving patient adherence.[6]

➢ **The potential candidates for delivering gastro-retentive medications**

1. Drugs with a short absorption window in the GI tract, like furosemide.
2. Medications that act locally in the stomach, such as antacids and ulcer-resistant drugs.
3. Drugs primarily absorbed in the stomach and upper GI tract, like calcium supplements.
4. Medications that break down in the colon, such as ranitidine HCl and metronidazole.
5. Drugs that disrupt normal colonic bacteria, like trihydrate amoxicillin.
6. Substances with poor solubility at high pH levels, such as diazepam.[7,8]

➢ **Drugs which are not suitable for gastro-retentive delivery**

1. Drugs with very limited acid solubility, like phenytoin.
2. Medications that are unstable in the stomach, such as erythromycin.
3. Drugs recommended for selective colon release, like corticosteroids.[9]

- **Criteria for drug release kinetics**

In a sustained-release system aim to deliver a drug at a rate that maintains a constant blood level. This means the delivery rate should be independent of the remaining drug in the dosage form and remain constant over time, ideally following zero-order kinetics. Although zero-order release is theoretically ideal, non-zero-order release rates can be clinically equivalent to constant release in many cases. To quickly achieve and maintain therapeutic levels, the dosage form typically consists of two parts: a loading dose and a maintenance dose. The loading dose is released immediately upon administration, characterized by a first-order kinetic process, to quickly reach therapeutic plasma levels. The remaining dose is released slowly and in a controlled manner to maintain constant plasma drug concentration, following zero-order kinetics. Thus, the release rate is independent of the remaining dose fraction. The controlled oral dosage form releases the maintenance dose at a rate matching the drug's elimination rate.[10,11]

- **Mechanism of floating microbeads**

Involves interaction with stomach acid after administration. The outer layer of these microbeads contains polysaccharides and polymers that hydrate to form a colloidal gel barrier, regulating the movement of the drug and gastric fluid in and out of the microbeads. This membrane traps air molecules, reducing bulk density and allowing the microbeads to float on the gastric fluid surface. A minimal amount of gastric fluid is needed for the floatation of the dosage form in most cases.[12]

Drug release from microbeads occurs through

1. EROSION

Some coatings can be designed to erode gradually with time, thereby releasing the drug contained within the particle. The polymer erosion, i.e. loss of polymer, is accompanied by accumulation of the monomer in the release medium. The erosion of the polymer begins with the changes in the microstructure of the carrier as the water penetrates within it leading to the plasticization of the matrix.

2. DIFFUSION

Rate limiting step is diffusion of drug through inert water-insoluble membrane barrier. In the case of a polymer matrix, the diffusion of the active ingredient can be through the intact polymer network or through the pores filled with water. Water-soluble drugs may also dissolve in the aqueous pore networks. Water uptake causes polymer chains to swell, indicating the formation of new pores and/or osmotic pressure. During swelling, the volume increases, the effective diffusion coefficient of the drug is increased, and more pharmacon molecules enter the aqueous part. The rate of release also depends upon where the polymer degradation by homogeneous or heterogeneous mechanism. The drug release depends on the rate of drug dissolution in the dissolution fluid, rate of penetration of dissolution fluid to the microbeads, and rate at which the dissolved drug escapes from the microbeads.

3. OSMOSIS

The osmosis mechanism involves water entering a semipermeable membrane due to osmotic pressure, dissolving an osmogen and the drug inside, creating pressure that forces the dissolved drug out through pores formed by water-soluble pore-formers leached from the coating, resulting in controlled, pH-independent drug release. This creates a microporous "osmotic pump," driving a steady flow of drug solution out as water continually enters.[13,14,15]

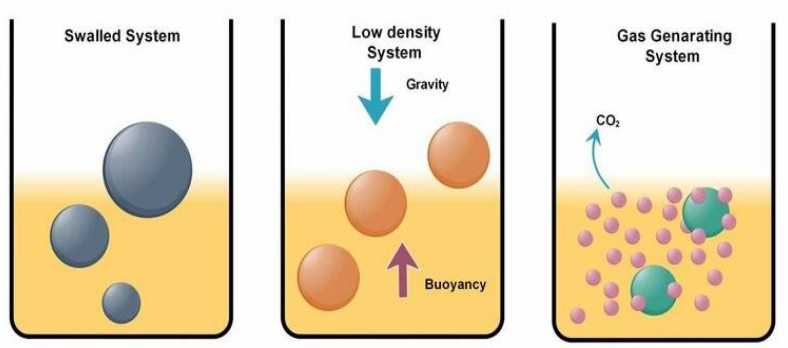

Fig. 2: Drug release mechanism.

Techniques employed in the Formulation of Microbeads

Ionotropic Gelation Method: This method involves the interaction between an ionic polymer and oppositely charged ions to trigger crosslinking. The interaction between polyanions and cations cannot be fully explained by the electro-neutrality principle, unlike simple monomeric ions. The three-dimensional structure and the presence of other groups affect the ability of cations to bind with anionic functionalities or vice versa.

There are two sub-methods for generating beads using the ionotropic gelation technique, differing in the source of the crosslinking ion. In one method, the cross-linker ion is located externally, while in the other, it is incorporated within the polymer solution in an inactive form.

Ionotropic gelation methods are classified into two types[16,17]

1. External Gelation Method

This method uses a metal ion solution as the source of the crosslinking ion. The polymer solution containing the drug is extruded through a needle into this solution with gentle agitation. Upon contact with the metal ion solution, the polymeric drop undergoes instant gelation, forming self-sustaining beads. The beads are cured in the gelation medium for a specified time before being removed and dried. External gelation results from the rapid diffusion of cross-linker ions into the partially gelled beads.

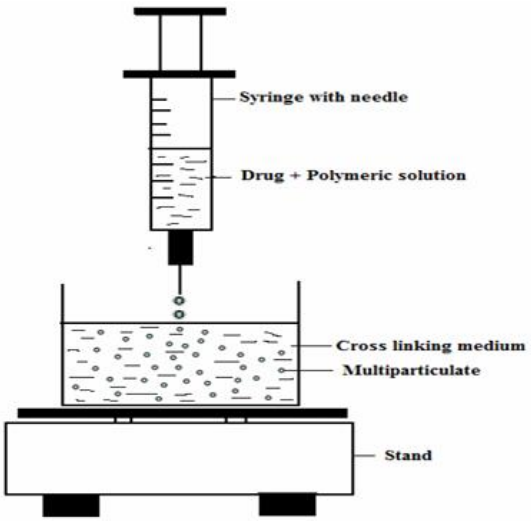

Fig. 3: External Gelation Method.

2. Internal Gelation Method

This method generates the cross-linker ion 'in situ.' It involves using an insoluble metal salt (such as calcium carbonate and barium carbonate) as the source of the crosslinking cation. The cation is released in situ by lowering the solution's pH, which solubilizes the metal salt and releases the metal ion.

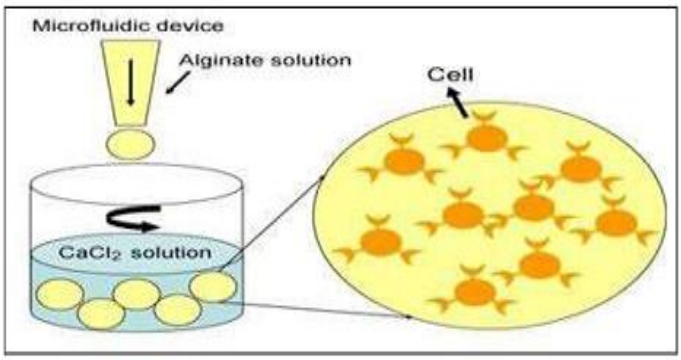

Fig. 4: Internal Gelation Method.

3. Emulsion Gelation Method

Another approach to microbead preparation is the emulsion gelation technique. A sodium alginate solution is prepared by dispersing a measured amount of sodium alginate in deionized water. An accurately weighed quantity of drug is added to the sodium alginate polymeric solution, and the mixture is stirred magnetically with gentle heat to achieve a homogeneous drug-polymeric mixture. A specific volume of the crosslinking agent is added to form a viscous dispersion, which is then extruded through a syringe with a flat-tipped needle of size no. 23 into oil containing span 80 and 0.2% glacial acetic acid, maintained under magnetic stirring at 1500 rpm. The microbeads are kept in the oil for 30 minutes to form rigid, discrete particles. They are collected by decantation, and the separated products are washed with chloroform to remove oil traces. The microbeads are dried at 400 ºC for 12 hours.

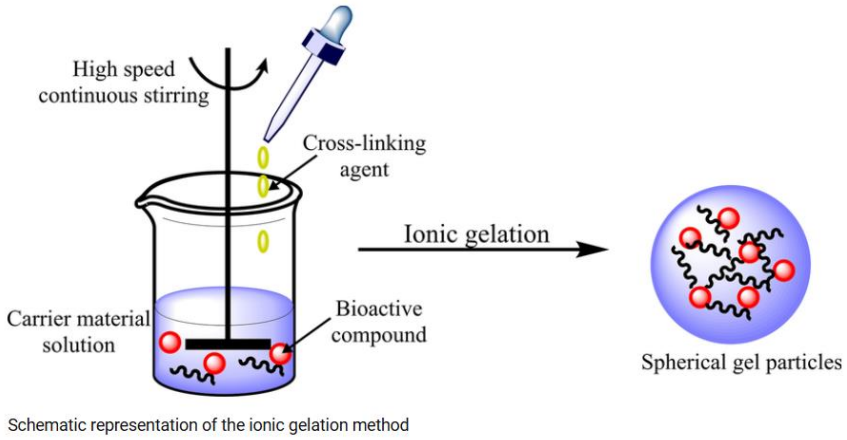

Fig. 5: Emulsion Gelation Method.

4. Polyelectrolyte Complexation Method

An alternative approach to creating microbeads involves the complex coacervation of poly electrolytes with opposite charges, specifically polycation and polyanion substances. Alginate-chitosan microcapsules, known for their biocompatibility and biodegradability, can be produced under gentle conditions, even under physiological

circumstances, making them ideal for biomedical applications. Recently, there has been a growing interest in exploring alginate-chitosan microcapsules as drug delivery systems for proteins and polypeptides. This method requires specific conditions of poly-ion concentration, pH, and ionic strength, leading to the separation of the mixture into a dense phase containing the microbeads and a dilute equilibrium phase. For instance, complex coacervation between alginic acid and chitosan is achieved by spraying a sodium alginate solution into a chitosan solution, resulting in robust microbeads that remain stable across a wide pH range. To optimize the yield of coacervative bead preparation, the conditions should be set to a pH of 3.9, an ionic strength of 1 mm, and a total poly-ion concentration of 0.15% w/v.[18,19]

POLYMERS USED FOR THE PREPARATION OF MICROBEADS[20,21,22]

Various biodegradable and non-biodegradable materials have been explored for creating microbeads. These include both natural and synthetic polymers, as well as modified natural substances. Examples of such polymers are Albumin, Gelatin, Sodium alginate, Chitosan, Starch, Dextran, Polylactide, Polyglycolide, Polyanhydride, and Polyphosphazene, among others. Sodium alginate microbeads are a type of multi-particulate drug delivery system designed to achieve prolonged or controlled drug release, enhance bioavailability or stability, and target specific sites for drug delivery. Multi-unit dosage forms like microspheres or beads have become popular as oral drug delivery systems due to their more uniform drug distribution in the gastrointestinal tract, consistent drug absorption, reduced local irritation, and prevention of unwanted intestinal retention of polymeric material compared to non-disintegrating single-unit dosage forms.

1. Alginates

Alginates are natural polysaccharide polymers derived from brown seaweed (Phaeophyceae). Alginic acid can be transformed into its salts, with sodium alginate being the most commonly used form. Alginates have various applications in drug delivery, such as in matrix-type alginate gel beads, liposomes, modulating gastrointestinal transit time, local applications, and delivering biomolecules in tissue engineering. The bioadhesive properties of alginates make them valuable in the pharmaceutical industry. Sodium alginate-based drug delivery systems have numerous applications and can be formulated as gels, matrices, membranes, nanospheres, microspheres, and microbeads, among others.

Alginate beads can be administered by encapsulating them in capsules or compressing them into tablets. A novel approach in the pharmaceutical field involves developing alginate polymer systems that can adjust drug release according to physiological needs (e.g., pH-responsive systems based on polymer swelling, magnetically triggered delivery systems). Alginate also has the physicochemical properties necessary to be a significant contributor to future research in this area.

2. Chitosan

Chitosan is a cationic natural polysaccharide derived from the chitin of crustaceans, with crab and shrimp shell waste as its primary source. Its properties, including the degree of deacetylation and average molecular weight, along with low toxicity and good bioavailability, make it a novel excipient in pharmaceutical formulations as a relatively new development. Chitosan is a biopolymer that can be used to prepare various polyelectrolyte complex products with natural polyanions like xanthan, alginate, and carrageenan. Many formulations have recently been developed and evaluated in different dosage forms, such as ophthalmic, nasal, sublingual, buccal, periodontal, gastrointestinal, colon-specific, vaginal, transdermal, and as gene carriers, based on the application of chitosan and its derivatives.

3. Pectin

Pectin serves as both a thickening and gelling agent. Essentially, it is a polymer composed of a-D galacturonic acid linked by 1-4 bonds. The unique chemistry and gel-forming properties of pectin have made it a valuable biopolymer in the pharmaceutical sector. It is also potentially utilized in pharmaceutical preparations and drug formulations as a carrier for a diverse range of biologically active agents. This includes applications for sustained release and as a vehicle for delivering drugs to the colon for either localized treatment or systemic effects.

4. Xanthan Gum

Xanthan gum is a naturally occurring, biosynthetic, edible gum, and an extracellular polysaccharide. It is made up of glucose, mannose, and glucuronic acid. Xanthan is highly soluble in both cold and hot water, a characteristic attributed to its polyelectrolyte nature. Primarily considered a non-gelling agent, xanthan gum is used to enhance viscosity. It quickly hydrates in cold water without forming lumps, providing consistent viscosity. Xanthan gum functions as a thickener, stabilizer, emulsifier, and foaming agent. It offers the potential benefit of drug release with zero-order kinetics. However, a significant limitation is that drug release is affected by the pH and the presence of ions in the medium.

EVALUATION OF FLOATING MICROBEADS[23,24,25,26]

1. **Particle Size:** The size of the microbeads was assessed using an optical microscope. The average size was calculated by measuring 100 particles with a calibrated ocular micro-meter.
2. **Bulk Density:** Bulk density is calculated as the mass of the powder divided by the bulk volume, expressed in gm/cm3.The formula for Bulk Density is Sample Weight / Sample Volume.
3. **Tapped Density:** Tapped density can be measured using a tapping method. After 100 and 1000 taps with a tapped density apparatus, the volume of the weighed microbeads was recorded. Tapped Density is calculated as Sample Weight / Volume Tapped.
4. **Hausner Ratio:** The compressibility index and Hausner ratio were derived from the bulk and tapped density values. The Compressibility Index percentage is calculated as (Tapped density - Bulk density) / Tapped density. The Hausner Ratio is Tapped Density / Bulk Density.
5. **Angle of Repose:** The angle of repose, which indicates the resistance to particle flow, was measured using the formula $\tan \theta = h/r$, where θ is the angle of repose, h is the height of the pile, and r is the radius of the pile.
6. **Percentage Yield:** The percentage yield of floating microbeads was calculated by dividing the actual weight of the product by the total weight of the components used in the preparation of the floating microbeads.
   The formula is % yield = (Actual weight of product / Total weight of drug and excipients) × 100.
7. **Surface Morphology**: The SEM sample was prepared by coating a mixture of gold and palladium, with a thickness of 250-450 Å, under an argon atmosphere in a high vacuum evaporator at 20KV, 10mA, and low pressure. The powder was spread on an aluminium stub coated with the content for photomicrographs.
8. **Drug Entrapment Efficiency (DEE):** The drug entrapment efficiency was determined by repeatedly crushing the microbeads and extracting them with aliquots of 0.1N HCl. The extract was transferred to a 100 ml volumetric flask, and the volume was adjusted with 0.1N HCl. The solution was filtered, and its absorbance was measured against a blank using a spectrophotometer.
   The Drug Entrapment percentage is calculated as (actual drug content / theoretical drug content) ~10 percent

9. **Swelling index:** The experiment involved immersing microspheres of a known weight in 0.1 N HCl at a temperature of 37 ± 0.5 °C for a designated period. The microbeads were allowed to expand and were extracted at different time intervals. Swelling Ratio = Weight of Wet Formulation / Weight of Formulation
10. **Buoyancy Analysis:** Microbeads were placed on the surface of a type II USP dissolution apparatus containing 900 ml of 0.1 N HCL with 0.02 percent between 80 and 20. The medium was stirred for 12 hours with a paddle rotating at 100 rpm. The floating and settled portions of the microbeads were collected separately. They were dried and weighed.

    Percentage buoyancy = Wf / (Wf+Ws) x 100

    Where, Wf represents the Floating Weight, and Ws represents the Settled Microbeads, respectively.
11. **In-vitro Drug Release Studies:** This study utilized USP dissolution devices operating at a specific speed. Distilled water and dissolution fluid were maintained at 37±0.5°C. The dissolution test was performed using 900mL of 0.1N HCL dissolution medium at 100 rpm for the required duration. Samples were taken at regular intervals, and the same volume of fresh medium was added to maintain spectrophotometrically analyzed sink conditions.

APPLICATIONS OF FLOATING MICROBEADS[27,28]

FDDS is particularly useful for drugs with low bioavailability due to the limited absorption window in the upper part of the GIT.

1. Sustained Drug Delivery

These systems have a bulk density of less than 1, allowing them to float on gastric contents. Their larger size and shape prevent them from passing through the pyloric opening.

2. Site-Specific Drug Delivery

Floating microbeads can greatly improve abdominal pharmacotherapy by releasing drugs locally, resulting in high concentrations in the gastric mucosa. This helps eliminate Helicobacter pylori from the submucosal tissue and facilitates the treatment of gastritis, stomach, and duodenal ulcers.

3. Absorption Enhancement

They are effective in delivering drugs that are poorly soluble or insoluble. As drug solubility decreases, the time available for drug dissolution becomes limited, making transit time a crucial factor affecting drug absorption.

4. As Carriers

These agents, including antiviral, antifungal, and antibiotic substances, serve as carriers for drugs with specific absorption windows, which are absorbed only at certain locations in the GI mucosa.

5. Maintaining Consistent Blood Levels

This system offers a convenient method to maintain steady blood levels, simplifying administration and enhancing patient compliance.

FUTURE PROSPECTIVES

A significant challenge in the pharmaceutical sector, particularly for drugs absorbed in the upper gastrointestinal tract, is the gastric retention time (GRT) of conventional dosage forms. The development of gastro-retentive drug delivery systems (GRDDS) can mitigate the drawbacks of traditional dosage forms, though further research is needed to address

its shortcomings. Numerous GRDDS technologies have been extensively explored to create an effective gastro-retentive approach. Future research on GRDDS should focus on integrating various mechanisms to extend the gastric residence time of formulations, even during fasting. It is crucial to assess gastro-retentive dosage forms on an individual basis, as the physicochemical properties of drugs and excipients, polymer types and structures, drug dosage, and manufacturability depend on product specifications. Understanding the influence of formulation and process variables on the critical quality attributes of GRDDS is vital for enhancing these systems. From a formulation perspective, comprehending polymer behaviour and its role in the formulation is essential for the rational production of gastro-retentive dosage forms. Additionally, selecting the appropriate polymer concentration is equally important for designing such dosage forms. In this context, the quality by design (QbD) approach can be a valuable tool to examine the impact of formulation and process variables on the critical quality attributes of GRDDS. The introduction of the QbD method in the pharmaceutical industry has significantly transformed the understanding and regulation of the manufacturing process, notably reducing the risk of product failure.

CONCLUSION

This review article highlights that microbeads offer a superior option for drug delivery compared to many other systems. Studies indicate that microbeads are created using the Ionotropic Gelation technique, which enhances bioavailability and decreases the frequency of doses, thus facilitating a controlled oral release of the drug. Looking ahead, by integrating various other strategies, microbeads are expected to play a pivotal role in innovative drug delivery, especially in areas such as diseased cell sorting, diagnostics, gene and genetic material delivery, and safe, targeted, specific, and effective in-vivo delivery. They may also serve as miniature models of diseased organs and tissues within the body.

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