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Review on Formulation of Floating Drug Delivery System (FDDS)/Gastro retentive Drug Delivery Systems (GRDDS): Past, Present and Future Perspectives.

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Abstract: Floating Drug Delivery Systems (FDDS) are advanced gastro retentive dosage forms designed to prolong gastric residence time and improve bioavailability of drugs exhibiting narrow absorption windows, poor intestinal stability, or localized gastric activity. Conventional oral dosage forms often suffer from rapid gastric emptying, resulting in incomplete drug absorption and fluctuating plasma drug concentrations. FDDS overcome these limitations by remaining buoyant in gastric fluids for extended durations, thereby enhancing drug release and absorption profiles. Various approaches such as effervescent systems, non-effervescent systems, raft-forming systems, expandable systems, and bio adhesive systems have been extensively investigated for achieving prolonged gastric retention. Recent advancements in FDDS include floating microspheres, nanoparticle-based gastro retentive systems, 3D printed tablets, and smart polymeric carriers capable of controlled and site-specific drug delivery. Polymers such as Hydroxypropyl Methylcellulose (HPMC), Carbopol, sodium alginate, xanthan gum, and chitosan play a critical role in maintaining buoyancy and sustaining drug release. Despite significant progress, challenges including variability in gastric emptying time, patient-specific physiological conditions, and scale-up difficulties remain important concerns. The present review comprehensively discusses the historical development, physiological basis, classification, formulation strategies, evaluation methods, recent advances, marketed products, challenges, and future perspectives of FDDS/GRDDS. The review aims to provide a detailed scientific overview of current gastro retentive technologies and their potential future applications in advanced oral drug delivery.

Keywords: FDDS, GRDDS, Floating tablets, Gastro retentive systems, Sustained release, controlled drug delivery

1. INTRODUCTION

Oral drug delivery systems are considered the most convenient and widely accepted route of drug administration due to their ease of administration, patient compliance, non-invasive nature, and cost effectiveness. Despite these advantages, conventional oral dosage forms often exhibit several limitations such as unpredictable gastric emptying, short gastrointestinal residence time, fluctuating plasma drug concentration, incomplete drug absorption, and poor bioavailability. These challenges become more significant in drugs possessing a narrow absorption window in the upper part of the gastrointestinal tract, drugs unstable in alkaline pH, drugs acting locally in the stomach, and drugs requiring sustained therapeutic action for prolonged periods. [1]

In recent decades, considerable research attention has been directed toward the development of novel oral controlled release systems capable of overcoming these physiological barriers. Among the various approaches developed, Gastro retentive Drug Delivery Systems (GRDDS) and Floating Drug Delivery Systems (FDDS) have emerged as highly promising technologies for improving oral drug bioavailability

and therapeutic efficacy. These systems are specifically designed to prolong gastric residence time by retaining the dosage form in the stomach for extended durations, thereby enhancing drug absorption and reducing dosing frequency. [2]

FDDS are low-density systems that remain buoyant over gastric fluids without significantly affecting gastric emptying rate. Once administered, these systems float on the stomach contents due to their lower bulk density than gastric fluid and continuously release the drug at a controlled rate while remaining in the gastric environment. After complete drug release, the residual system is expelled from the stomach. The prolonged gastric retention achieved through FDDS offers multiple therapeutic advantages including improved bioavailability, enhanced solubility of poorly water-soluble drugs, minimized drug wastage, reduced plasma concentration fluctuations, and improved patient compliance.[3]

The concept of gastro retention is particularly beneficial for drugs such as metformin, levodopa, ciprofloxacin, furosemide, riboflavin, and ranitidine, which are preferentially absorbed from the stomach or upper intestinal region. Moreover, FDDS are useful for drugs intended for local action in the stomach such as antacids, antibiotics used against *Helicobacter pylori*, and drugs used in gastric ulcer therapy. The success of FDDS largely depends on several physiological factors including gastric motility, fed or fasting state, gastric pH, size and density of dosage form, and nature of the meal consumed.[4]

Various approaches have been investigated to achieve gastro retention including floating systems, mucoadhesive systems, expandable systems, swelling systems, raft-forming systems, super porous hydrogels, and high-density systems. Among these approaches, floating systems have gained maximum commercial and research interest due to their simplicity of formulation, better patient acceptability, and efficient drug release characteristics. Depending upon the mechanism of buoyancy generation, FDDS are broadly classified into effervescent and non-effervescent systems. Effervescent systems utilize gas-generating agents such as sodium bicarbonate and citric acid, whereas non-effervescent systems employ swell able polymers like Hydroxypropyl Methylcellulose (HPMC), sodium alginate, Carbopol, and xanthan gum to maintain buoyancy.[5]

Advancements in polymer science, nanotechnology, computational pharmaceutics, and smart drug delivery technologies have significantly transformed the field of gastro retentive systems. Modern FDDS formulations include floating microspheres, floating beads, floating capsules, floating films, raft-forming systems, and multiparticulate gastro retentive systems capable of providing precise and sustained drug release profiles. Furthermore, emerging technologies such as 3D printing, artificial intelligence-assisted formulation optimization, and biodegradable natural polymers are expected to revolutionize the future development of GRDDS.[1–5]

Therefore, the present review aims to provide a comprehensive overview of the formulation and development of Floating Drug Delivery Systems and Gastro retentive Drug Delivery Systems with special emphasis on their historical development, physiological considerations, formulation strategies, polymers used, evaluation parameters, recent advancements, marketed products, and future perspectives in advanced oral drug delivery research.

2. NEED AND SIGNIFICANCE OF FDDS/GRDDS

Conventional oral drug delivery systems generally provide limited control over drug release and are often unable to maintain the dosage form at the desired site of absorption for prolonged durations. Rapid gastric emptying and variable gastrointestinal transit time frequently result in incomplete drug absorption, reduced bioavailability, and fluctuations in plasma drug concentration. These limitations are particularly observed in drugs that possess narrow absorption windows in the upper gastrointestinal tract, drugs that are poorly soluble at alkaline pH, and drugs that undergo degradation in the intestinal environment. [6]

Floating Drug Delivery Systems (FDDS) and Gastro retentive Drug Delivery Systems (GRDDS) were developed to address these drawbacks by prolonging the gastric residence time of dosage forms. By remaining in the stomach for extended periods, these systems ensure continuous and controlled drug release at the absorption site, thereby improving therapeutic efficacy and minimizing drug loss. The prolonged retention also enhances the contact time between the drug and gastric mucosa, resulting in better absorption and improved bioavailability. [7]

One of the major advantages of FDDS is their ability to maintain relatively constant plasma drug concentrations for prolonged periods. Conventional immediate-release formulations often produce sharp peaks and troughs in plasma drug levels, leading to sub therapeutic effects or dose-related adverse reactions. FDDS minimize these fluctuations through sustained drug release mechanisms, thereby improving patient safety and therapeutic outcomes. Additionally, reduced dosing frequency significantly enhances patient compliance, especially in chronic diseases requiring long-term pharmacotherapy. [8]

FDDS are highly beneficial for drugs that exhibit local action within the stomach. Drugs used for the treatment of gastric ulcers, gastroesophageal reflux disease (GERD), and *Helicobacter pylori* infections require prolonged gastric residence for optimum therapeutic activity. Gastro retentive systems can localize these drugs within the stomach for extended periods, thereby improving local drug concentration and reducing systemic side effects. Furthermore, FDDS improve the solubility of weakly basic drugs that dissolve better in acidic gastric conditions. [9]

The significance of FDDS has further increased with advancements in polymer technology and formulation science. Modern gastro retentive systems are capable of achieving controlled buoyancy, predictable release kinetics, enhanced mechanical strength, and better stability. Multiparticulate floating systems, floating microspheres, floating beads, raft-forming systems, and expandable dosage forms have demonstrated superior performance compared to conventional single-unit systems. These advancements have broadened the pharmaceutical applications of FDDS in both research and industrial formulation development. [10]

Despite their advantages, FDDS also possess certain limitations. These systems are generally unsuitable for drugs that cause gastric irritation, drugs unstable in acidic pH, and drugs with extensive first-pass metabolism. Moreover, successful performance of FDDS depends upon several physiological factors such as gastric motility, gastric pH, fed state, posture of patient, and volume of gastric contents. Nevertheless, due to their substantial therapeutic benefits and increasing commercial importance, FDDS continue to represent one of the most promising approaches in advanced oral controlled drug delivery research. [6–10]

3. PHYSIOLOGY OF STOMACH AND GASTRIC EMPTYING

A thorough understanding of gastric anatomy and gastrointestinal physiology is essential for the successful design and development of Floating Drug Delivery Systems (FDDS) and Gastro retentive Drug Delivery Systems (GRDDS). The physiological environment of the stomach plays a critical role in determining the gastric residence time, drug release behaviour, and overall performance of gastro retentive dosage forms. Various factors such as gastric motility, pH, volume of gastric fluid, feeding state, and gastric emptying patterns directly influence the effectiveness of FDDS formulations. [11]

The human stomach is anatomically divided into four major regions: fundus, body, antrum, and pylorus. The fundus and body primarily serve as storage regions for undigested food, whereas the antrum is mainly

responsible for mixing and grinding gastric contents. The pyloric region controls the passage of stomach contents into the duodenum. The acidic pH of the stomach generally ranges from 1.2 to 3.5 in fasting conditions and may increase temporarily after food intake. This acidic environment significantly influences the solubility and stability of orally administered drugs and polymers used in gastro retentive systems. [12]

Gastric emptying is a dynamic and complex physiological process that determines the movement of dosage forms from the stomach into the small intestine. During fasting conditions, the stomach exhibits a cyclic motor activity known as the Migrating Myoelectric Complex (MMC), which consists of four phases. Phase I is characterized by a resting period with minimal contractions, whereas Phase II involves intermittent contractions. Phase III, also known as the "burst phase," produces intense and regular contractions responsible for sweeping undigested materials out of the stomach. Phase IV acts as a transition period between Phase III and Phase I. This cyclic process generally repeats every 90 to 120 minutes and greatly affects the retention of gastro retentive dosage forms.[13]

In fed conditions, the gastric motility pattern changes significantly due to the presence of food. The onset of MMC is delayed, resulting in prolonged gastric retention time. This phenomenon favours the performance of FDDS by allowing the dosage form to remain buoyant within the stomach for longer durations. The composition, caloric content, viscosity, and frequency of meals can considerably influence gastric emptying behaviour. High-fat and high-protein meals generally increase gastric retention time compared to liquid or low-calorie meals.[14]

Several physiological factors influence the gastric residence behaviour of FDDS, including age, gender, posture, emotional state, disease conditions, and concurrent medication use. Elderly individuals and females often exhibit slower gastric emptying rates than young adult males. Diseases such as diabetes mellitus, Crohn's disease, and hypothyroidism may alter gastric motility and affect dosage form retention. Similarly, drugs like anticholinergic and opioids delay gastric emptying, whereas prokinetic agents accelerate gastrointestinal transit. [15]

The design of an effective gastro retentive system therefore requires careful consideration of these physiological variables. Proper selection of polymers, density-modifying agents, swelling agents, and gas-generating components is essential to achieve prolonged gastric retention and predictable drug release. A comprehensive understanding of gastric physiology enables formulation scientists to optimize FDDS performance and improve therapeutic efficacy in oral controlled drug delivery systems. [11–15]

4. CLASSIFICATION OF GASTRORETENTIVE DRUG DELIVERY SYSTEMS (GRDDS)

Gastro retentive Drug Delivery Systems (GRDDS) are specialized oral controlled release systems developed to prolong the residence time of dosage forms in the stomach. Based on the mechanism employed for gastric retention, GRDDS are classified into several categories including floating systems, bio adhesive systems, swelling systems, high-density systems, expandable systems, raft-forming systems, and super porous hydrogel systems. Each approach possesses distinct formulation strategies, advantages, and limitations depending upon the physicochemical properties of the drug and the desired therapeutic outcome. [16]

Among all gastro retentive approaches, Floating Drug Delivery Systems (FDDS) are the most extensively studied and commercially explored systems. FDDS are designed with a density lower than gastric fluids,

enabling them to float over stomach contents for prolonged periods without interfering significantly with gastric emptying. These systems continuously release the drug at a controlled rate while remaining buoyant in the stomach. FDDS are broadly classified into effervescent and non-effervescent floating systems. Effervescent systems generate carbon dioxide through reaction between gas-generating agents such as sodium bicarbonate and organic acids, whereas non-effervescent systems rely on swell able polymers like Hydroxypropyl Methylcellulose (HPMC), sodium alginate, and xanthan gum for maintaining buoyancy.[17]

Bio adhesive or mucoadhesive systems represent another important category of GRDDS. These systems utilize bio adhesive polymers capable of adhering to the gastric mucosal lining, thereby prolonging the residence time of the dosage form within the stomach. Polymers such as Carbopol, chitosan, polycarbophil, and sodium carboxymethyl cellulose are commonly used in mucoadhesive formulations. The adhesion occurs due to electrostatic interactions, hydrogen bonding, and polymer chain entanglement with gastric mucin. Mucoadhesive systems are especially advantageous for localized drug delivery and site-specific therapy in gastric disorders. [18]

Swelling and expandable systems are designed to increase their size after administration to prevent passage through the pyloric sphincter. These formulations absorb gastric fluid and undergo rapid swelling, resulting in enlargement of the dosage form dimensions. Such systems maintain prolonged gastric retention until the polymer gradually erodes or disintegrates. Swell able hydrophilic polymers including HPMC, polyethylene oxide, and cross-linked hydrogels are widely utilized in these formulations. Expandable systems are particularly suitable for sustained release applications and drugs requiring prolonged upper gastrointestinal absorption. [19]

High-density gastro retentive systems function by possessing a density significantly greater than gastric fluids, typically above 2.5 g/cm^3. Due to their high density, these systems settle at the lower part of the stomach and resist gastric emptying. Materials such as barium sulphate, zinc oxide, iron powder, and titanium dioxide are commonly incorporated to increase formulation density. Although this approach demonstrates prolonged gastric retention theoretically, practical challenges associated with formulation design and patient variability have limited its widespread application. [20]

Raft-forming systems are another unique category of gastro retentive systems commonly employed in the treatment of gastroesophageal reflux disease (GERD) and gastric ulcers. These systems form a viscous cohesive gel or “raft” upon contact with gastric fluid. The generated raft floats over gastric contents and acts as a physical barrier, preventing acid reflux into the oesophagus. Alginate-based formulations containing sodium alginate and bicarbonates are widely used in commercial raft-forming antacid preparations. [16–20]

Recent advancements in GRDDS have led to the development of sophisticated multiparticulate systems, floating microspheres, magnetic systems, super porous hydrogels, and nanoparticle-based gastro retentive formulations. These modern systems offer improved gastric retention, reduced dose dumping risk, enhanced drug release control, and better patient safety compared to conventional single-unit dosage forms. The continuous evolution of gastro retentive technologies has significantly expanded their pharmaceutical and clinical applications in modern drug delivery research. [16–20]

Sr. No.	Type of GRDDS	Principle/Mechanism	Common Polymers or Materials Used	Advantages	Limitations
1	Floating Drug Delivery Systems (FDDS)	Dosage form possesses lower density than gastric fluid and remains buoyant in stomach for prolonged duration	HPMC, Sodium alginate, Carbopol, Xanthan gum, Sodium bicarbonate	Prolonged gastric retention, improved bioavailability, controlled drug release	Requires sufficient gastric fluid, unsuitable for drugs unstable in acidic pH
2	Effervescent Floating Systems	Generation of carbon dioxide through reaction between acids and bicarbonates produces buoyancy	Sodium bicarbonate, Citric acid, Tartaric acid, HPMC	Rapid floating, easy formulation, sustained release possible	Gas generation may vary depending on gastric conditions
3	Non-Effervescent Floating Systems	Swell able polymers form gel barrier and maintain low density for flotation	HPMC, Hydroxyethyl cellulose, Sodium alginate, Polyethylene oxide	Stable floating behaviour, better matrix integrity	Delayed floating may occur
4	Bio adhesive/Mucoadhesive Systems	Adhesion of dosage form to gastric mucosal surface through hydrogen bonding and electrostatic interaction	Carbopol, Chitosan, Polycarbophil, Sodium CMC	Site-specific delivery, prolonged retention	Mucus turnover may reduce adhesion time
5	Swelling Systems	Dosage form swells after contact with gastric fluid and increases in size to prevent gastric emptying	HPMC, Cross-linked hydrogels, Polyethylene oxide	Enhanced gastric retention, sustained release	Risk of dose dumping if swelling is inadequate

Sr. No.	Type of GRDDS	Principle/Mechanism	Common Polymers or Materials Used	Advantages	Limitations
6	Expandable Systems	Dosage form expands significantly after administration and resists passage through pylorus	Biodegradable polymers, Hydrophilic matrices	Long gastric retention time	Complex formulation design
7	High Density Systems	Dosage form sinks to lower part of stomach due to density greater than gastric fluid	Barium sulphate, Zinc oxide, Iron powder	Less affected by gastric motility	Difficult to achieve optimum density
8	Raft Forming Systems	Formation of viscous floating gel barrier over gastric contents	Sodium alginate, Calcium carbonate, Sodium bicarbonate	Effective in GERD and gastric ulcer therapy	Limited application mainly for antacids
9	Super porous Hydrogel Systems	Rapid swelling due to interconnected porous structure leading to gastric retention	Super porous hydrogels, Polyacrylate derivatives	Fast swelling and prolonged retention	Mechanical strength issues
10	Magnetic Systems	External magnetic field controls gastric retention of dosage form containing magnetic materials	Ferrite, Magnetite, Magnetic beads	Controlled localization possible	Clinical applicability is limited

5. FORMULATION APPROACHES AND DEVELOPMENT STRATEGIES OF FDDS

The successful development of Floating Drug Delivery Systems (FDDS) primarily depends upon appropriate formulation design, selection of polymers, optimization of buoyancy, and controlled drug release behaviour. The formulation strategy is designed in such a manner that the dosage form remains buoyant within gastric contents for prolonged periods while releasing the drug in a predictable and sustained manner. Various formulation approaches have been investigated to achieve optimum floating characteristics, prolonged gastric residence time, mechanical stability, and enhanced therapeutic efficacy. [21]

The formulation development of FDDS begins with the careful selection of drug candidates suitable for gastro retentive delivery. Ideal drug candidates for FDDS include drugs possessing narrow absorption windows in the upper gastrointestinal tract, drugs acting locally in the stomach, drugs unstable in intestinal pH, and drugs exhibiting poor colonic absorption. Drugs such as metformin, levodopa, ciprofloxacin, ranitidine, furosemide, and riboflavin have demonstrated significant improvement in therapeutic efficacy when formulated as FDDS.[22]

Polymers play a critical role in the development of FDDS because they control swelling behaviour, matrix integrity, floating capability, and drug release kinetics. Hydrophilic polymers such as Hydroxypropyl Methylcellulose (HPMC), Hydroxyethyl Cellulose (HEC), Sodium Alginate, Carbopol, Xanthan Gum, and Polyethylene Oxide are commonly utilized in floating formulations. Upon contact with gastric fluid, these polymers hydrate rapidly and form a viscous gel barrier around the dosage form. This gel barrier not only controls drug diffusion but also traps generated carbon dioxide within the matrix, thereby maintaining buoyancy. [23]

Effervescent floating systems are among the most widely developed FDDS formulations. These systems utilize gas-generating agents such as sodium bicarbonate, calcium carbonate, and citric acid. In acidic gastric conditions, these agents release carbon dioxide gas, which becomes entrapped within the hydrated polymer matrix, decreasing system density and enabling flotation. The amount of gas-generating agents, polymer viscosity grade, tablet hardness, and compression force significantly influence floating lag time and total floating duration. [24]

Non-effervescent floating systems mainly depend upon swelling and gel formation mechanisms for achieving buoyancy. These systems generally contain highly swell able polymers capable of absorbing gastric fluid and increasing dosage form volume while maintaining density lower than gastric contents. Hydrodynamically Balanced Systems (HBS), floating beads, floating microspheres, and floating capsules are common examples of non-effervescent FDDS. Multiparticulate systems such as floating microspheres are particularly advantageous because they reduce dose dumping risk and provide more uniform gastric distribution compared to single-unit systems. [25]

Several advanced formulation techniques have been explored in recent years for improving FDDS performance. These include inotropic gelation, solvent evaporation, hot-melt extrusion, freeze drying, spray drying, and melt granulation techniques. Novel approaches involving nanotechnology, biodegradable natural polymers, and 3D printing technologies have further enhanced the precision and functionality of modern gastro retentive systems. Additionally, computational modelling and artificial intelligence-based optimization techniques are increasingly being used for predicting drug release behaviour and formulation stability.[21–25]

During formulation development, various parameters are optimized to achieve ideal gastro retentive performance. These include floating lag time, total floating duration, swelling index, matrix integrity, tablet hardness, friability, drug entrapment efficiency, and in vitro drug release characteristics. A successful FDDS formulation should ideally exhibit rapid buoyancy, prolonged floating duration exceeding 12 hours, controlled drug release, and adequate mechanical strength to withstand gastric motility. [21]

Thus, formulation development of FDDS represents a multidisciplinary pharmaceutical approach involving polymer science, bio pharmaceutics, physical pharmacy, and advanced drug delivery technologies. Continuous advancements in formulation methodologies and material sciences are expected

to significantly expand the future potential of FDDS in controlled oral drug delivery research and industrial pharmaceutical applications.

6. POLYMERS USED IN FLOATING DRUG DELIVERY SYSTEMS (FDDS)

Polymers are considered the backbone of Floating Drug Delivery Systems (FDDS) because they significantly influence buoyancy, swelling behaviour, matrix integrity, drug release kinetics, mechanical strength, and gastric retention capability of the dosage form. The selection of suitable polymers is one of the most critical steps in the formulation and development of gastro retentive systems. An ideal polymer used in FDDS should possess good swelling ability, high gel-forming capacity, excellent biocompatibility, non-toxicity, stability in gastric conditions, and compatibility with the drug molecule. [26]

Hydrophilic polymers are most commonly employed in FDDS formulations due to their ability to hydrate rapidly upon contact with gastric fluid and form a viscous gel barrier around the dosage form. This gel layer controls drug diffusion and helps entrap generated carbon dioxide gas within the matrix, thereby maintaining buoyancy for prolonged periods. Among all hydrophilic polymers, Hydroxypropyl Methylcellulose (HPMC) is the most extensively utilized polymer in floating systems because of its excellent swelling properties, pH-independent hydration behaviour, and ability to sustain drug release effectively.[27]

Different viscosity grades of HPMC such as HPMC K4M, HPMC K15M, and HPMC K100M are widely employed depending upon the desired drug release profile and floating behaviour. Lower viscosity grades generally produce faster hydration and shorter floating lag time, whereas higher viscosity grades provide prolonged matrix integrity and extended drug release. Combination of different viscosity grades is often used to optimize both buoyancy and sustained release characteristics. [28]

Natural polymers have also gained substantial importance in FDDS development due to their biodegradability, low toxicity, cost effectiveness, and eco-friendly nature. Polymers such as sodium alginate, guar gum, xanthan gum, pectin, chitosan, gallon gum, locust bean gum, and psyllium husk are increasingly being utilized in gastro retentive formulations. Sodium alginate is particularly useful in raft-forming systems and floating beads because of its excellent gel-forming capability in the presence of calcium ions. Xanthan gum and guar gum provide strong swelling behaviour and help maintain prolonged floating duration. [29]

Synthetic polymers such as Carbopol, Polyethylene Oxide (PEO), Eudragit, and Polyvinyl Alcohol (PVA) are also frequently employed in FDDS formulations. Carbopol exhibits excellent bio adhesive and swelling properties, making it suitable for both floating and mucoadhesive systems. Polyethylene oxide is highly hydrophilic and capable of producing strong gel matrices with prolonged drug release behaviour. Eudragit polymers are mainly used for controlled release and pH-dependent drug delivery applications. [30]

The concentration and combination of polymers significantly affect formulation performance. Increased polymer concentration generally enhances swelling index, matrix integrity, floating duration, and drug release retardation. However, excessively high polymer concentration may prolong floating lag time and hinder complete drug release. Therefore, optimization of polymer type, viscosity grade, and concentration is essential for developing an efficient FDDS formulation. [26]

In recent years, advanced polymer technologies involving biodegradable polymers, smart hydrogels, stimuli-responsive polymers, and Nano composite materials have further expanded the potential applications of FDDS. These modern polymeric systems provide improved control over drug release, enhanced gastric retention, better mechanical strength, and increased formulation stability. Furthermore, natural polymer-based formulations are gaining significant attention in pharmaceutical research due to their sustainability and patient safety advantages. [26–30]

Thus, proper polymer selection remains a fundamental aspect in the successful formulation and development of FDDS. Continuous advancements in polymer science are expected to play a major role in the future evolution of gastro retentive drug delivery technologies.

7. EVALUATION PARAMETERS OF FLOATING DRUG DELIVERY SYSTEMS (FDDS)

Evaluation of Floating Drug Delivery Systems (FDDS) is an essential step in formulation development to ensure the quality, stability, buoyancy, drug release behaviour, and overall performance of the dosage form. Proper evaluation helps in determining whether the developed formulation meets the desired pharmaceutical and therapeutic objectives. Various pre-compression, post-compression, buoyancy-related, swelling-related, and in vitro drug release parameters are assessed during the evaluation of FDDS formulations. [31]

Pre-compression parameters are mainly evaluated in powder blends before tablet compression to determine their flow properties and compressibility characteristics. These include angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio. Good flow ability and compressibility are essential for achieving uniform die filling and consistent tablet weight during manufacturing. Generally, angle of repose below 30°, Carr's index below 15%, and Hausner's ratio below 1.25 indicate satisfactory flow properties for tablet formulation. [32]

Post-compression evaluation parameters are performed after preparation of floating tablets or capsules. These include thickness, hardness, friability, weight variation, and drug content uniformity. Tablet hardness plays a major role in maintaining matrix integrity and preventing premature disintegration during gastric retention. Friability should generally remain below 1% to ensure adequate mechanical strength of the formulation. Drug content uniformity is evaluated to confirm uniform distribution of the active pharmaceutical ingredient throughout the dosage form. [33]

Floating behaviour is one of the most critical evaluation criteria for FDDS formulations. Floating Lag Time (FLT) represents the time required for the dosage form to rise to the surface of gastric fluid after administration, whereas Total Floating Time (TFT) indicates the duration for which the dosage form remains buoyant. An ideal FDDS formulation should exhibit minimum floating lag time and prolonged floating duration exceeding 12 hours. These parameters are usually evaluated using simulated gastric fluid maintained at 37 ± 0.5°C.[34]

Swelling studies are performed to evaluate the hydration and expansion behaviour of hydrophilic polymers used in FDDS formulations. The swelling index is calculated by measuring the increase in weight of the dosage form after immersion in gastric fluid for specific time intervals. Swelling behaviour directly affects buoyancy, drug diffusion, matrix integrity, and gastric retention capability. Proper swelling ensures efficient entrapment of generated gas within the polymer matrix and sustained drug release over prolonged periods.[35]

In vitro dissolution studies are carried out to determine the drug release profile from FDDS formulations. Dissolution testing is generally performed using USP dissolution apparatus type I or II in simulated gastric fluid (0.1 N HCl) maintained at 37°C. Drug release data obtained from dissolution studies are further analysed using various kinetic models such as zero-order kinetics, first-order kinetics, Higuchi model, Korsmeyer-Peppas model, and Hixson-Crowell model to understand the mechanism of drug release.[31]

Additional evaluation parameters include matrix integrity, surface morphology, stability studies, buoyancy strength, and in vivo gastric retention studies. Surface morphology is commonly examined using Scanning Electron Microscopy (SEM) to analyse pore structure and polymer distribution within the dosage form. Stability studies are conducted according to ICH guidelines to evaluate the effect of temperature and humidity on formulation performance. In vivo imaging techniques such as X-ray radiography, gamma scintigraphy, ultrasonography, and magnetic resonance imaging are also used to study gastric retention behaviour in humans and experimental animals. [31–35]

Comprehensive evaluation of FDDS formulations is therefore essential for ensuring consistent product quality, therapeutic efficacy, prolonged gastric retention, and controlled drug release. Proper optimization of these evaluation parameters significantly contributes to the successful development of stable and efficient gastro retentive drug delivery systems.

8. ADVANTAGES AND LIMITATIONS OF FLOATING DRUG DELIVERY SYSTEMS (FDDS)

Floating Drug Delivery Systems (FDDS) have gained considerable importance in modern pharmaceutics due to their ability to prolong gastric residence time and improve oral drug delivery efficiency. These systems offer several therapeutic, pharmacokinetic, and formulation-related advantages over conventional oral dosage forms. However, despite their numerous benefits, FDDS also possess certain physiological and formulation-related limitations that must be carefully considered during product development. [36]

One of the major advantages of FDDS is the enhancement of gastric residence time, which leads to improved bioavailability of drugs absorbed mainly from the upper part of the gastrointestinal tract. Drugs possessing narrow absorption windows such as levodopa, riboflavin, metformin, and furosemide show significantly improved absorption when retained in the stomach for prolonged durations. Extended gastric retention allows continuous drug release near the absorption site, thereby maximizing therapeutic efficacy and minimizing drug wastage. [37]

FDDS are highly beneficial for sustained and controlled drug delivery applications. By maintaining prolonged contact with gastric fluid, these systems provide controlled release of the drug over extended periods, resulting in reduced dosing frequency and improved patient compliance. Sustained drug release also minimizes fluctuations in plasma drug concentration, thereby reducing the risk of adverse effects associated with peak drug levels and sub therapeutic responses associated with rapid drug elimination. [38]

Another important advantage of FDDS is their utility in local drug delivery within the stomach. Gastro retentive systems can effectively deliver drugs intended for local action against gastric disorders such as peptic ulcers, gastritis, and *Helicobacter pylori* infections. By retaining the dosage form in the stomach, FDDS increase local drug concentration and therapeutic effectiveness while reducing systemic exposure. Moreover, FDDS improve dissolution and absorption of weakly basic drugs that exhibit better solubility in acidic gastric conditions. [39]

FDDS also provide formulation flexibility through various dosage forms including floating tablets, capsules, microspheres, beads, granules, powders, films, and raft-forming systems. Recent advancements involving multiparticulate systems, biodegradable polymers, nanotechnology, and smart hydrogels have further enhanced the safety, stability, and effectiveness of gastro retentive formulations. These advancements have expanded the commercial and clinical applications of FDDS in chronic disease management and targeted oral drug delivery. [40]

Despite these advantages, FDDS possess several limitations that restrict their universal applicability. These systems are generally unsuitable for drugs that are unstable in acidic gastric pH, drugs causing gastric irritation, and drugs exhibiting extensive first-pass metabolism. Drugs with poor solubility in acidic conditions may also demonstrate inadequate release from floating formulations. Additionally, successful performance of FDDS depends heavily upon the presence of sufficient gastric fluid for buoyancy generation and polymer hydration. [36]

Physiological variability among patients further affects FDDS performance. Factors such as gastric motility, fed or fasting state, age, posture, emotional stress, disease conditions, and concomitant medications can significantly alter gastric emptying behaviour and dosage form retention. Variability in gastric pH and stomach contents may also influence floating lag time, buoyancy duration, and drug release kinetics. These physiological challenges often lead to unpredictable in vivo performance of gastro retentive formulations. [37]

Certain formulation-related limitations are also associated with FDDS development. Achieving optimum balance between buoyancy, matrix integrity, swelling behaviour, and controlled drug release is technically challenging. Excessive swelling may cause formulation instability, whereas insufficient swelling can result in premature gastric emptying. Moreover, large-scale manufacturing, reproducibility, and stability of FDDS formulations require careful optimization of polymers, excipients, and processing conditions. [36–40]

Therefore, although FDDS offer substantial therapeutic and commercial advantages, careful drug selection, formulation optimization, and evaluation are essential to overcome their limitations and achieve successful gastro retentive drug delivery performance.

9. RECENT ADVANCEMENTS IN FLOATING DRUG DELIVERY SYSTEMS (FDDS)

Recent advancements in pharmaceutical technology, material science, and nanotechnology have significantly transformed the development of Floating Drug Delivery Systems (FDDS). Conventional gastro retentive formulations primarily focused on achieving prolonged gastric residence through simple floating mechanisms; however, modern FDDS are now designed to provide improved drug release control, enhanced stability, targeted delivery, better patient compliance, and optimized therapeutic outcomes. Continuous innovation in formulation strategies has expanded the scope of FDDS in advanced oral controlled drug delivery research. [41]

One of the major advancements in FDDS is the development of multiparticulate floating systems such as floating microspheres, micro balloons, pellets, beads, and nanoparticles. Unlike single-unit dosage forms, multiparticulate systems distribute uniformly throughout the stomach, thereby reducing the risk of dose dumping and local irritation. Floating microspheres prepared using solvent evaporation and inotropic gelation techniques exhibit excellent buoyancy, prolonged gastric retention, and controlled drug release

characteristics. These systems are particularly advantageous for drugs requiring site-specific absorption and sustained plasma drug concentrations. [42]

The incorporation of biodegradable and natural polymers has emerged as another important advancement in gastro retentive drug delivery research. Natural polymers such as sodium alginate, xanthan gum, guar gum, chitosan, pectin, and gellan gum are increasingly preferred because of their biodegradability, low toxicity, biocompatibility, and environmental safety. Researchers are actively exploring herbal and naturally derived excipients to develop safer and more economical FDDS formulations with enhanced swelling and mucoadhesive properties. [43]

Nanotechnology-based FDDS have gained significant research interest due to their ability to improve drug solubility, permeability, and bioavailability. Floating nanoparticles, Nano sponges, liposomes, and Nano emulsions provide enhanced surface area and controlled release behaviour while maintaining prolonged gastric retention. Nano carrier-based FDDS are especially useful for poorly water-soluble drugs and drugs exhibiting limited intestinal permeability. Furthermore, Nano-enabled systems allow targeted drug delivery with reduced systemic side effects. [44]

Advancements in smart polymers and stimuli-responsive hydrogels have also revolutionized FDDS development. These intelligent polymeric systems respond to environmental stimuli such as pH, temperature, ionic strength, and enzymatic activity, resulting in controlled swelling and drug release behaviour. Super porous hydrogels capable of rapid water uptake and expansion have demonstrated remarkable gastro retentive properties and prolonged gastric retention time compared to conventional hydrophilic matrices. [45]

The introduction of 3D printing technology in pharmaceutical formulation has opened new opportunities for personalized gastro retentive drug delivery systems. Three-dimensional printing enables precise control over tablet geometry, density, internal structure, and drug distribution, thereby improving buoyancy and release kinetics. Customized FDDS formulations with patient-specific drug doses and release profiles can now be fabricated using advanced additive manufacturing techniques. [41]

Artificial intelligence (AI) and computational pharmaceutics are also becoming increasingly important in FDDS optimization. AI-assisted formulation design helps predict polymer behaviour, swelling kinetics, drug release patterns, and stability characteristics using machine learning algorithms and statistical modelling techniques. Computational simulations significantly reduce formulation development time, minimize experimental trials, and improve formulation reproducibility.[42]

Recent research has additionally focused on combining multiple gastro retentive mechanisms within a single dosage form. Systems exhibiting simultaneous floating, swelling, and mucoadhesive properties demonstrate superior gastric retention and improved therapeutic performance compared to conventional single-mechanism systems. These multifunctional gastro retentive systems represent a promising direction in advanced oral controlled drug delivery research. [41–45]

Thus, recent advancements in FDDS technology have substantially improved the efficiency, safety, versatility, and clinical applicability of gastro retentive formulations. Continuous innovation involving smart materials, nanotechnology, artificial intelligence, and personalized medicine is expected to further revolutionize the future development of FDDS and GRDDS.

10. FUTURE PROSPECTS AND EMERGING TRENDS IN FDDS/GRDDS

Floating Drug Delivery Systems (FDDS) and Gastro retentive Drug Delivery Systems (GRDDS) continue to attract substantial attention in pharmaceutical research due to their ability to improve oral bioavailability, enhance therapeutic efficacy, and provide controlled drug release. Although significant progress has already been achieved in gastro retentive technology, ongoing advancements in material science, biotechnology, computational pharmaceutics, and personalized medicine are expected to further revolutionize the future development of FDDS. Emerging trends are now focused on developing highly efficient, patient-specific, intelligent, and multifunctional gastro retentive systems capable of overcoming the limitations associated with conventional formulations.[46]

One of the most promising future directions in FDDS research involves the use of biodegradable and naturally derived polymers. Growing concerns regarding environmental safety, derived polymers and herbal excipients for developing safer and more sustainable gastro retentive systems polymer toxicity, and patient compatibility have increased the demand for eco-friendly pharmaceutical excipients. Natural polymers such as chitosan, sodium alginate, xanthan gum, guar gum, pectin, and gellan gum are expected to play a major role in future FDDS formulations because of their biocompatibility, low toxicity, biodegradability, and cost effectiveness. Researchers are also exploring plant-. [47]

Nanotechnology-based gastro retentive systems are likely to dominate future pharmaceutical research due to their ability to enhance drug solubility, permeability, absorption, and targeting efficiency. Floating nanoparticles, nanofibers, Nano sponges, lipid-based carriers, and polymeric Nano carriers offer improved gastric retention and controlled drug release profiles. These advanced Nano systems are especially beneficial for poorly water-soluble drugs, peptides, proteins, and anticancer agents. Furthermore, targeted Nano-enabled FDDS can potentially reduce systemic toxicity and improve site-specific drug delivery. [48]

Artificial intelligence (AI), machine learning, and computational pharmaceutics are rapidly emerging as transformative tools in formulation development and optimization. AI-assisted drug delivery research enables prediction of polymer interactions, drug release kinetics, swelling behaviour, floating characteristics, and stability profiles with reduced experimental workload. Advanced mathematical modelling and simulation techniques can significantly accelerate formulation screening, improve reproducibility, and reduce overall development cost. Future pharmaceutical industries are expected to increasingly integrate AI-driven optimization into FDDS product development. [49]

Three-dimensional (3D) printing technology represents another revolutionary advancement in the future of gastro retentive drug delivery systems. 3D printing enables fabrication of personalized dosage forms with customized geometry, density, drug loading, and release patterns. This technology provides precise control over floating behaviour and internal tablet architecture, thereby improving gastric retention and therapeutic performance. Personalized FDDS formulations designed according to patient-specific needs may become an important component of future precision medicine approaches. [50]

Future research is also expected to focus on multifunctional gastro retentive systems combining multiple retention mechanisms such as floating, swelling, bio adhesion, and expandable properties within a single dosage form. These hybrid systems may provide superior gastric retention and more predictable drug release compared to conventional single-mechanism formulations. Additionally, development of smart stimuli-responsive systems capable of responding to pH, temperature, enzymatic activity, and physiological conditions may significantly improve controlled drug delivery efficiency. [46]

The application of FDDS is also expanding beyond conventional synthetic drugs toward biological therapeutics, peptides, vaccines, probiotics, and chemotherapeutic formulations. Gastro retentive systems capable of protecting sensitive biomolecules from intestinal degradation while improving gastric absorption may offer new opportunities in oral biologic drug delivery. Moreover, future FDDS research is likely to emphasize patient-centric formulations with improved palatability, reduced dosing frequency, enhanced compliance, and better therapeutic outcomes. [47–50]

Despite remarkable progress, several challenges remain in the clinical translation and commercialization of advanced FDDS formulations. Variability in gastric physiology, scale-up difficulties, regulatory requirements, and reproducibility issues continue to present formulation challenges. Nevertheless, continuous innovation in pharmaceutical sciences, material engineering, and computational technologies strongly suggests that FDDS and GRDDS will remain among the most promising and rapidly evolving fields in advanced oral drug delivery research.

11. MARKETED PREPARATIONS OF FDDS/GRDDS IN INDIA AND GLOBAL MARKET

The successful commercialization of Floating Drug Delivery Systems (FDDS) and Gastro retentive Drug Delivery Systems (GRDDS) demonstrates their significant therapeutic and industrial importance in modern pharmaceutics. Several pharmaceutical companies across India and globally have developed gastro retentive formulations for improving bioavailability, prolonging gastric residence time, reducing dosing frequency, and enhancing patient compliance. Most commercially available gastro retentive products are based on floating, raft-forming, colloidal gel-forming, and hydro dynamically balanced system (HBS) technologies. [41–45]

Globally marketed FDDS formulations mainly include floating capsules, floating tablets, controlled release capsules, and raft-forming liquid preparations. One of the earliest and most successful gastro retentive products was Madopar HBS (Prolopa HBS), developed by Roche Products, which utilizes hydro dynamically balanced system technology for controlled release of levodopa and benserazide in Parkinson’s disease management. Similarly, Valrelease floating capsules containing diazepam were introduced to prolong gastric residence and sustain drug release. [41]

Raft-forming gastro retentive systems such as Liquid Gaviscon became highly successful worldwide for the treatment of gastroesophageal reflux disease (GERD) and gastric acidity. These formulations form a floating viscous gel barrier over gastric contents, thereby preventing acid reflux into the oesophagus. The success of these preparations established raft-forming systems as one of the most clinically accepted gastro retentive technologies. [42]

In India, pharmaceutical companies such as Ranbaxy, Cipla, Sun Pharma, and other manufacturers have developed various floating and controlled release gastro retentive formulations. Cifran OD containing ciprofloxacin and Conviron containing ferrous sulphate are among the well-known Indian marketed gastro retentive preparations. These formulations were specifically designed to prolong gastric retention and improve drug absorption in the upper gastrointestinal tract. [43]

Recent industrial interest in FDDS has increased considerably due to the growing demand for sustained release formulations and targeted oral drug delivery systems. Modern pharmaceutical research is now focusing on advanced multiparticulate floating systems, gastro retentive microspheres, expandable

systems, and bio adhesive formulations to improve therapeutic performance and commercial applicability. Although only a limited number of gastro retentive products are currently available commercially, ongoing advancements in polymer science, nanotechnology, and controlled release technologies are expected to significantly increase the number of marketed FDDS formulations in the near future. [44]

The commercialization of FDDS remains challenging because successful gastro retentive performance depends upon various physiological factors including gastric motility, gastric pH, fed state, and patient variability. Additionally, large-scale manufacturing, reproducibility, regulatory approval, and long-term stability remain important industrial considerations. Nevertheless, the increasing clinical success of marketed gastro retentive formulations strongly supports the future potential of FDDS and GRDDS in advanced oral drug delivery systems. [45]

Sr. No.	Brand Name	Drug	Delivery System	Company	Country
1	Valrelease	Diazepam	Floating Capsule	Hoffmann-La Roche	USA
Sr. No.	**Brand Name**	**Drug**	**Delivery System**	**Company**	**Country**
2	Madopar HBS / Prolopa HBS	Levodopa + Benserazide	Hydrodynamically Balanced Capsule	Roche Products	USA
3	Liquid Gaviscon	Aluminium Hydroxide + Magnesium Carbonate	Raft Forming Floating Liquid	GlaxoSmithKline	India/Global
4	Topalkan	Aluminium-Magnesium Antacid	Floating Liquid Alginate System	Pierre Fabre Drug	France
5	Almagate Flot-Coat	Al-Mg Antacid	Floating Dosage Form	Pierre Fabre Drug	France
6	Conviron	Ferrous Sulphate	Colloidal Gel Forming FDDS	Ranbaxy	India
7	Cytotech	Misoprostol	Bilayer Floating Capsule	Pharmacia	USA
8	Cifran OD	Ciprofloxacin	Gas Generating Floating Tablet	Ranbaxy	India
9	Glumetza	Metformin HCl	Gastroretentive Extended Release Tablet	Depomed	USA
10	Gabitril	Tiagabine	Controlled Gastroretentive Tablet	Abbott Laboratories	USA

11	Acuform Technology Tablets	Various APIs	Polymer-Based GRDDS	Depomed Inc.	USA
12	Oflin OD	Ofloxacin	Floating Sustained Release Tablet	Indian Pharma Market	India

12. CHALLENGES IN DEVELOPMENT AND COMMERCIALIZATION OF FDDS/GRDDS

Despite the remarkable therapeutic advantages and growing research interest in Floating Drug Delivery Systems (FDDS) and Gastro retentive Drug Delivery Systems (GRDDS), several scientific, physiological, technological, and industrial challenges remain associated with their successful development and commercialization. These challenges significantly influence formulation stability, gastric retention behaviour, reproducibility, large-scale manufacturing, regulatory approval, and clinical performance of gastro retentive dosage forms. [46]

One of the major challenges in FDDS development is the variability of gastric physiology among individuals. Gastric emptying rate differs depending upon age, gender, posture, emotional state, disease conditions, and feeding pattern. The gastric residence time of dosage forms may vary considerably between fasting and fed conditions. During fasting conditions, the Migrating Myoelectric Complex (MMC) can rapidly expel the dosage form from the stomach, leading to unpredictable gastro retentive behaviour and inconsistent therapeutic outcomes. [47]

Another important challenge involves maintaining optimum buoyancy and matrix integrity throughout the desired period of gastric retention. The dosage form must possess sufficient mechanical strength to withstand gastric contractions while simultaneously maintaining low density for flotation. Improper balance between swelling, buoyancy, and matrix erosion may result in premature disintegration, dose dumping, or failure of gastric retention. Additionally, prolonged exposure to acidic gastric conditions may alter polymer behaviour and drug release kinetics. [48]

Drug selection also plays a critical role in the success of FDDS formulations. Gastro retentive systems are unsuitable for drugs that are unstable in acidic pH, irritate gastric mucosa, or exhibit extensive first-pass metabolism. Drugs having poor solubility in gastric fluid may demonstrate incomplete release from floating systems. Furthermore, highly water-soluble drugs may undergo rapid diffusion from hydrophilic matrices, making sustained release difficult to achieve. [49]Scale-up and industrial manufacturing represent additional challenges in commercialization of FDDS. Achieving reproducible floating behaviour, uniform drug distribution, consistent swelling characteristics, and controlled release kinetics on large-scale production requires precise optimization of processing parameters. Variations in compression force, granulation technique, polymer concentration, and environmental conditions can significantly influence formulation performance. Stability issues related to moisture sensitivity and polymer aging also complicate long-term storage and packaging. [50]

Regulatory and clinical evaluation challenges further limit the widespread commercialization of FDDS formulations. Demonstrating prolonged gastric retention and in vivo performance requires sophisticated imaging techniques such as gamma scintigraphy, X-ray radiography, magnetic resonance imaging, and ultrasonography. These studies are expensive, time-consuming, and technically demanding. Additionally,

lack of standardized regulatory guidelines for evaluation of gastro retentive systems presents difficulties during product approval and commercialization. [46]

Patient-related factors also influence the success of FDDS therapy. Insufficient gastric fluid volume, irregular food intake, gastrointestinal disorders, and co-administration of motility-modifying drugs may adversely affect floating behaviour and drug release performance. In certain cases, large swell able systems may cause discomfort or gastric obstruction risk if not properly designed. Therefore, patient safety and formulation tolerability remain important considerations during product development.[47–50]

Although these challenges continue to affect the development of gastro retentive systems, continuous advancements in polymer science, nanotechnology, smart materials, and computational pharmaceutics are gradually overcoming many of these limitations. Future innovations focusing on multifunctional systems, biodegradable polymers, AI-assisted optimization, and personalized medicine approaches are expected to improve the reliability, scalability, and commercial success of FDDS and GRDDS technologies.

13. CONCLUSION

Floating Drug Delivery Systems (FDDS) and Gastro retentive Drug Delivery Systems (GRDDS) have emerged as highly promising approaches in advanced oral controlled drug delivery technology due to their ability to prolong gastric residence time, improve bioavailability, and enhance therapeutic efficacy of orally administered drugs. Conventional oral dosage forms often suffer from rapid gastric emptying, incomplete drug absorption, fluctuating plasma drug concentration, and reduced therapeutic effectiveness, particularly in drugs possessing narrow absorption windows in the upper gastrointestinal tract. FDDS and GRDDS effectively overcome these limitations by maintaining the dosage form within the stomach for prolonged durations and providing controlled drug release behaviour.[51]

Various gastro retentive approaches including floating systems, bio adhesive systems, swelling systems, expandable systems, raft-forming systems, and high-density systems have demonstrated significant potential in improving oral drug delivery performance. Among these approaches, floating drug delivery systems remain the most extensively investigated and commercially successful due to their simple design, effective buoyancy mechanism, and patient acceptability. The incorporation of hydrophilic polymers, gas-generating agents, biodegradable materials, and advanced matrix technologies has substantially improved the performance and stability of FDDS formulations.[52]

The present review highlights the importance of gastric physiology, polymer selection, formulation strategies, evaluation parameters, recent technological advancements, and marketed preparations associated with FDDS and GRDDS. Recent innovations involving multiparticulate systems, nanotechnology, biodegradable natural polymers, artificial intelligence-assisted optimization, and 3D printing technologies have further expanded the pharmaceutical applications of gastro retentive systems. These advancements are expected to improve formulation precision, patient compliance, therapeutic efficacy, and commercial feasibility in future oral drug delivery research.[53]

Despite numerous advantages, FDDS still face several formulation and physiological challenges including variability in gastric emptying behaviour, instability of certain drugs in acidic pH, reproducibility issues, and scale-up difficulties during industrial manufacturing. Therefore, careful drug selection, optimization of polymer combinations, and advanced evaluation techniques remain essential for successful gastro retentive formulation development.[54]

Future research in FDDS and GRDDS is likely to focus on multifunctional gastro retentive systems combining floating, swelling, mucoadhesion, and stimuli-responsive mechanisms within a single dosage form. The integration of smart polymers, computational pharmaceutics, personalized medicine, and Nano carrier technologies may revolutionize gastro retentive drug delivery in the coming years. With continuous scientific advancements and growing industrial interest, FDDS and GRDDS are expected to remain among the most important and rapidly evolving fields in novel oral drug delivery systems. [55]

14. FUTURE RESEARCH RECOMMENDATIONS

Although significant progress has been achieved in the formulation and development of Floating Drug Delivery Systems (FDDS) and Gastro retentive Drug Delivery Systems (GRDDS), continuous research is still required to overcome the limitations associated with conventional gastro retentive technologies. Future research should primarily focus on improving gastric retention predictability, formulation reproducibility, patient compliance, and large-scale industrial applicability. The integration of modern pharmaceutical technologies with gastro retentive systems may lead to the development of highly efficient and patient-specific oral controlled release formulations.[56]

One important area requiring further investigation is the development of multifunctional gastro retentive systems capable of combining multiple retention mechanisms such as floating, swelling, mucoadhesion, and expandable properties within a single dosage form. Such hybrid systems may provide more reliable gastric retention and superior therapeutic performance compared to single-mechanism formulations. Additionally, research should focus on improving the mechanical strength and stability of swell able and floating matrices under varying physiological conditions.[57]

Natural and biodegradable polymers are expected to play a major role in future FDDS development due to increasing demand for eco-friendly and biocompatible pharmaceutical excipients. Further exploration of plant-derived polymers, marine polysaccharides, and herbal excipients may result in safer, economical, and sustainable gastro retentive formulations. Advanced polymer modification techniques may also improve swelling behaviour, bio adhesion, and controlled drug release characteristics of natural polymers.[58]

Nanotechnology-based gastro retentive systems represent another promising research direction. Future studies should focus on development of floating nanoparticles, nanofibers, lipid carriers, and Nano emulsion-based FDDS for enhancing solubility and bioavailability of poorly water-soluble drugs. Targeted Nano carrier systems may also improve site-specific drug delivery while reducing systemic toxicity and adverse effects.[59]

Artificial intelligence, machine learning, and computational pharmaceutics are expected to significantly transform future formulation development strategies. AI-assisted optimization can reduce formulation development time, minimize experimental workload, and improve prediction of drug release kinetics, polymer interactions, and formulation stability. Integration of computational modelling with Quality by Design (QbD) approaches may improve formulation reproducibility and industrial scalability.[60]

Further clinical studies and in vivo investigations are also necessary to establish the long-term safety, efficacy, and therapeutic superiority of advanced FDDS formulations. Standardization of evaluation methods and regulatory guidelines for gastro retentive systems may accelerate industrial acceptance and commercialization of these technologies. Therefore, continuous interdisciplinary research involving

pharmaceutics, polymer science, nanotechnology, biotechnology, and computational sciences will be essential for the future advancement of FDDS and GRDDS.

15. PHARMACEUTICAL AND THERAPEUTIC APPLICATIONS OF FDDS/GRDDS

Floating Drug Delivery Systems (FDDS) and Gastro retentive Drug Delivery Systems (GRDDS) have demonstrated wide pharmaceutical and therapeutic applications in modern oral controlled drug delivery research. These systems are particularly useful for drugs requiring prolonged gastric residence time, site-specific absorption, sustained plasma concentration, and localized drug action within the stomach. Due to their ability to enhance bioavailability and reduce dosing frequency, FDDS have gained considerable importance in the treatment of chronic diseases and gastrointestinal disorders.[61]

One of the major applications of FDDS is the enhancement of bioavailability of drugs possessing narrow absorption windows in the upper gastrointestinal tract. Drugs such as riboflavin, levodopa, metformin, ciprofloxacin, and furosemide are primarily absorbed from the stomach or proximal small intestine. Conventional dosage forms often pass rapidly through the absorption region, resulting in incomplete drug absorption and improve reduced therapeutic efficacy. FDDS prolong gastric retention time the extent of drug absorption by continuously releasing the drug near its optimal absorption site. [62]

FDDS are also highly beneficial for drugs intended for local action in the stomach. Gastro retentive systems can maintain high local drug concentration for prolonged periods, thereby improving therapeutic effectiveness in gastric disorders such as peptic ulcers, gastritis, and *Helicobacter pylori* infections. Antibiotics like amoxicillin and clarithromycin exhibit improved anti-*H. Pylori* activity when delivered through gastro retentive formulations due to increased contact time with gastric mucosa. [63]

Another important application of FDDS is in sustained and controlled drug delivery. Gastro retentive formulations provide prolonged drug release over extended durations, reducing dosing frequency and improving patient compliance. Sustained release FDDS are especially useful in chronic disease management including diabetes mellitus, hypertension, Parkinson's disease, and psychiatric disorders where maintenance of consistent plasma drug concentration is essential for effective therapy.[64]

FDDS are additionally useful for improving the solubility and dissolution of weakly basic drugs that exhibit better solubility in acidic gastric pH. Drugs with poor solubility in intestinal fluid often demonstrate enhanced dissolution and absorption when retained in the acidic environment of the stomach. This application is particularly important for Biopharmaceutical Classification System (BCS) Class II drugs exhibiting poor aqueous solubility.[65]

The application of FDDS has further expanded toward advanced drug delivery areas such as peptide delivery, protein delivery, nanoparticle-based systems, chemotherapeutic formulations, and targeted oral delivery. Modern gastro retentive systems are now being investigated for oral delivery of biological therapeutics and drugs requiring prolonged regional absorption. Furthermore, multifunctional FDDS combining floating, swelling, and mucoadhesive mechanisms are being explored to achieve superior therapeutic performance and patient-specific drug delivery. [61–65]

Thus, FDDS and GRDDS have emerged as versatile and highly promising drug delivery approaches capable of improving therapeutic efficacy, enhancing patient compliance, and overcoming major limitations associated with conventional oral dosage forms.

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Abbreviation	Full Form
FDDS	Floating Drug Delivery System
GRDDS	Gastroretentive Drug Delivery System
HPMC	Hydroxypropyl Methylcellulose
HBS	Hydrodynamically Balanced System
GERD	Gastroesophageal Reflux Disease
MMC	Migrating Myoelectric Complex
TFT	Total Floating Time
FLT	Floating Lag Time
SEM	Scanning Electron Microscopy
PEO	Polyethylene Oxide
GI	Gastrointestinal
AI	Artificial Intelligence
QbD	Quality by Design
BCS	Biopharmaceutical Classification System
API	Active Pharmaceutical Ingredient