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FORMULATION DEVELOPMENT OF FAMOTIDINE FLOATING TABLETS USING MELT-SOLIDIFICATION METHOD

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ABSTRACT

The goal of the current study is to create floating famotidine tablets employing a variety of excipients, including DCP, HPMC K4M, and HPMC K100. The goal is to increase patient compliance and treatment effectiveness for illnesses related to acid reflux. tablets made using the melt-solidification method. The formulation was designed to give regulated release of famotidine and prolong gastric resistance. The tablets were able to float in the stomach because sodium bicarbonate produced carbon dioxide. A factor in the persistent release was HPMC K4M. The impact of HPMC's viscosity grades and polymer concentration on the medication release profile was assessed. The drug release profile was not significantly impacted by changing the viscosity grade of HPMC from K4M to K100MCR. The tablets' floating behaviour, drug release, and other characteristics, such as weight fluctuation, hardness, friability, and homogeneity of drug content, were assessed.

Keywords: HPMC K 4 M, Tablet, HPMC K 100, Gastric Resistance

INTRODUCTION

When compared to alternative drug intake methods, oral administration is the most practical way to distribute medications and is linked to higher patient compliance. Oral administration is only useful for significant medications from a variety of pharmacological categories that have low oral bioavailability because of partial absorption and/or GI tract breakdown. A narrow absorption window at the upper

portion of the gastrointestinal tract is a characteristic of some of these medications. This is because the small intestine's proximal region has longer absorption characteristics, such as wider spaces between tight junctions and a high density of active transporters. The duodenum and jejunum have broad absorption capabilities; however, because of their quick passage, the amount of absorption at these locations is restricted. Improving a NAW drug's gastric residence time (GRT) may greatly increase the net extent of its absorption **[1]**. Since dosage forms stay in the stomach longer than traditional dosage forms, the ability to extend and regulate the emptying time is a crucial asset. Gastric emptying of dosage forms is a highly variable process. Designing controlled release systems for improved absorption and increased bioavailability presents a number of challenges. The difficulty in limiting the dose form in the intended region of the gastrointestinal tract is one of these challenges. The process of drug absorption from the gastrointestinal tract is intricate and influenced by numerous factors **[2]**.

Floating drug delivery systems, low-density systems, raft systems using alginate gel, bioadhesive or mucoadhesive systems, high-density systems, superporous hydrogel, and magnetic systems are some of the current techniques used to create an efficient gastroretentive drug delivery system. The floating dosage forms have been utilized the most out of all of these.

Floating medication delivery devices remain afloat in the stomach for a long period without affecting the stomach's pace of emptying because their bulk density is lower than that of gastric fluids. While the system is floating on the contents of the stomach, the medication is gradually eliminated at the proper rate. The residual system in the stomach is emptied once the medicine is released. As a result, the stomach retention time is prolonged and the variance in plasma drug concentration is managed.

Famotidine is a thiazole ring that contains substances that inhibit acid secretion and have a strong effect on H2 receptors. Famotidine is classified as a biopharmaceutical BCS class 2 medicine because of its high permeability and low solubility. Famotidine also speeds up the healing of duodenal ulcers and reduces food-stimulated and basal acid secretion by 90% **[3]**.

MATERIALS & METHOD

Materials

Cerata Pharmaceuticals Ltd. sent us famotidine as a gift. Sakshi Chem Sciences Pvt. Ltd. provided Surat, HPMC. Vizag Chemicals in Visakhapatnam supplied Nagpur and DCP, FMC Health and Nutrition in Gujarat provided talc, while Merk Pvt. Ltd. in Mumbai supplied

magnesium stearate and sodium bicarbonate.

Methods

Preparation of floating tablets

Table 1 displays the ingredients of several famotidine floating tablet formulations. Each component, including famotidine, was weighed independently before being run through sieve number 80. DCP, HPMC K4M, HPMC K100, the active substance, and the other ingredients were combined. Using 9.5 mm flat-faced round tooling on a single-punch tablet machine, the powder mixes were compressed into tablets after being lubricated with 2% w/w magnesium stearate and 1% w/w talc.

To create the final blend, the remaining lubricant, magnesium stearate, was then added and combined with the combination above. Tablets with a hardness of 4.5 to 5 kg/cm2 were obtained by adjusting the compression force. From FT1 to FT6, six formulas were created and programmed.

After undergoing evaluation trials, the granules were compressed using a 6.45 mm flat punch with Shakti Tab press, Ahmadabad, into floating tablets weighing roughly 40 famotidine.

Additional assessment trials were conducted using the prepared floating pills.

Table 1: Composition (mg/tablet) of floating tablets of Famotidine

Ingredients	F1	F2	F3	F4	F5	F6
Famotidine	40	40	40	40	40	40
HPMC K4M	45	60	75	-	-	-
HPMC K 100	-	-	-	45	60	75
DCP	36	36	36	36	36	36
MCC	110	95	80	110	95	80
Sodium bicarbonate	60	60	60	60	60	60
Magnesium stearate	6	6	6	6	6	6
Talc	3	3	3	3	3	3
Total Weight	300	300	300	300	300	300

Preformulation studies

As part of preformulation research, parameters such as the melting temperature, IR spectra, angle of repose, bulk density, tapped density, and Hausner's ratio were ascertained **[4]**.

Drug-excipient compatibility studies

To determine any potential interactions between famotidine and the excipients utilized in the formulation, compatibility studies were conducted. Using the Infra-Red spectrophotometer, physical combinations of the medicine and excipients were made in order to investigate compatibility **[5]**.

Evaluation of floating tablets

Physical parameters

Thickness

The tablets' thickness was measured using a vernier calliper. After testing tablets from every batch, average values were determined and reported in millimeters.

Hardness

The ability of a tablet to withstand breaking

during handling, storage, shipment, and transit is known as its hardness. The Monsanto hardness tester was used to measure the tablets' hardness.

Friability

The friability was tested using the Roche Friabilator. This is how the percentage of friability (% F) was determined.

% F = [Initial weight - Final weight / Initial weight] × 100

Weight variation test

The test was conducted in accordance with the guidelines and specifications provided by the pharmacopoeia.

Floating Behavior

Floating lag time and floating time were used to calculate the in-vitro buoyancy. The tablets were put in a dissolving vessel with 200 milliliters of 0.1N HCl. Floating lag time was defined as the amount of time needed for the tablet to float and rise to the surface. Floating time is the amount of time the tablet stays afloat on the solution's surface **[6-7]**.

Drug content uniformity

After being weighed, ten tablets were transported to a mortar and smashed into a powder. A 100 mL volumetric flask was filled with a quantity of powder weighing 100 mg of the medication, then 0.1 N HCl was added. After that, it was cooked for 30 minutes at 60°C. A membrane filter (0.45µm) was used to filter the solution, and a UV-visible spectrometer was used to detect the absorbance at 260 nm. A standard graph was used to calculate the amount of medication contained in one tablet **[8]**.

In-Vitro Dissolution Studies

Using the conditions listed below, an in-vitro dissolution research was conducted on an Electrolab TDT 06-P.

Method:- The dissolution vessel was filled with 900 mL of enzyme-free simulated stomach fluid with a pH of 1.2. The medium's temperature was fixed at 37°C ± 0.5°C. Each dissolution tank contained a single tablet from a different batch, and the paddle's rotating speed was set at 50 rpm. For up to 12 hours, 5 mL of the sample was taken out at prearranged intervals of one hour, and the same volume of fresh medium was supplied right away. A 0.45µ µm membrane filter was used to filter the 2.5 mL of the extracted material that had been diluted to 25 mL in a volumetric flask. Using a UV-visible spectrophotometer, the resulting samples were examined for drug content at 260 nm using enzyme-free simulated stomach juice as a blank for the Famotidine floating tablets. The following expression was used to determine the drug's content. The following formula was also used to determine the percentage cumulative drugs release **[9]**.

Stability study

Stability studies were conducted in accordance with ICH recommendations to

evaluate the stability of the medication and formulation. For their drug content and other parameters, the promising formulation was examined for short-term testing for one month at 25°C ± 2°C/ 60% RH ± 5% and for accelerated testing for two months at 40°C ± 2°C/ 75% RH ± 5%. **[10]**.

RESULTS & DISCUSSIONS

A number of physical characteristics of the prepared floating tablets were assessed. It was determined that the floating tablets' physical characteristics were adequate. No typical tablet flaws were found. As stated in the procedures, preformulation studies were conducted. It was found that the melting point was between 1620 and 1640 degrees Celsius, indicating that the famotidine medication was pure. The direct granulation process was used to manufacture the floating tablet formulation. Following preparation, the tablets were assessed for variables such as weight fluctuation, hardness, thickness, friability, and floating lag time **[11]**.

Famotidine's IR spectra were obtained using Bruker's ATR method in order to verify the drug's purity. Famotidine's distinctive peaks can be seen in the spectra, which resemble the typical spectra provided by the instrumental analysis. **Figure 1** shows the infrared spectrum.

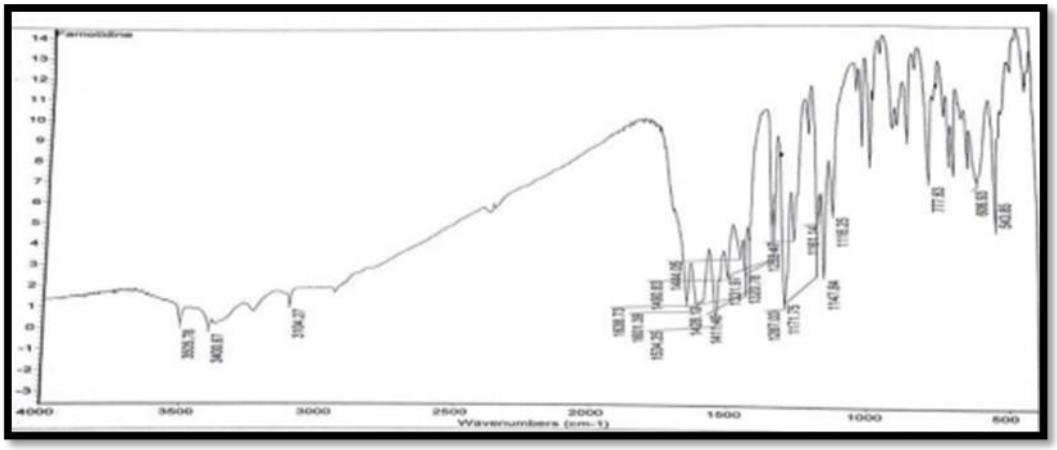

Figure 1: FTIR Spectra of Famotidine

Table 2: Characteristic IR absorption peaks of functional groups in Famotidine

Functional group	Range cm-1	Peak cm-1
C-H Alkane	2900 – 3000	2937.1
C=N Imines	1620-1660	1638
N-H Amine	3200-3300	3200.7
C-H Aromatic ring	1600-1680	777.

The flow characteristics of the powder mixtures made for compressing floating tablets were assessed. The range of the angle of repose was 19.24 to 20.29. It was discovered that the taped density ranged from 0.66 to 0.72 (g/ml). For the powder mixture of various formulations, Hausner's ratio was between 1.11 and 1.17, and Carr's

index was between 13.05 and 14.19. All of the results showed that the powder blends had good compressibility and flowability **(Table 2)**.

Table 3: Preformulation parameters for powder blend

Blends	Angle of Repose (%)	(θ) Carr's Index	Hausner's ratio	Tapped Density	Bulk Density	Flow property
F1	20.03°±0.625	13.96±0.361	1.15±0.002	0.72	0.60	Excellent
F2	20.78°±0.686	14.19±0.383	1.17±0.005	0.71	0.58	Excellent
F3	20.29°±0.639	14.07±0.372	1.16±0.003	0.72	0.60	Excellent
F4	20.70°±0.695	14.16±0.380	1.16±0.003	0.68	0.57	Excellent
F5	19.74°±0.581	13.24±0.349	1.15±0.002	0.66	0.56	Excellent
F6	19.24°±0.533	13.05±0.336	1.11±0.002	0.71	0.61	Excellent

The sample tablets ranged in weight from 299.9 to 303.2 mg. The weight variance was within a ±5% range, which complies with pharmacopoeia requirements. It was discovered that the various formulations' hardness ranged from 4.9 to 5.1 Kg/cm², which indicates adequate mechanical strength. For every formulation, the friability was less than 1%, indicating that the tablet had strong mechanical resistance. The tablets were determined to be between 3.4 and 3.7 mm thick **(Table 4)**.

Table 4: Results of post-compression properties of famotidine floating tablets

Formulation	Thickness (mm)	Hardness (kg/cm2)	Friability (%)	Weight Variation (mg)	Drug Content (%)	Floating lag time (min)
F1	3.72±0.019	5.13±0.234	0.63±0.081	302.89±2.821	98.42±0.234	4.5
F2	3.52±0.037	5.00±0.367	0.71±0.062	302.32±2.892	99.24±0.267	5.0
F3	3.42±0.043	4.98±0.291	0.59±0.078	299.91±0.998	99.45±0.231	2.9
F4	3.52±0.048	4.99±0.492	0.63±0.085	301.86±1.784	98.02±0.194	3.1
F5	3.62±0.026	5.10±0.231	0.69±0.093	299.85±1.028	97.86±0.289	3.7
F6	3.52±0.038	5.06±0.362	0.72±0.084	303.22±2.995	97.91±0.281	4.2

One minute to five minutes was the range of the floating lag time. The tablet expands (hydrates) as it comes into contact with the contents of the stomach, which raises the pressure and bulk volume of internal voids in the center of the tablet. The tablet floats because of this phenomenon.

The gas-producing chemical sodium bicarbonate may improve the tablets' ability to float. It creates gas when it comes into contact with the stomach's acidic environment. The formulation floats in the acidic environment of the stomach because this gas becomes trapped in the water-soluble polymer matrix. While the drug release decreased as the HPMC content increased, the tablet's swelling increased.

Based on the aforementioned statistics, F3 was selected as the optimal batch for tablet optimization out of all the design batches since it exhibits lower friability (<1), good hardness (4.9 kg/cm2), and a lower floating lag time (2.9 min).

To determine the drug release mechanism, in vitro drug release data from all floating formulations were subjected to linear regression analysis using the Zero order, First order, Higuchi, and Korsmeyer-Peppas models **(Table 5)**.

Table 5: Release kinetics data of famotidine prepared formulations F1 to F6

Formulations	Zero order	First order	Higuchi	Korsmeyer-Peppas	Drug release mechanism
F1	0.989	0.060	0.896	0.943	Fickian
F2	0.986	0.058	0.868	0.947	Fickian
F3	0.993	0.044	0.900	0.928	Fickian
F4	0.986	0.069	0.903	0.927	Fickian
F5	0.991	0.057	0.889	0.972	Fickian
F6	0.981	0.062	0.873	0.924	Fickian

Stability Study

For one and three months, the optimized formulation (F-3) was tested for stability. The drug release for 12 hours after 1, 2, and 3 months was found to be within the range of the planned release profile in the in-vitro drug release research **(Table 6)**. Hardness, friability, weight variation, and drug content did not significantly alter. It was shown that after one, two, and three months, the formulation remained unchanged. It suggests that the formulation that was produced was stable.

Table 6: Stability study of formulation F3

Parameters	1st month	2nd month	3rd month
Physical appearance	Off white, flat-faced	Off white, flat-faced	Off white, flat-faced
Weight variation (mg)	299.83±0.764	299.48±0.921	299.8±0.81
Hardness (kg/cm2)	4.98±0.367	4.98±0.568	4.98±0.89
Friability	0.59±0.082	0.59±0.089	0.59±0.098
Drug content (%)	98.98±0.462	98.87±0.481	98.51±0.91

CONCLUSION

Famotidine floating tablets were successfully manufactured in the current investigation by employing the direct compression approach. Using HPMC K100M, HPMC K4M, and DCP polymers, the current work was conducted to produce the floating medication delivery of famotidine. By producing CO2 gas, sodium bicarbonate allowed the tablet to float in the stomach. Famotidine's regulated release was facilitated by HPMC K4M. Floating pills may decrease gastrointestinal adverse effects, decrease the frequency of doses, and increase the absorption of famotidine. The study showed that it is feasible to produce floating famotidine pills using the direct compression technique, providing a viable method for targeted and long-lasting medication delivery.

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Conflict of interest statement

The authors declared no conflict of interest in this study.

Authors' contributions

All authors approved the final version of the manuscript.

REFERENCES

[1] Streubel A, Siepmann J, Bodmeier R. Gastroretentive drug delivery systems. Expert opinion on drug

delivery. 2006 Mar 1;3(2):217-33.

[2] Hirtz J. The gastrointestinal absorption of drugs in man: a review of current concepts and methods of investigation. British journal of clinical pharmacology. 1985 Apr;19(S2):77S-83S.

[3] Li J, Wang H, Yang B, Xu L, Zheng N, Chen H, Li S. Control-release microcapsule of famotidine loaded biomimetic synthesized mesoporous silica nanoparticles: Controlled release effect and enhanced stomach adhesion in vitro. Materials Science and Engineering: C. 2016 Jan 1;58:273-7.

[4] Srivastava A. K., Wadhwa Saurabh, Mishra B.(2005),Oral Sustained Delivery of Atenolol from Floating Matrix Tablets – Formulation and In Vitro Evaluation. Drug, Dev. Ind. Pharm., 31(4-5), 367-374.

[5] Dave BS, Amin AF, Patel MM. Gastroretentive drug delivery system of ranitidine hydrochloride: formulation and in vitro evaluation. Aaps PharmSciTech. 2004 Jun;5(2):34.

[6] Nakamichi K, Yasuura H, Fukui H, Oka M, Izumi S. Evaluation of a floating dosage form of nicardipine hydrochloride and hydroxypropylmethylcellulose acetate succinate prepared using a twin-screw extruder. International journal of pharmaceutics. 2001 May 7;218(1-2):103-12.

[7] Fell JT, Whitehead L, Collett JH. Prolonged gastric retention: using floating dosage forms. Pharmaceutical technology. 2000 Mar;24(3):82-90.

[8] Talwar N, Sen H, Staniforth JN, inventors; Ranbaxy Laboratories Ltd, assignee. Orally administered controlled drug delivery system providing temporal and spatial control. United States patent US 6,261,601. 2001 Jul 17.

[9] Newman AW. Micromeritics: Brittain HG; Physical Characterization of Pharmaceutical Solids. Marcel Dekker Inc, Newyork; Basel, 1995; 70; 293-94.

[10] "Stability Testing of New Drug Substances and Products", Eur Medicines Agency, 2003; 1-20.

[11] Banker GS, Anderson NR; Tablets: Lachman L, Lieberman HA, Kanig JL; The Theory and Practice of Industrial Pharmacy. 3rd edi, Varghese Publication House, Bombay, 1987; 296-303.