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FORMULATION AND DEVELOPMENT OF GASTRORETENTIVE DRUG DELIVERY SYSTEM FOR IMPROVED THERAPEUTIC EFFICACY

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Abstract: In the contemporary world of pharmaceutical sciences and drug delivery research, there is a swift and notable rise in the regulation as well as organizational governance of medications administered via the oral route. This significant increase occurs primarily due to its numerous well-established benefits, the wide availability of multiple diverse formulations that cater to various therapeutic needs. Within this evolving field, a particularly unique and innovative method known as Gastro Retentive Drug Delivery Systems (GRDDs) has emerged as a comprehensive and highly effective approach. These systems are specifically designed to enhance and prolong the duration that the drug remains present in the stomach environment, thereby facilitating the targeted and controlled release of the medication specifically in the upper section of the gastrointestinal tract (GIT). This targeted release mechanism supports both local actions within the gastric region and systemic therapeutic impacts throughout the body as required.including their detailed classification into different categories, the major benefits they offer, the associated constraints and limitations, the critical elements that influence stomach retention duration, methods of assessment and evaluation, the latest developments and innovations in the field, established guidelines criteria, and the promising future outlook of GRDDs moving forward in pharmaceutical research and application.

Keywords: *Uses, Categorization, Assessment, Elements, Prospective outlooks, Approach of preparation, Polymers, Recent developments, Regulatory factors.*

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INTRODUCTION

The method of delivering pharmaceuticals to specific therapeutic areas in humans or animals through various routes of administration such as oral, transmucosal, topical, inhalation, and intravenous is known as drug delivery. The history of drug supply shows that major technological advances did not occur until the 1970s. Since then, advances have focused on improving drug delivery to not only target but also maintain controlled release rates, increase cellular uptake, and minimize nonspecific effects, often requiring improved shelf life and stability of drugs. Although the cytotoxicity and therapeutic efficacy of drugs still play an important role, the use of a suitable drug delivery system (DDS) is essential to protect the drug during the administration process and release the drug at the desired site. The oral route is the most established and practical method of drug administration. The pharmaceutical industry considers the tremendous drug benefits of controlled oral release to be more attractive than the therapeutic benefits. Gastroretentive drug delivery systems are suitable for oral administration of drugs that have an absorption window in a specific part of the gastrointestinal tract and remain in the stomach. These methods maintain the highest level of bioavailability by continuously releasing the drug before it reaches its absorption range. Now, before we get into the details of GRDD, we need to look at the anatomy and physiology of the gastrointestinal tract, specifically the stomach. The digestive tract of multicellular animals, also called the alimentary canal or gastrointestinal tract, is an organ system that absorbs food, breaks it down to release nutrients and energy, and removes leftover waste products [1-4]. The GI tract\'s primary roles include secretion, absorption and motility, The motility phases of GIT is generally divided in 4 phases, i.e. phase I to phase 4, The most quiescent phase, Phase I (45-60 min), has few or no contractions; Phase II (30-45 min) has sporadic action potentials and contractions that progressively get stronger and more frequent as the phase goes on; and Phase III (5-15 min).

1. ANATOMY OF THE GASTROINTESTINAL TRACT

The human digestive system begins at the mouth and ends at the anus through a system of organs which each perform their designated functions. The digestive system contains four main parts which include the esophagus and stomach and small intestine and colon. The digestive system consists of intestines and colon and rectum and bile ducts and gallbladder and liver and pancreas. Place proximally for further mixing before pouring into the duodenum. Throughout the process of vitamin B12 absorption intrinsic factors which the stomach releases play a crucial role.

2. ANATOMY OF STOMACH

The stomach is a pouch-like extension of the digestive system, located between the stomach.the esophagus and small intestine of most vertebrates. Before the food is transferred the intestine, the stomach, serves as an intermediate structure for storage and organization. Distribution.

3. FACTORS OF GASTRIC RETENTION

3.1 Density:Low-density forms float and stay longer in the stomach.
3.2 Size:Larger dosage forms increase gastric residence time (GRT).
3.3 Shape:Tetrahedron and ring shapes show better retention (up to 24 hours).
3.4 Single/Multiple Units:Multiple-unit systems provide controlled release and better safety.
3.5 Fed or Unfed State:Food increases GRT and improves drug absorption.
3.6 Nature of Meal:Fatty or indigestible meals slow gastric emptying and prolong drug action.
3.7 Calorie Content & Frequency:High-protein and high-fat meals increase GRT (4-10 hours).
3.8 Posture:Body position affects GRT.
3.9 Age & Gender:Elderly and females have slower gastric emptying.

4. FORMULATION STRATEGIES OF GRDDS

4.1 Polymer selection

Many features are available for selecting dosage form polymers and various drug delivery systems to improve drug efficacy and exposure Some of the features considered are listed below.

- Must be inert and compatible with the environment.
- Easy to use, non-toxic, and easy to make.
- Inexpensive and high mechanical strength [5-6].

4.2 Natural polymers used in GRDD

The world contains natural biodegradable polymers which exist in nature while living organisms create these materials [7].

5. CLASSIFICATION OF GRDDS

The two main categories of GRDDS are floating and non-floating systems. Based on their buoyancy, floating systems are further classified into effervescent and non-effervescent systems, while non-floating systems are categorized into four groups depending on their method of gastro retention.

5.1 Floating GRDDS

These systems possess a lower bulk density compared to the contents of the stomach. They are capable of continuously releasing medication and remaining in a fluid state within the stomach for prolonged durations. Ultimately, the residual system is evacuated. Fasting leads to a significantly quicker emptying of the stomach, and floating systems primarily depend on food intake to delay this emptying and provide sufficient fluid to maintain their buoyancy [8].

5.1.1 Effervescent GRRDS

Effervescent systems use gas-generating agents, carbonates (e.g. sodium bicarbonate) and other organic acids (e.g., citric and tartaric acid) in the composition to create carbon dioxide (CO_2) a gas that reduces the density of the system and causes it to float in the gastric fluid.

5.1.2 Volatile liquid system

These systems include an inflatable chamber that expands in the stomach due to the presence of liquid ether, which gasifies at body temperature The medication is continually pumped into the stomach fluid from the reservoir. e.g. lamivudine [9].

5.1.3 Matrix tablets

The drug release process from the tablet polymer matrix occurs when the user operates the folding spring mechanism. The development of these systems requires the use of resin balls which contain bicarbonate and have an ethylcellulose coating. For example, Satwudin [10].

5.1.4 non-effervescent GRDDS

Non-effervescent systems contain high concentrations of sodium carboxymethyl cellulose, polysaccharides, matrix polymers, and numerous gelling and swelling cellulose hydrocolloids in tablets or capsules.

5.1.5 Hydrodynamically balanced system

The HBS system uses polymers which function as its base materials because the system uses this method to combine drug and polymer materials into gelatin capsules. Hydrophilic gelling polymers for medicine creation can be blended until they reach a single uniform state. Floating shelves should be developed as a design element. Polymers undergo hydration which results in their gradual size increase.

5.1.6 Layered tablets

In a layered tablets more than one layer is present, the first layer is called the immediate release layer and it releases the first dose from the system. The second layer is called the sustained release layer and it absorbs the gastric fluid, forming an impermeable barrier on its surface made of colloidal gel and keeping its bulk density below 1 as a result the Gastro retentive time of these tablets is increased and release the drug for extended period of time.

5.1.7 The Raft Forming System's Design

The raft forming system's formulation is influenced by the drug's physicochemical characteristics, the patient population, the ailment that has to be treated and marketing preferences. Anatomical and physiological aspects include membrane transport and tissue fluid pH; formulation factors include pH, gelation temperature, viscosity, osmolarity and spreadability [11-12].

5.2 non-floating GRDDS

The dosage form of the gastro-retentive drug delivery system does not float within the stomach; instead, it remains there through a specific mechanism characteristic of non-floating drug delivery systems. This system is dependent on pH and dissolves at a particular pH level. The medication can settle in the stomach [13].

5.2.1 Mucoadhesion and Bioadhesion

The state in which interfacial forces hold two materials together for a prolonged amount of time-at least one of which is biological in nature-is referred to as bioadhesion. Three types of bioadhesion can be found in biological systems [14].

5.2.2 High density system

The density of gastric contents measures 1.004g/cm3, which closely resembles that of water. When high-density pellets are administered to a patient, they tend to settle at the bottom of the stomach [15].

5.2.3 Magnetic system

In order to achieve target-specific action, this device is designed to incorporate a tiny internal magnet into the dosage form of a magnetically active molecule, For instance, Ito et al. used bioadhesive granules containing ultrafine ferrite (g-Fe_2O_3) in rabbits that were kept in the stomach area for 2 hr after being exposed to an external magnet of 1700 G [16].

6. ADVANTAGES OF GRDDS

- Improved drug absorption.
- Regulated drug delivery.
- Administration of drugs for localized action within the stomach.
- Reduction of mucosal irritation due to a gradual and controlled release rate [17-18].

7. DISADVANTAGES OF GRDDS

- Not appropriate for medications with low acid solubility.
- Not suitable for drugs that are unstable in acidic conditions.
- Medications that cause irritation or gastric lesions during slow release, such as Aspirin and NSAIDs [19].

8. APPLICATION OF GASTRO-RETENTIVE DRUG DELIVERY SYSTEM

1. 1 Enhance bioavailability
2. 2 Sustained drug delivery
3. 3 Site–specific drug delivery systems
4. 4 Absorption enhancement
5. 5 Minimize adverse activity at the colon

9. EVALUATION OF GASTRORETENTIVE DOSAGE FORMS

9.1 In vitro evaluation

i) Floating system

a) Buoyancy lag

This evaluation parameter is performed to know the time required for administration.

b) Swimming time

The total time or duration of ingesting the dosage form is always displayed on the screen. The dissolution medium was 37°C.

c) Density/specific gravity

This test is evaluated using the displacement method using benzene.travel environment.

9.2 In vivo evaluation test

Radiology: Barium sulfate helps view internal organs.

Scintigraphy: Uses radioactive 99mTc for imaging.

Gastroscopy:Endoscopy method with minimal radiation.

10. RECENT ADVANCEMENTS IN GRDDS

Various methods have been proposed to increase the gastric residence of drug delivery systems in the upper part of the gastrointestinal tract, including Floating Drug Dosage Systems (FDDS), swelling or expanding systems, mucoadhesive systems, magnetic systems, modified-shape systems, high density systems and other delayed gastric emptying devices. In recent years, scientific and technological advancements have been made in the research and development of Gastro retentive drug delivery systems [20]. Copolymers, 3D printing technology, Biodegradable materials.

11. RECENT PATENTS OF GRDDS

In the recent time various patents are filed and obtain in various

- Osmotic Gastro retentive Drug Delivery System with Self-Regulation.
- A Gastro retentive item for detecting alcohol.
- 3D printing of various drug delivery vehicles for gastric retention.
- It remains in the stomach for a long time due to its very long buoyancy. Hydrogel rafts.

12. LIMITATIONS OF GRDDS

- Require sufficient stomach contents.
- Must be taken with 200–250 mL water.
- High mucus turnover reduces adhesion.
- Mucus degradation may cause discomfort.
- Gastric retention time varies with digestion and post-meal state.

13. FUTURE PROSPECTIVE OF GRDDS

The future of GRDDS systems will achieve better accuracy and operational efficiency through the development of smart polymers and personalized medicine and artificial intelligence and remote activation technologies.

1. Smart Polymers
2. Personalized Medicine
3. Artificial Intelligence and Machine Learning
4. Remote Activation Technology

14. CONCLUSION

Recently, several medications are developed to be gastro-retentive. medication delivery mechanism aimed at prolonged and regulated discharge of the medication for the regional and overall impacts. GRDDs hold significant potential for the future of drug delivery. To create a necessary gastro-retentive dosage form, various methods have been employed such as the floating system and the non-floating system. system and raft assembly system among which the buoyant the system is the most effective method for enhancing gastric residence duration, the utilization of different biodegradable materials enhance 3d printing, natural polymers, the GRDDs and in the future different technologies such as A.I. (Artificial Intelligence), 3D Innovation, distant initiation and diverse emerging technologies will render it one of the most significant method of delivering medication.

15. AUTHOR CONTRIBUTIONS

All authors are contributed equally.

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17. DECLARATION COMPETING INTEREST

The authors have no conflicts of interest to declare.

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