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FORMULATION AND EVALUATION OF PANTOPRAZOLE FLOATING TABLET

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ABSTRACT:-

Oral administration is the preferred route for drug delivery due to its convenience and high patient compliance. Floating tablets offer a promising approach to achieve prolonged and predictable drug release in the gastrointestinal tract, enhancing gastric residence time. This study aimed to develop and evaluate floating pantoprazole tablets, utilizing a gastro-retentive drug delivery system (GRDDS) to improve therapeutic outcomes .Floating drug delivery systems (FDDS) enhance buoyancy, prolonging drug release and reducing dosing frequency. By maintaining intimate contact with the absorbing membrane, GRDDS can maximize drug absorption and modulate its rate. Pantoprazole floating tablets are designed to treat and prevent bacterial infections in the stomach and intestines. Challenges in Oral Controlled Drug Delivery Systems .The primary goal of oral controlled drug delivery systems is to achieve predictable and enhanced bioavailability. However, several physiological challenges exist, including: Limited control over gastric retention: Difficulty in retaining the dosage form in the desired region of the gastrointestinal tract. Variable gastric emptying: Gastric emptying time (normally 2-3 hours) can lead to incomplete drug release, reducing efficacy. These challenges can compromise the effectiveness of oral controlled drug delivery systems.

KEYWORDS: - Pantoprazole, Floating Drug Delivery, Buoyancy, Sustained release.

INTRODUCTION:-

Gastro retentive drug delivery systems are designed to remain in the stomach for a prolonged duration, gradually releasing active ingredients to provide sustained medication delivery to the upper gastrointestinal tract [1,2]. Medications that are effective in the stomach, have specific absorption sites, are prone to degradation in the intestine, or have solubility issues at higher pH levels can benefit from gastro retentive drug delivery systems. These systems provide prolonged retention in the stomach, enhancing therapeutic outcomes [3]. Polymer technology advancements have significantly improved controlled drug delivery systems, enabling functions like targeted release, responsive delivery, and enhanced bioavailability. These developments lead to more effective treatments. These formulations provide a steady release of the active ingredient over 12 to 24 hours, maintaining consistent drug levels[4].

Pantoprazole is a proton pump inhibitor (PPI) that effectively treats conditions like: Acute duodenal ulcers, Acute benign gastric ulcers, Gastro esophageal reflux disease (GERD), Prevents duodenal ulcer recurrence .It works by reducing stomach acid production. Pantoprazole acts locally in the stomach, reducing acid production by inhibiting the H+/K+ ATPase enzyme in gastric parietal cells[5].

As the system floats on the gastric contents, it slowly releases the drug at a controlled rate. Once the drug is released, the remaining system is emptied from the stomach, leading to prolonged gastric retention and stable plasma drug levels[6]. The concept of floating drug delivery systems was introduced by Davis in 1968, inspired by the risk of choking hazards associated with swallowing large pills[7]. Gastric emptying of dosage forms is highly variable, making it challenging to control residence time. Prolonged gastric retention can be beneficial for certain medications. To address this, various drug delivery systems have been developed to: Extend gastric retention time, Maintain therapeutic drug levels, Reduce dosing frequency, Minimize plasma concentration fluctuations.

These systems are particularly useful for drugs that are less soluble in high pH environments [8].

MECHANISM OF ACTION

Pantoprazole, a proton pump inhibitor (PPI), works by irreversibly binding to the (H+, K+)-ATPase enzyme system on gastric parietal cells. This blocks the final step of gastric acid production, effectively suppressing both basal and stimulated acid secretion. The binding is long-lasting, resulting in an antisecretory effect that persists for over 24 hours.

FLOATING SYSTEM

Floating drug delivery systems (FDDS) remain buoyant in the stomach due to their low bulk density, allowing for: Prolonged gastric retention, Controlled drug release, Consistent drug absorption .As the drug is released, the system is eventually emptied from the stomach [9].

Classification of floating tablet:-

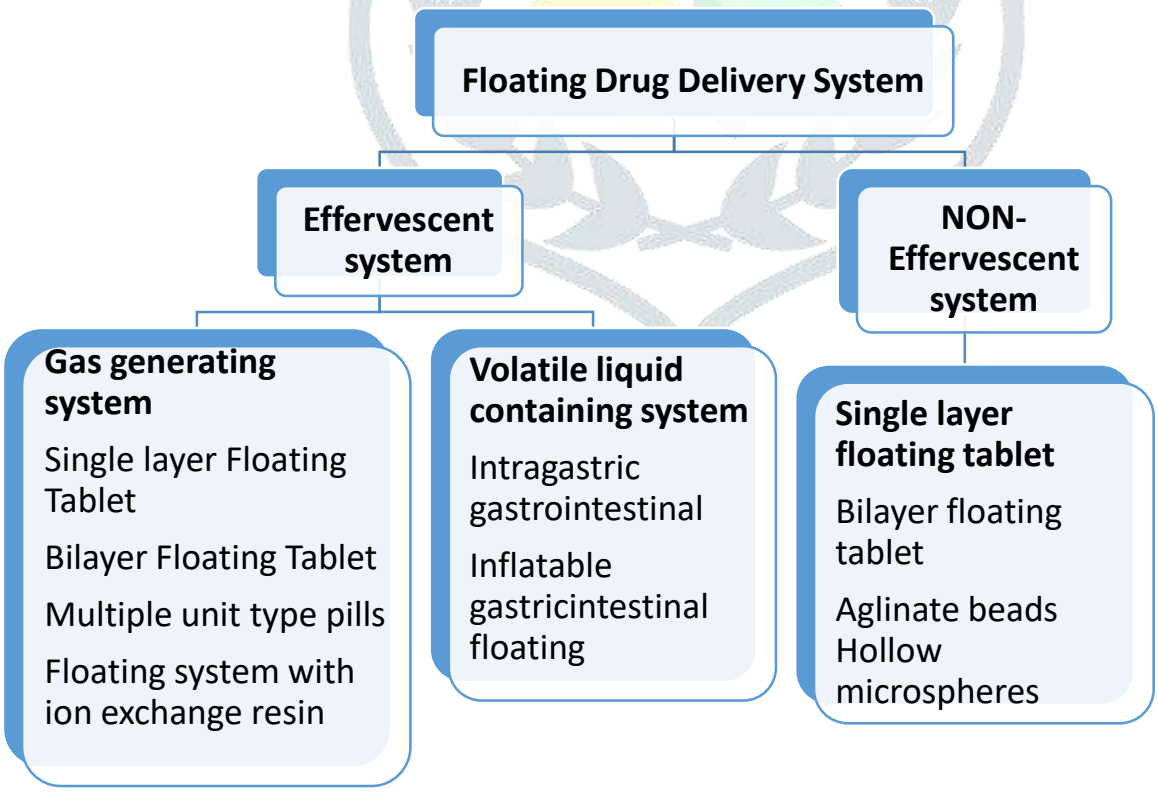

Figure 1: Schematic diagram classification of floating drug delivery system.

Drug profile:

Drug name	Pantoprazole
Chemical name	C16H15F2N304S
IUPAC name	6(difluromethoxy)-2[(3,4-dimenthoxypyridine2yl)methanesulfinyl]-1H1,3benzodiazole.
Molecular weight	383.4g/ml.
Category	Acid Reducer.
Solubility	Freely soluble in water.

Structure:

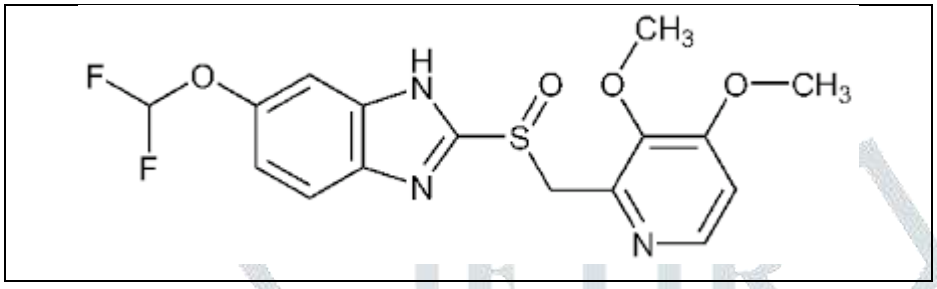

Figure 2: Pantoprazole.

Excipients:

1.Dilutents:

Diluents are commonly used to increase the bulk of solid unit dosage forms when the drug's quantity is insufficient to produce a suitable size.

eg- Microcrysatalline cellulose.

2.Buffer:

Buffers act by binding hydrogen ions in acidic environments and releasing hydrogen ions in basic environments, maintaining a stable ph.

eg- Citric acid.

3.Lubricants:

Lubricants form a thin layer between the tablet mass and die wall, reducing -Friction between particles, Adhesion to dies and punches, Facilitating smooth tablet ejection ,Improving granulation flow .This ensures efficient tablet production.

eg- Talc , magnesium stearate.

4 . Coating materials:

Coatings protect tablets from -Moisture degradation, Masking unpleasant tastes.Making them easier to swallow.

eg. Ethylcellulose.

rocedure for Formulation:

Step 1: Blending

1. Pass drug and polymers through a 40-mesh sieve separately.

2. Combine and mix in a poly bag for 3 minutes.

Step 2: Mixing with Excipients

1. Add diluents and other excipients to the mixture.

2. Incorporate glidant (Magnesium Stearate) and lubricant (Talc).

3. Mix for 2 minutes.

Step 3: Compression

1. Compress the lubricated blend into tablets using 10mm round punches.

Conclusion:

This study aimed to develop pantoprazole floating tablets to prolong gastrointestinal residence time and enhance bioavailability. The formulation utilized various polymers to achieve sustained drug release in the upper gastrointestinal tract . Pantoprazole floating tablets were prepared using direct compression. Pre-formulation studies identified suitable excipients, which were combined in varying proportions to optimize formulations. The tablets were evaluated for properties such as floating lag time, floating duration, and encapsulation efficiency. Floating drug delivery systems can extend gastric retention, potentially improving bioavailability. This approach may enhance therapeutic outcomes by maintaining the dosage form in the stomach for longer periods.

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