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Formulation and Evaluation of Bilayer Floating Drug Delivery System of Clarithromycin and Omeprazole

Tekale Samiksha Sanjay, Salunke Nikita Babusha, Thorat Ganeesh Chandrakant
Jogdand Tejaswini Dharmraj, Shinde S. S.
Aditya Diploma Institute of Pharmacy Collage. Beed

Abstract: *In the current study, a successful attempt was made to formulate bilayer floating tablets of clarithromycin and omeprazole by the direct compression method. The formulation consisted of a loading dose and superdisintegrants in the immediate release layer, along with a maintenance dose, rate-controlling polymers, and gas-generating agents in the floating layer.*

The extended-release layer was prepared using Hydroxypropyl Methylcellulose (HPMC K15 and HPMC K4) and Polyvinylpyrrolidone (PVP K30) as sustained-release polymers. Sodium bicarbonate was used as a gas-generating agent to reduce floating lag time. The immediate-release layer was formulated using superdisintegrants such as sodium starch glycolate, croscarmellose sodium, and crospovidone through the direct compression method.

Gastro-retentive floating drug delivery systems were designed to increase the residence time of the dosage form in the stomach. The prepared granules were evaluated for bulk density, tapped density, compressibility index, and Hausner's ratio. The results indicated that the granules exhibited satisfactory flow properties.

The optimized granules were further compressed to obtain bilayer tablets. These tablets were evaluated for various physicochemical parameters and subjected to dissolution studies. Additionally, accelerated stability studies were performed on the bilayer tablets.

The omeprazole tablet demonstrated more than 99.45% drug release within 15 minutes, while the clarithromycin tablet showed more than 99.76% drug release at the end of 12 hours following an initial lag time. Both layers were successfully compressed together to form a bilayer tablet.

The bilayer tablets exhibited a release pattern similar to that of the individual layers. Furthermore, the tablets were found to be stable after 6 months of storage as per ICH guidelines. Both layers of the bilayer formulation showed the desired drug release profile over the specified time period.

Keywords: Floating Tablets, Gastro-retentive Drug Delivery System, Omeprazole, Sustained Release, Floating Microspheres, Drug Delivery System, HPMC K15M, HPMC K4M, Solvent Evaporation Technique. write downlide keywords topic

I. INTRODUCTION

The oral route is increasingly used for the delivery of therapeutic agents due to its low cost, ease of administration, and high patient compliance. More than 50% of the drug delivery systems available in the market are oral drug delivery systems (Arora, 2005). The floating drug delivery system was first described by Davis in 1968. Since then, several approaches have been developed to prolong gastric retention time, among which floating drug delivery systems (FDDS) have gained significant importance.

Floating Drug Delivery Systems, also known as hydrodynamically balanced systems (HBS) or low-density systems, are designed to increase the gastric residence time of drugs. These systems typically consist of natural or synthetic

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polymers and are characterized as free-flowing powders, ideally having a particle size of less than 200 µm. The primary goal of any drug delivery system is to deliver a therapeutic amount of drug to the desired site in the body promptly and to maintain the required drug concentration for an appropriate duration.

Fixed-dose combination therapy offers several advantages over conventional monotherapy, such as a simplified dosage regimen, improved patient compliance, enhanced therapeutic outcomes, reduced side effects, and lower costs associated with manufacturing, handling, packaging, and distribution. Conventional dosage forms often produce wide fluctuations in drug concentration in the bloodstream, which has led to the development of sustained and controlled drug delivery systems.

Gastro-retentive drug delivery systems represent a novel approach aimed at prolonging gastric emptying time. Various techniques such as floating systems, low-density systems, raft-forming systems, mucoadhesive systems, and high-density systems are currently under investigation. Among these, floating drug delivery systems remain buoyant in gastric contents for an extended period, thereby improving the bioavailability of drugs with a narrow absorption window and poor solubility or stability in alkaline pH.

Gastroesophageal reflux is defined as the involuntary movement of gastric contents into the oesophagus. It is a normal physiological process that occurs several times a day without symptoms or damage to the oesophageal mucosa in most otherwise healthy individuals. However, when reflux becomes frequent or severe, it leads to gastroesophageal reflux disease (GERD), a condition that negatively affects the individual's quality of life and may result in damage to the oesophagus, pharynx, or respiratory tract.

To overcome limitations such as poor solubility and low stability of drugs in intestinal fluids, floating drug delivery systems have been developed. The fundamental concept behind FDDS is to design the dosage form with a density lower than that of gastric fluids so that it can float on them. These systems remain buoyant in the stomach for a prolonged period without affecting the gastric emptying rate, allowing for continuous and controlled drug release.

While floating on gastric contents, the drug is slowly released at a predetermined rate, ensuring sustained therapeutic action. After complete drug release, the residual system is eventually emptied from the stomach. This mechanism enhances gastric retention time and reduces fluctuations in drug concentration.

Floating drug delivery systems function as a type of gastro-retentive drug delivery system that controls the pharmacokinetic release of a drug to achieve its desired pharmacological action. Controlled gastric retention of solid dosage forms can be achieved through various mechanisms such as mucoadhesion, floatation, sedimentation, expansion, modified shape systems, or by the administration of agents that delay gastric emptying.

Scintigraphic studies evaluating gastric emptying rates have revealed that orally administered controlled-release dosage forms often face challenges such as:

I. Short gastric residence time

II. Unpredictable gastric emptying rate

These limitations highlight the need for advanced drug delivery systems like FDDS, which can effectively overcome these challenges by prolonging gastric retention, ensuring controlled drug release, and improving overall therapeutic efficacy.

Thus, floating drug delivery systems play a vital role in modern pharmaceutical research by enhancing drug bioavailability, maintaining consistent plasma drug levels, and improving patient compliance and treatment outcomes.

II. LITERATURE AND REVIEW

D. S. Goswami et al. (2013) developed Pioglitazone HCl gastroretentive tablets by employing natural gum (xanthum gum) in comparison to HPMC K15M, a synthetic cellulose derivative, as a matrix former. The tablets were prepared by the direct compression method. The prepared tablets were evaluated in terms of precompression parameters, physical characteristics, in vitro release, floating duration, and floating lag time. The results of in vitro release studies showed that the optimized formulation (F13) could release the drug (98%) for 12 hours and remain buoyant for 12 hours[60].

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S. C. Basak et al. (2007) developed a hydrodynamically balanced system of Metformin Hydrochloride as a single-unit floating tablet. Various grades of low-density polymers were used for the formulation of this system. The tablets were prepared by physical blending of Metformin HCl and the polymers in varying ratios. The formulation was optimized on the basis of in vitro buoyancy and in vitro release in simulated gastric fluid of pH 1.2. Tablets prepared with HPMC K15M and Carbopol showed the best in vitro percentage release and were selected as the optimized formulation. All the formulations were robust tablets with optimum hardness, consistent weight uniformity, and low tablet friability. In vitro drug release tests indicated that the sustained release of Metformin HCl could be retarded up to 8 hours[61].

Bharath et al. (2014) formulated Metoprolol tartrate floating tablets using HPMC 5 cps. The results of the study clearly indicated a promising potential of the Metoprolol tartrate floating system as an alternative to the conventional dosage form for sustaining drug release and improving bioavailability[62].

Rajneesh et al. (2014) concluded that optimized multi-unit floating microspheres are expected to provide clinicians with a new choice of an economical, safe, and more bioavailable formulation in the effective management of diverse diseases[63].

Sunil et al. (2013) studied an intragastric drug delivery system for Atenolol to evaluate the contribution of HPMC K4M / HPMC K100M ratio on drug release. Formulations were evaluated for in vitro buoyancy and drug release study using USP 24 paddle type dissolution apparatus with 0.1N HCl as dissolution medium. It was found that polymer concentration and viscosity greatly affect the drug release pattern[64].

Chabria et al. (2013) developed floating matrix tablets of Nicardipine HCl to evaluate the contribution of HPMC K15M and HPMC K100M on drug release. Overall, the study concluded that viscosity is a major factor affecting drug release and floating properties of FDDS. From the dissolution study, it was observed that formulation F3 containing HPMC K100M polymer showed the lowest release rate compared to others due to its high molecular weight and viscosity[65].

Prasad et al. (2012) developed gastroretentive dosage forms of Stavudine using low-density polymers. The percentage swelling index and drug release patterns varied significantly with the concentration of the polymer[66].

Basvaraj et al. (2012) developed a twice-daily formulation for oral administration of Glipizide. The formulations were composed of polymers such as HPMC K15M, HPMC K100M, and Carbopol 940P. The gel-forming polymers created a hydrated gel matrix that entrapped gas, causing the tablet to float and be retained in the stomach or upper part of the small intestine. The hydrated gel matrix created a tortuous path for the drug, resulting in sustained drug release[67].

Hemanth et al. (2011) developed Levofloxacin effervescent sustained-release tablets. Various release-retarding polymers such as HPMC and Ethyl cellulose were optimized to achieve a drug release profile of up to 14 hours. The formulations were evaluated for in vitro drug release profile, buoyancy lag time, and total floating time. Formulation F7 was found to be the optimized formulation[68].

Upender Rao et al. (2011) prepared floating tablets of Ciprofloxacin HCl by direct compression technique. HPMC K4M and HPMC K15M were incorporated for gel-forming properties. Buoyancy was achieved by adding an effervescent mixture of sodium bicarbonate and anhydrous citric acid. It was concluded that the release of the active compound was better controlled compared to conventional dosage forms due to delayed pyloric passage[69].

Suresh Bandari et al. (2010) developed a biphasic gastro-retentive drug delivery system of Fenoverine to maintain constant plasma concentration. The delivery system consisted of a loading-dose tablet and a floating multiple matrix tablet prepared by direct compression. The drug release from biphasic GRDDS in 0.1 mol L^{-1} HCl and simulated gastric fluid was sustained over 12 hours with good buoyant properties. Stability studies showed no significant change in dissolution profiles (f_2 value > 50). Based on release kinetics, it was concluded that the floating multiple matrix tablet containing HPMC was a suitable gastro-retentive drug delivery system with zero-order release[70].

III. AIM AND OBJECTIVES

Aim :-

The aim of the present study is to develop a gastro-retentive floating drug delivery system of Omeprazole in order to improve gastric retention time and enhance oral sustained drug delivery.

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Objective:-

• To formulate gastro-retentive floating tablets that can be retained in the stomach for a prolonged period.

• To improve the oral sustained delivery of drugs having a narrow absorption window in a specific region of the gastrointestinal tract.

• To ensure continuous release of the drug before it reaches the absorption window, thereby achieving optimal bioavailability.

• To enhance local delivery of Omeprazole at the receptor site of the gastric parietal cell wall.

• To increase the bioavailability of the drug at the stomach wall receptor site and improve its ability to reduce acid secretion.

• To evaluate the prepared formulation for various physicochemical and in-vitro parameters.

IV. MATERIALS AND METHOD

Materials: -

Hydroxypropyl Methylcellulose (HPMC K15, HPMC K4), Polyplasdone XL (Crospovidone), and glycols such as Sodium Starch Glycolate were generously gifted by Colorcon Asia Pvt. Ltd. (Goa, India), International Specialty Products Ltd. (Mumbai, India), and Roquette India Pvt. Ltd. (Mumbai, India), respectively.

Ac-Di-Sol (Croscarmellose Sodium) and Microcrystalline Cellulose were supplied by Signet Chemical Corporation Pvt. Ltd. (Mumbai, India).

Talc, Lactose, Citric Acid, and Sodium Bicarbonate ($NaHCO_3$) were purchased from Loba Chemie Pvt. Ltd. (Mumbai, India).

All other chemicals and reagents used in the study were of analytical grade.

Method: -

The formulation of floating tablets was carried out using the direct compression method. All the required ingredients were accurately weighed and passed through a suitable sieve to ensure uniform particle size. The drug and excipients were thoroughly mixed to achieve a homogeneous blend.

The blend was then lubricated using talc and magnesium stearate to improve flow properties and prevent sticking during compression. The final mixture was compressed into tablets using a tablet compression machine.

The prepared tablets were further evaluated for various physicochemical parameters such as hardness, friability, weight variation, drug content, floating lag time, and in vitro drug release.

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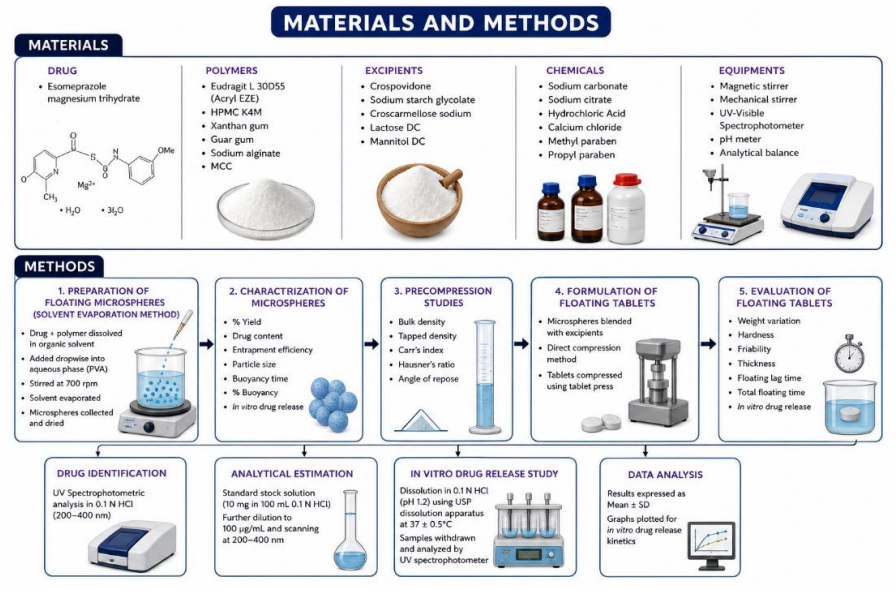

Fig. No. 1: Materials and Method

Methods and Preparation

Chemicals and Reagents

Esomeprazole magnesium trihydrate was gifted by Aurobindo Pharma Limited, A.P., India.

Crospovidone, Sodium Starch Glycolate, and Croscarmellose Sodium were obtained from Danmed Pharmaceuticals Pvt. Ltd., Hyderabad.

Lactose DC and Mannitol DC were procured from SD Fine Chemicals Limited, Mumbai.

Acryl EZE (Eudragit L 30 D55, Colorcon) was supplied by Med Reich Limited, Bangalore.

Polypropylene, Calcium Silicate, and Aerosil were purchased from Sigma Aldrich, Bangalore.

Xanthan gum, Guar gum, HPMC K4M, and Microcrystalline Cellulose (MCC) were purchased from INR Chem and Yarrow Chemicals, Mumbai.

Omeprazole magnesium was kindly provided by Dr. Reddy's Laboratories, Hyderabad.

Sodium carbonate, sodium alginate, methyl paraben, and propyl paraben were procured from Arora and Company, Delhi.

Sodium citrate and Hydrochloric Acid were obtained from Central Drug House (P) Ltd., New Delhi, and Calcium chloride was obtained from Loba Chemicals, Mumbai.

All chemicals and reagents used were of analytical grade, and de-ionized water was used throughout the study.

Preformulation Studies

Preformulation studies were carried out to ensure the development of a stable, safe, and therapeutically effective dosage form. These studies focused on the physicochemical properties of the drug that could influence formulation development and performance.

Description of Drug

Organoleptic properties of the drug, including colour, odour, and taste, were observed and recorded.

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Identification of Drug

The drug was identified by UV spectrophotometric analysis.

A solution of 100 µg/ml in 0.1 N HCl was prepared and scanned in the range of 200–400 nm to determine its characteristic absorption maxima.

Analytical Estimation of Drug

The standard stock solution of omeprazole magnesium was prepared by dissolving 10 mg of drug in 0.1 N HCl in a 100 ml volumetric flask.

The stock solution was further diluted with 0.1 N HCl to obtain a standard solution of 100 µg/ml.

The resulting solution was scanned between 200–400 nm using a UV-visible spectrophotometer.

Preparation of Omeprazole Floating Microspheres

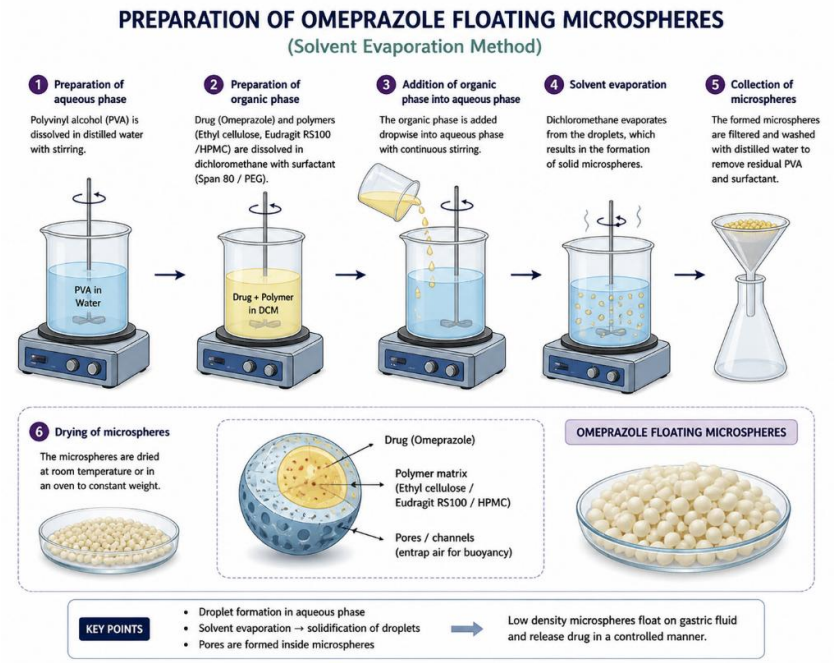

Fig. No. : Preparation of Omeprazole

The floating microspheres were prepared by the solvent evaporation method.

Initially, 0.75 g of polyvinyl alcohol was dissolved in 100 ml of distilled water. Different quantities of Ethyl cellulose and Eudragit S100 were dissolved in dichloromethane using a magnetic stirrer.

A known quantity of Omeprazole was dissolved in the above polymer solution along with a surfactant (Span 80). The resulting solution was added dropwise into the aqueous phase containing polyvinyl alcohol with continuous stirring at 700 rpm using a mechanical stirrer.

In another preparation, 0.46 g of polyvinyl alcohol was dissolved in 100 ml distilled water. Different quantities of Ethyl cellulose, HPMC, and Eudragit RS100 were dissolved individually and in combination using dichloromethane.

A known quantity of Omeprazole (40 mg) was dissolved in the polymeric solution along with 0.1% polyethylene glycol (surfactant).

The resulting solution was poured into a 500 ml beaker containing 150 ml of polyvinyl alcohol (0.46% w/v) to obtain microspheres.

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Characterization of Microspheres

The prepared floating microspheres were evaluated for the following parameters:

- Product yield
- Drug content
- Entrapment efficiency
- In vitro drug release
- Buoyancy time
- Percentage buoyancy

Process parameters such as stirring time, stirring speed, and organic-to-aqueous phase ratio were optimized.

Floating microspheres were prepared at 1:2, 1:5, and 1:10 ratios. No microsphere formation was observed at 1:2 ratio, while successful formation was observed at 1:5 and 1:10 ratios.

Five formulations were prepared by altering the drug-to-polymer ratio to study the effect of polymer concentration on evaluation parameters.

Evaluation of Omeprazole Microspheres

1. Percentage Yield

The dried microspheres were accurately weighed and the percentage yield was calculated using:

% Yield = (Practical Yield / Theoretical Yield) × 100

2. Drug Content

Different batches of microspheres were analysed to determine the drug content.

3. Bulk Density and Tapped Density

Bulk density and tapped density were measured using a 10 ml graduated cylinder.

Bulk Density = Mass / Volume

Tapped Density = Mass / Tapped Volume

4. Carr's Index

$I = (Dt - Db) / Dt \times 100$

Where:

Dt = Tapped density

Db = Bulk density

5. Hausner's Ratio

$H = Dt / Db$

6. Angle of Repose

$\theta = \tan^{-1} (h / r)$

Where:

h = Height of pile

r = Radius of pile

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V. TYPES OF FLOATING DRUG DELIVERY SYSTEM

The systems that are developed to increase the gastric residence time of oral dosage forms are as follows:

- Non-effervescent system
- Effervescent system

Non-Effervescent System

The non-effervescent FDDS is based on the mechanism of swelling of polymer or adhesion to the mucosal layer in the GI tract. The most commonly used excipients in non-effervescent FDDS are gel-forming or highly swellable cellulose-type hydrocolloids, hydrophilic gums, polysaccharides, and matrix-forming materials such as polycarbonate, polyacrylate, polymethacrylate, and polystyrene, as well as bioadhesive polymers such as chitosan and carbopol.

The formulation method includes a simple approach of thoroughly mixing the drug and the gel-forming hydrocolloid. After oral administration, this dosage form swells in contact with gastric fluids and attains a bulk density of < 1. The air entrapped within the swollen matrix imparts buoyancy to the dosage form.

The so-formed swollen gel-like structure acts as a reservoir and allows sustained release of the drug through the gelatinous mass.

The various types of this system are as follows:

- Colloidal gel barrier systems / Single Layer Floating Tablets
- Bi-layer floating tablets
- Microporous compartment systems
- Multi-particulate system: Floating Beads / Alginate Beads
- Micro balloons / Hollow Microspheres

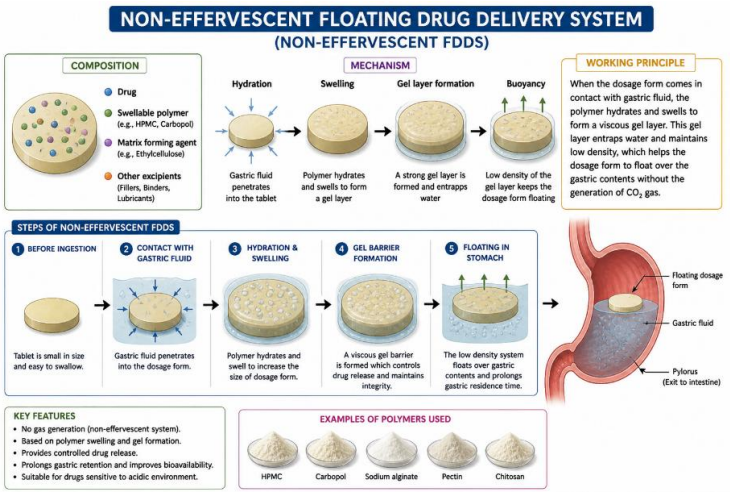

Fig. No. : Non-Effervescent System

Effervescent System

These are matrix-type systems prepared with the help of swellable polymers such as methylcellulose and chitosan and various effervescent compounds, for example, sodium bicarbonate, tartaric acid, and citric acid.

They are formulated in such a way that when in contact with acidic gastric contents, CO_2 is liberated and the gas gets entrapped in swollen hydrocolloids, which provides buoyancy to the dosage forms.

The various types of this system are:

- Volatile liquid-containing systems
- Gas generating systems

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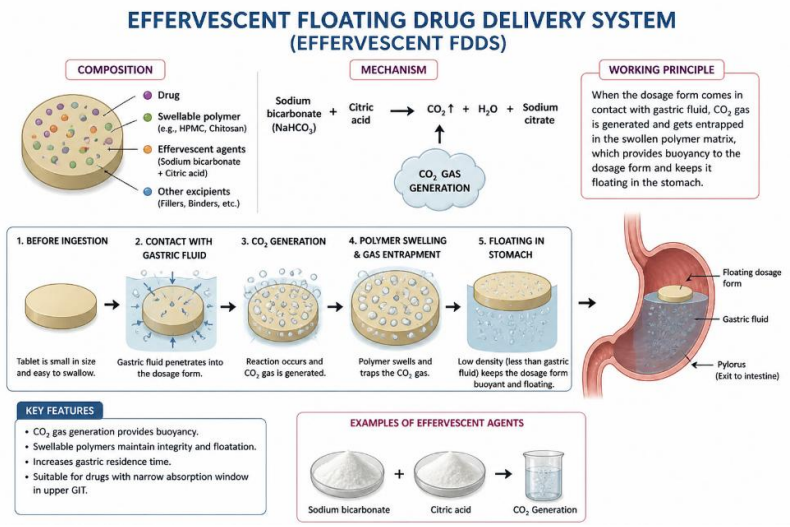

Fig. No. 6: Effervescent System

GASTRO-RETENTIVE DRUG DELIVERY SYSTEMS (GRDDS)

Floating Systems

The formulation is able to float in the gastric fluid due to the low density of floating systems, where it may stay for a longer period of time without changing the pace at which the stomach empties. The low density is due to the swelling of polymer and gas generation.

Polymer-based systems expand in the presence of gastric fluid and float in the gastric juice. The low-density gas-generating system works by the production of carbon dioxide when it comes in contact with gastric fluids.

This system is suitable for H. pylori bacteria due to its localized action, which will directly deliver antibiotics in the gastric mucosa for longer periods. According to Javadzadeh et al., the floating system is suitable for medications that act locally on the stomach's gastric mucosa, such as metronidazole.

Using this system, antimicrobial drugs can be applied topically to cure H. pylori infection, which may be helpful to prevent the adverse effects of traditional triple therapy.

The floating microspheres of clarithromycin developed by Tejaswi et al. to eradicate H. pylori bacteria showed 71% entrapment efficiency of the drug, and 82% of the microspheres floated for more than 12 hours.

Patel et al. and Emara et al. reported that floating tablets of clarithromycin and amoxicillin improved the prolonged release of the drug to the intestinal mucosa.

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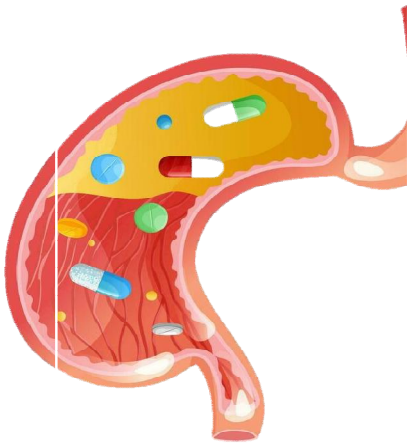

Fig. No. 1: Floating system

Mucoadhesive Systems

Bioadhesive polymers are used in this method so that they may stick to the stomach epithelial lining. Hydrophilic gelling chemicals coupled with several hydrogen-bond forming groups such as sulphate, carboxyl, amide, and hydroxyl groups are characteristic of macromolecular bioadhesive polymers.

These include polycarbophil, carbopol, lectins, chitosan, and gliadin, etc.

Villegas et al. developed a mucoadhesive system (mucolast) to eradicate H. pylori infection using amoxicillin and clarithromycin. Pharmacokinetic evaluation of the formulation showed more drug concentration on the stomach lining than in systemic circulation.

In-vivo efficiency of mucolast was studied in H. pylori-infected mice and showed significant results in terms of histopathological findings.

Dey et al. prepared floating mucoadhesive beads of amoxicillin trihydrate. The developed beads showed good floating behavior for more than 24 hours with a floating lag time of 46.3 ± 3.2 seconds.

The optimized batch completely inhibited H. pylori development in in vitro culture after 15 hours. A floating and mucoadhesive system combination showed good in vitro results and localized action.

Drug release from these beads was maintained via a mucin layer that was not disturbed, replicating in vivo conditions where H. pylori is found in the gastric lining.

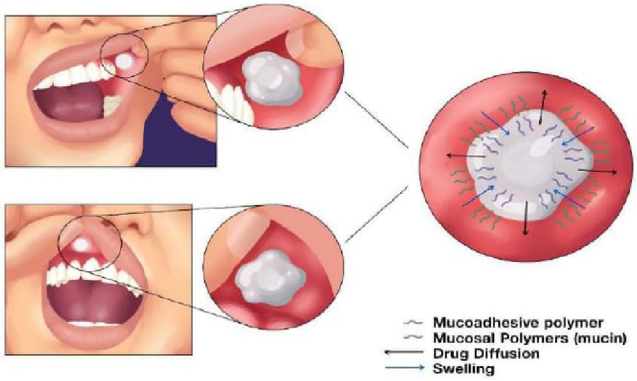

Fig. No. 6: Mucoadhesive system

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High-Density Systems

The density of the system is an essential feature for the stomach retention of the formulation. A high-density system uses its weight for the retention mechanism.

When the system's density is higher than gastric fluid, it descends to the bottom of the stomach below the pylorus. Due to resistance to peristaltic contraction, the system becomes trapped in the antrum.

As a result, gastric residence time is significantly increased.

Commonly used density enhancers include iron powder, titanium dioxide, barium sulphate, and zinc oxide powder, increasing density up to 1.5–2.4 g/cm³.

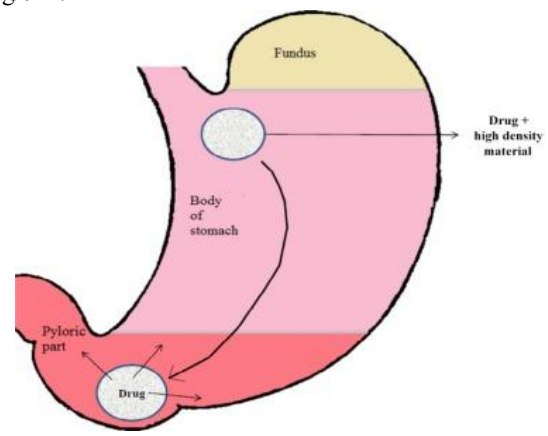

Fig. No. 2: High density system

Magnetic Systems

In this system, a dosage form is made of excipients, internal magnets, and active medicinal components. An external magnet is placed over the stomach to control the position of the dosage form.

The intensity of the external magnetic field can affect gastro-retention. Studies have shown that magnetic systems increase gastro-protection and bioavailability.

However, this system has drawbacks such as difficulty in precise positioning of the magnet and low patient compliance.

Silva-Freitas et al. developed magnetic polymeric stimulus-responsive particles for antimicrobial therapy in the stomach. The final composition of microparticles included magnetite, Eudragit, and amoxicillin with a particle size of approximately 17.2 ± 0.4 µm.

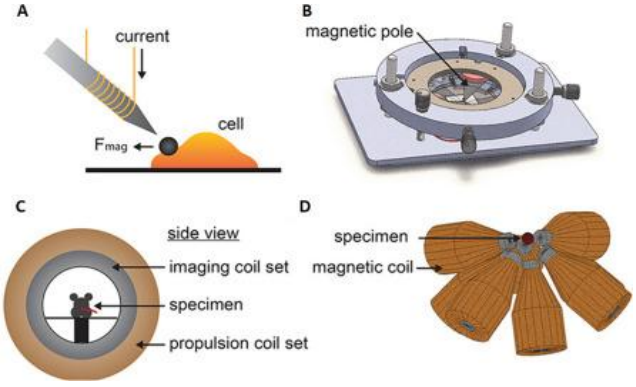

Fig. No. 3: Magnetic system

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Expandable Systems

This system is designed to increase gastric retention time by expanding in size or changing shape.

To function properly, an expandable system must:

• Be small enough for oral administration

• Expand in the stomach to avoid passing through the pylorus

• Contract after drug release to allow elimination

This system is also called a "plug-type" system as it can block the pyloric sphincter.

Expansion occurs by swelling or unfolding mechanisms, allowing modification of volume and shape.

Yang et al. developed a swellable asymmetric triple-layer tablet containing tetracycline, metronidazole, and bismuth for the treatment of H. pylori. The formulation used floating characteristics to increase gastric retention time.

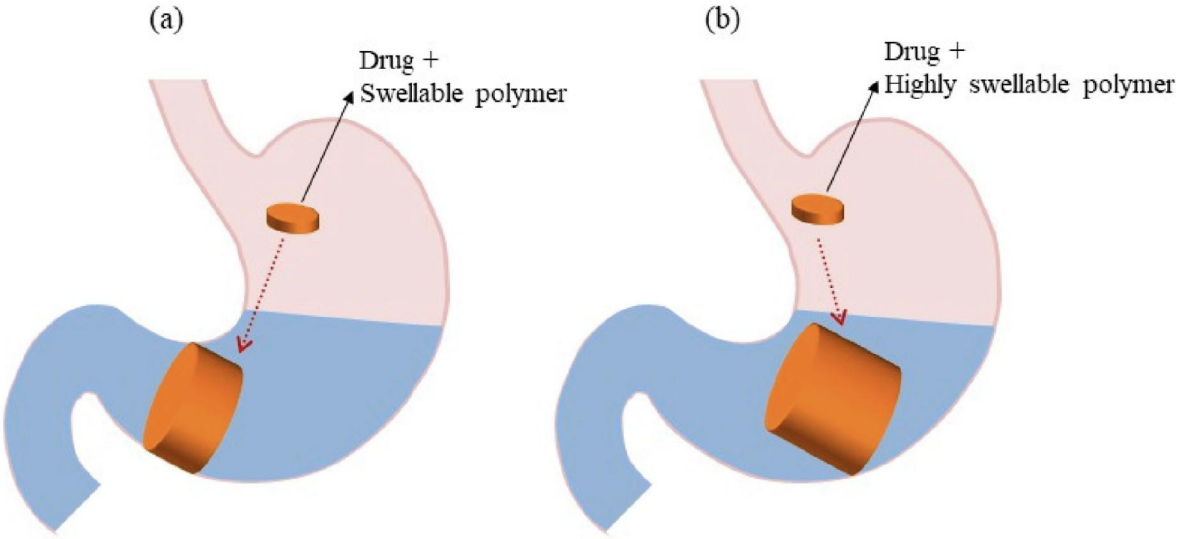

Fig. No. 4: Expandable system

VI. ADVANTAGES AND DISADVANTAGES OF FDDS

ADVANTAGES

• FDDS is advantageous for drugs meant for local action in the stomach, e.g., antacids.

• The FDDS is advantageous for drugs absorbed through the stomach, e.g., ferrous salts and antacids.

• A floating dosage form is a widely accepted approach, especially for drugs that have limited absorption sites in the upper small intestine.

• FDDS dosage forms are advantageous in cases of vigorous intestinal movement and diarrhea, as they help retain the drug in the stomach in a floating condition, resulting in better therapeutic response.

• Acidic substances like aspirin may irritate the stomach wall when they come into contact with it; hence, HBS/FDDS formulations may be useful for the administration of aspirin and similar drugs.

• Provides ease of administration and better patient compliance.

• Reduces the frequency of dosing.

• Enhances the bioavailability of drugs.

• The active ingredient is administered directly to the site of action, which reduces or eliminates adverse effects.

DISADVANTAGES

• Many factors affect gastric retention, including gastric motility, pH, and the presence of food. Because these variables are not constant, buoyancy cannot always be predicted.

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• Drugs that irritate or damage the stomach mucosa should not be formulated as floating drug delivery systems.
• Due to the all-or-none gastric emptying process, there is significant variation in stomach emptying time.
• Floating dosage forms should not be administered immediately before bedtime.
• For drugs with poor solubility or non-uniformity in gastric fluids, floating systems may not be suitable.

TREATMENT

Proton Pump Inhibitors (PPIs)

All currently approved proton pump inhibitors are benzimidazole derivatives, which are heterocyclic organic molecules containing both a pyridine and benzimidazole moiety linked by a methylsulfonyl group.

The prototypical example of this structure, Omeprazole, was the first clinically useful proton pump inhibitor. Subsequently introduced drugs include Lansoprazole, Pantoprazole, Rabeprazole, and the stereoisomeric compounds Esomeprazole and Dexlansoprazole.

Although these drugs differ in substitutions on their pyridine and/or benzimidazole rings, they are generally similar in pharmacological properties.

Mechanism of Action

The mechanism of action of PPIs is characterized by irreversible inhibition of the enzyme system H^+/K^+ ATPase (proton pump), which is located in the gastric parietal cells.

This enzyme promotes the secretion of protons (H^+ ions) into the gastric lumen, which is the final step in gastric acid production.

PPIs are administered as prodrugs (inactive form) and require activation through protonation of tertiary amines present in their structure. This leads to a rearrangement process that converts them into their active form.

Once activated, PPIs bind irreversibly to the proton pump, resulting in a significant reduction in gastric acid secretion

TABLE: CATEGORY OF DRUGS, MECHANISM OF ACTION, AND ADVERSE EFFECTS

Category	Drug	Mechanism of Action	Adverse Effects
Proton Pump Inhibitors	Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole	Inhibition of gastric H^+/K^+ ATPase (proton pump) enzyme system	Headache, abdominal pain, diarrhea, nausea, vomiting, constipation, flatulence, Vitamin B12 deficiency, osteoporosis
H_2 Receptor Blockers	Cimetidine, Famotidine, Nizatidine, Ranitidine	Blocking histamine action at H_2 receptors of parietal cells	Headache, anxiety, depression, dizziness, cardiovascular effects, thrombocytopenia
Antacids	Aluminium hydroxide, Magnesium hydroxide	Neutralizes gastric acid by increasing gastric pH above 4	Constipation (Aluminium), diarrhea (Magnesium), electrolyte imbalance
Antacids	Magnesium hydroxide	Inhibits the proteolytic activity of pepsin and causes osmotic retention of fluid	Constipation, abdominal cramping, diarrhea, electrolyte imbalance
Potassium-Competitive Acid Blocker	Vonoprazan	Inhibits H^+, K^+ ATPase in gastric	Nasopharyngitis, fall, confusion

Category Drug Mechanism of Action Adverse Effects

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VI. INGREDIENTS AND FORMULATIONS

Ingredients

The formulation of floating drug delivery systems was carried out using various pharmaceutical excipients selected based on their functional properties.

Omeprazole was used as the active pharmaceutical ingredient (API) due to its effectiveness in the treatment of gastric disorders such as peptic ulcers and gastroesophageal reflux disease.

Hydroxypropyl Methylcellulose (HPMC K4M and HPMC K15M) was used as a rate-controlling polymer, which helps in sustaining the drug release and maintaining the integrity of the dosage form.

Ethyl cellulose and Eudragit polymers were used as matrix-forming agents to provide structural support and control drug release.

Polyvinyl alcohol (PVA) was used as a stabilizing agent in the aqueous phase during the preparation of microspheres.

Sodium bicarbonate and citric acid were used as gas-generating agents in floating systems to produce carbon dioxide, which helps in achieving buoyancy.

Crospovidone, Sodium Starch Glycolate, and Croscarmellose Sodium were used as superdisintegrants in the immediate release layer.

Lactose and Mannitol were used as diluents to increase bulk and improve compressibility.

Talc and Magnesium Stearate were used as lubricants to reduce friction during tablet compression.

Polyethylene glycol (PEG) and Span 80 were used as surfactants to enhance solubility and stabilize the emulsion during microsphere preparation.

All excipients used were of analytical grade and were compatible with the drug.

Formulation

Different formulations were prepared by varying the drug-to-polymer ratio to study the effect of polymer concentration on drug release behavior and floating properties.

The floating microspheres were prepared using different organic-to-aqueous phase ratios, such as:

- 1:2 ratio
- 1:5 ratio
- 1:10 ratio

It was observed that microsphere formation did not occur at the 1:2 ratio, whereas successful formation was achieved at 1:5 and 1:10 ratios.

A total of five formulations (F1–F5) were prepared by altering the concentration of polymers. These formulations were evaluated for:

- Product yield
- Drug content
- Entrapment efficiency
- In vitro drug release
- Percentage buoyancy

Among all formulations, the optimized formulation (F5) showed:

- Highest product yield
- Maximum drug content
- Better entrapment efficiency
- Sustained drug release behavior

Thus, the formulation variables such as polymer concentration and phase ratio play a significant role in determining the performance of the floating drug delivery system.

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VII. RESULTS AND DISCUSSION

The melting point of Clarithromycin and Omeprazole was found to be 220–221°C and 155–157°C, respectively.

The UV absorption of 10 µg/ml solution for clarithromycin (reacted with methyl orange and extracted with chloroform) and omeprazole in 0.1 N HCl in the range of 200–800 nm exhibited maximum absorption at 306 nm in the case of omeprazole and at 416 nm in the case of clarithromycin using UV spectrophotometry.

The results of Omeprazole Floating Microspheres formulated at 1:5 organic to aqueous phase ratio showed that five formulations were prepared and evaluated for product yield and other parameters.

Table 2: Omeprazole Floating Microspheres at 1:5 Organic to Aqueous Phase Ratio

Code	Ratio	Practical Yield (%)	Drug Content (%)	Entrapment Efficiency (%)	% Drug Release	% Buoyancy
F1	1:15	75.9	50.0	94.1	67.2	74.8
F2	1:20	78.5	52.8	94.3	66.0	76.1
F3	1:25	80.1	53.8	87.5	63.2	70.9
F4	1:30	79.1	53.3	93.2	58.4	76.3
F5	1:35	86.4	93.9	98.0	62.9	72.8

In Vitro Drug Release

Different formulations of Omeprazole microspheres prepared at 1:5 organic to aqueous phase ratio were evaluated for in vitro drug release.

Table 3: In Vitro Drug Release Data of Omeprazole Floating Microspheres

Time	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)
30 min	5.5	4.2	9.5	5.3	4.5
1 hr	8.4	8.4	18.2	6.0	7.2
2 hr	11.9	12.6	20.0	8.4	12.3
3 hr	14.1	14.2	24.3	13.2	14.5
4 hr	17.9	18.3	26.4	14.1	17.2
5 hr	21.6	19.9	28.5	16.6	18.9
6 hr	26.5	22.5	31.7	18.9	21.5
7 hr	30.6	25.0	35.0	21.5	32.1
8 hr	33.2	27.3	39.6	24.0	37.6
9 hr	38.4	32.3	42.2	27.1	39.9
10 hr	40.7	39.4	44.0	27.8	48.2
11 hr	51.0	42.5	48.0	32.5	49.0
12 hr	67.2	66.0	63.2	58.4	62.9

Observations

• The micromeritic properties such as bulk density, tapped density, angle of repose, compressibility index, Hausner's ratio, and particle size distribution of the omeprazole instant release layer blend and clarithromycin gastro-retentive layer were studied.

• All the blends/granules showed good compression properties, and the values of bulk density indicated good packing characteristics.

• Treatment of peptic or gastric ulcer requires an antibacterial agent like Clarithromycin, a broad-spectrum antibiotic effective against H. pylori, along with a gastric acid suppressing drug such as Esomeprazole magnesium trihydrate, a proton pump inhibitor.

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• Clarithromycin has its absorption window in the stomach, whereas esomeprazole is absorbed well from the small intestine due to its instability in gastric conditions.
• Based on previous studies, a novel core-in-coat gastro-retentive tablet was developed using the compression coating method.
• The dosage form contained 20 mg of esomeprazole as an enteric-coated core tablet within a coat formulation containing 250 mg clarithromycin as a single unit.
• The clarithromycin coat tablets were formulated as FDDS/GRDDS, whereas the esomeprazole core was designed as an enteric release tablet.

DISCUSSION

In the present investigation, Omeprazole-loaded floating microspheres were successfully prepared by the solvent evaporation technique. The process parameters, such as stirring time, stirring speed, and organic-to-aqueous phase ratio, were optimized to obtain a stable formulation.

Floating microspheres were prepared at 1:2, 1:5, and 1:10 organic-to-aqueous phase ratios. It was observed that no microsphere formation occurred at the 1:2 ratio, whereas successful microsphere formation was observed at 1:5 and 1:10 ratios.

A total of five formulations were prepared at each of the 1:5 and 1:10 ratios by varying the drug-to-polymer ratio, in order to study the effect of polymer concentration on evaluation parameters such as:

• Product yield
• Drug content
• Entrapment efficiency
• In vitro drug release
• Percentage buoyancy

Among the five formulations prepared at the 1:5 organic-to-aqueous phase ratio, the F5 formulation was identified as the optimized formulation due to:

• Highest product yield
• Maximum drug content
• Highest entrapment efficiency
• Sustained drug release characteristics

The percentage buoyancy of the optimized F5 formulation was found to be 72.8%, indicating good floating behavior.

The in vitro drug release profiles of all formulations were compared. It was observed that the F5 formulation prepared at 1:5 ratio released 68.9% of the drug over a period of 12 hours, demonstrating its sustained release property.

Further, various kinetic plots were constructed for the F5 formulation to determine the order of drug release and mechanism. From these plots, it was concluded that the formulation follows zero-order kinetics with a Fickian diffusion mechanism, indicating controlled and predictable drug release.

VIII. CONCLUSION

The optimized bilayer tablet of Clarithromycin and Omeprazole was successfully formulated and evaluated for various parameters, including hardness (5.13 kg/cm²), friability (0.82%), thickness (5.42 mm), and floating time (12 hours). All evaluation results were found to be within acceptable limits.

The final optimized bilayer formulation showed 98.23% drug release within 12 hours, indicating effective sustained release characteristics.

Thus, the optimized bilayer floating tablets of Clarithromycin and Omeprazole appear to be suitable for further pharmacodynamic and pharmacokinetic studies to evaluate their clinical safety in suitable animal and human models.

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This study demonstrates that the bilayer floating tablet system is a valuable drug delivery approach, providing controlled drug release at a specific site of action. Over the years, various attempts have been made to control the time course and site specificity of drug delivery through different dosage forms and modifications.

The development of microspheres and floating systems aims to produce a drug delivery system that is safe, effective, and capable of maintaining consistent therapeutic drug levels in the body for an extended period. Additionally, such systems improve the handling and stability of the drug.

The study conclusively demonstrated that floating tablets of Omeprazole, prepared using a combination of HPMC K15M and HPMC K100M polymers, were successfully developed by the wet granulation method, resulting in improved patient compliance and product quality.

A comparative drug release study of Omeprazole from the pure drug and optimized formulation in 0.1 N HCl (pH 1.2) confirmed the enhanced release characteristics of the developed formulation.

REFERENCES

[1]. Kaushal Sahil, Dev Dhruv, Prasad D. N., Sharma Rajni. Formulation and optimization of omeprazole floating tablet by wet granulation technique. Journal of Drug Delivery & Therapeutics. 2019; 9(3-s): 679–687.

[2]. Gaurav Kumar, Vivek Jain, Shradha Shende, Prabhat Jain. Formulation and evaluation of bilayer tablets of clarithromycin and omeprazole against Helicobacter pylori infection. The Pharma Innovation Journal. 2019; 8(1): 407–412.

[3]. Bhavna Patel. Formulation and evaluation of omeprazole gastroretentive floating tablets for the treatment of peptic ulcer. International Journal of Scientific Research and Management Studies. 2015; 4(6): 51–52.

[4]. Putta Rajesh Kumar, Hiremath Doddayya, S. Rajendra Reddy. Design and evaluation studies on novel floating tablets for peptic ulcer treatment. Journal of Advanced Pharmacy Education & Research. 2011; 2: 159–176.

[5]. Ramya Shivani B., Krishna Sailaja A. Preparation and evaluation of floating microspheres by solvent evaporation method. International Journal of Basic and Applied Chemical Sciences. 2015; 5(3): 67–78.

[6]. Mohanty Chandan, Tabassum Rahila, M. Srikanth, G. Natesh. Design and in-vitro evaluation of stomach-specific floating microspheres of omeprazole. Journal of Drug Delivery & Therapeutics. 2013; 3(5): 31–40.

[7]. Waleed A. Ismail, Ehab F. Mostafa. A comparison between conventional triple therapy and sequential therapy on tolerance of treatment and eradication of Helicobacter pylori infection in Egyptian patients. The Egyptian Journal of Internal Medicine. 2018; 30: 90–95.

[8]. Mohamed Saeed Hussein Gomaa, Maha Mosaad Mosaad. Correlation between Helicobacter pylori infection and reflux esophagitis: still an ongoing debate. The Egyptian Journal of Internal Medicine. 2017; 29: 24–29.

[9]. Rui Zhang, Pengpeng Guo, Jinping Zhou, Peixia Li, Jing Wan, Chunxiao Yang, Jiali Zhou, Yani Liu, Shaojun Shi. Pharmacokinetics and bioequivalence evaluation of omeprazole and sodium bicarbonate dry suspensions in healthy Chinese volunteers. Scientific Reports. 2023; 13: 1–10.

[10]. Guilherme A. Soares, Deivid W. Pires, Leonardo A. Pinto, Gustavo S. Rodrigues, André G. Prospero, Gabriel G. A. Biasotti, Gabriela N. Bittencourt, Erick G. Stoppa, Luciana A. Corá, Ricardo B. Oliveira, José R. A. Miranda. The influence of omeprazole on the dissolution processes of pH-dependent magnetic tablets assessed by pharmacomagnetography. Pharmaceutics. 2021; 13(8): 1274.