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Advancements in Gastroretentive Drug Delivery Systems: A Comprehensive Review

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ABSTRACT

Drug delivery devices known as GRDDs target particular regions of the upper gastrointestinal tract to release drugs for either local or systemic effects. Gastrointestinal retentive dosage forms, or GRDFs, have long been utilized to enhance treatment with several significant medications. GRDFs significantly enhance stomach pharmacotherapy by releasing drugs locally, which may lead to higher drug concentrations in the gastric mucosa that last longer. GRDDs make it possible for a medication to be continuously and continuously released into the upper portion of the gastrointestinal tract (GIT), prolonging the dosing interval and enhancing patient compliance by greatly extending the length of drug release and improving the bioavailability of medications with a limited therapeutic window. This paper aims to provide a brief overview of gastroretentive drug delivery (GRDD), including its components, advantages, disadvantages, and significance compared to conventional drug delivery techniques GRDDS are special systems that have grown in importance during the past thirty years. It has several benefits, including site-specific, regulated, and gradual release of medications from various gastroretentive dosage forms, which enhances patient adherence and lowers side effects by limiting the frequency of doses.

Keywords: Gastrointestinal tract, Migrating Myoelectric Complex, Patient Compliance, Sustained Release, Helicobacter Pylori, Upper Gastrointestinal Tract

INTRODUCTION:

The best GRDFs (gastro-retentive dosage forms) are those that can withstand all physiological barriers while remaining in the stomach for an adequate amount of time, release the active ingredient in a controlled way, and then be readily metabolized by the body [1]. The capacity to prolong and regulate the emptying time is a significant advantage since dosage forms remain in the stomach for a longer period than traditional dosage forms, and the process of gastric emptying of dosage forms is particularly unpredictable [2]. One of the biggest challenges in oral controlled drug delivery is that not all medications are absorbed consistently throughout the GIT. Certain medications are either absorbed in one GIT segment exclusively or in other GIT segments to differing degrees [3].

By progressively releasing the medication into the gastrointestinal tract while maintaining an effective drug concentration in the systemic circulation for an extended period of time, oral sustained controlled release formulations aim to get around this restriction. Such drug delivery would remain in the stomach following oral administration and release the medication in a regulated manner, enabling the drug to be constantly delivered to the GIT's absorption sites [4]. An unfoldable, extendable, or swellable system that restricts the amount of available dosage forms that can pass through the stomach's pyloric sphincter, a high density (sinking) system that is retained in the 2,3,4mucoadhesive systems that cause bioadhesion to the stomach mucosa, and other gastro-retentive drug delivery techniques have been designed and developed over the past few decades magnetic system, super porous hydrogel system etc. [5].

Global pharmaceutical researchers developed a novel drug delivery mechanism that was substantially different from the traditional ones. Essentially referred to as the controlled drug delivery system, it aims to achieve significantly improved clinical viability and negligible toxicity by delivering a coordinated, anticipated, and predetermined pace [6]. Under some circumstances,

such as an H. pylori infection that results in peptic ulcers, gastro-retentive dose formulations are also helpful for both local and continuous drug delivery. Retentive drug delivery systems, such as hydrodynamically balanced systems (HBS) or floating drug delivery systems, low density systems, raft systems incorporating alginate gels, bioadhesive or mucoadhesive systems, high density systems, and less variation in therapeutic levels reduce the risk of resistance, particularly in the case of β-lactam antibiotics (penicillin and cephalosporins), retentive drug delivery system, such as hydrodynamically balanced system (HBS)/floating drug delivery system, low density systems, raft systems incorporating alginate gels, bioadhesive or mucoadhesive systems, high density system, superporous hydrogels and magnetic systems [7].

For researchers and R&D personnel, creating an oral controlled release system and formulating a medication for targeted drug administration in the GI tract are difficult tasks. Maintaining medication plasma levels within the therapeutic window for an extended amount of time in order to ensure sustained therapeutic effectiveness is the primary motivation for the development of controlled drug delivery and the growing interest in novel system developments [8]. Several strategies have been used to develop GRDDSs in order to increase the GRT: blockage of the pyloric sphincter through the use of "plug-type" swelling or expanding systems; the application of an external magnetic field to increase the retention of magnetically active systems; increasing the interaction with the stomach wall by imparting mucoadhesion; and modulating the product density, such as making it denser or less dense than the gastric liquid, to resist the peristaltic movement by settling at the bottom of the stomach or floating on the gastric fluid surface, respectively [9].

Consequently, in order to solve such difficulties, The purpose of gastro-retentive drug delivery systems is to extend the duration of gastric retention for medications that are:

- locally active in the stomach.
- The gut environment is unstable.
- The GIT has a limited absorption window.
- Are poorly soluble in areas with high pH [10].

With the ability to remain in the stomach region for several hours, gastro-retentive mechanisms can further prolong the gastric residence length of medications. Increased solubility, reduced drug waste, and increased bioavailability are all benefits of prolonged stomach retention for drugs that are less soluble in high pH conditions. It can also be utilized for local drug administration to the stomach and proximal small intestine. Improved pharmaceutical availability, novel therapeutic options, and substantial patient benefits are all facilitated by gastro retention [11].

A few key aspects that can be taken into account while creating gastroretentive formulations are basic human physiology, including the specifics of gastric emptying, motility pattern, and physiological and formulation variables influencing the cosmic emptying. Formulations that are gastro-retentive will stay in the stomach area for a longer period of time, which should increase bioavailability, decrease drug waste, and increase solubility for medications that are less soluble in high pH environments. Better therapeutic potential and high patient compliance are characteristics of this kind of system that should always be included in formulation design. One such instance is the creation of floating tablet formulation [12,13].

Weakly acidic medications, such as papaverine and domperidone, were efficiently administered by gastro-retentive drug delivery devices (GRDDs) to improve solubility and lower dosage. Furthermore, the dose form for gastro-resistant tablets purposefully postpones the release of the drug so that it might travel from one area to another after a while. Appropriate possibilities for creating delayed release dose forms include medications such as NSAIDs, insulin administration, H-2 blockers, and proton pump inhibitors [14].

Stomach:

Three regions make up the stomach's anatomy: the fundus, body, and antrum (pylorus). The antrum serves as the primary location for mixing motions and propels the stomach emptying process, whereas the proximal portion, which is composed of the fundus and body, serves as a reservoir for undigested materials [15,16].

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Fig no:1

An intraperitoneal organ is the stomach. The two layers of the lesser omentum extend from the liver's inferior surface to the stomach's lesser curvature. The two layers continue as the greater omentum at the greater curvature, encircling the stomach. In front of the stomach are the diaphragm, the left hepatic lobe, and the front abdominal wall. The structures behind this organ, meanwhile, are located deep within the omental bursa, or lesser sac. Thus, structures behind the smaller sac's posterior wall are posteriorly connected to the stomach. The pancreas, left diaphragm dome, spleen, left kidney and suprarenal gland, splenic artery, and transverse mesocolon are some of these structures [17, 18].

During fasting, the stomach and intestines go through an electrical series of inter-digestional events that happen every two to three hours. This is referred to as the inter-intestinal myloelectric cycle (fig. 2) or the migrating myloelectric cycle (MMC), and it can be further divided into the four phases listed below:

Four phases:

- **Phase I:** Also known as the basal phase, this stage, which lasts for 40 to 60 minutes, is characterized by the constriction of dread.

- **Phase II:** This 40–60 minutes period, which is frequently called the pre-burst phase, is marked by recurrent contractions and action potentials. Over time, the regularity and severity of the phase increase.

- **Phase III:** also known as the Burst Phase, is characterized by intense, regular contractions that last four to six minutes.

- **Phase IV**: This stage lasts from 0 to 5 minutes following a meal and falls between phases III and I. The digestive motility pattern is the name given to it [19].

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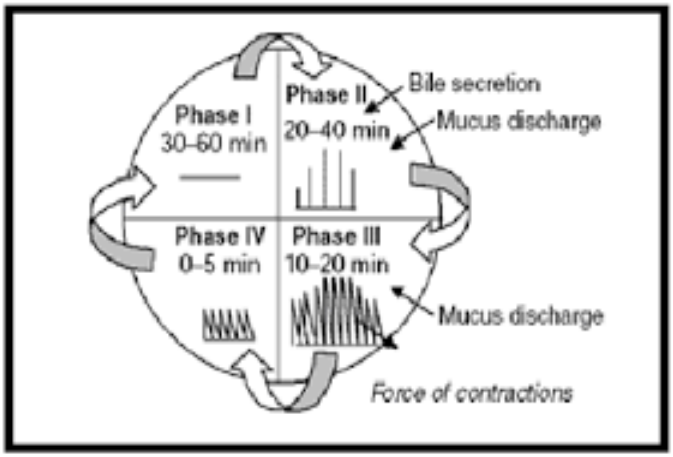


Fig no: 2

Needs for gastro-retention:

- Drugs absorbed from the proximal portion of the gastrointestinal tract (GIT).
- Drugs that, because of the GIT's alkaline pH, are less soluble or degrade in the bottom section.
- Substances absorbed due to variations in stomach emptying time.
- Local or continuous drug distribution to the stomach and proximal small intestine for the treatment of certain conditions; particularly beneficial for peptic ulcers caused by H. Pylori infections [20].

Factor affecting the gastro-retentive drug delivery system:

1. **Density**
2. **Size and shape**
3. **Nature of drugs**
4. **Age and gender**
5. **Fed or unfed state**
6. **Body posture**
7. **Diseased state**
8. **Nature of meal**
9. **Frequency of feed**

1. Density:

The density of the gastric contents (1.004g/ml) should be higher than the density of the dose form.

2. Size and shape:

The duration of stomach residency is longer for dose forms larger than 7.5 mm than for those with a diameter of 9.9 mm. The duration of the tetra hedron's stay in the stomach was longer than that of other devices of similar size. Single or multiple unit formulations have a higher margin of safety against dosage form failure, a more consistent release profile, less performance impairment from unit failure, and the ability to co-administer units with different release profiles or containing incompatible substances than single unit dosage forms [21,22,23].

3. Nature of drugs:

Medications that impact the transit time of the gastrointestinal tract, such as. Metoclopramide and Cisapride are pharmacokinetic medications that raise GRT, as is codeine.

4. Age and gender:

In general, women take longer than men to empty their stomachs. For mobile, upright, and recumbent individuals, posture has no appreciable impact on mean GRT. Stomach emptying occurs more slowly in older people.

5. Fed and unfed state:

Periods of intense motor activity or the migrating myoelectric complex (MMC), which happens every 1.5 to 2 hours, are characteristics of GI motility during fasting. The MMC removes undigested material from the stomach, and if the formulation is administered at the same time as the MMC, the unit's GRT should be quite brief. However, GRT is significantly longer and MMC is delayed in the fed condition.

6. Body posture:

Between the patient's supine and upright ambulatory phases, GRT can change; the floating and non-floating systems exhibited distinct behaviors. The floating systems demonstrated prolonged GRT when in the upright position because they floated to the top of the stomach contents and stayed there for a longer period. However, the floating units stayed away from the pylorus, while the non-floating units settled to the lower portion of the stomach and experienced rapid emptying due to peristaltic contractions. However, compared to non-floating units of the same size, the floating units are emptied more quickly when in the supine position.

7. Disease state:

GRT is increased by diabetes, hypothyroidism, and stomach ulcers. GRT is decreased by duodenal ulcers and hyperthyroidism. Concurrent administration of drugs Prokinetic drugs like metoclopramide and cisapride, anticholinergic drugs like atropine, and propantheline opiates like codeine.

8. Nature of meal:

The stomach's motility pattern can be altered to a fed state by feeding indigestible polymers or fatty acid salts, which slows down the pace at which the stomach empties and extends the release of drugs.

9. Frequency of feed:

GRT can be increased by up to 400 times by eating more frequently, which is reliant on the low frequency of migrating myoelectric complex (MMC) [24,25,27,28,29,30].

Advantages:

• For drugs with comparatively short half-lives, sustained release may result in flip-flop pharmacokinetics, allowing for decreased dosage frequency and improved patient compliance [31].

- In order to achieve gastro-retentive drug delivery—which extends and maintains the release of pharmaceuticals from dosage forms—local treatment in the stomach and small intestine can be employed. Consequently, they are useful in the treatment of stomach and small intestinal disorders [32].

- GRDDS decreases P-glycoprotein activity, increasing the bioavailability of the duodenum.

- By prolonging the residency period, they can offer local action. These techniques have increased patient compliance and enhanced the bioavailability of medications that are readily absorbed in the GIT.

- Better treatment efficacy and efficiency are made possible by GRDDS [33].

- Reduces the dosage's frequency.

- Targeted treatment for localized disorders of the upper digestive system.

- Higher bioavailability is expected for drugs that are easily absorbed in the gastrointestinal tract following release, such as cyclosporine, captopril, ranitidine, amoxicillin, ciprofloxacin, and others.

- To guarantee compliance, treatment is given once every day.

- Excellent accessibility.

- First pass metabolism increases drug bioavailability [34, 35].

Disadvantages:

- Drugs that irritate the stomach mucosa, have very low solubility in acidic conditions, or have stability issues in highly acidic environments are not allowed to be included in GRDDS.

- Bio/muco- adhesive systems suffer from a high mucus layer turnover rate, a thick mucus layer, and limitations relating to soluble mucus.

- Before leaving the stomach, swellable dose forms need to be able to swiftly expand to a size larger than the pylorus aperture. It must be resilient to MMC Phase III's housekeeping waves.

- Gastric retention is influenced by a number of factors, such as stomach motility, pH, and food content. Buoyancy cannot be predicted since these factors are never constant.

- One of the main issues with a bio-adhesive system is the high turnover rate of stomach mucous.

- Additionally, esophageal binding with bio-adhesive drug delivery methods is a potential.

- These systems are not the best places for medications with GIT stability and solubility problems [36].

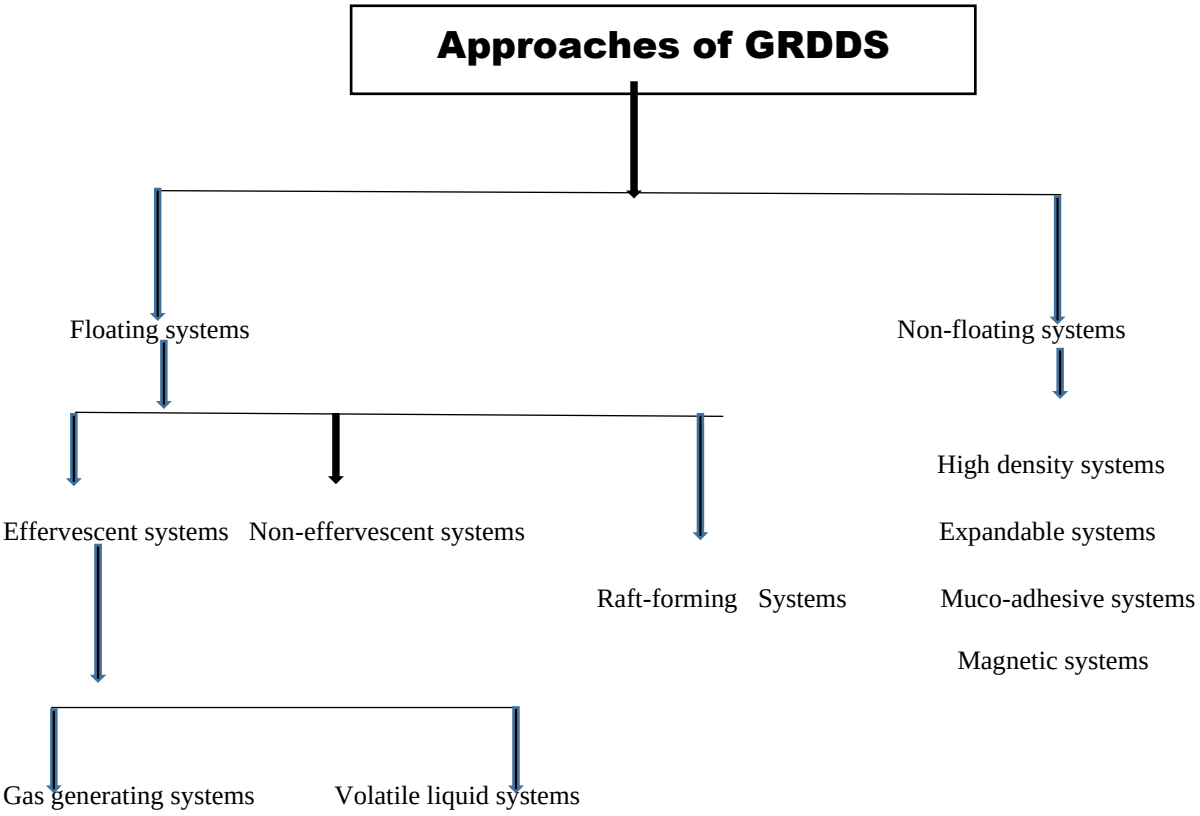
- To postpone their stomach emptying, these systems also need food.

- It is not appropriate to manufacture medications that irritate or damage the stomach mucosa as floating drug delivery devices [37].

Gastro-retentive drug delivery systems (GRDDSs) have been developed to extend and maintain the release of pharmaceuticals from dosage forms while remaining in the stomach region for an adequate amount of time, release the active ingredient in a controlled way, and then be readily metabolized by the body. The purpose of GRDDSs is to extend the duration of gastric residence length for medications that are: -lactam antibiotics (penicillin and cephalosporins), -1,2-diazepam, and -2,2-diphenyl-1-

picrylhydrazyl (DPH)) as well as maintain an effective drug concentration in the systemic circulation for an extended period of time. In order to achieve this goal, it is necessary to establish an oral controlled release system and formulate a medication for targeted drug administration in the gastrointestinal tract.

- **Different approaches of Gastroretentive drug delivery system:**



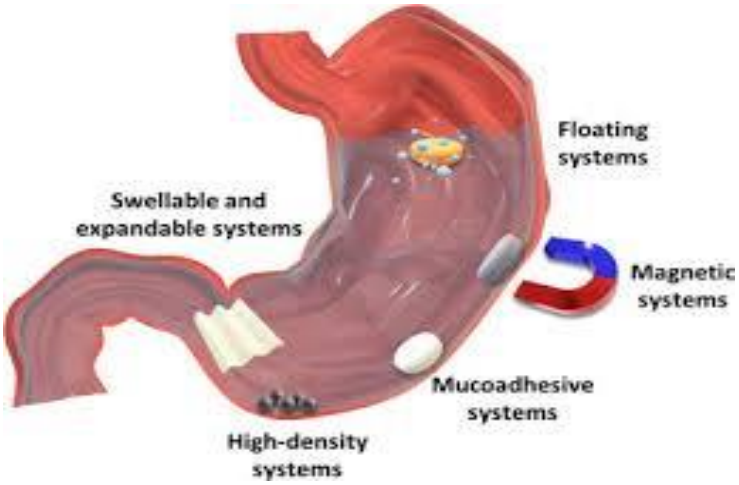


Fig no:3

1. Floating systems:

Order for the floating system, also called the Hydrodynamically Balanced System (HBS), to work, the density of the various developed dosage forms must be less than 1 g/ml. This allows the formulated pellets to float in the stomach's gastric fluid, where they release the drug in a sustainable manner.

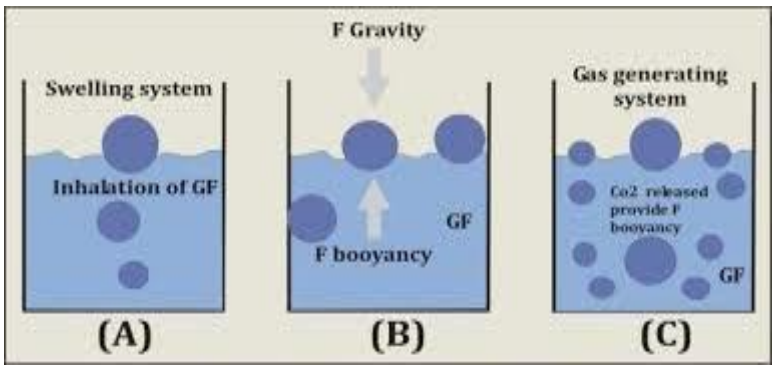


Fig.no:4

Classification of Floating systems:

It is classified into two types i.e.

1. Effervescent systems

a. Gas generating systems

b. Volatile liquid vacuum systems

2. Non-effervescent systems

3. Raft-forming systems

1.Effervescent systems:

The effervescent floating system, which is made up of an effervescent agent and volatile liquids that release carbon dioxide gas when they come into contact with stomach juice, relies on the phenomena of effervescence to operate as a GRDDS. By changing the buoyancy property, this gas becomes trapped in the hydrocolloid matrix of the produced dosage form and has a major impact on its drug-releasing properties [38,39,40,41].

Three distinct groups can be distinguished from the effervescent floating systems.

• Single-layer effervescent floating system.

• Double layer effervescent floating system.

• Multiple-unit buoyant-type floating systems.

A study found that adding sodium bicarbonate to the HPMC matrix formulation enhanced the surface area available for drug diffusion, resulting in a higher hydration volume and a better GRT time [42, 43].

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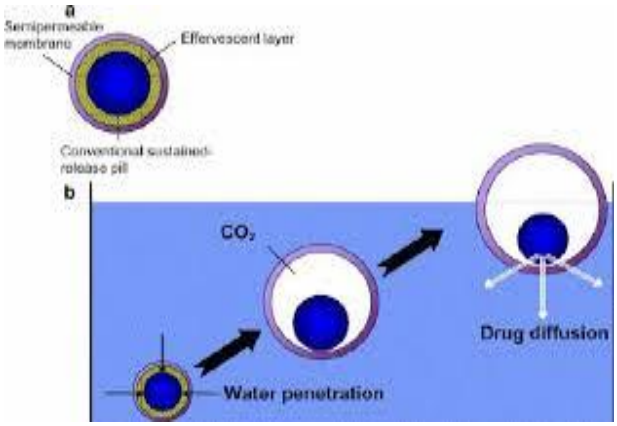

Fig no:5

A. Gas generating systems:

These buoyant delivery techniques use the effervescent reaction between carbonate/bicarbonate salts and citric/tartaric acid to release CO2, which is trapped in the jellified hydrocolloid layer of the system, lowering its specific gravity and making it float over a chime. Moreover, floating pills with multiple CO2-producing units have been developed, with a sustained release (SR) pill acting as the seed of the system and encased in two layers, with sodium bicarbonate and tartaric acid present in the effervescent inner layer. The outer layer is composed of a swellable membrane layer that contains PVA, shellac, and other ingredients. To control the release of the medication from the polymer matrix, an additional effervescent mechanism consisting of a collapsible spring has been developed. Usually, ethyl cellulose-coated resin beads loaded with bicarbonate are used to create these systems. Despite being insoluble, the coating is porous, allowing water to flow through it. Because carbon dioxide is released, the beads float in the stomach [44].

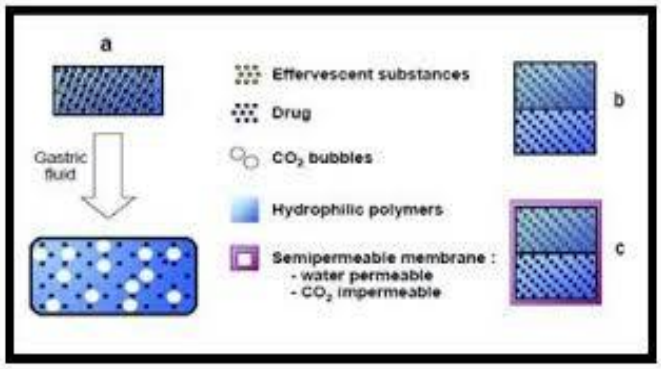

Fig no:6

B. Volatile liquid systems:

These have an inflatable chamber that is filled with a liquid, such ether or cyclopentane, which, when it gasifies at body temperature, causes the chamber to expand in the stomach. These systems are osmotically controlled floating devices with a hollow deformable unit. The system's first chamber contains the medication, while the second chamber contains the volatile liquid [45].

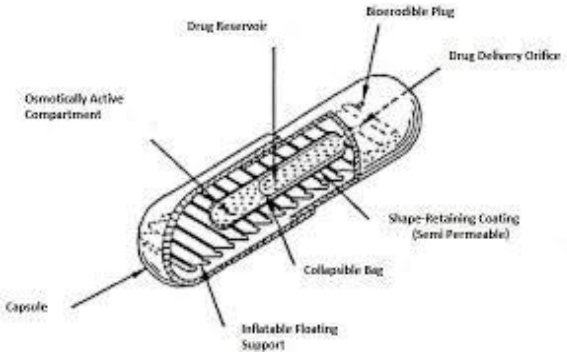

Fig no:7

2. Non-effervescent systems:

Polysaccharides, matrix-forming polymers such polycarbonates, polymethacrylate, and polystyrene, and gel-forming or swellable cellulose hydrocolloids are all present in these dosage forms. Following oral administration of this dosage form, the medication and the gel-forming hydrocolloid are combined to create a formulation that swells in contact with stomach fluids and reaches a bulk density of 1. By trapping air in the swelling gel-like structure, the dosage form became buoyant. This allows for continuous drug release through the gelatinous mass and serves as a reservoir. Examples of drugs are levodopa and famotidine [46].

Advantages of floating systems:

- **Sustained drug delivery:**

These systems can release the medication over an extended length of time since they can stay in the stomach for extended periods of time. These approaches can thereby solve the issue of short gastric residence time that arises with an oral CR formulation. These systems can float on the contents of the stomach since their bulk density is less than 1.

- **Site-Specific drug delivery:**

For medications that are selectively absorbed from the stomach or the proximal portion of the small intestine, these systems are very beneficial. For instance, ciprofloxacin, furosemide, riboflavin, etc.

- **Absorption enhancement:**

Potential candidates for formulation as floating drug delivery systems to maximize absorption include medications with low bioavailability due to site-specific absorption from the upper gastrointestinal tract [47].

3. Raft-forming systems:

Raft forming systems have sparked a lot of interest in the use of medicine delivery to treat gastrointestinal disorders and infections. Each component of the stomach fluid expands when viscous cohesive gel comes into contact with it, creating a continuous layer called a raft. This is among the processes that lead to the formation of rafts. Due to the low bulk density caused by CO2 generation, this raft floats on stomach contents. The components of the system frequently include a gel-forming agent and alkaline bicarbonates or carbonates that produce CO2 in order to reduce the system's thickness and enable it to float on the stomach contents. A method for generating a floating antacid raft was presented by Jorgen et al. To prevent the reflux of stomach contents, including gastric acid, into the esophagus, a foaming sodium alginate gel (raft) is created by combining sodium bicarbonate, acid neutralizer, and a gel forming agent (like sodium alginate). This gel floats on gastric fluids and serves as a barrier between the stomach and the esophagus [48,49].

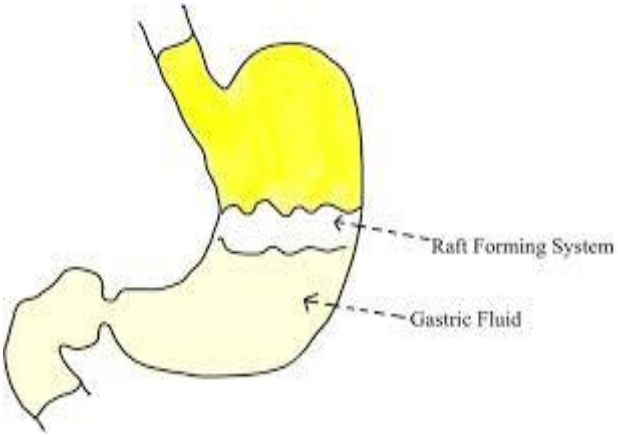

Fig no:8

2. Non-floating systems:

1. High density systems:

This method entails creating dosage forms whose density must be higher than the typical stomach content density (1.004g/ml). The medicine is coated onto a heavy core or combined with heavy inert materials as barium sulfate, zinc oxide, titanium dioxide, or iron powder to create these formulations. Diffusion-controlled membranes can be applied to the resulting pellets [50].

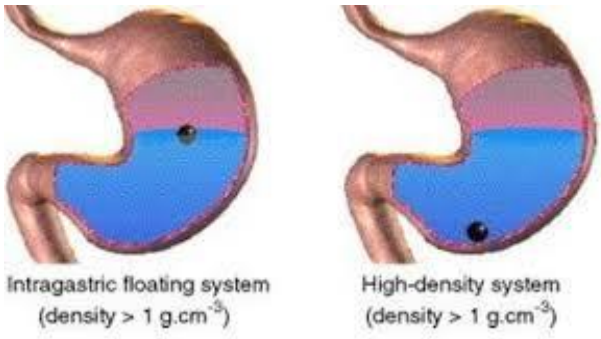

Fig no:9

2. Expandable systems:

Utilizing a tool that can enter the digestive system and absorb liquids, causing it to swell two to five times so that it can remain in the stomach for an extended period of time. After that, the hydrogel-containing tiny pills are discharged from the apparatus and delivered to the intestines or stomach for absorption. The patents in this category describe how to use the device's size to absorb gastric fluid and cause an expandable polymeric substance to swell in order to keep it in the stomach. Expanding GRDFs have the advantage of unfolding GRDFs in that since their industrial manufacturing is regarded as "shelf pharmaceutical technology," commercialization is relatively easy [51,52].

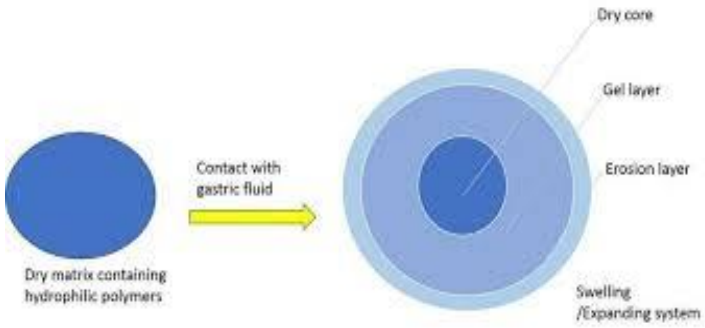

Fig no:10

3. Muco-adhesive systems:

By facilitating a closer and longer connection between the drug and the biological membrane, the bio/mucoadhesive system can extend the stomach residence duration of the drug delivery system. They attach themselves to the mucin or stomach epithelial cells. The two types of polymers bind to the interfaces of mucin and epithelium [53]. Mucoadhesion is promoted by chemicals including gliadin, chitosan, carbopol, polycarbophil, and carboxymethyl cellulose selection. Nevertheless, the force applied by the stomach wall seems to be greater than the mucoadhesive power of the stomach [54].

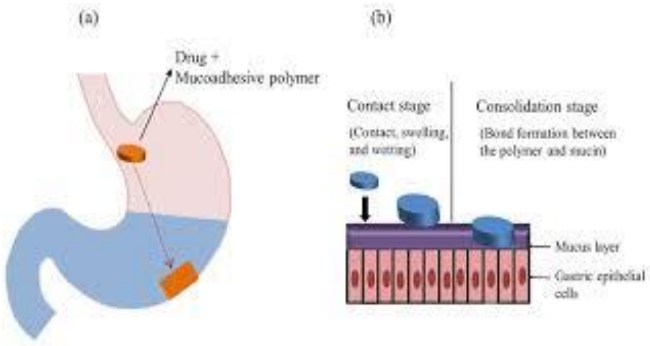

Fig no:11

4. Magnetic systems:

The fundamental idea behind this procedure is that a magnet is put on the abdomen above the location of the stomach, and a tiny internal magnet is included in the dose form. An extracorporeal magnet can be used to lengthen the duration of the dose form's longer stomach residence period. Clinical studies were conducted on three different delivery systems. A magnetic depot pill and an extracorporal magnet were employed in the first system; no extracorporal magnet was used in the second; and an immediate release formulation was used in the third [55].

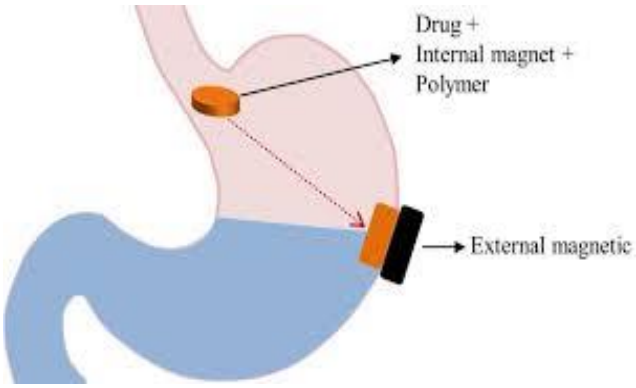

Fig no:12

When a strong enough magnet is introduced to the body surface in the stomach region, these systems, which resemble tiny gastroretentive capsules filled with a magnetic substance, are prevented from being eliminated from the stomach. The actual usefulness of such systems is questionable despite multiple reports of successful tests, as the intended outcomes can only be obtained if the magnet position is chosen with extreme precision. This idea will most likely be enhanced by the creation of new, easily used magnetic field sources [56].

Future work

Future work in GRDDSs includes the development of novel systems and formulations that can overcome the limitations of current systems.

Future work may involve the development of new magnetic field sources to enhance the effectiveness of magnetic GRDDS.

The study suggests that future research should focus on the development of new GRDDS technologies and the evaluation of their safety and efficacy in clinical trials.

Practical applications

The practical applications of GRDDSs include the treatment of peptic ulcers caused by H. pylori infections, and the administration of medications that are poorly soluble in high pH conditions.

GRDDS can be used to improve the bioavailability and absorption of drugs, and can be used to treat localized disorders of the upper digestive system.

The study notes that GRDDS have practical applications in the treatment of various diseases, including peptic ulcers, gastroesophageal reflux disease, and diabetes.

Conclusion:

In conclusion, gastro-retentive drug delivery systems (GRDDS) have revolutionized drug delivery by targeting specific regions of the upper gastrointestinal tract for enhanced treatment. These systems address challenges such as unpredictable gastric emptying and varying drug absorption throughout the gastrointestinal tract, offering advantages like prolonged drug release and improved patient compliance. Various approaches like floating systems, high-density systems, expandable systems, mucoadhesive systems, and magnetic systems have been developed to achieve gastro retention and extend drug residence in the stomach. Despite the advantages, there are considerations such as drug solubility, mucous layer turnover, and the influence of stomach motility and food content on gastric retention. Overall, GRDDS offers promising solutions for locally targeted drug delivery, enhanced bioavailability, and improved patient adherence, contributing to advancements in pharmaceutical research and patient care.

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