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RAFT-FORMING DRUG DELIVERY SYSTEMS: A COMPREHENSIVE REVIEW

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ABSTRACT: Raft-forming drug delivery systems (RF-DDS) are a novel approach within gastro-retentive drug delivery systems (GRDDS), designed to enhance therapeutic efficacy and patient compliance. These systems form a gel-like raft that floats on gastric contents, offering prolonged retention, localized drug delivery, and reduced systemic side effects. RF-DDS have been particularly effective in managing gastroesophageal reflux disease (GERD), peptic ulcers, and Helicobacter pylori infections. The core mechanism involves effervescence and gelation, where polymers like sodium alginate interact with gastric fluids and cross-linking agents, forming a robust, floating gel matrix. Effervescent agents provide buoyancy, while cross-linkers stabilize the raft structure. Advantages of RF-DDS include localized drug action, sustained release, acid reflux prevention, and enhanced patient compliance. Applications extend to GERD management, ulcer healing, and targeted drug delivery for gastric conditions, with a growing emphasis on antibiotics, proton pump inhibitors, and anti-inflammatory agents. Despite their potential, challenges like formulation stability, interpatient variability, and complex manufacturing processes must be addressed. Future directions in RF-DDS development include smart polymers, nanotechnology integration, and personalized medicine. These advancements aim to improve drug delivery precision, expand therapeutic options, and optimize patient outcomes. This review highlights the principles, historical evolution, key components, advantages, challenges, and applications of RF-DDS, providing a foundation for ongoing innovation in gastro-retentive drug delivery.

INTRODUCTION: Drug delivery systems (DDS) have revolutionized modern medicine by enhancing the efficacy, safety, and patient adherence of therapeutic interventions. These systems aim to deliver active pharmaceutical ingredients (APIs) to their target sites with precision while minimizing systemic side effects. Among the various delivery routes, the gastrointestinal (GI) tract remains one of the most explored due to its non-invasive nature and extensive absorptive surface area. However, drug delivery via the GI tract is not without challenges.

Physiological factors such as rapid gastric emptying, varying pH levels, enzymatic activity, and motility significantly affect drug stability, solubility, and absorption. These challenges necessitate innovative solutions to ensure drugs remain in the stomach long enough to exert their intended therapeutic effects¹.

Raft-forming drug delivery systems (RF-DDS) represent one such innovation. These systems leverage a unique mechanism of forming a gel-like raft that floats on the gastric contents. This floating raft acts as a physical barrier, localizing the drug's action and extending its retention time in the stomach. As a result, RF-DDS offer site-specific drug delivery and prolonged therapeutic activity, particularly for conditions such as gastroesophageal reflux disease (GERD) and peptic ulcers. This review aims to provide an in-depth exploration of RF-DDS, encompassing their historical

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development, underlying principles, key components, and diverse applications. Additionally, it examines their advantages, challenges, and the future directions in this promising field. By understanding the advancements in RF-DDS, researchers and healthcare professionals can better appreciate their role in addressing unmet clinical needs and optimizing patient outcomes²⁻⁴.

Historical Background:

Gastro-Retentive Drug Delivery Systems (GRDDS): The gastrointestinal tract presents

significant challenges for conventional drug delivery systems, primarily due to its dynamic and variable environment. Factors such as gastric emptying time, pH gradients, and enzymatic degradation often limit the efficacy of orally administered drugs. To address these issues, gastro-retentive drug delivery systems (GRDDS) were developed to prolong the gastric residence time (GRT) of drug formulations. By enhancing GRT, GRDDS allow drugs to remain in the stomach longer, facilitating sustained release, localized action, and improved bioavailability⁴.

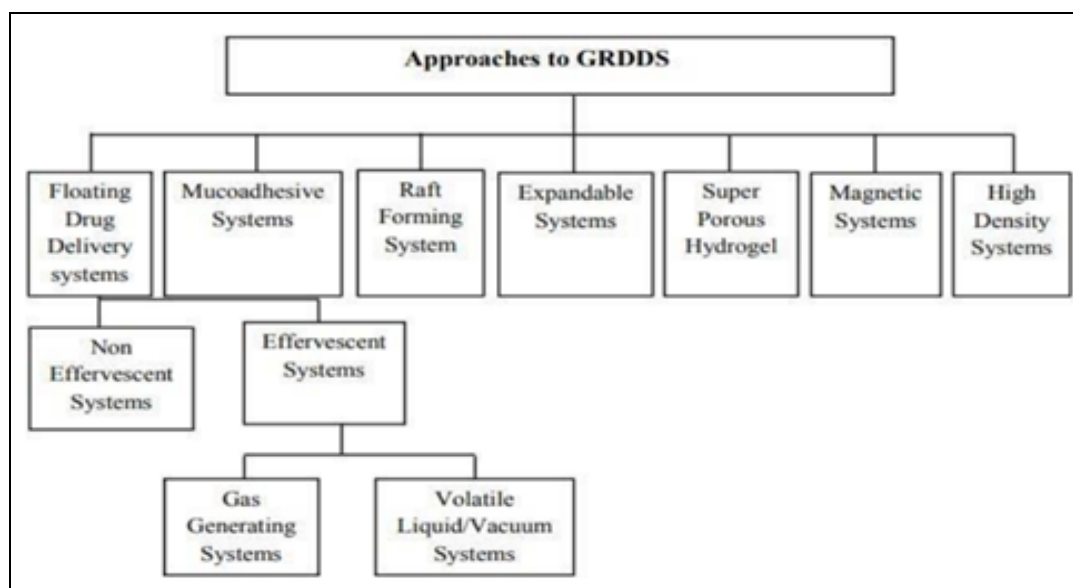


FIG. 1: APPROACH TO GRDDS⁶

Key approaches in GRDDS Include⁷:

High-Density Systems: Designed to sink and settle at the bottom of the stomach. These systems utilize materials with densities greater than gastric fluids ($\sim 1.0 \text{ g/cm}^3$). However, their efficacy depends on sufficient food intake to delay gastric emptying.

Low-Density Floating Systems: These systems are less dense than gastric fluid and float on its surface. The floating mechanism is typically achieved using gas-generating agents like bicarbonates, which react with gastric acid to produce carbon dioxide. Floating systems are particularly advantageous for drugs targeting the upper stomach or having narrow absorption windows.

Mucoadhesive Systems: These formulations adhere to the gastric mucosa, resisting gastric motility and ensuring prolonged retention.

Mucoadhesive polymers such as chitosan and carbomers enhance the adhesion process.

Swellable Systems: These systems expand upon contact with gastric fluids, increasing their size to prevent passage through the pylorus. Polymers such as hydroxypropyl methylcellulose (HPMC) and xanthan gum are commonly employed for swelling behavior.

Collectively, these GRDDS strategies have paved the way for more sophisticated and targeted delivery methods, addressing the limitations of conventional formulations.

Evolution of Raft-Forming Systems: Raft-forming drug delivery systems (RF-DDS) emerged in the late 20th century as a specific solution for conditions such as gastroesophageal reflux disease (GERD) and peptic ulcers. Unlike other GRDDS,

RF-DDS rely on a gel-like structure, or "raft," that forms upon contact with gastric fluid and floats on the stomach contents. This raft acts as a mechanical barrier to acid reflux, protects the gastric lining, and provides localized drug delivery⁸.

Early Development:

Initial RF-DDS formulations utilized basic components such as:

Sodium Alginate: A natural polymer extracted from brown algae, known for its gel-forming properties upon interaction with divalent cations like calcium.

Bicarbonates and Carbonates: These agents react with gastric acid to produce carbon dioxide, imparting buoyancy to the raft.

Calcium Salts: Act as cross-linking agents, strengthening the gel structure. The first commercially available raft-forming systems, such as alginate-based antacids, demonstrated effectiveness in managing GERD symptoms by creating a floating barrier that prevented acid reflux.⁹

Advancements in Polymer Science: Over the years, advancements in polymer chemistry and an improved understanding of gastrointestinal physiology have significantly enhanced the performance of RF-DDS. Innovations include:

- ❖ Development of synthetic polymers like carbopol and polyacrylates, offering greater control over gel strength and drug release profiles.
- ❖ Integration of mucoadhesive properties, enabling better interaction with gastric mucosa for prolonged retention.
- ❖ Enhanced formulation techniques, allowing for the encapsulation of diverse APIs, including antibiotics, anti-inflammatory agents, and antacids¹⁰⁻¹¹.

Clinical Significance¹²: Raft-forming systems are particularly effective in treating GERD, where they act as a physical barrier, preventing acid reflux into the esophagus.

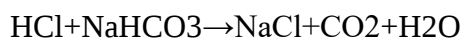
Their localized action reduces systemic side effects and improves patient compliance, especially in chronic conditions requiring long-term management.

Principles of Raft Formation¹³⁻¹⁶:

Mechanism of Action: Raft-forming systems operate on a sequence of chemical and physical processes that transform the formulation into a gel-like raft upon exposure to the gastric environment. This raft provides both therapeutic and protective benefits. The mechanism can be detailed as follows:

Contact with Gastric Fluid: When the formulation is administered orally, it comes into contact with gastric fluid, which typically has an acidic pH (ranging from 1.5 to 3.5 in fasting conditions). This initial interaction triggers a series of reactions that lead to raft formation.

Effervescence: Effervescent agents, such as sodium bicarbonate or calcium carbonate, react with the hydrochloric acid (HCl) present in the stomach. This reaction produces carbon dioxide gas:



The release of carbon dioxide imparts buoyancy to the forming gel, enabling it to float on the gastric contents.

Gel Formation: Polymers such as sodium alginate or pectin in the formulation hydrate and swell in the acidic environment. Cross-linking agents, typically divalent cations like calcium ions (Ca^{2+}), induce ionic interactions with the polymer chains. This results in the formation of a robust gel matrix.

Raft Formation: The gel matrix forms a cohesive layer that floats atop the stomach's contents due to its low density and gas entrapped within the structure.

This raft acts as a mechanical barrier, preventing the backflow of gastric acid into the esophagus (helpful in GERD management) and ensuring localized drug delivery over the gastric mucosa. The raft's integrity and retention time are critical for sustained therapeutic action.

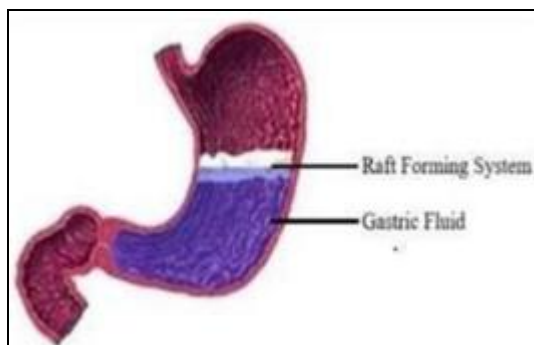


FIG. 2: SCHEMATIC ILLUSTRATION OF THE BARRIER FORMED BY RAFT FORMING SYSTEM ¹⁵

Key Components: Raft-forming systems are composed of specific ingredients, each playing a vital role in the formulation and function. Below is a detailed analysis of these components ¹⁷:

Polymers:

Role: Polymers are the backbone of raft-forming systems, responsible for gel formation and strength.

Natural Polymers:

Sodium Alginate: The most widely used polymer, derived from brown seaweed, forms a gel upon reaction with calcium ions.

Pectin: Found in fruits, forms gels in acidic conditions and provides additional bioadhesive properties.

Synthetic Polymers:

Carbopol: A cross-linked polyacrylic acid polymer known for its ability to form viscous gels.

HPMC (Hydroxypropyl Methylcellulose): Enhances swelling and gel consistency.

Effervescent Agents:

Role: These agents produce gas (CO₂) when reacting with gastric acid, creating buoyancy.

Common Agents:

- Sodium bicarbonate
- Calcium carbonate

Function: These agents ensure that the raft remains afloat for prolonged periods, optimizing therapeutic efficacy.

Cross-Linking Agents:

Role: Enhance the gel's mechanical strength by cross-linking polymer chains.

Common Agents: Calcium salts (e.g., calcium carbonate, calcium chloride).

Mechanism: The divalent cations (Ca²⁺) interact with the negatively charged groups (e.g., carboxyl groups in alginate) to form a stable, three-dimensional gel network.

API (Active Pharmaceutical Ingredient):

Role: The therapeutic component delivered by the system.

Selection Criteria: The API must be stable in acidic environments and compatible with the gel matrix. Common APIs include:

- Antacids (e.g., magnesium hydroxide).
- Proton pump inhibitors (e.g., omeprazole).
- Antibiotics (e.g., amoxicillin for H. pylori).
- Anti-inflammatory agents (e.g., ibuprofen).

Excipients:

Role: Provide stability, enhance patient compliance, and improve the sensory properties of the formulation.

Types of Excipients:

Stabilizers: Protect the formulation during storage (e.g., citric acid to regulate pH).

Flavoring Agents: Improve taste, especially for oral suspensions.

Preservatives: Extend shelf life by preventing microbial growth (e.g., sodium benzoate).

Functional Significance of the Components in Raft Formation ¹⁸:

Raft Stability: Achieved through a balance of polymer concentration and cross-linking efficiency. Stronger gels resist mechanical disruption in the stomach.

Buoyancy: Effervescent agents ensure that the raft remains afloat, enhancing retention time in the gastric environment.

Advantages:

TABLE 1: ADVANTAGES OF RFDDS ¹⁹⁻²³

Advantage	Key Benefit	Examples
Localized Drug Delivery	Targets the stomach or upper GI tract, minimizing systemic exposure and side effects.	GERD, peptic ulcers, H. pylori eradication.
Prolonged Retention	Enhances therapeutic efficacy through sustained drug release and improved absorption.	Drugs with narrow absorption windows like metformin or levodopa.
Protection Against Reflux	Acts as a barrier to prevent gastric acid backflow, alleviating GERD symptoms.	Alginate-based formulations for GERD.
Enhanced Patient Compliance	Easy-to-administer and less frequent dosing improves adherence.	Once- or twice-daily antacid suspensions or chewable tablets.
Versatility	Suitable for various APIs and adaptable to diverse patient needs and conditions.	Antibiotics for H. pylori, anti-inflammatory agents for gastritis, antacids for hyperacidity.

Applications:

TABLE 2: APPLICATION OF RFDDS ²⁴⁻²⁷

Application	Mechanism of Action	Benefits	Examples
GERD	Creates a floating barrier to prevent acid reflux.	Symptom relief, prevention of complications.	Alginate-based antacids (e.g., Gaviscon).
Peptic Ulcers	Forms a protective layer over ulcer sites, releasing drugs locally.	Accelerated healing, localized delivery, reduced side effects.	RF-DDS with PPIs or H2-receptor antagonists.
H. pylori Eradication	Enhances antibiotic delivery to the stomach with prolonged gastric retention.	Improved eradication rates, reduced systemic effects.	RF-DDS with antibiotics like amoxicillin + PPI.
Gastritis	Neutralizes acid and protects inflamed gastric mucosa.	Reduces inflammation, promotes healing.	RF-DDS with antacids or anti-inflammatory drugs.
Zollinger-Ellison Syndrome	Sustained acid neutralization to manage excessive gastric acid secretion.	Symptom relief, prolonged therapeutic action.	RF-DDS with PPIs or antacids.
Gastroparesis	Ensures consistent drug delivery during delayed gastric emptying.	Optimized absorption, reduced dosing frequency.	RF-DDS with prokinetic drugs or other therapies.

Challenges and Limitations: Despite their advantages, RF-DDS face challenges:

Formulation Stability: Ensuring stability during storage and transportation.

Interpatient Variability: Differences in gastric pH and motility affect performance.

Compatibility Issues: Interactions between API and excipients may impact efficacy.

Complex Manufacturing: Specialized techniques and equipment are required.

Formulation and Evaluation:

Drug Release: The gel matrix provides controlled and sustained release of the API, ensuring therapeutic levels are maintained.

Localized Action: The raft remains in the stomach, targeting specific gastric disorders like GERD, peptic ulcers, or *H. pylori* infections.

Ingredients ²⁵⁻²⁷: Raft-forming drug delivery systems rely on a combination of key ingredients to achieve their desired therapeutic effects. Alginates, as primary gel-forming polymers, play a crucial role in forming the raft structure. Carbonates or bicarbonates serve as gas-forming agents that react with gastric acid to produce carbon dioxide, ensuring buoyancy. Acids, such as citric acid, are included as pH controllers to regulate the formulation's reactivity and stability. Cross-linking agents, typically divalent cations like calcium salts, strengthen the gel matrix by forming bonds between polymer chains. The active pharmaceutical ingredient (API) is the therapeutic component,

delivered locally or systemically. Additionally, flavoring agents and preservatives may be added to improve patient acceptability and ensure stability during storage.

Formulation Procedure: The formulation process for raft-forming systems involves a series of steps designed to optimize the product's performance. First, the polymer solution is prepared by dissolving alginate in water to form the gel base. Gas-forming agents, such as carbonates or bicarbonates, and the API are then incorporated into the mixture.

The pH of the formulation is adjusted using acids to ensure the proper reactivity and stability of the system. Cross-linking agents, such as calcium salts, are introduced to enhance the gel's structural integrity. Optional ingredients, including flavoring agents and sweeteners, are added for improved palatability. Finally, the mixture is homogenized to ensure uniformity and then packaged appropriately²⁸⁻³¹.

Evaluation Parameters: The evaluation of raft-forming systems involves assessing multiple parameters to ensure their efficacy and stability. Raft strength is tested to determine the gel's mechanical ability to withstand the harsh conditions of the stomach. Floating capacity is evaluated to confirm the raft's ability to remain buoyant over gastric contents for an extended period. The gelation time, or the time taken for the raft to form upon contact with gastric fluid, is another critical parameter. Raft volume and thickness are measured to assess the system's effectiveness in protecting the stomach lining. The acid neutralization capacity (ANC) is analyzed to determine the formulation's ability to neutralize gastric acid, while the drug release profile is studied to ensure controlled and sustained delivery of the API. Raft integrity and stability are monitored to confirm that the structure remains intact during its functional duration. Lastly, *in vivo* performance is assessed through imaging techniques or pharmacokinetic studies to validate the formulation's behavior in a biological environment³²⁻³⁵. This comprehensive approach to formulation and evaluation ensures that raft-forming systems are effective, stable, and suitable for therapeutic use.

Future Perspectives³⁶⁻³⁸: The future of RF-DDS is promising, with advancements in:

Smart Polymers: Stimuli-responsive materials for enhanced functionality.

Nanotechnology Integration: Improved drug loading and targeting.

Personalized Medicine: Tailored systems for individual needs.

Regulatory Approvals: Streamlined processes for commercialization.

CONCLUSION: Raft-forming drug delivery systems represent a significant advancement in gastro-retentive drug delivery. Their ability to provide localized, sustained drug release while addressing the limitations of conventional formulations makes them a valuable tool in managing gastric disorders. Continued research and innovation in materials and design are expected to expand their applications and improve therapeutic outcomes.

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CONFLICT OF INTEREST: We declare that we have no conflict of interest.

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