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Formulation and Evaluation of Famotidine Floating Tablet

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Abstract: *The aim of this study is to prepare the famotidine gastric retention system. Famotidine Floating tablet were prepared by using Guar gum and Xanthan gum by effervescent Technique. Sodium bicarbonate is added to make fuel. Floating tablets are evaluated for weight uniformity, hardness, friability, drug content, in vitro buoyancy, and dissolution studies. The effect of citric acid on drug release profile and flotation properties was investigated. It has been shown that the prepared tablets have a positive effect on the body. All preparations showed good buoyancy in vitro. In in vitro flotation studies, tablets expandradially and axially. It has been found that the tablet remains floating for 6 hours. Lowering the citric acid level increases floating time, but the tablets float longer the aim of this study is to prepare a floating drug carrier system of famotidine. Famotidine is poorly absorbed in an acidic environment (upper gastrointestinal tract). When taken orally, its bioavailability is close to 50%. To overcome these shortcomings, this study aims to investigate the variable data of famotidine. The aim of this study is to prolong the residence time in the stomach by creating floating tablets of famotidine and to investigate the effects of different polymers on its release. Three famotidine formulations containing various polymers were developed through optimization The prepared tablets were evaluated in terms of physicochemical parameters such as hardness, floating properties (swimming delay time, floating time) and chemical content. Physicochemical parameters of the formulated tablets were found within normal limits.*

Keywords: Famotidine

I. INTRODUCTION

Famotidine is a histamine H2 receptor antagonist. It is widely used in the treatment of stomach ulcers, duodenal ulcers, Zollinger-Gehrig-Ellison syndrome and gastroesophageal reflux. For the treatment of stomach and duodenal ulcers the dose is 40 mg orally every day at bedtime for 4 to 8 weeks. The recommended dose for gastroesophageal reflux disease is 20 mg orally twice daily for 6 to 12 weeks; If gastroesophageal reflux disease is associated with esophageal ulceration, the recommended dose is 40 mg twice daily for a similar period. For short-term symptoms such as heartburn or painless indigestion, the recommended dose is 10 mg twice daily. The initial oral dose for Zollinger-Ellision syndrome is 20 mg every 6 hours and increased as needed; Doses up to 80 mg per day have been used . Famotidine's low bioavailability (40-45%) and short biological half-life (2.5-4.0 hours) after oral administration Support the development of sustained-release formulations. Stomach-protecting drug delivery systems can be placed in the stomach and help improve the oral administration of drugs that have an absorption window in certain areas of the intestine. These systems facilitate the release of drugs before they reach the absorption window, providing better bioavailability. Gastrointestinal Oral treatment of H2 receptor antagonists, such as famotidine or ranitidine, in combination with anti-inflammatory drugs has been reported to promote local delivery of these drugs to receptors in the parietal cell wall. Gastroretentive drug delivery systems can be placed in the stomach and help improve the oral delivery of drugs with an window to certain areas of the intestine. These systems facilitate the release of the drug before it reaches the absorption window, thus ensuring good bioavailability. Oral treatment of gastric infection with h2 receptor antagonists such as famotidine or ranitidine combined with anti-inflammatory drugs has been reported to promote local drug delivery to receptors in the parietal cell wall. Drug administration also increases the absorption bioavailability of receptor sites in the stomach wall, making the drug effective in reducing stomach acid. Therefore, this principle can be used to improve the body and local delivery of famotidine, which will reduce stomach acid.

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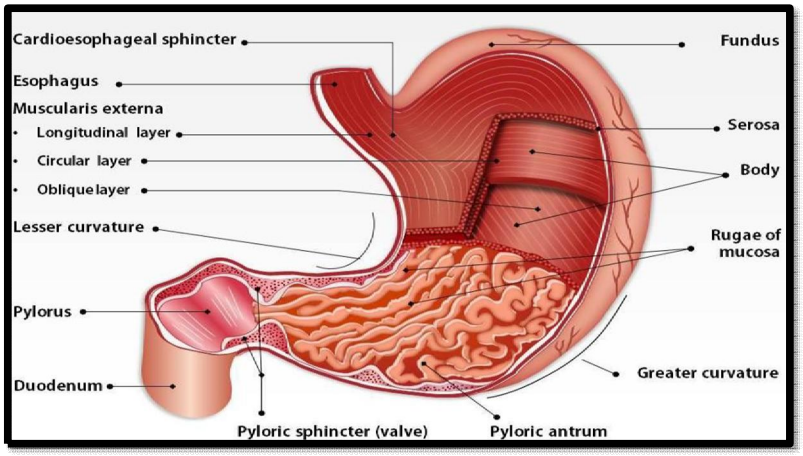
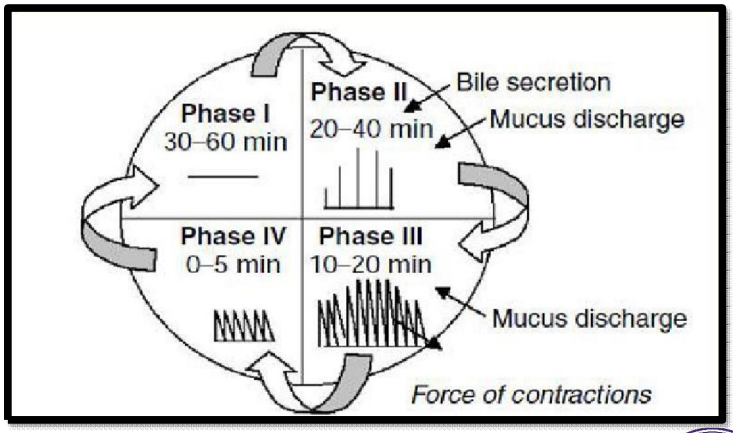
Stomach Anatomy:

The basic function of the stomach is to process and transport nutrients. It acts as a short-term store and can consume large amounts of food. Most enzymatic digestion, especially the digestion of proteins, begins in the stomach. The strength of the stomach smooth muscles mixes and digests the food with the intestines, causing the food to liquefy. As food liquefies in the stomach, it is gradually released into the small intestine for further processing. Anatomically, the stomach is divided into 3 regions: fundus, body and antrum (pylorus).The vision includes the money and body of the stomach as the basis of negative things,The antrum is used as the main mixing place and the milk pump on an empty stomach.It is reported that the average pH value in a healthy diet is 1.1±0.15.But when food enters the stomach, the pH will rise to levels of 3.0 to 4.0 due to the buffering capacity of protein. However, during fasting, women's basal gastric secretions are slightly lower than men.



Gastric emptying occurs in both fasting and eating situations. However, the movement patterns of these two states are different. During the fasting period, electrical disturbances occur that make the stomach and intestines work every 2-3 hours. This is called the interdigestive myoelectric cycle or migration myoelectric cycle (MMC) and is divided into 4 stages below

1. The first phase (basal phase) lasts 30 to 60 minutes and there are some contractions.
2. The second phase (pre-burst phase) lasts 20 to 40 minutes and is accompanied by the capacity for interaction and commitment. As the stage progresses, intensity and frequency gradually increase.
3. The third phase (burst phase) lasts 10 to 20 minutes. It requires short-term strength and regularity. Due to this wave, not all material in the stomach can be transferred to the intestines. He is also known as a real estate agent. 4. Phase 4 lasts from 0 to 5 minutes and occurs between Phase 3 and Phase 1 of 2 consecutive phases.



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Mechanism of Floating system:

The system floats on the stomach and a reasonable amount of the drug is slowly released during passage through the stomach.The remainder is properly removed after release. However, In order to achieve the principle of paying attention to buoyancy and keeping the dose in buoyant form, In addition to the appropriate buoyancy level (F), the core content must be minimal. On the food. Its work involves measuring the balance (with respect to time) of F, the force that holds the object in water; if RW is on the better side, the object floats better (see Figure 3(b)). Optimize FDDS and prevent its deficiencies Unpredictable intragastric buoyancy Capacity change related to stability and enduranceRW or

F = F Buoyancy-F Gravity = (Df-Ds) gV

Where,

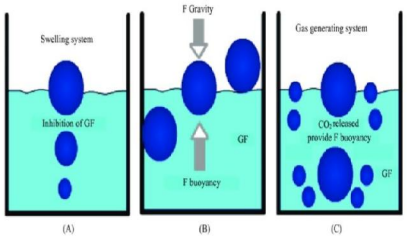
F= total vertical force,

Df=liquid density,

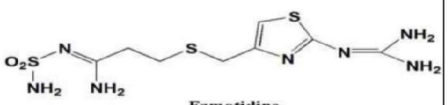
Ds=object density,

V=volume,

G=acceleration due to gravity.



DRUG PROFILE

Parameter	Information
Drug Name	Famotidine
Brand Name	Pepcid & zantac
Structure	 Famotidine
Weight	337.45g/mol
Chemical formula	C8H15N7O2S3
IUPAC Name	3-[({2-[(diaminomethylidene)amino]-1,3-thiazol-4yl}methyl)sulfanyl]-N-sulfamoylpropanimidamide
BCS Class	Class II
Half life	0.18 to 0.5 Hrs
Pka 1	6.76 , 6.98 & 6.89
Pka2	6.76 , 6.98 & 6.89
Log P	0.6
Particle size	250 – 850 micron
Hygroscopicity	Non- hygroscopic
Polymorphic form	Form A ,Form B & From C(Mixture)
Solid state Stability	Proper storage, away from moisture and at controlled temperatures, helps maintain its stability
Melting Point	167°C
T max	1 to 3h
Solubility	Freely soluble in glacial acetic acid; very slightly soluble in water; insoluble in ethanol

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II. MATERIALS AND METHODS

Materials:

Famotidine was purchased from Balaji drugsB-28, Thakordwar Soc., B/h. Spinning MIII, Varachha Road, Surat-395010 (Gujrat). And other excipients are available at samarth institute of pharmacy belhe.

Method of Preparation:

The composition of different formulations of famotid inefloating tablets is shown in TableFamotidine, HPMCK4M, Xanthan gum,starch ,talc ,DCP were passed through sieve no. 80 separately. Sodium bicarbonate was passed through sieve no. 44. All the ingredients were mixed in proportion shown in Table . The powder blends were lubricated with Magnesium stearate and these lubricated blends were compressed into tablets using tablet punching machine.

Ingredients	F1	F2	F3	F4	F5	F6
Famotidine	40	40	40	40	40	40
HPMC K4M	90	80	70	72	72	72
Xanthan gum	3	4	5	6	9	12
DCP	36	36	36	36	36	36
Starch	47	57	67	59	56	52
Sodium bicarbonate	78	78	78	78	78	78
Magnesium stearate	6	6	6	6	6	6
Talc	3	3	3	3	3	3
Total weight	303	304	305	300	300	330

Evaluation Parameters :

Pre compression parameters-

Evaluation of the mixture of and granules of the main properties of fluiditygranules and powders (before pressing) were characterized by the angle of compressibility index (Carr's index) and Hausner ratio, bulk density, Tappeddensity.

Post compression parameters-

Thickness and Diameter-

The thickness and diameter of the tablets were measured With a screw micrometer that had a scale of 0–25 mm and was capable of Differentiation to 0.01.

Evaluation of Weight variation-

20 tablets of each formulation were weighed individually and the average weight was calculated Have been determined. Between 20 tablets; just two tablets can be of 5% of the average weight and None deviated by more than twice this percentage. The weight change test The United State Pharmacopeia (USP) weight change test was performed by weighing 20 tablets individually to calculate the average weight and compare the individual Tablet weight to average weight.

Deviation (%) = Average tablet weight – Individual tablet weight / Average weight Tablet X 100

Hardness test –

Resistance of tablets to transportation or breakage under storage conditions, Transportation and handling before use depends on its hardness. Hardness The tablet of each formulation was measured with a Monsanto Hardness Tester. The Hardness was measured in units of kg/cm2. The hardness or crushing strength of tablets is The force required to break the tablet under diametrical compression. Power is measured In kg and a hardness of approx. 3-5 kg/cm2 is considered satisfactory for Uncoated tablets.

Friability Test-

Tablet friability determined using a Roche friabilizer. This device is subject to tablet to the combined effect of abrasion and impact in a plastic rotating chamber at 25 rpm and dropping the tablet 6 inches each revolution. Before a weighed sample of tablets was placed in the fribilator and subjected to the test 100 revolutions. The tablets were dusted with a soft muslin cloth and reweighed. USP the limit is 0.5 to 1%.

Friability (%) = (Initial wt of tablet- Final wt of tablet /Initial wt of tablet) X 100

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Disintegration Time –

One tablet was placed in each USP tube to record the disintegration time disintegration apparatus. The device is used to move the basket assembly containing tablet up and down at a distance of 25-32 cycles per minute.

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