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Design, Optimization and Evaluation of Floating Drug Delivery System of Granisetron Hydrochloride for Enhanced Gastric Retention

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Abstract
The present study aims to design, optimize, and evaluate a gastroretentive floating drug delivery system of granisetron hydrochloride to enhance gastric retention and therapeutic efficacy. Due to its short half-life and absorption in the upper gastrointestinal tract, granisetron is a suitable candidate for floating systems. Floating tablets were prepared using hydrophilic polymers (HPMC K4M and HPMC K100M) along with a gas-generating agent. Different formulations were developed by varying polymer concentrations and evaluated for pre- and post-compression parameters, in vitro buoyancy, and drug release behavior. The optimized formulation exhibited rapid floating, prolonged buoyancy, and sustained drug release. Drug release followed a diffusion-controlled mechanism, and stability studies confirmed formulation integrity.
Overall, the developed system demonstrated improved gastric retention and controlled drug release, indicating its potential to enhance bioavailability and therapeutic effectiveness

Keywords: Granisetron hydrochloride, Floating drug delivery system, Gastroretentive system, HPMC, Sustained release

I. Introduction

Oral drug delivery is the most widely accepted route of administration due to its convenience, patient compliance, and cost-effectiveness. However, certain drugs exhibit limited bioavailability because of their narrow absorption window in the upper gastrointestinal tract (GIT), rapid gastric emptying, or instability in the intestinal environment. These limitations can reduce therapeutic efficacy and require frequent dosing.

Gastroretentive drug delivery systems (GRDDS) have been developed to overcome such challenges by prolonging the residence time of dosage forms in the stomach. Among these, floating drug delivery systems (FDDS) are particularly effective, as they remain buoyant in gastric fluids due to their lower density than gastric contents. This buoyancy allows the system to stay in the stomach for an extended period, thereby improving drug absorption and enhancing bioavailability.

Granisetron hydrochloride is a selective 5-hydroxytryptamine (5-HT_3) receptor antagonist widely used in the prevention and treatment of chemotherapy-induced nausea and vomiting. It possesses a relatively short biological half-life and is primarily absorbed in the upper part of the GIT. These characteristics make it a suitable candidate for the development of a gastroretentive drug delivery system. Conventional dosage forms of granisetron may lead to fluctuating plasma drug concentrations and require multiple dosing, which can affect patient compliance.

The development of a floating drug delivery system for granisetron hydrochloride offers several advantages, including prolonged gastric retention, controlled drug release, reduced dosing frequency, and improved therapeutic effectiveness. Hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC) play a crucial role in forming a gel barrier that controls drug release, while gas-generating agents facilitate buoyancy by producing carbon dioxide in acidic conditions.

Therefore, the present study focuses on the design, optimization, and evaluation of a floating drug delivery system of granisetron hydrochloride using suitable polymers and excipients. The objective is to enhance gastric retention time and achieve sustained drug release, thereby improving bioavailability and overall therapeutic performance

Oral drug delivery is the most preferred route due to patient compliance and convenience. However, drugs with narrow absorption windows or instability in the intestinal environment show reduced bioavailability.

Floating Drug Delivery Systems (FDDS) are designed to remain buoyant in gastric fluid, thereby increasing gastric residence time and improving drug absorption .

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Granisetron hydrochloride is an antiemetic drug with:

- Short half-life (~4–9 hours)
- Site-specific absorption in the stomach and upper intestine
- Need for sustained release

Thus, development of FDDS for granisetron is beneficial to:

- Improve bioavailability
- Reduce dosing frequency
- Maintain constant plasma drug concentration

1.1 . Mechanism of Floating System

FDDS works based on buoyancy principle:

- Gas-generating agents release CO_2 in acidic pH
- CO_2 gets trapped in polymer matrix
- Density of tablet becomes lower than gastric fluid
- Tablet floats and releases drug slowly

These systems maintain buoyancy and sustained drug release for several hours.

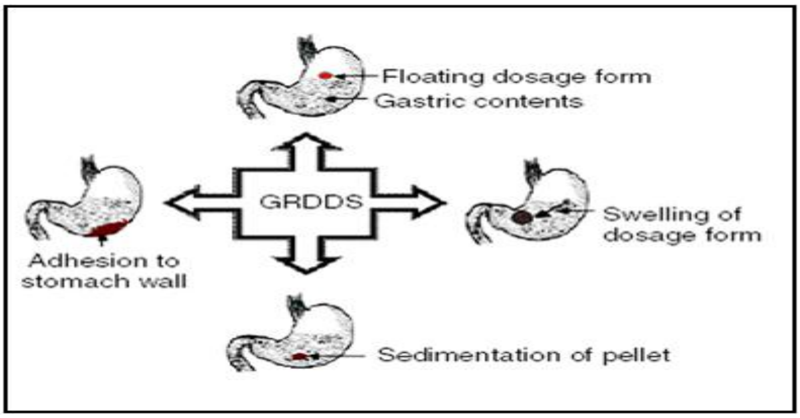

Fig. 1.4: Classification of gastroretentive drug delivery system.

1.2. Rationale for Selecting Granisetron

Granisetron is a suitable candidate for floating systems because:

- It is freely soluble in gastric pH
- Has short biological half-life
- Undergoes extensive first-pass metabolism
- Shows better absorption in upper GIT

FDDS helps maintain the drug in the stomach for a longer duration, enhancing therapeutic performance.

II. Objectives

- To design floating tablets of granisetron
- To enhance gastric retention time
- To achieve controlled and sustained drug release
- To evaluate formulation parameters and optimize the system

III. Materials and Methods

3.1 Materials

All materials used in the present investigation were of analytical grade and utilized without further purification. The selection of excipients was based on their functional roles in the formulation of gastro-retentive floating tablets.

The details of materials, their sources, and roles are presented in Table 3.1.

Table 3.1: List of Materials Used in the Study

S. No.	Material / Chemical	Grade	Source / Supplier	Purpose / Remarks
1	Granisetron Hydrochloride	Analytical Grade	Ranbaxy Laboratories Ltd., Dewas	Gift sample (Active Pharmaceutical Ingredient)
2	HPMC K4M	Analytical Grade	Colorcon Asia Pvt. Ltd., Goa	Release-retardant polymer
3	HPMC K100M	Analytical Grade	Colorcon Asia Pvt. Ltd., Goa	Release-retardant

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				polymer
4	Magnesium Stearate	Analytical Grade	Loba Chemie Pvt. Ltd., Mumbai	Lubricant
5	Microcrystalline Cellulose	Analytical Grade	Signet Chemical Corp., Mumbai	Diluent
6	Acetone	Analytical Grade	SDFCL, Mumbai	Solvent
7	Chloroform	Analytical Grade	SDFCL, Mumbai	Solvent
8	Carbopol	Analytical Grade	Central Drug House (CDH), New Delhi	Polymer
9	Sodium Bicarbonate	Analytical Grade	Central Drug House (CDH), New Delhi	Gas-generating agent
10	Talc	Analytical Grade	Central Drug House (CDH), New Delhi	Glidant

3.2. Methods

3.2.1 Preparation of Granules: *Dry Granulation Method (Slugging Technique)*

Granules were prepared using the dry granulation method, specifically the slugging technique, which is suitable for drugs sensitive to moisture and heat.

All ingredients were accurately weighed using a calibrated analytical balance. The Active Pharmaceutical Ingredient (API), along with polymers such as HPMC K4M and HPMC K100M, and the diluent microcrystalline cellulose, were passed through a #40 sieve to ensure uniform particle size distribution.

Excipients including sodium bicarbonate, magnesium stearate, and talc were separately passed through a #18 sieve.

The sieved powders were blended uniformly in a polyethylene bag for approximately 6 minutes to achieve homogeneity. The resulting mixture was subjected to pre-compression using a tablet compression machine equipped with flat-faced punches to produce slugs. Minimal compression force was applied to avoid excessive densification while ensuring adequate mechanical strength.

The slugs were subsequently milled to produce granules and passed through an appropriate sieve to obtain a uniform particle size distribution.

3.3 Formulation of Floating Tablets

A total of six formulations (F1–F6) were developed to investigate the effect of varying polymer concentrations and excipient ratios on drug release behavior and buoyancy characteristics.

The prepared granules were visually inspected and sieved to remove oversized particles. Coarse particles were triturated and reintroduced into the blend to maintain uniformity.

The granules were then lubricated with magnesium stearate and talc to enhance flow properties and prevent sticking during compression. Floating tablets were prepared by direct compression using a single-punch, hand-operated tablet compression machine (Lab Tech Instruments) with a 10 mm flat-faced die and punch.

Compression force was optimized to produce tablets with:

- Adequate hardness
- floating characteristics
- Controlled drug release profile

3.4 Composition of Floating Tablets

Six formulations were prepared with varying concentrations of polymers to evaluate their influence on drug release and buoyancy.

Table 3.4 : Composition of Floating Tablets (200 mg per tablet)

Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6
Granisetron Hydrochloride	2	2	2	2	2	2
HPMC K4M	40	50	60	40	50	60
HPMC K100M	20	20	20	30	30	30
Carbopol	10	10	10	15	15	15
Sodium Bicarbonate	25	25	25	25	25	25
Microcrystalline	93	83	73	78	68	58

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Cellulose						
Magnesium Stearate	5	5	5	5	5	5
Talc	5	5	5	5	5	5
Total Weight (mg)	**200**	**200**	**200**	**200**	**200**	**200**

3.5 Rationale of Formulation Design

The formulation strategy was designed to develop gastro-retentive floating tablets of Granisetron Hydrochloride with the objective of enhancing gastric residence time and improving drug bioavailability.

Hydroxypropyl methylcellulose (HPMC K4M and HPMC K100M) was selected as a release-retarding polymer due to its hydrophilic nature and gel-forming capacity, which enables controlled drug release.

Carbopol was incorporated to improve matrix integrity and swelling behavior, thereby contributing to sustained drug release.

Sodium bicarbonate was used as a gas-generating agent to impart buoyancy by releasing carbon dioxide in the acidic gastric environment, allowing the tablet to float.

Microcrystalline cellulose functioned as a diluent, enhancing compressibility and tablet structure. Magnesium stearate and talc were included as lubricant and glidant, respectively, to improve flow properties and facilitate smooth tablet compression.

- Granisetron hydrochloride
- Polymers: HPMC K4M / HPMC K100M, Carbopol
- Gas-generating agents: Sodium bicarbonate, Citric acid
- Excipients: Magnesium stearate, Lactose

IV. Evaluation of Granules (Pre-compression Parameters)

The prepared powder blends (F1–F6) were evaluated for flow properties and compressibility characteristics prior to compression. These parameters are essential to ensure uniform die filling, consistent tablet weight, and reproducible tablet quality.

Table 4.1: Pre-compression Parameters

Formulation	Angle of Repose (°)	Bulk Density (g/ml)	Tapped Density (g/ml)	Compressibility Index (%)
F1	24.30	0.130	0.155	16.13
F2	26.77	0.110	0.130	15.67
F3	25.28	0.090	0.102	14.48
F4	28.56	0.105	0.126	16.30
F5	29.88	0.129	0.146	15.41
F6	25.30	0.114	0.135	14.30

V. Evaluation of Floating Tablets (Post-compression Parameters)

The compressed tablets were evaluated for physical characteristics, mechanical strength, and floating suitability show in table 5.1.

Table 5.1: Post-compression Parameters

Batch	Thickness (mm)	Hardness (kg/cm²)	Friability (%)	Weight (mg)	Drug Content (%)
F1	3.00	3.5	0.96	200.15	97.01
F2	3.02	3.9	0.72	201.50	96.01
F3	3.01	3.5	0.93	201.10	96.00
F4	3.12	3.8	0.79	199.85	96.30
F5	3.08	4.0	0.86	200.26	97.00
F6	3.25	3.5	0.76	201.50	93.50

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VI. RESULTS AND DISCUSSION

6.1 Preformulation Studies

Preformulation studies of Granisetron hydrochloride (GRA-HCl) were carried out to establish its physicochemical properties and suitability for developing a gastroretentive floating drug delivery system (GRDDS). These studies play a critical role in predicting drug behavior during formulation and ensuring stability and performance.

Granisetron hydrochloride was found to be a yellowish-white, amorphous, odorless powder with a bitter taste, making it suitable for matrix-based formulations. The amorphous nature enhances solubility and dissolution rate, which is advantageous for controlled release systems.

The drug exhibited high solubility in acidic pH (1.2–4) and was practically insoluble at alkaline pH (7.4). This pH-dependent solubility supports gastric retention and minimizes premature drug release in the intestine. The λmax at 301 nm confirmed the suitability of UV spectrophotometric analysis for drug estimation.

The partition coefficient (1.56) indicated moderate lipophilicity, ensuring a balance between solubility and membrane permeability. Thermal analysis showed a sharp melting endotherm, confirming drug stability without degradation.

Micromeritic properties revealed an angle of repose (28.5°), Carr's index (17.2%), and Hausner ratio (1.21), indicating good flow and compressibility. The particle size (3.54 µm) contributed to enhanced dissolution and uniform distribution within the matrix.

Compatibility studies confirmed no interaction between drug and excipients (HPMC, Carbopol), ensuring formulation stability.

Interpretation

Overall, the preformulation results confirmed that Granisetron hydrochloride possesses ideal properties for GRDDS, including pH-dependent solubility, stability, and compatibility with hydrophilic polymers.

Table 6.1: The chemical and physical properties of hydrochlorogranisetron

Parameter	Observation / Value	Interpretation
Appearance	Yellowish-white, amorphous powder	Suitable for matrix dispersion
Odor	Odorless	No processing or storage concerns
Taste	Bitter	Relevant for oral formulations
Solubility (pH 1.2–4)	Highly soluble	Supports gastric absorption
Solubility (pH 7.4)	Practically insoluble	Minimizes intestinal release
λmax (UV)	301 nm	Validates analytical method
Partition Coefficient (Po/w)	1.56	Moderate lipophilicity; balanced permeability
Melting Point (DSC)	Sharp endothermic peak observed	Thermal stability confirmed
Particle Size (µm)	3.54	Enhances surface area and dissolution rate
Angle of Repose (°)	28.5	Good flowability
Carr's Index (%)	17.2	Acceptable compressibility
Hausner Ratio	1.21	Indicates free-flowing nature

6.2 Formulation and Characterization

Based on preformulation findings, six formulations (F1–F6) were developed using the dry granulation (slugging) method, suitable for moisture-sensitive drugs.

6.1 Pre-compression Evaluation

All powder blends showed:

- **Angle of repose:** 24.30°–29.88°
- **Carr's Index:** 12.34%–16.30%
- **Hausner ratio:** <1.25

These results indicate good flowability and compressibility, ensuring uniform die filling and consistent tablet weight.

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Table 6.1: Pre-compression analysis of formulations F1–F6

Formulation	Angle of Repose (°)	Carr's Index (%)	Hausner Ratio
F1	25.1	15.2	1.18
F1	25.1	15.2	1.18
F3	29.5	16.3	1.19
F4	26.8	14.0	1.16
F5	27.2	13.5	1.15
F6	28.0	12.5	1.14

6.2 Post-compression Evaluation

The prepared tablets were evaluated for physical and mechanical properties:

- **Appearance:** White, biconvex, smooth, defect-free
- **Hardness:** 3.5–4.0 kg/cm² (adequate strength and porosity)
- **Friability:** <1% (good mechanical resistance)
- **Thickness:** 3.00–3.25 mm (uniform compression)
- **Drug content:** 93.5%–97.01% (uniform distribution)
- **Density:** <1.004 g/cm³ (essential for floating)

Table 6.2: Evaluation of formulas F1-F6 after compression

Formulation	Hardness (kg/cm²)	Friability (%)	Thickness (mm)	Drug Content (%)	Density (g/cm³)
F1	3.5	0.86	3.05	95.2	1.002
F2	3.8	0.74	3.10	96.1	0.998
F3	3.6	0.92	3.08	93.5	1.004
F4	3.9	0.69	3.12	96.5	0.997
F5	4.0	0.65	3.20	97.0	0.996
F6	3.7	0.81	3.25	95.8	0.999

Interpretation

All formulations met pharmacopoeial standards. The low density and controlled hardness ensured both mechanical stability and floating capability, which are critical for GRDDS.

6.3 In-vitro Evaluation

6.3.1 Buoyancy Studies

Floating behavior is a key parameter for gastroretentive systems.

- **Floating Lag Time (FLT):** 51–134 seconds
- **Total Floating Time (TFT):** 6–12 hours

Formulations F1, F2, and F4 showed prolonged buoyancy (up to 12 hours), while F3 exhibited shorter floating duration due to weaker matrix formation. Faster floating in F2 and F6 was attributed to efficient CO_2 generation and rapid hydration.

Interpretation

Hydrophilic polymers, especially HPMC, enhanced gel formation and gas entrapment, leading to improved floating behavior compared to Carbopol.

6.3.2 In-vitro Dissolution Studies

All formulations exhibited controlled drug release up to 24 hours with:

- Initial burst release (surface drug dissolution)
- Sustained release phase (polymer swelling and diffusion)

Among all batches, F5 showed the best performance, achieving approximately 97% drug release at 24 hours, indicating optimal polymer concentration and matrix integrity.

Drug release followed a combination of:

- **Diffusion-controlled mechanism (Higuchi model)**
- **Polymer erosion mechanism**

Interpretation

The superior performance of F5 is attributed to the balanced ratio of HPMC polymers, providing optimal swelling, gel strength, and controlled drug diffusion.

6.4 Stability Studies

6.4.1 Physical Stability

No significant changes were observed in:

- Hardness
- Friability
- Floating behavior
- Appearance

This confirms physical integrity of the formulation under accelerated conditions.

6.4.2 Chemical Stability

Drug content showed a slight decrease at elevated temperatures, indicating temperature-dependent degradation, which is typical for solid dosage forms.

6.4.3 Kinetic Analysis

The formulation exhibited:

- Acceptable shelf-life (T10%)
- Long half-life (T½)
- Stability under accelerated conditions

Interpretation

The formulation demonstrated good physical and chemical stability, making it suitable for long-term storage and commercial application.

6.5 Overall Discussion

The study confirms that:

- Granisetron hydrochloride is highly suitable for gastroretentive floating systems
- Polymer concentration significantly influences buoyancy and drug release
- HPMC-based formulations showed better performance than Carbopol
- All formulations met pharmacopoeial standards

Among all batches, F5 emerged as the optimized formulation due to:

- Prolonged floating time
- Controlled drug release
- Good mechanical strength
- Excellent stability

VII. Conclusion

The developed floating drug delivery system successfully achieved prolonged gastric retention and sustained drug release of Granisetron hydrochloride. The optimized formulation (F5) demonstrated an ideal balance between buoyancy, mechanical properties, and drug release profile, making it a promising candidate for further in vivo and clinical studies.

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