INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH An official Publication of Human Journals



Human Journals **Research Article** February 2024 Vol.:30, Issue:2 © All rights are reserved by SARFARAZ MD et al.

Preparation and Evaluation of Gastro Retentive Matrix Tablets of Famotidine Using Natural Polymers



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Submitted:	19 January 2024
Accepted:	24 January 2024
Published:	29 February 2024





ijppr.humanjournals.com

Keywords: Famotidine, gastroretentive matrix tablets, in-vitro buoyancy, peptic ulcer, natural polymers, xanthan gum

ABSTRACT

Famotidine has been the most widely used drug for the treatment of peptic ulcers for many decades. Famotidine is indicated for active and maintenance therapy of different types of ulcers and hyper secretory conditions. The gastroretentive matrix tablets of famotidine were developed using natural polymers like guar gum, xanthan gum, pectin and tamarind seed powder, gas-forming agent's sodium bicarbonate and citric acid using direct compression technique. The powder blend was subjected to various precompression properties like flow properties, tapped density, bulk density, Carr's compressibility index and Hausner's ratio. The prepared tablets were evaluated for post-compression parameters. The thickness, diameter, hardness, friability, weight variation and drug content were within the limits. Swelling index (%) was found in between 160 - 60% for all formulations. All floating tablets had buoyancy lag time in the range of 4 ± 0.3 (F14) to 25 ± 0.6 (F12) sec. The total floating time was found to be 12 h for all the tablets. Formulation F4 prepared using Xanthan gum released maximum drug - 97% at the end of 12 h. The order of release for different natural polymers used was Xanthan gum>Guar gum>Pectin>Tamarind seed powder. Tamarind seed powder showed maximum controlled release of drug than other polymers. The kinetic studies revealed formulations released the drug by non-fiction super case II type transport mechanism. FT-IR studies concluded that no interaction was observed between the drug and various types of polymers used.

INTRODUCTION

Famotidine is a histamine H₂-receptor antagonist. It is prescribed widely in active duodenal ulcers, gastric ulcers, Zollinger-Ellison syndrome, gastroesophageal reflux disease and erosive esophagitis. It is reported to be about 7.5 and 20 times more potent than ranitidine and cimetidine, respectively, in inhibiting gastric acid secretion. Famotidine reportedly undergoes minimal first-pass metabolism and its oral bioavailability in man has been reported to be low and variable (ranging from 40% to 50%) due to its poor aqueous solubility, high polarity, and gastric degradation. It has a low biological half-life of 2.5 - 4.0 h. Oral administration is the most convenient and preferred means of any drug delivery to systematic circulation. Oral controlled-release drug delivery has recently been of increasing interest in pharmaceutical field to achieve improved therapeutic advantages, such as ease of dosing administration, patient compliance and flexibility in formulation. Drugs that are easily absorbed from gastrointestinal tract (GIT) and have short half-lives are eliminated quickly from the systemic circulation. Frequent dosing of these drugs is required to achieve suitable therapeutic activity. To avoid this limitation, the development of oral sustained-controlled release formulations is an attempt to release the drug slowly into the GIT and maintain an effective drug concentration in the systemic circulation for a long time. After oral administration, such a drug delivery would be retained in the stomach and release the drug in a controlled manner, so that the drug could be supplied continuously to its absorption sites in the GIT.^[1] To formulate a site-specific orally administered controlled-release dosage form, it is desirable to achieve a prolonged gastric residence time by the drug delivery. Prolonged gastric retention improves bioavailability, increases the duration of drug release, reduces drug waste, and improves the drug solubility that are less soluble in a high pH environment. ^[2] Also prolonged gastric retention time (GRT) in the stomach could be advantageous for local action in the upper part of the small intestine e.g. treatment of peptic ulcer, etc. Gastroretentive drug delivery is an approach to prolong gastric residence time, thereby targeting site-specific drug release in the upper GIT for local or systemic effects. ^[3, 4] Over the last few decades, several gastroretentive drug delivery approaches have been designed and developed like high density (sinking) systems, low-density (floating) systems, mucoadhesive systems, super porous hydrogel systems, magnetic systems etc.^[5] Polymers are used in floating system so as to target the drug delivery at specific region in the GI tract i.e. stomach. Both synthetic and natural polymers are used in the floating drug delivery. Natural polymers used in floating system are Guar gum, Chitosan, xanthan gum, Gellan gum, Sodium alginate, etc. Synthetic

polymers used for the floating drug delivery are hydroxypropyl methylcellulose (HPMC), Eudragit, ethyl cellulose, etc. ^[6] Biodegradable or natural polymers can be produced by living organism and are naturally available. They show no adverse reaction on human or on environmental health. Most of the natural polymers are nontoxic and biocompatible because these plant materials are carbohydrates in nature. Natural sources are easily collected in different seasons in large quantities and have low cost. Now in developing countries their productions have been promoted because of its wide use in different industries. ^[7]

Hence the aim of the present investigation was to prepare and evaluate gastro retentive matrix tablets of Famotidine employing natural polymers like tamarind seed powder, guar gum, xanthan gum etc., by direct compression method to prolong the gastric residence time, increase drug bioavailability and effectively treat stomach ulcer.

2.0) MATERIALS AND METHODS

2.1) Materials

Famotidine was received as a gift sample from Hetero Labs Limited- Hyderabad, Telangana, India. Guar gum, Xanthan gum, Pectin were purchased from S.D. Fine chemicals Pvt. Ltd., Mumbai, India. Tamarind seed powder was purchased from Finar chemicals, Ahmedabad, Gujarat. Isabgol husk was purchased from HiMedia Laboratories Pvt. Ltd., Mumbai. Sodium bicarbonate was purchased from Helios Pharmaceuticals, Gujarat. Talc and Citric acid was purchased from S.D. Fine chemicals Pvt. Ltd., Mumbai.

2.2) Pre-compression evaluation of powder blend

The method employed for the preparation of matrix tablets in the study was direct compression for which the drug or the mixture of the drug and polymer should possess good flow properties. Various pre-compression parameters were evaluated for estimating the flow ability of powder. Pre-compression parameters such as angle of repose, bulk density, tapped density; Hausner's ratio and Carr's index of all formulations were evaluated. Since in the study natural polymers were used which usually do not have good flow properties, Lubricants such as magnesium stearate and talc were used to improve the flow property of drug and polymers.

2.3) Preparation of famotidine gastro retentive matrix tablets

The gastro retentive matrix tablets of famotidine were prepared by direct compression method using 10 mm flat-faced punch of 10 station Rimek compression machine employing different natural polymers like guar gum, xanthan gum,pectin and tamarind seed powder in varying concentrations alone and in combination. The formula used in the tablet preparation (F1 - F15) is shown in the Table 1. For the preparation of matrix tablets, weighed quantities of drug, natural polymers, diluents and gas-forming agent (sodium bicarbonate) were taken in a mortar and pestle and thoroughly mixed. White bees wax (q.s.) was melted in a china dish and in a molten state it was gradually added to the powder blend and kneaded to get a soft mass. ^[8] The soft mass was passed through sieve no 10 to get the granules. The granules obtained were dried at room temperature. Later the dried granules were mixed with magnesium stearate and talc as flow promoters and compressed directly using 10 mm flat punches on a 10-station rotary compression machine to give matrix tablets.

2.4) Post compression evaluation

All tablets were evaluated for various parameters related to physical characteristics, mechanical strength and drug release.

2.4.1) General appearance

Morphological characters like shape, colour and texture were determined visually.

2.4.2) Thickness and diameter

Thickness and diameter of prepared tablets (10 no) were tested using Vernier callipers. The test was done in triplicate and the average was determined.

Ingredients (mg)	Formulation Codes														
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	F14	F15
Famotidine	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20
Guar gum	150	200	250	-	-	-	-	-	-	-	-	-	75	-	-
Xanthan gum	-	-	-	150	200	250	-	-	-	-	-	-	75	75	-
Pectin	-	-	-	-	-	-	150	200	250				-	75	75
Tamarind seed powder	-	-	-	-	-	-	-	-	-	150	200	250	-	-	75
Isabgol husk	90	90	90	90	90	90	90	90	90	90	90	90	90	90	90
Sodium bicarbonate	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20
Citric acid	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18
Lactose	100	50	0	100	50	0	100	50	0	100	50	0	100	100	100
Magnesium stearate	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Talc	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Bees wax	qs	qs	qs	qs	qs	qs	qs	qs	qs	qs	qs	qs	qs	qs	qs
Total (mg)	400	400	400	400	400	400	400	400	400	400	400	400	400	400	400

Table 1: Composition of famotidine gastro retentive matrix tablets

Note: qs - Quantity sufficient

2.4.3) Hardness

The hardness of prepared tablets (10 no) was determined by using a Monsanto hardness tester and measured in terms of kg/cm^2 . Test was done in triplicate.

2.4.4) Friability

Roche friability was used for testing the friability of prepared tablets. 10 tablets were accurately weighed and placed in the friability and operated for 100 revolutions. The tablets were de-dusted and reweighed.

Friability (F) was calculated using the following formula:

 $\%F = (W_0 - W/W_0) \times 100$ -----(1)

Where, W_0 and W are the weights of the tablets before after the test respectively. ^[9]

2.4.5) Weight Variation

The weight variation test was done by weighing 20 tablets (Shimadzu digital balance) individually, calculating the average weight and comparing the individual tablet weights to the average. The percentage difference in the weight variation should be within the permissible limits (\pm 5%). The percent deviation was calculated using the following formula [10].

% Deviation = $\frac{\text{Individual weight-Average weight}}{\text{Average weight}} \ge 100$ -----(2)

2.4.6) Drug content

Weighed tablets (5 nos) were powdered using a glass mortar and pestle. An accurately weighed quantity of powder equivalent to 20 mg of famotidine was taken into a 100 ml volumetric flask and dissolved in methanol (5 ml) while shaking for 10 min. Further sample was diluted with 0.1N HCl and volume was made up to 100 ml. The solution in the volumetric flask was filtered and the drug content was determined at 266 nm by using a UV-spectrophotometer against blank.

2.4.7) Swelling index

Swelling of tablet involves the absorption of a liquid by tablet matrices increasing weight and volume of tablet. The extent of swelling was measured in terms of %weight gain by the tablet. For each formulation batch, one tablet was weighed and placed in a beaker containing 200 ml of 0.1 N HCl. After each time interval, the tablet was removed from beaker and weighed again up to 12 h.^[11] The swelling index was calculated using the following equation:

Where, S.I. = Swelling index, Wt = Weight of tablet at time t, Wo = Weight of tablet before placing in the beaker.

2.4.8) Floating or buoyancy lag time and total floating time

The time taken for the tablet to emerge on the surface of the medium is called the floating lag time or buoyancy lag time and the duration of time the tablet constantly remains on the surface of the medium is called the total floating time. The buoyancy of the tablets was studied in USP type II dissolution apparatus at $37^{\circ}C\pm0.5^{\circ}C$ in 900 ml of 0.1 N HCl (pH 1.2). The time of duration of floatation was observed visually.^[12]

2.4.9) In-vitro drug release studies

In-vitro dissolution studies were conducted to determine the release pattern of the drug from the matrix tablet. A dissolution test for gastroretentive matrix tablets of famotidine was carried out using 8 station USP Type II dissolution test apparatus (Electro Lab, TDT-O8L, Mumbai). The dissolution studies were carried out in 900 ml 0.1 N HCl (pH 1.2) at $37 \pm 0.5^{\circ}$ C. The speed of the paddle was set at 100 rpm. Sampling was done every 1 h interval. An aliquot of 5 ml sample was withdrawn at each time interval and replaced with equal volume of fresh medium. The samples were withdrawn after suitable dilution were analysed in the UV spectrophotometer at 266 nm.^[13]

2.4.10) Kinetic study

The mechanism of release was determined by fitting the release data to the various kinetic equations such as first-order, zero-order, Higuchi, and Korsmeyer-Peppas and the r^2 values of the release profile corresponding to each model were found.^[14]

2.4.11) Fourier transform infrared spectroscopy studies (FTIR)

The Pure drug and formulation (F4) was subjected for FTIR analysis to check the compatibility/interaction between the drug and excipients. The samples were prepared on potassium bromide-press (Bruker Alpha FT-IR Spectrometer: ATR MODE, Chitradurga). The samples were scanned over a range of 4000-400 cm⁻¹ using Fourier transformer infrared spectrophotometer. The spectra were analyzed for drug carrier interactions.^[15]

2.4.12) Differential scanning calorimetry

A differential scanning calorimetry (DSC) study was carried out to study compatibility between drug and polymer or excipients. DSC thermograms of pure drug and optimized gastroretentive matrix tablet of famotidine F4 was obtained using Shimadzu DSC-60 (Shimadzu, Kyoto, Japan) instrument. DSC aluminium cells were used as sample holder, and blank DSC aluminium cell was used as references. 2-3 mg sample was used for analysis. Thermograms were recorded over the range of 20 $^{\circ}$ C – 420 $^{\circ}$ C at a constant rate of 20 $^{\circ}$ C per min under nitrogen purge at 20 ml/min.

3. RESULTS AND DISCUSSION

3.1) Pre-compression evaluation of powder blend

The angle of repose of the powder blend of all formulations F1-F15 was in the range of $20.0\pm0.6 - 30.4\pm0.3^{\circ}$. It was below 30° indicating good flow properties of blend. Bulk density was found in between $0.32\pm0.2 - 0.46\pm0.7$ gm/cm³ and tapped density between $0.30\pm0.20 - 0.52\pm0.15$ gm/cm³ for the formulations. Carr's index value of $6.25\pm0.2 - 15.22.\pm 4.44\%$ and Hausner's ratio of $1.04\pm0.02 - 1.22\pm0.45$ were observed for all precompressional blends. Carr's index and Hauser's ratio of below 15% and 1.25 respectively indicated good compressibility. Hence powder mixture was found suitable for direct compression on 10 station rotary compression machine.

3.2) Evaluation of famotidine gastro retentive matrix tablets

Morphological characters like shape colour and texture was determined visually. The tablets were Off-white coloured having spherical shapes, sharp edges, flat rough surface on both sides. Since natural polymers were used the colour of polymer was easily visible and tablets were not completely white.

3.2.1) Post-compression evaluation

The results of the compression evaluation of tablets are given in Table 2 - 3. As the material was free flowing, tablets obtained were of uniform weight due to uniform die filling. The thickness was found in the range of $4.1\pm0.31 - 4.4\pm0.20$ mm. The diameter of tablets was found to be $10\pm0.11 - 10.0\pm0.18$ mm and was uniform for all tablets. Hardness of tablets was between $3.7\pm0.12 - 4.0\pm0.14$ kg/cm² for all the formulations. Friability was found in between $0.20\pm0.22 - 0.50\pm0.24\%$. The value below 1% was an indication of good mechanical resistance of the tablet. The weight variation of tablets was within the specified limits. The drug content was found to be $19.06\pm0.36 - 19.09\pm0.21$ mg which was within the acceptable limits. Swelling index (%) was found in between 160 - 60% for all formulations.

The swelling index studies showed a gradual increase with the increase in concentration of polymers used. Xanthan gum exhibited maximum swelling index of 160%, which indicates the natural tendency of it to swell 5-10 times of its original value. Lowest swelling index was with guar gum of 60%. Rate of hydration of guar gum varies. Hydration rate and viscosity of guar gum does not remain constant but change with conditions like temperature, pH, solute,

concentration, etc. Hydrogen bonding activity of guar gum is due to the presence of hydroxyl group in guar gum molecule. Guar gum shows hydrogen bonding with cellulosic material and hydrated minerals. The hydration rate of guar gum largely depends on particle size of guar gum powder. Hence, for quick initial viscosity, very fine mesh guar gums should be used. However, a considerable time interval is required for maximum hydration and viscosity to be achieved. Hence guar gum showed least swelling index (%). ^[16] The swelling index for all polymers was in the order Xanthan gum > Pectin > Tamarind seed powder > Guar gum.

3.2.2) Floating or buoyancy test

Gastro-retentive matrix tablets need to possess certain characteristics for floating. Therefore experiments were conducted for buoyancy lag time as well as total floating time.

Sodium bicarbonate induces CO_2 generation in the presence of hydrochloric acid. The gas generated is trapped and protected within the gel formed by hydration of the polymer, thus decreasing the density of the tablet below 1 gm/ml and the tablet becomes buoyant. The optimized concentration of sodium bicarbonate was found to be 5% of total tablet weight and it was maintained constant in all the floating tablets prepared. All floating tablets had buoyancy lag time in the range of 4 ± 0.3 (F14) to 25 ± 0.6 (F12) sec. All the tablets prepared floated for 12 h. The total floating time was found to be 12 h indicating a stable gel layer formation by all natural polymers selected and sodium bicarbonate that persists for a longer time. The results of the buoyancy lag time and total floating time for the different gastro retentive matrix tablets is given in Fig. 1 and Table 3.

3.2.3) In-vitro drug release studies

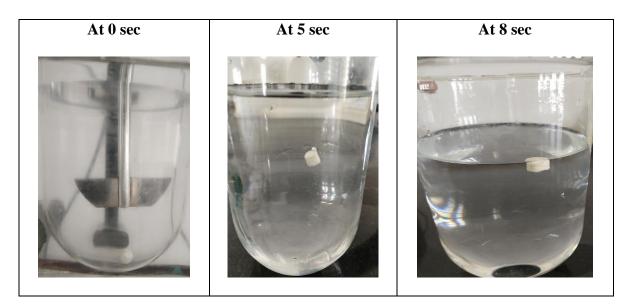
The gastroretentive matrix tablets F1 - F15 released 97.00 - 71.67% of drug in 12 h. The matrix tablets comprising Guar gum as polymer F1 – F3 showed drug release between 93.02 - 90.31% at the end of 12 h. The matrix tablets comprising Xanthan gum as polymer F4 – F6 showed drug release between 97.00 - 88.54% at the end of 12 h. Further, the gastro retentive matrix tablets composed of Pectin as natural polymer F7 – F9 released about 94.59 - 87.79% of famotidine at the end of 12 h. Formulations F10 – F12 composed of Tamarind seed powder as polymer showed a release about 82.67 - 71.67% of drug at the end of 12 h respectively. In another set of formulations F13 – F15 prepared employing combination of different polymers the drug release was F13 (Guar gum + Xanthan gum) – 86.73%, F14 (Xanthan gum + Pectin) – 90.32% and F15 (Pectin + Tamarind seed powder) – 94.50%. The maximum drug release was observed with F4 – 97.00% at the end of 12 h. F4 prepared using

Xanthan gum released the maximum amount of drug and was selected as an Optimised formulation. In case of different natural polymers used the order of release was Xanthan gum>Guar gum>Pectin>Tamarind seed powder. Tamarind seed powder showed maximum controlled release of drug than other polymers.

Formulation Code	Thickness (mm)**	Diameter (mm)**	Hardness Test (kg/cm ²)**	Friability (%)**	Weight Variation (%)***	Drug Content (mg)*	Swelling index (%)	
F1	4.1 ± 0.33	10 ± 0.18	3.9 ± 0.22	0.26 ± 0.21	3.33 ± 0.12	19.8 ± 0.36	78.12 ± 0.61	
F2	4.2 ± 0.31	10 ± 0.11	4.0 ± 0.15	0.21 $0.42 \pm$ 0.27	0.12 2.99 ± 0.17	0.30 19.7 ± 0.23	$\frac{0.01}{79.98 \pm}$ 0.52	
F3	4.3 ± 0.22	10 ± 0.13	4.0 ± 0.12	0.15 ± 0.31	$\frac{0.17}{2.87 \pm}$ 0.13	19.9 ± 0.25	$\frac{0.52}{82.65 \pm 0.76}$	
F4	4.3 ± 0.22	10 ± 0.20	4.0 ± 0.18	0.20 ± 0.12	2.55 ± 0.44	19.6 ± 0.11	77.72 ± 0.23	
F5	4.4 ± 0.14	10 ± 0.16	3.8 ± 0.22	0.42 ± 0.22	3.33 ± 0.48	19.7 ± 0.41	79.45 ± 0.43	
F6	4.5 ± 0.25	10 ± 0.15	4.0 ± 0.05	0.25 ± 0.16	2.37 ± 0.53	19.8 ± 0.24	81.23 ± 0.67	
F7	4.3 ± 0.29	10 ± 0.12	4.0 ± 0.17	0.06 ± 0.34	2.12 ± 0.31	19.6 ± 0.26	71.39 ± 0.76	
F8	4.2 ± 0.12	10 ± 0.14	4.2 ± 0.19	0.42 ± 0.13	3.13 ± 0.28	19.7 ± 0.22	75.43 ± 0.13	
F9	4.4 ± 0.32	10 ± 0.25	4.0 ± 0.17	0.20 ± 0.34	2.50 ± 0.24	19.7 ± 0.28	77.59 ± 0.15	
F10	4.1 ± 0.13	10 ± 0.12	3.7 ± 0.13	0.66 ± 0.23	3.65 ± 0.12	19.8 ± 0.23	$78.71 \pm \\ 0.98$	
F11	4.2 ± 0.21	10 ± 0.11	4.0 ± 0.13	$\begin{array}{c} 0.33 \pm \\ 0.32 \end{array}$	2.99 ± 0.15	19.6 ± 0.25	81.62 ± 0.67	
F12	4.4 ± 0.24	10 ± 0.13	4.0 ± 0.12	$\begin{array}{c} 0.20 \pm \\ 0.14 \end{array}$	2.75 ± 0.18	19.9 ± 0.22	85.59 ± 0.68	
F13	4.4 ± 0.23	10 ± 0.11	4.0 ± 0.13	0.20 ± 0.12	3.48 ± 0.16	19.7 ± 0.32	75.41 ± 0.86	
F14	4.2 ± 0.33	10 ± 0.14	4.1 ± 0.12	0.48 ± 0.22	1.54 ± 0.12	19.8 ± 0.15	76.78 ± 0.54	
F15	4.3 ± 0.31	10 ± 0.15	4.0 ± 0.14	$\begin{array}{c} 0.20 \pm \\ 0.43 \end{array}$	$\begin{array}{c} 2.50 \pm \\ 0.22 \end{array}$	19.7 ± 0.18	$\begin{array}{c} 74.65 \pm \\ 0.56 \end{array}$	

 Table 2: Post-compression evaluation of famotidine gastro retentive matrix tablets

All values are expressed as mean± SD, n=5/10**/20***



The results also indicated that the rate of release of the drug decreased as the amount of polymer in the matrix increased (F1-93.02, F2 – 92.30, F3-90.31%). The same results were observed with other polymers used. The slow release of the drug with an increase in polymer content may be due to formation of thick gel layer, causing the difficulty in drug diffusion through the matrix and thus decreasing the overall drug release from the matrix.

The most common explanation of the effect of increase in the polymer level on drug release is that, it increases thickness of the gel layer, which retards drug diffusion out of the tablet. ^[17] The results of in-vitro release studies are given in Fig. 2.

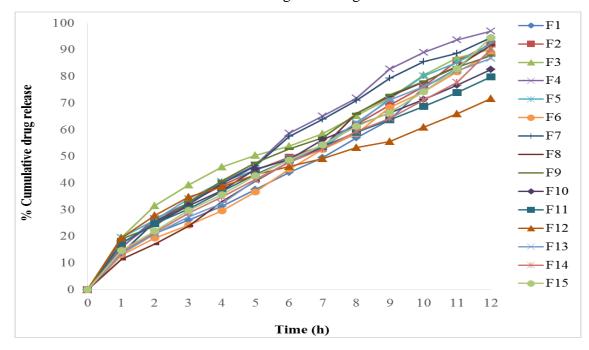


Fig. 2: In-vitro release profile of famotidine gastro retentive matrix tablets

3.2.4) Kinetic study

When the data was plotted as per zero-order kinetics, plots were obtained with high correlation coefficient values ranging from 0.9320 - 0.9967. First order plots showed low correlation coefficient values ranging from 0.8296 - 0.9801. From the observations it was concluded that the selected formulations followed zero order release. Higuchi equation gave linear plots with high correlation coefficient values ranging from 0.9127 - 0.9916 indicating the drug release from all the gastroretentive matrix tablets was diffusion controlled. In the Korsemayer-Peppas model the n values of different gastro retentive matrix tablets were found in the range of 1.013 - 1.282, indicating non-fickian super case II type transport mechanism. Hence all the gastroretentive matrix tablets followed diffusion controlled zero order kinetics.

3.2.5) Fourier Transform Infrared Spectroscopy studies (FTIR)

Since natural polymers have been used in the present investigation, to ascertain the behaviour of the polymer in combination with the synthetic drug FTIR studies were used. The detailed study of IR spectra of drug and formulation clearly suggested that the drug was in pure form and all the peaks were under the standard IR of pure sample of drug (Fig. 3). The IR spectra of formulation F4 (Xanthan gum) exhibited characteristic absorption bands in the corresponding IR regions and spectra is shown in Fig. 4. Thus it can be said that the spectra of drug and formulations are almost identical suggesting that the drug remains in the same normal form before and after its formulation as gastro retentive matrix tablet.

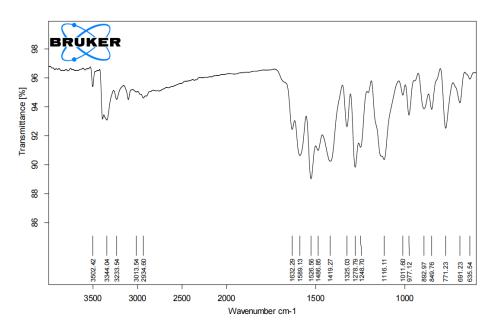
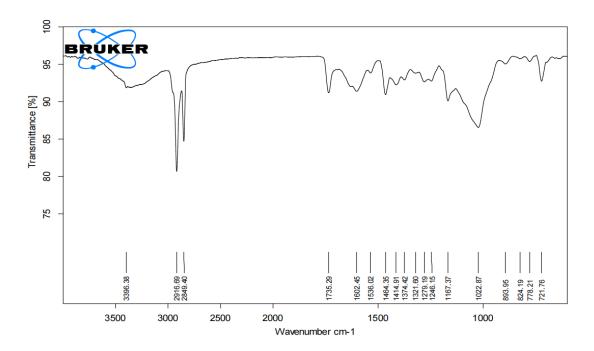
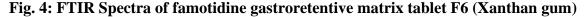


Fig. 3: FTIR Spectra of pure drug famotidine

Citation: SARFARAZ MD et al. Ijppr.Human, 2024; Vol. 30 (2): 217-232.





3.2.6) Differential Scanning Calorimetry

The DSC thermogram study of drugs and its formulation is also utilized for establishing physical characteristics. The thermogram of pure famotidine shows an endothermic peak at 165 °C indicating drug starts melting and it gets completed at 173.4 °C. The sharp endothermic peak is obtained at 168.81 °C which corresponds to the sharp melting point of the drug. The melting point derived from the thermogram is 168.81°C and is the theoretical melting point that is 167-170 °C of famotidine. This shows that the drug is crystalline in nature and is a pure drug.

The thermogram of the Optimised formulation (F4) showed an endothermic peak and melting point range as 155-162 °C which is slightly less than the melting point of the pure drug range 165-173 °C. It is due to the fact that the formulation which is a composition of drug and excipient has to slightly differ in melting point as the presence of excipient lowers the melting point of the pure drug within the admissible range. In the present work such change of drug in formulation are not observed. Thermogram of drug and formulation indicate that the drug has not undergone any kind of interaction and is thermally stable. The DSC reports are shown in Fig. 5 and 6.

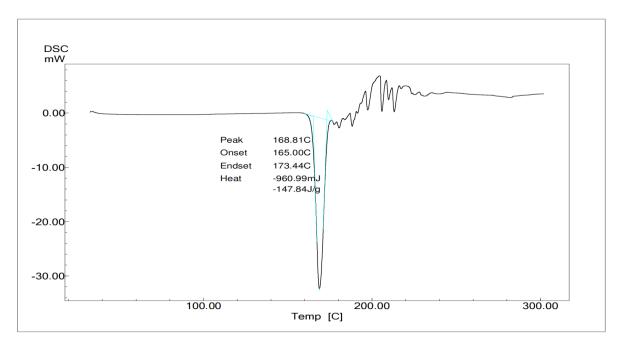


Fig. 5: DSC thermogram of pure drug famotidine

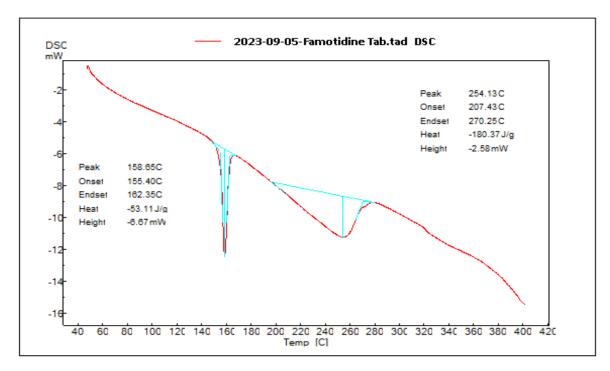


Fig. 6: DSC thermogram of optimised famotidine gastro retentive matrix tablet F4 (Xanthan gum)

4. CONCLUSION

Famotidine gastro-retentive matrix tablets were developed successfully using natural polymers like Guar gum, Xanthan gum, Pectin, and Tamarind seed powder. Sodium bicarbonate induces CO₂ generation which is trapped and protected within the gel formed by

hydration of the polymer, thus decreasing the density of the tablet below 1 gm/ml and the tablet becomes buoyant. The high floating ability of the formulation likely increases its gastrointestinal residence time and eventually improves the extent of bioavailability, reduces the frequency of administration of the drug and helps to minimize dose of the drug and side effects associated with the drug. Famotidine gastroretentive matrix tablets with better dissolution profiles could be successfully developed by using natural polymers and direct compression method. Moreover, formulations prepared using natural polymers can be considered as promising gastro-retentive agents supported by more elaborate research in this aspect.

5. ACKNOWLEDGEMENT

The authors are thankful to Mr. Ch. Suryanarayana, General Manager - IPM Formulations, Hetero Labs Limited- Hyderabad, Telangana, for providing gift sample of drug Famotidine to carry out the research work. The authors are also thankful to Dr. R. H. Udupi NET Pharmacy College, Raichur for providing help to carry out this research.

6. CONFLICT OF INTEREST

None declared.

7. REFERENCES

1. Streubel A, Siepmann J, Bodmeier R. Gastroretentive drug delivery system. Expert Opin Drug Deliv. 2006; 3(2):217-233.

2. Garg R, Gupta GD. Progress in controlled gastroretentive delivery systems. Trop J Pharm Res. 2008; 7(3):1055-1066.

3. Dixit N. Floating drug delivery system. Int J Curr Pharm Res. 2011; 7(1):6-20.

4. Badoni A, Gnanarajan G, Ojha A. Review on gastro retentive drug delivery system. Pharma Innovation. 2012; 1(8):32-42.

5. Rouge N, Allemann E, Gex-Fabry M, Balant L, Cole ET, Buri P, Doelker E. Comparative pharmacokinetic study of a floating multiple-unit capsule, a high density multiple unit capsule and an immediate-release tab containing 25 mg atenolol. Pharm Acta Helv. 1998; 73(2):81-87.

6. Menon A, Ritschel WA, Sakr A. Development and evaluation of a monolithic floating dosage form for furosemide. J Pharm Sci. 1994; 83:239Y245.

7. Bharat WT, Yogita AC. Gums and mucilages: Excipients for modified drug delivery system. J Adv Pharm Edu & Res. 2013: 3(4): 359-367.

8. Lacy ER, Ito S. Microscopic analysis of ethanol damage to rat gastric mucosa after treatment with a prostaglandin. Gastroenterol. 1982 Sep 1; 83(3):619-625.

9. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy. 2nd ed. Philadelphia: Lea & Febiger; 1976.

10. United States Pharmacopoeia Convention. United States Pharmacopoeia 38-National Formulary 33, Stationery Office, USA, 2010.

11. Bardonnet PL, Faivre V, Pugh WJ, Piffaretti JC, Falson F. Gastroretentive dosage forms. J Control Release. 2006; 111(1-2):1-18.

12. Khan R. Gastro retentive drug delivery System – A review. Int J Pharm Bio Sci. 2013; 4(2):630-646.

13. Robinson JR, Lee VHL. Controlled Drug Delivery: Fundamentals and applications. 2nd ed. New York: Marcel Dekker Inc; 1987.

14. Reza MS, Quadir MA, Haider SS. Comparative evaluation of plastics, hydrophilic polymers as matrices for controlled-release drug delivery. J Pharm Sci. 2003; 6(2):282-291.

15. Chella N, Shastri N, Tadikonda RR. Use of the liquisolid compact technique for improvement of the dissolution rate of valsartan. Acta Pharmaceutica Sinica B. 2012; 2(5):502-508.

16. Mudgil D, Barak S, Khatkar BS. Guar gum: processing, properties and food applications-A Review. J Food Sci Technol. 2014; 51(3):409-418.

17. Simancas-Herbada R, Fernández-Carballido A, Aparicio-Blanco J, Slowing K, Rubio-Retama J, López-Cabarcos E, Torres-Suárez AI. Controlled release of highly hydrophilic drugs from novel poly (magnesium Acrylate) matrix tablets. Pharmaceutics. 2020; 12(2):174-189.

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