

Formulation and optimisation of raft-forming chewable tablets containing H₂ antagonist

Shailesh T Prajapati, Anant P Mehta, Ishan P Modhia, Chhagan N Patel¹

Departments of Pharmaceutics and Pharmaceutical Technology, ¹Pharmaceutical Chemistry, Shri Sarvajani Pharmacy College, Gujarat, India

Abstract

Purpose: The purpose of this research work was to formulate raft-forming chewable tablets of H₂ antagonist (Famotidine) using a raft-forming agent along with an antacid- and gas-generating agent. **Materials and Methods:** Tablets were prepared by wet granulation and evaluated for raft strength, acid neutralisation capacity, weight variation, % drug content, thickness, hardness, friability and *in vitro* drug release. Various raft-forming agents were used in preliminary screening. A 2³ full-factorial design was used in the present study for optimisation. The amount of sodium alginate, amount of calcium carbonate and amount sodium bicarbonate were selected as independent variables. Raft strength, acid neutralisation capacity and drug release at 30 min were selected as responses. **Results:** Tablets containing sodium alginate were having maximum raft strength as compared with other raft-forming agents. Acid neutralisation capacity and *in vitro* drug release of all factorial batches were found to be satisfactory. The F₅ batch was optimised based on maximum raft strength and good acid neutralisation capacity. Drug–excipient compatibility study showed no interaction between the drug and excipients. Stability study of the optimised formulation showed that the tablets were stable at accelerated environmental conditions. **Conclusion:** It was concluded that raft-forming chewable tablets prepared using an optimum amount of sodium alginate, calcium carbonate and sodium bicarbonate could be an efficient dosage form in the treatment of gastro oesophageal reflux disease.

Key words: Acid neutralisation capacity, famotidine, raft-forming agent, raft strength, sodium alginate, texture analyzer

INTRODUCTION

Gastro-oesophageal reflux disease (GERD) is an ongoing condition in which the contents of the stomach come back into the oesophagus (the tube that carries food from the mouth to the stomach). Doctors call this “acid reflux.” GERD often causes heartburn, a burning feeling in the chest and throat. Heartburn may happen many times a week, especially after eating or at night. GERD can also cause cough or have asthma symptoms. It can also make your voice sound hoarse and raspy. Various treatment options available for GERD are taking medicines like antacids,

H₂ antagonist, proton pump inhibitor, etc.; surgery to strengthen the barrier between the stomach and the oesophagus may be a treatment option for acid reflux and endoscopic treatments help strengthen the muscle that keeps food and acid from going up into the oesophagus.

Raft-forming anti-reflux preparations are generally used in the treatment of gastric acid-related disorders, especially GERD, heartburn and oesophagitis.^[1] Raft-forming anti-reflux preparations forms a viscous, gelatinous neutral layer or barrier on the top of the gastric acid contents. The floating barrier remains located at the lower oesophageal sphincter (LES) and prevents the acidic gastric content from getting refluxed into the oesophagus and provides symptomatic relief to GERD patients. Since this barrier floats on the surface of the stomach content like a raft on water, the barrier is called a raft and the formulations are called as “raft-forming anti-reflux preparations”. The unique mechanism of action to provide relief in symptomatic GERD separates raft-forming anti-reflux preparations from traditional antacids and other therapeutic classes for treatment of GERD.^[1-3]

A raft-forming formulation requires sodium or potassium bicarbonate; in the presence of gastric acid, the bicarbonate is converted to carbon dioxide, which becomes entrapped within the gel precipitate, converting it into foam, which floats on

Address for correspondence:

Dr. Shailesh T Prajapati,
Shri Sarvajani Pharmacy College, Department of Pharmaceutics
and Pharmaceutical Technology, Near Arvind Baug,
Mehsana - 384 001, Gujarat, India.
E-mail: stprajapati@hotmail.com

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the surface of the gastric contents. The antacid components contained in formulations provide a relatively pH-neutral barrier.^[1,4] Calcium carbonate can be used as an antacid as well as a raft-strengthening agent. It releases calcium ions, which react with alginate and form an insoluble gel.^[5,6] Various polymers, especially different polysaccharides, have been used in various research works. Alginic acid, alginates and pectin are the most widely used raft-forming agents.^[2] Other polysaccharides are also being used, which include guar gum, locust bean gum, carrageenan, pectin and ispagol.^[2,4,7]

All recent treatments available for GERD either have one or more problems like side effects, costly or painful. Hence the objective of the present investigation was to formulate a chewable raft-forming tablet containing an H₂ antagonist (Famotidine). Famotidine blocks the action of histamine on the H₂ receptors present in the stomach and thereby decreases acid secretion.^[8]

MATERIALS AND METHODS

Materials

Famotidine was purchased from Yarrow Chem. (Mumbai, India). Sodium alginate was purchased from Finar Chemicals Ltd. (Ahmedabad, India). All other excipients used to prepare chewable tablets were of standard pharmaceutical grade and all chemical reagents used were of analytical grade.

Methods

Preparation of raft-forming chewable tablets

Drug, polymer and other ingredients were weighed accurately. All ingredients except the binder, volatile ingredients and lubricant were mixed thoroughly. PVP K₃₀ M was dissolved in sufficient quantity of isopropyl alcohol and added to a powder mixture to prepare a dough wet mass. The prepared wet mass was passed through a 22# sieve. The granules were allowed to dry in a hot air oven and then resifted through a 40# sieve. The granules were collected and other ingredients were added and lubricated. Tablets were compressed by a 12-mm diameter flat punch with the help of a rotary tablet compression machine.

Preliminary screening

Preliminary screening was carried out to select a good raft-forming agent, which has good raft strength. Six different raft-forming agents, viz., sodium alginate, pectin, guar gum, xanthan gum, gellan gum and ispagol were used in the study. The formulas of the different preliminary batches (batch PB₁-PB₆) are shown in Table 1.

Optimisation by 2³ full-factorial design

A 2³ randomised full-factorial design was used in the present investigation. In this design, three factors were evaluated, each at two levels, and experimental trials were performed at all eight possible combinations. The amount of sodium alginate, amount of calcium carbonate and amount of sodium bicarbonate were chosen as independent variables in the 2³ full-factorial design, whereas raft strength, acid neutralisation capacity and cumulative

percent release at 30 min (Q₃₀) were selected as dependent variables (responses). Different levels and their respective values are depicted in Table 2. The formulation layout of the factorial batches (F₁-F₈) is shown in Table 3. Tablets of all the factorial batches were evaluated for weight variation, hardness, drug content, friability, raft strength, acid neutralisation capacity and *in vitro* drug release. The polynomial equations can be used to draw conclusions after considering the magnitude of the coefficient and the mathematical sign it carries (i.e., negative or positive). Data were analysed for regression using Microsoft Excel.

Evaluation of raft-forming chewable tablets

General evaluation parameters for tablets

Weight variation test

Twenty tablets were selected at random, weighed and average weight was calculated. Not more than two of the individual

Table 1: Composition of different preliminary batches (PB₁-PB₆)

Ingredients	Quantity (mg)/tablet					
	PB ₁	PB ₂	PB ₃	PB ₄	PB ₅	PB ₆
Famotidine	20	20	20	20	20	20
Sodium alginate	250	-	-	-	-	-
Pectin	-	250	-	-	-	-
Guar gum	-	-	250	-	-	-
Xanthan gum	-	-	-	250	-	-
Ispagol husk	-	-	-	-	250	-
Gellan gum	-	-	-	-	-	250
Sodium bicarbonate	50	50	50	50	50	50
Calcium carbonate	150	150	150	150	150	150
PVP K ₃₀ M	50	50	50	50	50	50
Mannitol	427	427	427	427	427	427
Menthol	3	3	3	3	3	3
Aspartame	25	25	25	25	25	25
Flavour	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Talc	10	10	10	10	10	10
Magnesium stearate	15	15	15	15	15	15
Total weight	1000	1000	1000	1000	1000	1000

q.s.: Quantity sufficient

Table 2: Coding of variables

Level	Factor X ₁ : Amt. of sodium alginate (mg)	Factor X ₂ : Amt. of calcium carbonate (mg)	Factor X ₃ : Amt. of sodium bicarbonate (mg)
-1	250	150	25
+1	350	210	50

Mannitol was added up to 1000 mg and all other excipients were added as shown in Table 2

Table 3: Formulation layout for the factorial batches

Batch	X ₁	X ₂	X ₃
F ₁	-1	-1	-1
F ₂	+1	-1	-1
F ₃	-1	+1	-1
F ₄	-1	-1	+1
F ₅	+1	+1	-1
F ₆	+1	-1	+1
F ₇	-1	+1	+1
F ₈	+1	+1	+1

weights should deviate from the average weight by more than 10%.

Friability

For each formulation, a pre-weighed tablet sample (six tablets) was placed in a Roche friabilator (Electrolab, Mumbai, India), which is then operated for 100 revolutions. The tablets were de-dusted and reweighed. Conventional compressed tablets that lose < 0.5 to 1% of their weight are considered acceptable.

Hardness

Hardness of tablets was determined using a Pfizer hardness tester (Campbell Electronics, Mumbai, India).

Content uniformity

Twenty tablets were weighed and powdered in a glass mortar. A quantity of powder equivalent to 20 mg of Famotidine was accurately weighed and transferred into a 10 ml volumetric flask. Dimethyl formamide was added up to 10 ml and shaken well. The solution was filtered and 1 ml of the above solution was transferred into a 100 ml volumetric flask. A solution of 0.1 N HCl was added and the final volume in the flask was adjusted up to 100 ml. Absorbance of the resulting solution was measured at a λ_{\max} of 265 nm using UV-Visible spectrophotometer and the amount of the Famotidine was calculated by using the calibration curve method.

Raft strength measurement by in-house method

A tablet powder equivalent to unit dose was transferred to 150 ml of 0.1 N HCl and maintained at 37°C in a 250 ml glass beaker. Each raft was allowed to form around an L-shaped wire probe (diameter: 1.2 mm) held upright in the beaker throughout the whole period (30 min) of raft development.^[9] Raft strength was estimated using the modified balance method. Water was added dropwise to the pan and the weight of water required to break the raft was recorded.

Note: A double-pan dispensing balance was modified for raft strength measurement. One pan of the dispensing balance was replaced with an L-shaped wire probe as shown in Figure 1.

Acid neutralisation capacity

A tablet powder equivalent to unit dose was transferred to a 250 ml beaker; 50 ml of water was added to it and was mixed on a magnetic stirrer for 1 min. A 30-ml volume of 1.0 N HCl was

added with continued stirring on the magnetic stirrer for 10 min after addition of the acid. Stirring was discontinued briefly and the gum base was removed using a long needle without delay. The needle was promptly rinsed with 20 ml of water, and the washing was collected in the beaker; stirring was resumed for 5 min. Titration was begun immediately. Excess HCl was titrated against 0.5 N sodium hydroxide to attain a stable pH of 3.5. The number of mEq of acid consumed by the tablet tested was calculated by the following formula:^[10]

$$\text{Total mEq} = (30 \times N \text{ HCl}) - (V \text{ NaOH} \times N \text{ NaOH}) \quad (1)$$

Where, N HCl = Normality of HCl; V NaOH = Volume of NaOH required; and N NaOH = Normality of NaOH.

In vitro drug release study

In vitro drug release study of Famotidine chewable tablets ($n=3$) was performed using USP (United States Pharmacopoeia) apparatus II (TDT-08T; Electrolab) fitted with a paddle (50 r.p.m.) at $37 \pm 0.5^\circ\text{C}$ using a simulated gastric fluid (pH 1.2; 900 ml) as a dissolution medium. The tablet was powdered and then added to the dissolution medium. At pre-determined time intervals, 10-ml samples were withdrawn, filtered through a 0.45- μm membrane filter and analysed at 265 nm using a Shimadzu UV 1800 double-beam spectrophotometer (Shimadzu, Kyoto, Japan). Cumulative percentage drug release was calculated using an equation obtained from a calibration curve, which was developed in the range 5-25 $\mu\text{g/ml}$ for 0.1 N HCl.

Raft strength measurement by Texture Analyzer

The raft strength of the most satisfactory formulation (batch F₃) was determined by a sophisticated instrument called Texture Analyzer (Brookfield QTS).

Powder of tablets equivalent to unit dose was transferred to 150 ml of 0.1 N HCl and maintained at 37°C in a 250 ml glass beaker. The raft was allowed to form around an L-shaped wire probe (diameter: 1 mm) held upright in the beaker throughout the whole period (30 min) of raft development. After 30 min of raft development, the probe was pulled vertically up through the raft at a rate of 30 mm/min. The force required to pull the wire probe up through the raft was recorded by the Texture Analyzer.^[9]

Drug-excipient compatibility study

Fourier transform infrared spectrophotometry

A drug-excipient interaction plays a vital role in the release of drug from the formulation. Fourier transform infrared (FTIR) spectroscopy has been used to study the physical and chemical interactions between drugs and excipients. The FTIR spectra of Famotidine and a mixture of Famotidine with major excipients were recorded using the KBr mixing method using an FTIR instrument (FTIR-8400S; Shimadzu).

Differential scanning calorimetry study

Differential scanning calorimetry (DSC) study was carried out using the Shimadzu DSC-60 (Shimadzu) instrument to check

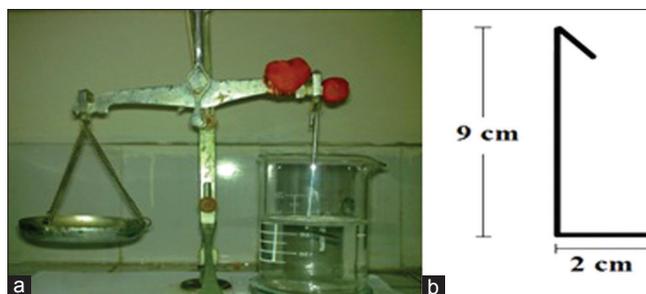


Figure 1: (a) Modified balance method. (b) Wire probe for raft strength measurement

drug–excipient compatibility. The DSC thermograms of the pure drug Famotidine and of the physical mixtures of Famotidine with excipients were obtained. DSC aluminium cells were used as a sample holder and a blank DSC aluminium cell was used as reference. A 2- to 3-mg weight of sample was used for analysis. Thermograms were recorded over the range 50–300°C.

Stability studies of the optimised formulation

Stability testing of drug products begins as a part of drug discovery and ends with the demise of the compound or commercial product. To assess drug and formulation stability, short-term stability studies were done for 1 month. The stability studies were carried out on the most satisfactory formulations (batch F₅). The most satisfactory formulations were sealed in aluminium packaging and kept in a humid chamber maintained at 40 ± 2°C/75 ± 5% relative humidity (RH) for 1 month. The optimised formulation sealed in aluminium foil was also kept at room temperature and humid condition. At the end of the storage time, the samples were analysed for raft strength, *in vitro* drug release and % drug content.

The *in vitro* drug release profiles for both formulations (initial and after storage at 40 ± 2°C/75 ± 5% RH for 1 month) were compared by the similarity factor (f₂).

RESULTS AND DISCUSSION

Results of preliminary screening

Tablets prepared using different raft-forming agents were tested for raft strength in 0.1 N HCl.

Among all six batches prepared with six different raft-forming agents, tablets prepared using sodium alginate (batch B₁) had maximum raft strength. So sodium alginate was selected as the

raft-forming agent for further studies. All results are shown in Table 4.

Results of 2³ full-factorial design

All results for physicochemical parameters like hardness, weight variation, thickness, % drug content and friability are shown in Table 5. All results were found to be satisfactory and within a normal range. The raft strength and acid neutralisation capacity of all factorial batches are shown in Table 6. Batch F₅ was found to have maximum raft strength of 6.5 g. All batches had acid neutralisation capacity in the range of 6.7 ± 0.17 to 9.2 ± 0.15, which was as per the limits described in USP 28. It was concluded that the amount of calcium carbonate critical for raft strength (cross-linking with sodium alginate) and the amount sodium bicarbonate critical for floating (porous structure formation) of raft and neutralisation. High level of calcium carbonate and low level of sodium bicarbonate showed better raft strength and neutralisation capacity [Table 6]. *In vitro* drug release study showed that more than 80% of the drug was released in 30 min and the entire drug was released within 60 min in all factorial batches. The *in vitro* drug release profiles of all factorial batches are shown in Figure 2. All parameters were found to be satisfactory for all factorial batches, so the batch with maximum raft strength, that is batch F₅, was selected as the optimised batch. Table 7 shows a summary of the regression analysis of the factorial design batches. R²-value for raft strength (g) and acid neutralisation capacity was 0.9997 and 0.9951, respectively, indicating good correlation between the dependent and independent variables. The reduced models were developed for response variables by omitting insignificant terms with P > 0.05.

Table 4: Raft strength of preliminary batches PB₁-PB₆

Batch	Raft-forming agent	Raft strength (g)
PB ₁	Sodium alginate	4.5±0.25
PB ₂	Pectin	2.2±0.26
PB ₃	Guar gum	1.2±0.10
PB ₄	Xanthan gum	1.0±0.15
PB ₅	Isapgol husk	1.0±0.20
PB ₆	Gellan gum	0.9±0.15

All values are mean±SD (n=3)

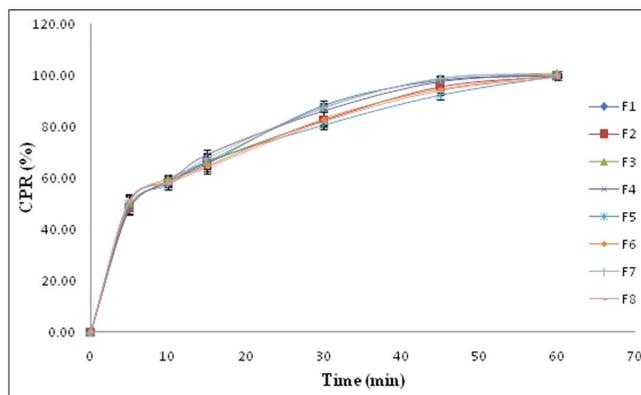


Figure 2: *In vitro* drug release profile of factorial batches

Table 5: Physicochemical properties of tablets of factorial batches

Batch code	Weight variation*(mg)	Hardness (kg/cm ²)	Thickness (mm)	% Drug content	Friability# (%)
F ₁	992.39±2.38	5.47±0.15	5.91±0.025	99.78±0.59	0.67
F ₂	990.71±2.98	6.20±0.26	5.83±0.032	99.33±1.04	0.57
F ₃	992.6±2.86	5.23±0.12	5.95±0.031	99.44±1.27	0.94
F ₄	991.37±2.07	5.40±0.17	5.89±0.070	100.17±0.93	0.70
F ₅	991.41±3.89	5.97±0.25	5.88±0.045	99.39±0.63	0.68
F ₆	993.21±1.97	6.17±0.15	5.90±0.036	99.50±0.73	0.40
F ₇	992.81±3.02	5.13±0.21	5.84±0.062	98.44±0.67	0.96
F ₈	993.62±2.42	5.60±0.10	5.90±0.035	100.72±0.95	0.69

All values are mean±SD (n=3), *n=20, #n=1

Terms with $P < 0.05$ were considered statistically significance and retained in the reduced model.

Results of raft strength measurement by Texture Analyzer

The raft strength of the optimised formulation (batch F₅) was measured by the Texture Analyzer. The graph of load vs. time is shown in Figure 3. Initially load was increased with time, maximum load was shown when the raft was broken and then it decreased sharply. The maximum raft strength observed at the breaking (rupture) point of the raft was found to be 5.0 g.

Results of fourier transform infrared spectrophotometry

The IR spectra of pure drug Famotidine and of the physical

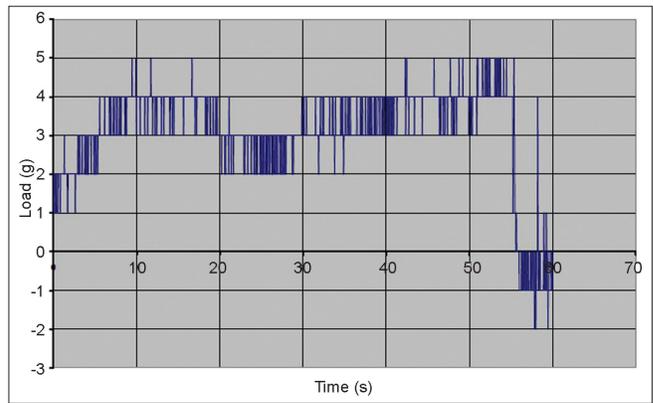


Figure 3: Graph of load vs. time for batch F₅

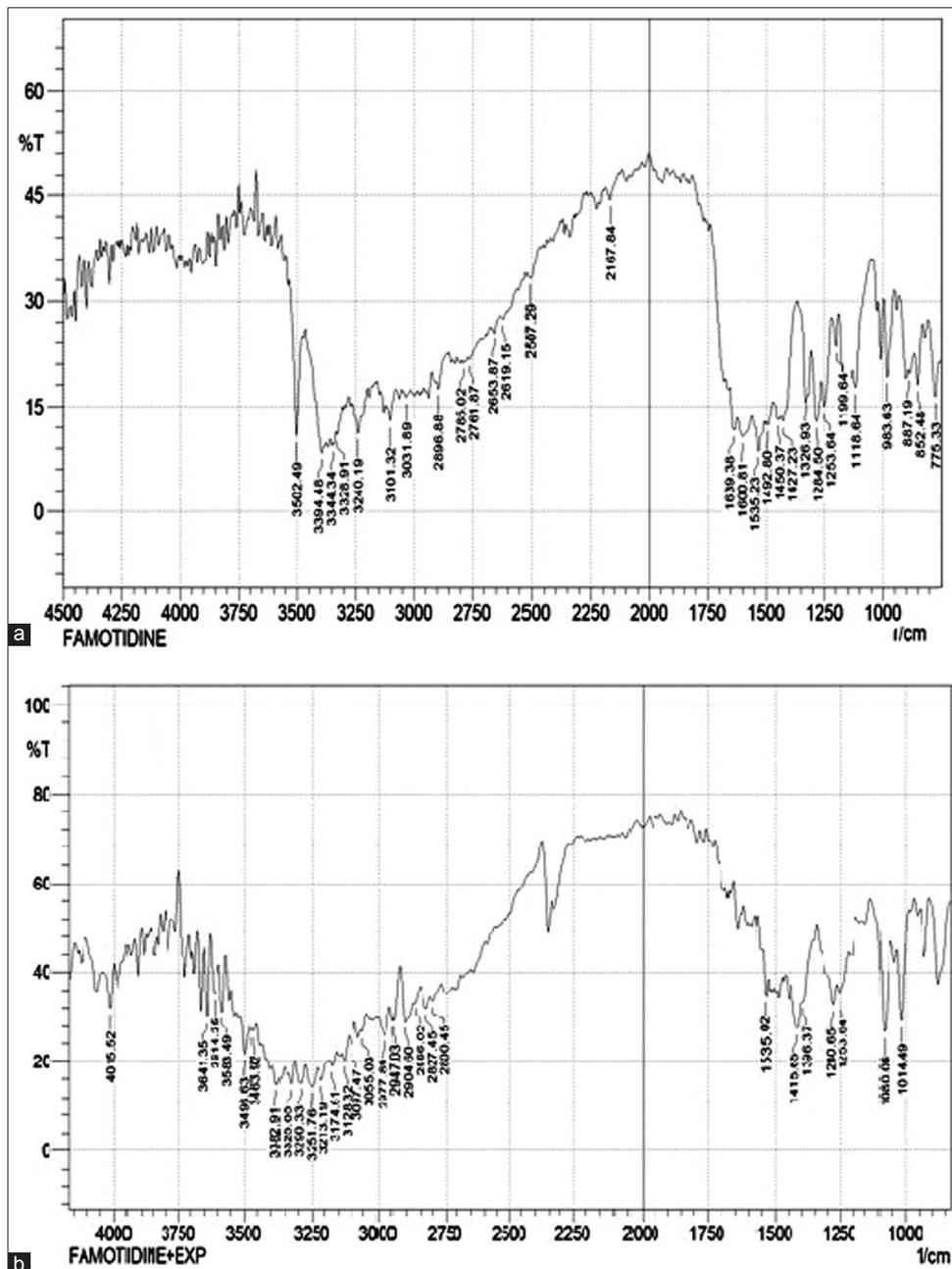


Figure 4: Fourier transform infrared spectra of Famotidine (a) and Famotidine with excipients (b)

mixtures of the drug with excipients are as shown in Figure 4. Pure drug Famotidine exhibited various peaks due to the presence of specific functional groups. Peaks of the major functional groups of the drug were obtained at 1284.50, 1535.23, 3101.32 and 3394.48. It was observed that the same peaks of drug functional groups were present in the IR spectra of the drug–excipients mixture and other peaks of excipients were present. Hence it was concluded that no interaction was found between the drug and excipients.

Results of DSC study

DSC thermograms were obtained for pure Famotidine and chewable tablet containing Famotidine and other excipients. Pure powdered Famotidine showed a melting endotherm at 169.23°C. The DSC thermogram of chewable tablet showed a melting peak of the drug at 171.21°C. There was no significant difference in melting point of drug in both samples. It indicated that the drug was present in its characteristic physical and chemical form. It was compatible with all excipients present in the tablet and there was no major interaction of drug with excipients. The DSC thermograms of drug and of the mixture of drug and excipients are shown in Figure 5.

Results of stability studies

The optimised formulation (batch F₅) stored at 40 ± 2°C/75 ± 5% was found stable. After storage at 40 ± 2°C/75 ± 5%, cumulative percentage drug release, raft strength, acid neutralisation capacity and % drug content were nearly similar to the initial results. So, it was clear that the drug and the formulation were thermally stable as well as not affected by the high humidity at 40 ± 2°C/75 ± 5%. The similarity factor of the batch after the stability study was

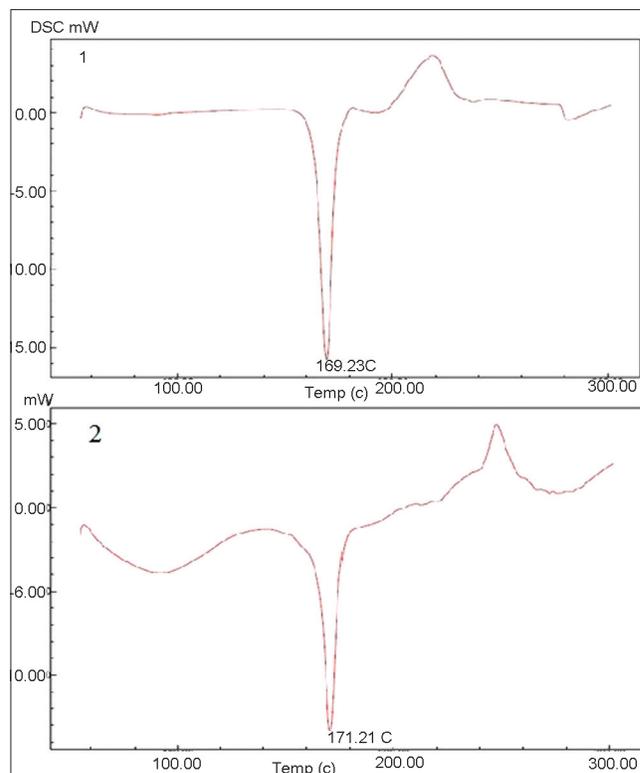


Figure 5: Differential scanning calorimetry thermograms of Famotidine and Famotidine chewable tablet

Table 6: Raft strength and acid neutralisation capacity of factorial batches

Batch	Raft strength (g)	Acid neutralisation capacity (mEq)
F ₁	5.3±0.15	6.7±0.17
F ₂	5.8±0.10	6.8±0.10
F ₃	4.5±0.21	8.6±0.06
F ₄	4.9±0.15	7.3±0.21
F ₅	6.5±0.15	8.8±0.12
F ₆	5.3±0.21	7.6±0.25
F ₇	4.3±0.06	9.1±0.21
F ₈	6.2±0.06	9.2±0.15

All values are mean±SD (n=3)

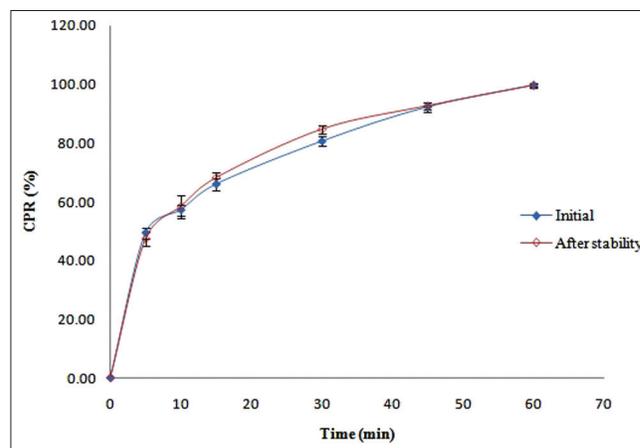


Figure 6: In vitro drug release profile of batch F₅ after stability study and comparison with initial

Table 7: Summary of results of regression analysis of factorial design batches

For raft strength							
Response (raft strength)	b ₀	b ₁	b ₂	b ₃	b ₁₂	b ₂₃	b ₁₃
P value	0.001	0.013	0.204	0.040	0.021	0.144	0.257
FM	5.35	0.59	0.04	-0.20	0.37	0.05	-0.03
RM	5.35	0.59	-	-0.20	0.37	-	-
For ANC							
Response (ANC)	b ₀	b ₁	b ₂	b ₃	b ₁₂	b ₂₃	b ₁₃
P value	0.001	0.125	0.009	0.0261	0.344	0.169	0.344
FM	7.98	0.06	0.88	0.30	-0.02	-0.046	0.02
RM	7.98	-	0.88	0.30	-	-	-

ANC: Acid neutralisation capacity, FM: Full model, RM: Reduced model

found to be 79.61 when compared with the initial drug release profile. The comparative dissolution profile of batch F₅ before and after stability study is shown in Figure 6.

CONCLUSION

It was concluded that chewable tablet prepared by sodium alginate (raft-forming agent) in combination with calcium carbonate (antacid) and sodium bicarbonate (gas generating agent) can form a floating raft in the presence of 0.1 N HCl. Raft strength was directly proportional to the amount of sodium alginate in the tablet. The amount of calcium carbonate and amount of sodium bicarbonate in the tablet were critical parameters in the formulation development. The optimised formulation had good raft strength, sufficient acid neutralisation capacity and satisfactory *in vitro* drug release. The drug was also compatible with all excipients used in the formulation. The formulation was also stable at accelerated conditions of temperature and humidity.

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