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Gastroretentive Drug Delivery System GRDDS

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Abstract: *The oral route is considered the most convenient method of drug delivery because of its high patient compliance, reliability, ease of administration, and formulation flexibility. Gastro-retentive drug delivery systems (GRDDS) offer several advantages, including prolonged gastric residence time, improved bioavailability, reduced drug wastage, and enhanced solubility for drugs that are poorly soluble in high pH environments. Another key feature of gastro-retentive systems is their ability to facilitate localized drug delivery to the stomach and proximal small intestine'This technology represents an innovative approach for drugs with a narrow absorption window in the gastrointestinal tract. GRDDS are specifically designed to remain in the stomach for an extended period, allowing controlled and sustained drug release to the upper gastrointestinal tract. Over the past few decades, growing interest in this system has been driven by its potential to improve solubility, enhance bioavailability, and achieve site-specific drug release—ultimately leading to better therapeutic outcomes. Given its reliability and effectiveness, gastro-retentive drug delivery holds significant promise for future pharmaceutical applications*

Keywords: Gastro-retentive drug delivery, Solubility, Gastric residence, Bioavailability

I. INTRODUCTION

Despite remarkable progress in drug delivery technologies, the oral route remains the most preferred method for administering various active pharmaceutical ingredients due to its ease of administration, cost-effectiveness, patient compliance, and flexibility in formulation design. However, conventional oral dosage forms often lack proper control over drug release, leading to considerable fluctuations in plasma drug concentrations. Many drugs are absorbed only from specific regions of the gastrointestinal (GI) tract and thus require targeted release at those sites for optimal absorption. To address this, controlled release drug delivery systems have been developed to deliver precise amounts of drug at specific locations within the GI tract.

These systems offer several advantages, including prolonged therapeutic action, reduced dosing frequency, and improved bioavailability. Among them, gastro-retentive drug delivery systems (GRDDS) represent a specialized form of controlled release technology designed to remain in the stomach for an extended duration by modifying gastric emptying and GI motility patterns. GRDDS are particularly beneficial for drugs that exhibit poor absorption in the lower GI tract, instability or low solubility at alkaline pH, and a short biological half-life.

Several formulation-related factors—such as the type of polymer (cationic or anionic), polymer composition, viscosity, molecular weight, and drug solubility—can significantly influence the performance and quality of gastro-retentive dosage forms. Anatomically, the stomach is a J-shaped organ located in the abdominal cavity beneath the diaphragm. It connects the oesophagus to the duodenum, the first section of the small intestine, serving as a critical site for initial drug release and absorption in gastro-retentive systems.

Anatomy of the Stomach:-

The stomach is divided into four major regions: the cardia, fundus, body and pyloric part. The cardia surrounds the upper opening where the oesophagus enters the stomach. Above and to the left of the cardia lies the fundus, a dome-shaped region. Below the fundus is the body, which forms the main central portion of the stomach. The pyloric part is

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further subdivided into three sections: the pyloric antrum, which connects to the body; the pyloric canal , which follows the antrum; and the pylorus, which opens into the duodenum of the small intestine.

When the stomach is empty, the inner lining or mucosa forms large visible folds known as rugae. The pylorus connects to the duodenum through a circular band of smooth muscle called the pyloric sphincter, which regulates the passage of stomach contents. The lesser curvaturerepresents the concave inner border of the stomach, while the greater curvature forms the convex outer border.

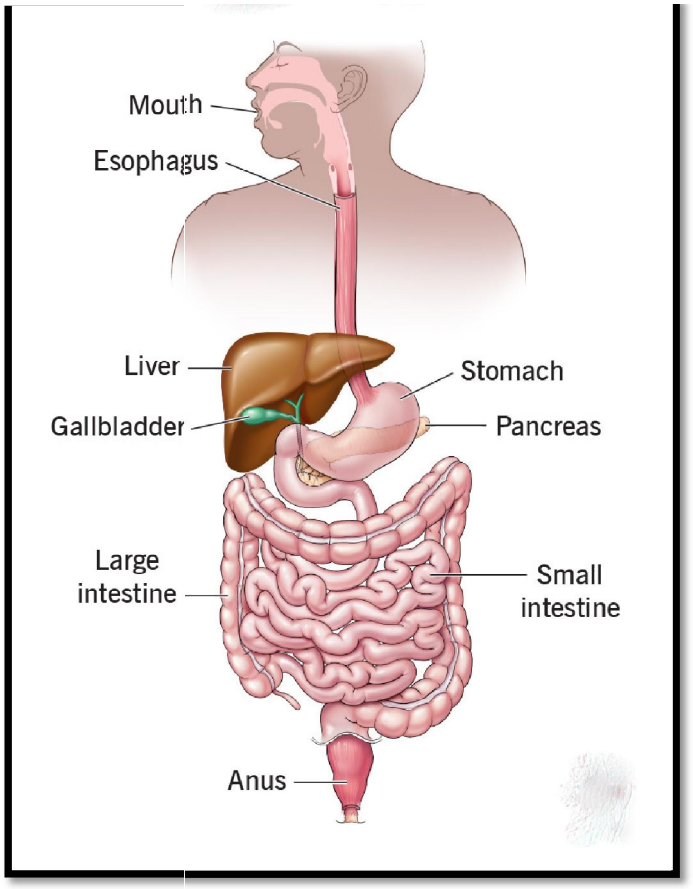

Fig 1: Anatomy of the Stomach

Functions of the Stomach

1. Temporary Storage

The stomach acts as a storage chamber, allowing sufficient time for digestive enzymes, particularly pepsin, to begin the digestion process.

2. Chemical Digestion

The enzyme pepsin facilitates the breakdown of proteins into smaller peptide fragments known as polypeptides.

3. Mechanical Breakdown

The three layers of smooth muscle in the stomach enable strong churning movements, mixing food with gastric juice to form a semi-liquid substance called chyme Gastric activity and secretion are enhanced by parasympathetic nerve stimulation.

4. Limited Absorption

The stomach absorbs only small amounts of certain substances such as water, alcohol, and some lipid-soluble drugs.

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5. Non-Specific Defense Against Microorganisms

The hydrochloric acid (HCl) present in gastric juice acts as a natural defense mechanism by destroying harmful microbes. Additionally, vomiting may occur as a protective reflex when irritants like toxins or microorganisms are ingested.

6. Iron Preparation for Absorption

The acidic environment of the stomach helps solubilize iron salts, which is essential for their absorption later in the small intestine.

7. Intrinsic Factor Secretion

The stomach produces and secretes intrinsic factor, a glycoprotein vital for the absorption of vitamin B_{12} in the terminal ileum.

8. Regulation of Gastric Emptying

The stomach carefully regulates the release of chime into the duodenum. When the contents are adequately liquefied and acidified, the pyloric sphincter allows small portions to pass through while remaining closed to prevent any backward flow.

Need of study

1. Low density dosage form causes buoyancy in gastric fluid.
2. Dosage form with high density which is retained at the bottom ofstomach.
3. Bioadhesion to stomach mucous.
4. Expansion by swelling to a large size which restricts emptying to the dosage form through the pyrolic sphincter.
5. Concomitant administrations of drugs causes slow motility of gastric intestinal tract.

Physiology of the Stomach

The migrating myoelectric complex (MMC) is a cyclic pattern of electrical and muscular activity in the stomach and small intestine, described by Wilson and Washington, and is divided into four distinct phases:

1. Phase I (Basal Phase):

This phase lasts for about 40 to 60 minutes and is characterized by minimal or rare contractions, allowing the stomach to remain relatively inactive.

2. Phase II (Preburst Phase):

Also lasting 40 to 60 minutes, this phase involves intermittent action potentials and contractions. As the phase continues, both the frequency and intensityof contractions gradually increase

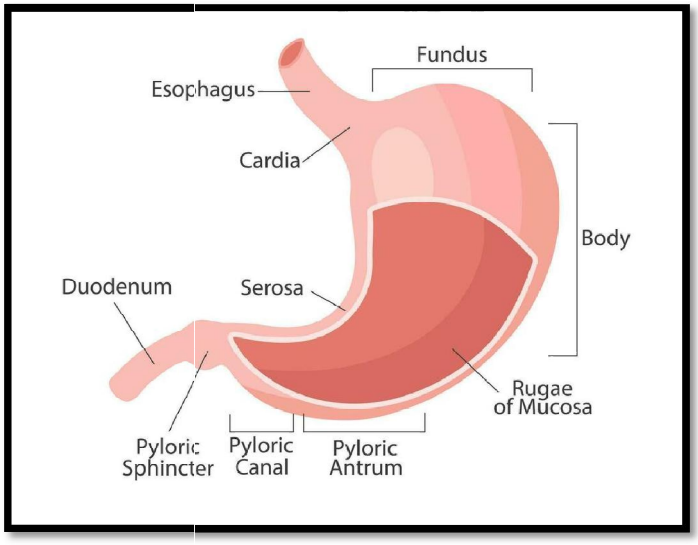

Fig 2 : Diagram of human stomach

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3. Phase III (Burst Phase)

Known as the active or burst phase, it lasts for approximately 4 to 6 minutes and features strong, rhythmic, and regular contractions that help propel gastric contents forward.

4. Phase IV:

This brief transitional phase lasts about 0 to 5 minutesand serves as a bridge between Phase III and Phase I of the next cycle.

Together, these phases coordinate the stomach's motility pattern, playing a vital role in the digestion and movement of gastric contents through the gastrointestinal tract.

Advantages

Suitable for achieving localized drug action in the stomach.
Useful in the treatment of peptic ulcers.
Ideal for drugs that have a narrow absorption window in the small intestine.
Helps in reducing the dosing frequency.
Enhances the drug's bioavailability.
Suitable for drugs that are unstable in intestinal fluids.
Maintains systemic drug levels within the therapeutic range.
Enables site-specific drug delivery.

Disadvantages

Requires sufficient gastric fluid levels for proper floating behavior.
Not suitable for drugs with poor stability or solubility issues, or those undergoing extensive first-pass metabolism.
Drugs causing gastric irritation limit its use.

Factors Affecting Gastro-Retentive Drug Delivery Systems (GRDDS)

1. Density:

The dosage form must have a density lower than that of gastric fluids (approximately 1.004 g/mL) to ensure it remains buoyant in the stomach.

2. Size:

Larger dosage forms (greater than 7.5 mm in diameter) generally stay in the stomach longer than smaller ones (around 9.9 mm).

3. Shape of the Dosage Form:

The shape of the dosage form influences its retention; certain shapes remain in the stomach longer than others of similar size. Multiple-unit formulations offer more consistent drug release, reduce the risk of dose dumping, and enhance safety compared to single-unit systems.

4. Fed or Unfed State:

During fasting, strong gastric contractions (Migrating Motor Complex, MMC) occur every 1.5–2 hours, clearing stomach contents. If the dosage form is administered during MMC, its retention time decreases. In the fed state, MMC is delayed, resulting in prolonged gastric retention.

5. Nature of the Meal:

Meals containing fatty substances or indigestible polymers slow gastric emptying and extend the duration of drug release.

6. Caloric Content and Meal Frequency:

High-calorie or repeated meals can significantly increase gastric retention time (up to 400 minutes) compared to a single meal because of reduced MMC activity.

7. Gender:

On average, males exhibit shorter gastric retention times (around 3.4 hours) than females (approximately 4.6 hours), regardless of body size or weight.

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8. Age

Elderly individuals (over 70 years old) typically have a longer gastric retention time compared to younger adults.

9. Concomitant Drug Administration:

Certain medications, such as anticholinergics (e.g., atropine, propantheline) and opioids (e.g., codeine), can delay gastric emptying and increase gastric retention time.

Requirements for Formulating Gastro-Retentive Drug Delivery Systems (GRDDS)

Drugs acting locally in the stomach - Such as antacids and medications used to treat Helicobacter pyloriinfections (e.g., Misoprostol).

2. Drugs primarily absorbed in the stomach- For example, Amoxicillin.
3. Drugs with poor solubility in intestinal fluids- Such as Furosemide, Diazepam, and Verapamil.
4. Drugs with a narrow absorption window- Including Cyclosporine, Methotrexate, and Levodopa.
5. Drugs absorbed rapidly from the gastrointestinal tract- Such as Metronidazole and Tetracycline.
6.Drugs unstable or degraded in the colon-For instance, Ranitidine and Metformin HCl.
7.Drugs that can disrupt normal colonic microflora- Such as antibiotics targeting Helicobacter pylori.

Approaches to Achieve Gastric Retention

1. High-Density (Sinking) Systems or Non-Floating Drug Delivery Systems:

This approach involves formulating dosage forms with a density higher than that of the gastric contents (approximately 1.004 g/cm³). Such systems are designed to sink to the bottom of the stomach and remain there for a prolonged period. These formulations are prepared either by coating the drug onto a dense core or by blending it with heavy, inert materials like iron powder, barium sulfate, zinc oxide, or titanium dioxide. These substances can increase the overall density to about 1.5–2.4 g/cm³, and a density close to 2.5 g/cm³ is typically required for effective gastric retention.

High-Density (Sinking) Systems, also known as Non-Floating Drug Delivery Systems, are designed to sink to the bottom of the stomach and remain there for a prolonged period, releasing the drug slowly. These systems have a density greater than that of the gastric fluids (>1.004 g/cm³), allowing them to sink and stay in the stomach.

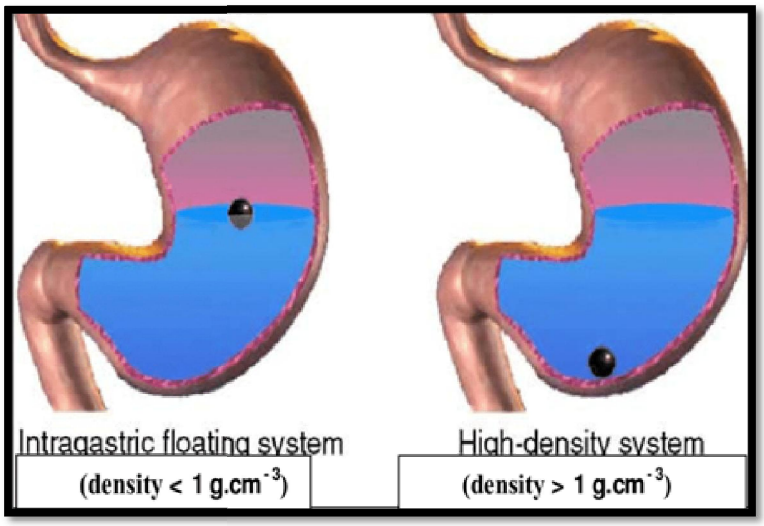

Figure 3: Schematic localization of an intragastric floating and high density system in the stomach.

2. Floating Drug Delivery Systems (FDDS)

Floating systems are among the most common and effective methods for enhancing gastric retention and improving bioavailability. They are particularly useful for drugs that are absorbed in the upper part of the small intestine. These

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systems have a bulk density lower than that of gastric fluids, enabling them to float on the stomach contents without significantly altering the gastric emptying rate. As the system floats, it gradually releases the drug in a controlled manner, maintaining therapeutic levels and reducing plasma concentration fluctuations.

Key requirements for FDDS:

The system should release the drug at a controlled rate.

It must have a specific gravity lower than that of gastric contents (1.004–1.01 g/cm³).

It should form a cohesive gel barrier to maintain buoyancy and control drug release.

3. Hydrodynamically Balanced Systems (HBS):

The concept of hydrodynamically balanced systems was first proposed by Sheth and Tossounian. These are typically single-unit dosage forms containing one or more gel-forming hydrophilic polymers. Commonly used excipients include hydroxypropyl methylcellulose (HPMC), hydroxyethyl cellulose, hydroxypropyl cellulose, sodium carboxymethyl cellulose, polycarbophil, polyacrylate, polystyrene, agar, carrageenan, and alginic acid. In these systems, the drug is combined with the polymer within a capsule, forming a gel-like matrix upon contact with gastric fluids that maintains buoyancy and ensures controlled drug release. drugs and administered. When capsule shell comes in contact with water get dissolves and mixture swells to form a gelatinous barrier, which imparts buoyancy to dosage form in gastric juice for a long period.

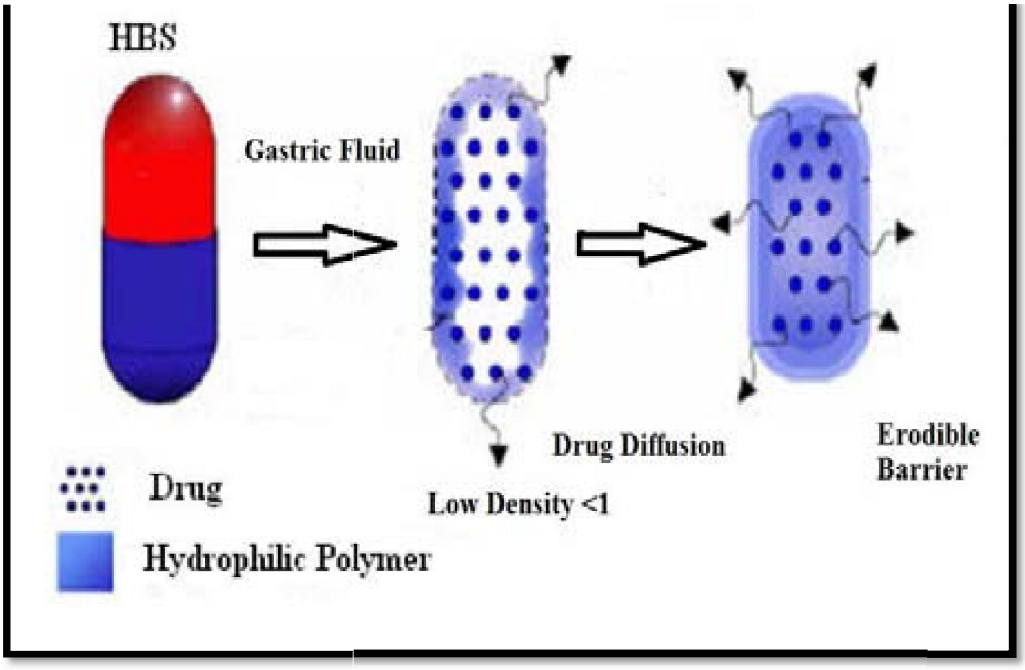

Fig 4: Hydrodynamically Balanced Systems (HBS)

Hydrodynamically Balanced Systems (HBS) are gastro-retentive drug delivery systems designed to prolong gastric residence time and enhancedrug bioavailability. They consist of gel-forming hydrophilic polymerssuch as hydroxypropyl methylcellulose (HPMC), hydroxyethyl cellulose, or sodium carboxymethyl cellulose mixed with the drug and enclosed in a capsule.

4. Bioadhesive or Mucoadhesive Drug Delivery Systems:

These systems are designed to enhance drug absorption at specific sites by adhering to the gastric mucosa. Bioadhesive polymers enable the dosage form to attach to the epithelial lining of the stomach, thereby increasing gastric residence

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time and improving localized drug delivery. Based on the mechanism of adhesion, the dosage form can adhere to the mucosal surface through the following theories:

1. Wetting Theory: Describes the ability of bioadhesive polymers to spread and form close contact with the mucus layer.
2. Diffusion Theory: Suggests that adhesion occurs due to the interpenetration or entanglement of mucin strands with flexible polymer chains or within the porous structure of the polymer.
3.Absorption Theory: Attributes bioadhesion to secondary bonding forces such as van der Waals interactions and hydrogen bonding.
4. Electronic Theory: Proposes that attractive electrostatic interactions occur between the negatively charged mucin network and positively charged bioadhesive materials.

5. Expandable, Unfoldable, and Swellable Systems:

These systems are designed to retain the dosage form in the stomach by expanding to a size larger than the pyloric sphincter, preventing premature emptying. However, the dosage form must still be smaenough to be swallowed easily and must not cause gastric blockage. To achieve this balance, expandable or swellable configurations are developed, which increase in size upon contact with gastric fluids, thereby prolonging gastric residence time.

1) for oral intake a small configuration,

2) an expanded gastroretentive form.

a. Swellable systems

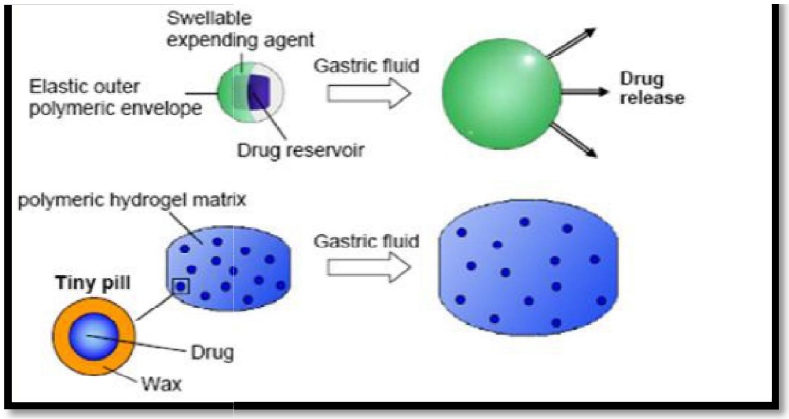

Fig 5: Swellable systems

b. Unfolding system

Unfolding takes place due to mechanical shape memory i.e. the gastroretentive dosage form (GRDF) is fabricated in a large size and is folded into a pharmaceutical carrier e.g. a gelatin capsule, for convenient intake.

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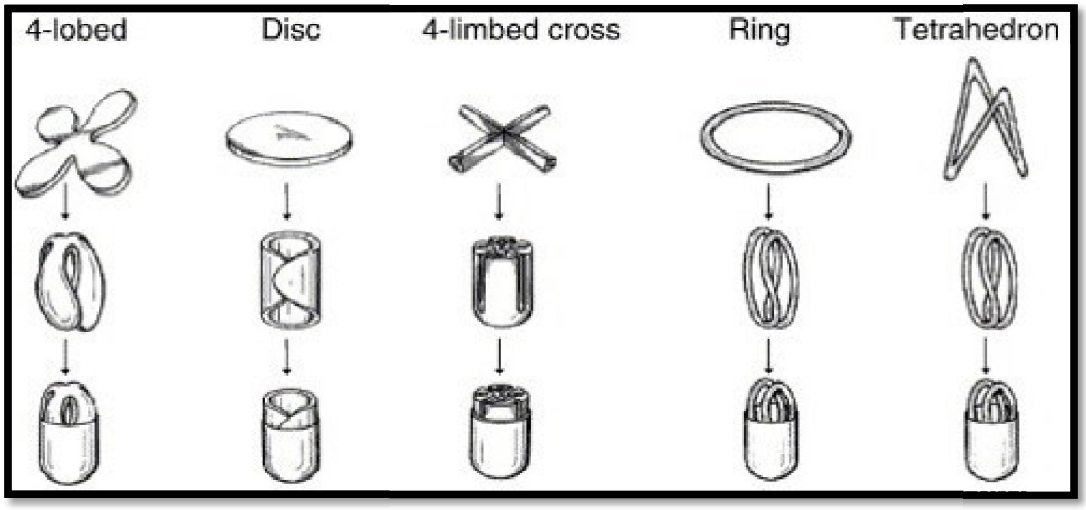

Figure 6: Different geometric shapes of unfolding systems.

MECHANISM OF GASTRORETENTIVE DOSAGE FORMS

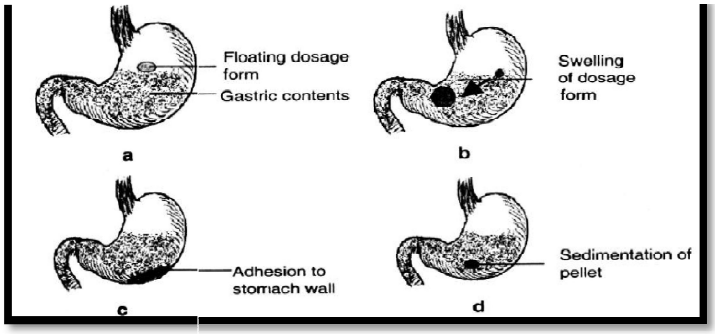

Figure 7:Various types of gastroretentive drug delivery systems:
(a) Floating systems, (b) Swelling systems, (c) Bioadhesive systems, and (d) High-density systems.

To increase the retention time of dosage forms in the stomach, several strategies have been developed, including floating systems, mucoadhesive systems high-density systemsmodified shape systems, and gastric-emptying delaying devices. Among these, floating drug delivery systems (FDDS) are the most widely used.

Floating systems possess a lower density than gastric fluids, allowing them to remain buoyant in the stomach for extended periods without affecting the gastric emptying rate. While floating on gastric fluid, the drug is released gradually at a controlled rate, after which the empty system is expelled from the stomach. This mechanism leads to prolonged gastric retention time (GRT) and better control over plasma drug concentration fluctuations.For proper buoyancy and retention, a minimum gastric contentis necessary, along with a sufficient floating force (F) to ensure stable flotation. The floating force kinetics can be measured using a specially designed apparatus that continuously records the resultant weight (or buoyant force) of the system over time. A positive floating force (F) indicates successful flotation. This apparatus aids in optimizing FDDS formulations for **stability and consistent buoyancy**, minimizing unpredictable variations in intragastric floating behavior.

The total vertical force (F) acting on the system can be expressed as:

$$F = F_{\text{buoyancy}} - F_{\text{gravity}} = (D_f - D_s) , g , v$$

Where:

* (F) = total vertical force

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* (D_f) = density of the fluid
* (D_s) = density of the dosage form
* (v) = volume
* (g) = acceleration due to gravity

Types of Floating Drug Delivery Systems :

Floating systems are classified into two main categories:

1. Effervescent systems
2. Non-effervescent systems

1. Effervescent Systems:

These systems generate gas (usually carbon dioxide) through a chemical reaction between acidic and alkaline components in the presence of gastric fluid. The released gas gets trapped in the polymer matrix, decreasing the system's density and enabling it to float on the gastric fluid.

A] Volatile liquid containing systems.

a) Intragastric floating gastrointestinal drug delivery system.

In this systems floating can be made in the stomach because of floatation chamber, which may be a vacuum or filled with gas, while the encapsulation of drug reservoir inside a microporus compartment carried out.

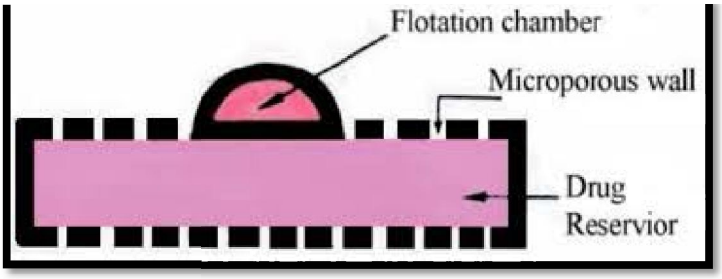

Fig 8: Intragastric floating gastrointestinal drug delivery system.

b) Inflatable gastrointestinal delivery systems

Incorporation of inflatable chamber which contains liquid ether that gasifies at body temperature to cause the chamber to inflate in the stomach. Fabrication of these system by loading the inflatable chamber with a drug reservoir, which can be a drug, impregnated polymeric matrix, then encapsulated in a gelatin capsule. The capsule dissolves to release the drug reservoir together with the inflatable chamber after oral administration. Inflation occur automatically and retains the drug reservoir compartment in the stomach. From the reservoir the drug continuously released into the gastric fluid.

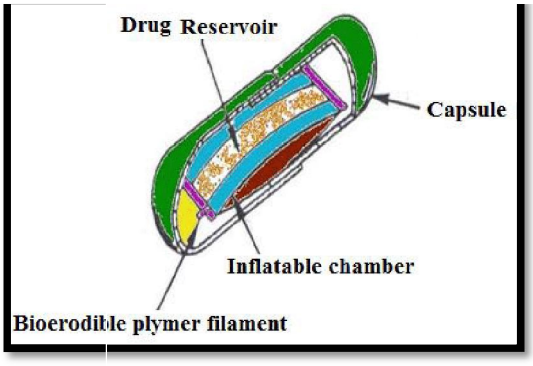

Fig 9: Inflatable gastrointestinal delivery system.

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2. Non-effervescent Systems

Production of non-effervescent floating drug delivery systems from gel-forming or highly swellable cellulose type hydrocolloids, polysaccharides or matrix forming polymers like polyacrylate, polycarbonate, polystyrene and polymethacrylate. Mixing of drug with a gel forming hydrocolloid which results in contact with gastric fluid after oral administration and sustain a relative integrity of shape and a bulk density. The air trapped by the swollen polymer confers buoyancy. Excipients employed include hydroxypropyl methylcellulose polyacrylates, polyvinyl acetate, carbopol, agar, sodium alginate, calcium chloride, polyethylene oxide and polycarbonates.

A. Microballoons / Hollow Microspheres

Microballoons or hollow microspheres are drug-loaded polymeric systems prepared using the solvent evaporation technique to extend gastric retention time . Commonly used polymers include polycarbonate, cellulose acetate, calcium alginate, Eudragit S, and agar.

The drug release rate and buoyancy of these systems depend on factors such as the polymer concentration,plasticizer-to-polymer ratio, and the type of solvent used during formulation. These microballoons are capable of floating continuously on acidic dissolution media containing surfactant for more than 12 hours.

Because hollow microspheres combine the advantages of multi-unit dosage forms with excellent floating ability, they are regarded as one of the most promising systems for gastroretentive drug delivery.

B. Alginate beads

Development of a multiple-unit floating system based on cross-linked beads by Talukdar and Fassihi. They were prepared by using Ca2+ and low methoxylated pectin and sodium alginate. Usually, sodium alginate solution is dropped into aqueous solution of calcium chloride and causes the precipitation of calcium alginate. Separation of these beads and dried by air convection and freeze drying, causing the formulation of a porous system, which can sustain a floating force for over 12 hrs. It improve gastric retention time more than 5.5 hrs

C. Microporous compartment system

Microporous compartment system is based on the principle of the encapsulation of a drug reservoir inside a microporous compartment with pores along its top and bottom walls.The walls of the apparatus were completely sealed to present any direct contact of the gastric surface with the undissolved drug. In the stomach the floatation chamber containing entrapped air leads to the delivery system to float in the gastric fluid.

EVALUATION

1. Time (TFT) and Floating Strength.

For low-density and raft-forming systems, the evaluation is performed in simulated gastric fluid (SGF) at 37°C. The floating lag time (FLT) is the duration between introducing the dosage form and its initial buoyancy, while the total floating time (TFT) is the period the dosage form remains afloat. Floating strength is determined using a specially designed basket holder connected to an analytical balance, where the decrease in weight over time reflects the floating strength.

2. Swelling Studies

Applicable to super porous hydrogel and expandable systems, this test involves placing a pre-weighed sample in 0.01N HCl as the swelling medium. The weight, diameter, and length of the swollen dosage form are recorded at specific time intervals to assess swelling behavior.

3. Viscosity and Rheology

For raft-forming and mucoadhesive systems, polymer viscosity influences the consistency of the formulation upon contact with gastric fluid. Measurements are typically performed using a Brookfield or Ostwald viscometer, and a texture analyzer is also used to evaluate rheological properties.

4. In Vitro Unfolding Study

This test is specific to expandable systems , where the folded dosage form is placed in a dissolution medium and its unfolding behavior is observed at predetermined time intervals to assess expansion characteristics.

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5. Particle Size, Ion Exchange Capacity, and Moisture Content

For ion-exchange resin systems, particle size is determined using a sieve shaker, laser diffraction, or Coulter counter. The ion exchange capacity** depends on the number of active functional groups available for cross-linking, while moisture content is analyzed using the Karl Fischer method.

Applications of Floating Drug Delivery Systems.

1. Enhanced Bioavailability

The bioavailability of riboflavin CR-GRDF is significantly enhanced in comparison to the administration of non-GRDF CR polymeric formulations. There are numerous different approaches, related to absorption and transit of the drug in the gastrointestinal tract, that act concomitantly to influence the magnitude of drug absorption.

2. Sustained drug delivery

Oral CR formulations are encountered with problems such as gastric residence time in the GIT. These problems can be overcome with the 'Hydro dynamically balanced systems' which can remain in the stomach for prolong periods and have a bulk density <1 as a result of which they can float on the gastric contents. Passing from the pyloric opening is prohibited because these systems are relatively larger in size.

3. Site specific drug delivery systems

These systems are specifically benefits for drugs that are significantly absorbed from the proximal part of the small intestine .The controlled, slow delivery of drug to the stomach provides sufficient local therapeutic levels and restricts the systemic exposure to the drug. This decreases side effects that are caused by the drug in the systemic circulation. However,the prolonged gastric availability from a site directed delivery system may reduce the dosing frequency. Eg: Furosemide and Riboflavin.

4. Absorption enhancement

Drugs with poor bioavailability due to site specific absorption from the upper part of the GIT are potential candidates to be formulated as floating drug delivery systems, thereby maximizing their absorption.

5. Minimized adverse activity at the colon

Retention of the drug in the HBS systems at the stomach minimizes the amount of drug that reaches the colon. Thus, undesirable activities of the drug in colon may be prevented. This Pharmacodynamic aspect provides the rationale for gastric retention dosage form formulation for beta-lactam antibiotics that are absorbed only from the small intestine, and whose presence in the colon leads to the development of microorganism's resistance.

6. Reduced fluctuations of drug concentration

Fluctuations in drug effects are reduced and prevention of concentration dependent adverse effects that are associated with peak concentrations. This feature is specifically important for drugs with a narrow therapeutic index.

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