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FORMULATION AND EVALUATION OF FAMOTIDINE GASTRORETENTIVE DRUG DELIVERY TABLETS

M.Ramakrishna*, K.Israel, K.Kurumaiah, G.Tejaswi, G.Baaleshwar

Avanthi Institute of Pharmaceutical Sciences, Affiliated to JNTUH Gunthapally, Hyderabad, Telangana, India.

Keywords:

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For Correspondence:

M.Ramakrishna

Avanthi Institute of Pharmaceutical Sciences, Affiliated to JNTUH Gunthapally, Hyderabad, Telangana, India

E-mail:

visiloki.pharma@gmail.com

ABSTRACT

Gastroretentive drug delivery systems are the systems which are retained in the stomach for a longer period of time and thereby improve the bioavailability of drugs. Famotidine, an anti-ulcer drug, suffers from poor bioavailability (50%), as famotidine is very less soluble in alkaline P^H. famotidine used in combination with antacids promotes local delivery of these drugs to the receptor of the parietal cell wall. Local delivery also increases bioavailability at the stomach wall receptor site and increases the efficacy of drugs to reduce acid secretion. Thus, the present work is aimed to formulate floating tablets of famotidine using an effervescent approach for gastroretentive drug delivery system.Floating tablets were prepared using directly compression technique using polymers like HPMC K4M and HPMCK100M for their gel-forming properties. The HPMC alone polymer unable to controlled on release rate it release drug >90% in 4-6 hrs while in combination with Xanthan gum it release >90% in 8 hrs. The results indicate that gas powered gastroretentive floating Tablets of famotidine containing 40mg HPMCK100M and Xanthan gum provides a better option for controlled release action and improved bioavailability.

INTRODUCTION

Famotidine is a histamine H2-receptor antagonist. It is widely prescribed in active duodenal ulcers, gastric ulcers, Zollinger-Ellison syndrome, gastroesophageal reflux disease, and erosive esophagitis [1]. The recommended adult oral dosage of famotidine is 20 mg twice daily or 40 mg once daily. The effective treatment of erosive esophagitis requires administration of 20 mg of Famotidine 4 times a day. a conventional dose of 20 mg can inhibit gastric acid secretion up to 5 hours but not up to 10 hours. An alternative dose of 40 mg leads to plasma fluctuations; thus a sustained release dosage form of famotidine is desirable. the short biological half-life of drug (~2.5-4 hours) also favors development of a sustained release formulation.The gastro retentive drug delivery systems can be retained in the stomach and assist in improving the oral sustained delivery of drugs that have an absorption window in a particular region of the gastrointestinal tract[2]. These systems help in continuously releasing the drug before it reaches the absorption window, thus ensuring optimal bioavailability.

METHODOLOGY

Famotidine obtained as a gift sample from Hetero labs Hyderabad. HPMC K4M, HPMC K15M were obtained from Signet Chemical Corporation, Mumbai, Avicel pH 101, Lactose Mono hydrate, Conc. Hydrochloric acid, Conc. Hydrochloric acid, Aerosil, Sodium bicarbonate obtained from S.D. Fine Chemicals, Mumbai.

PREPARATION OF FAMOTIDINE FLOATING TABLETS

The Compositions of different formulation trials with different polymers are presented in the Tables 1. Accurately weighed quantities of polymer, avicel were taken in a mortar and mixed geometrically. To this mixture required quantity of Famotidine was added and mixed slightly with pestle. This mixture was passed through 40# and later collected in a plastic bag and blended for 5 min. To this required amount of sodium bi carbonate was added and again mixed for 5 min. Later required quantity of magnesium stearate and aerosol were added and the final blend was again passed through 40#. Thus obtained blend was mixed thoroughly for 10 min and compressed into tablets on a rotary tablet punching machine

Table 1 → Composition of Famotidine Floating Tablets

INGREDIENTS	FT1	FT2	FT3	FT4	FT5	FT6	FT7	FT8	FT9	FT10
Famotidine	40	40	40	40	40	40	40	40	40	40
HPMC K4M	40	-	-	-	80	-	40	-	40	20
HPMC K100M	-	40	-	80	-	-	40	40	-	40
Xanthan gum	-	-	40	-	-	80	-	40	40	20
Sodium bicarbonate	20	20	20	20	20	20	20	20	20	20
Citric acid (anhydrous)	10	10	10	10	10	10	10	10	10	10
PVP-K-30	20	20	20	20	20	20	20	20	20	20
Avicel PH-102	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Magnesium Stearate	1	1	1	1	1	1	1	1	1	1
Talc	2	2	2	2	2	2	2	2	2	2

STANDARD CALIBRATION CURVE OF FAMOTIDINE:

Standard calibration curve of famotidine was determined by plotting absorbance V/s concentration at 266.2 nm.and it follows the Beer's law.

PREFORMULATION STUDIES[4]

It is one of the important prerequisite in development of any drug delivery system. Preformulation studies were performed on the drug, which included melting point determination, solubility and compatibility studies

Compatibility Studies:

Compatibility with excipients was conformed by carried out I R studies. The pure drug and its formulations along with excipients were subjected to IR studies. In the present study, the potassium bromide disc (pellet) method was employed

Preparation of Standard Calibration Curve of Famotidine: 100mg of famotidine was accurately weighed and transferred into 100ml volumetric flask. It was dissolved and diluted to volume with 0.1N HCL to give stock solution containing 1000µg/ml.

The standard stock solution was then serially diluted with 0.1N HCL to get 1 to 10µg/ml of famotidine. The absorbances of the solution were measured against 0.1N HCL as blank at 266.2 nm using UV spectrophotometer. The absorbance values were plotted against concentration (µg/ml) to obtain the standard calibration curve.

Evaluation of Precompression Blend[5,6]

The powder blend of all formulations was evaluated for Bulk density, Tapped density, Compressibility Index, Hausner ratio and Angle of repose.

A) Bulk Density

30gms of material was passed through a sieve no. 25 to break up agglomerates and introduced into a dry 100mL cylinder, without compacting, the powder was carefully leveled without compacting and the unsettled apparent volume, Vo, was read. The bulk density was calculated, in grams per ml, using the formula.

$$\mathbf{(M) / (Vo)}$$

Where M = Total weight of the powder blend and V_0 is the bulk volume of the powder blend

B) Tapped Density

After carrying out the procedure as given in the measurement of bulk density the cylinder containing the sample was tapped using a mechanical tapped density tester (Electrolab) that provides a fixed drop of 14±2 mm at a nominal rate of 300 drops per minute. The cylinder was tapped 500 times initially followed by an additional tap of 750 times until difference between succeeding measurement was less than 2% and then tapped volume V_f, was measured to the nearest graduated unit. The tapped density was calculated, in g per ml, using the formula:

$$\mathbf{(M) / (V_f)}$$

Where M = Total weight of the powder blend and V_f is the tapped volume of the powder blend

C) Measures of Powder Compressibility

The Compressibility Index and Hausner Ratio are measures of the propensity of a powder to be compressed. As such, they are measures of the relative importance of inter particulate interactions. As such, they are measures of the relative importance of inter particulate interactions. In a free-flowing powder, such interactions are generally less significant, and the bulk and tapped densities will be closer in value. For poorer flowing materials, there are frequently greater interparticle interactions and a greater difference between the bulk and tapped

densities will be observed. These differences are reflected in the Compressibility Index and the Hausner Ratio, which are calculated using the following formulae [7].

Compressibility Index = **(Vr-Vo) * 100 / Vr**

Where , Vr = Tapped density ; Vo = Bulk density

D) Hausner Ratio:

It is the ratio of bulk density to tapped density

Vo/ Vf

Vo = Bulk density; Vr= Tapped density

E) Angle of Repose

The fixed funnel method was employed to measure the repose angle. A funnel was secured with its tip at a given height, H above a graph paper that was placed on a flat horizontal surface. The blend was carefully pored through the funnel until the apex of the conical pile just touched the tip of the funnel. The radius, R, of the base of the conical pile was measured. The angle of repose, α, was calculated using the following formula.

$$\alpha = \tan^{-1} H/R$$

DETERMINATION OF PHYSICAL PARAMETERS OF FLOATING TABLETS [8, 9]**.**

Weight Variation test

Twenty (20) tablets from each batch were individually weighed in grams on an analytical balance. The average weight and standard deviation were calculated, individual weight of each tablet was also calculated using the same and compared with average weight

Thickness test

The thickness in millimeters (mm) was measured individually for 10 pre weighed tablets by using a Vernier Caliperse. The average thickness and standard deviation were reported.

Hardness test

Tablet hardness was measured using a Monsanto hardness tester. The crushing strength of the 10 tablets with known weight and thickness of each was recorded in kg/cm^2 and the average hardness, and the standard deviation was reported.

Friability test

Twenty (20) tablets were selected from each batch and weighed. Each group of tablets was rotated at 25 rpm for 4 minutes (100 rotations) in the Roche friablator. The tablets were then dusted and re-weighed to determine the loss in weight. Friability was then calculated as per weight loss from the original tablets.

Determination of Drug Content

Ten tablets with pre determined weight from each batch were taken and crushed in a mortar and weight equivalent to one average tablet was taken, transferred to a 250 ml volumetric flask and 0.1N HCl was added. The volume was then made up to the mark with 0.1N HCl. The solution was filtered and the filtrate was sufficiently diluted and the absorbance was recorded against the blank at 272 nm. The drug content of the Standard containing the drug powder was also determined. The Drug content was determined by the formula[10].

$$\text{Drug content} = \frac{\text{Amount in test}}{\text{Amount in standard}} \times 100$$

The tablet passes the requirements if the amount of the active ingredient in each of the 10 tested tablets lies within the range of 85% to 115% of the stated amount.

***In-vitro* buoyancy Studies.**

The in-vitro buoyancy (n= 3) was determined by floating lag times according to the method described by Rosa et al.The tablets were placed in a beaker containing 100 ml of 0.1N HCL. The time required for the tablet to rise to the surface and float was taken as floating lag time. Total floating time was also measured.

***In vitro* Drug Release Studies**

The release rate of Doxofylline floating tablets was determined using USP Type 2 Apparatus. The dissolution test was performed in triplicate, using 900ml of 0.1N HCL,at 37± 0.5˚C at 50 rpm for 12 hrs. A 5ml sample was withdrawn from the dissolution apparatus at specified time points and the samples were replaced with fresh dissolution medium.The samples were filtered through a 0.45-µm membrane filter and diluted if necessary. Absorbance of these solutions was measured at 272nm using Elico SL -159, U.V-Visible Spectrophotometer. Cumulative drug release was calculated using the equation (y = 0.03x + 0.024) generated from Beer Lambert's Calibration curve in the linearity range of 1-32µg/ml.

Kinetic Analysis of Dissolution Data

To analyze the *in vitro* release data various kinetic models were used to describe the release kinetics. The zero order rate Eq. (1) describes the systems where the drug release rate is independent of its concentration. The first order Eq. (2) describes the release from system where release rate is concentration dependent [11]. Higuchi [12] described the release of drugs from

insoluble matrix as a square root of time dependent process based on Fickian diffusion Eq. (3). The Hixson-Crowell cube root law Eq. (4) describes the release from systems where there is a change in surface area and diameter of particles or tablets.

$$C = K_0 t \quad (1)$$

Where, K_0 is zero-order rate constant expressed in units of concentration/time and t is the time.

$$LogC = LogC_0 - K_1 t / 2.303 \quad (2)$$

Where, C_0 is the initial concentration of drug and K_1 is first order constant.

$$Q = K_H t^{1/2} \quad (3)$$

Where, K_H is the constant reflecting the design variables of the system.

$$Q_0^{1/3} - Q_t^{1/3} = K_{HC} t \quad (4)$$

Where, Q_t is the amount of drug remained in time t, Q_0 is the initial amount of the drug in tablet and K_{HC} is the rate constant for Hixson-Crowell rate equation.

RESULTS AND DISCUSSION

Hydrodynamically balanced tablets of famotidine (gastroretentive drug delivery systems) were prepared and evaluated to increase its local action and bioavailability

In the present study 10 formulations with variable concentration of polymer were prepared and evaluated for physio-chemical parameters, invitro buoyancy studies, invitro release studies and stability studies.

Compatibility studies:

Compatibility studies were performed using IR spectrophotometer. The IR spectrum of pure drug and physical mixture of drug and polymer were studied. The characteristic absorption peaks of were obtained at 3504.66cm^{-1}, 1591.27cm^{-1}, 981.77cm^{-1}.

Drug- excipient interactions play a vital role with respect to release of drug from the formulation amongst others. FTIR techniques have been used here to study the physical and chemical interaction between drug and excipients used. In the present study, it has been observed that there is no chemical interaction between Famotidine and the polymers used. Drug has given peaks due to furan ring and secondary diamine groups. It was observed that there were no changes in these main peaks in IR spectra of mixture of drug and polymers, which show there were no physical interactions because of some bond formation between drug and polymers.

The peaks obtained in the spectras of each formulation correlates with the peaks of drug spectrum. This indicates that the drug was compatible with the formulation components.

Identification of Famotidine:

A solution of famotidine was prepared in 0.1 N HCl and UV spectrum was taken using Shimadzu UV-1601 UV/Vis double beam spectrophotometer. The UV maxima of Famotidine were found to be 266.2 nm in 0.1 N HCl. which complied with BP standards, indicating purity of the drug sample.

EVALUATION OF TABLET FORMULATIONS:

1. Pre-compression Parameters:

Angle of Repose (θ):- The angle of repose for the formulated blend was carried out and the results were shown in table 2.It concludes all the formulations blend was found to be in the range 24^0.88' to 29.30'.

Compressibility Index: - Compressibility index was carried out, it found between 12.34% to 16.30% indicating the powder blend have the required flow property for compression.

Post-compression Parameters:

a) Shape of the tablet:-

Microscopic examinations of tablets from FT1 to FT10 were found as circular shape, no cracks.

b) Hardness test:-

The measured hardness of tablets of each batch ranged between 4.3 to 6.4kg/cm^2 (Table 8).This ensures good handling characteristics of all batches.

c) Friability Test:-

The values of friability test were tabulated in Table 8.The % friability was less than 1% in all the formulations ensuring that the tablets were mechanically stable.

d) Weight Variation Test:-

The percentage weight variations for all formulations were tabulated in Table no 8.All the formulated (FT1 to FT10) tablets passed weight variation test as the % weight variation was within the pharmacopoeial limits of ±7.5% of the weight. The weights of all the tablets were found to be uniform with low standard deviation values.

e) Drug Content Uniformity:-

The percentage of drug content for FT1 to FT10 was found to be between 97.11% to 99.69% of famotidine, it complies with official specifications. The results were shown in Table 3.

f) Tablet density:-

When tablet contacts the test medium, tablet expanded (because of swellable polymers) and there was liberation of CO_2 gas (because of effervescent agent, $NaHCO_3$). The density decreased due to this expansion and upward force of CO_2 gas generation. This plays an important role in ensuring the floating capability of the dosage form.

To provide good floating behavior in the stomach, the density of the tablets should be less than that of the gastric contents the density below (1.004g/cm^3) than of gastric fluid. For formulation FT1-FT10 density were found to be less than that of the gastric content.

In vitro Buoyancy Study:-

On immersion in 0.1N HCl solution pH (1.2) at 37^0C, the tablets floated, and remained buoyant without disintegration. Table 5 Buoyancy character of prepared tablet.

From the results it can be concluded that the batch containing only HPMC polymer showed good Buoyancy lag time (BLT) and Total floating time (TFT). Formulation containing HPMC K4M, HPMC K100M and Xanthan gum showed good BLT of 45 sec, while the formulation containing Xanthan gum(alone) did not float more than 1.5 hrs. This may be due to the nature of polymer and gas generating agent, which were kept constant in the present study. The gas generated cannot be entrapped inside the gelatinous layer, and it escapes leading to variation in BLT and TFT.

Swelling Study:-

Swelling study was performed on all the batches (FT1 to FT10) for 5 hr. The results of swelling index were shown in Table 6 swelling index against time (hr) plotted in Fig. 12.

From the results it was concluded that swelling increases as the time passes because the polymer gradually absorb water due to hydrophilicity of polymer. The outermost hydrophilic polymer hydrates and swells and a gel barrier are formed at the outer surface. As the gelatinous layer progressively dissolves and/or is dispersed, the hydration swelling release process is continuous towards new exposed surfaces, thus maintaining the integrity of the dosage form.

In the present study, the higher swelling index was found for tablets of batch FT10 containing HPMC K4M, HPMC K100M and Xanthan gum having nominal viscosity of more than 1, 04,000 cps. Thus, the viscosity of the polymer had major influence on swelling process, matrix integrity, as well as floating capability, hence from the above results it can be concluded that linear relationship exists between swelling process and viscosity of polymer.

Effect of hardness on Buoyancy Lag Time:-

The effect of hardness on buoyancy lag time for batch FT10 was studied. The results of floating lag time of tablets with hardness of 4 kg/cm^2 ,5kg/cm^2, 7kg/cm^2 and 8 kg/cm^2 were 47,58,76,89 and 186 sec respectively and the results were shown Table 10. Buoyancy lag time (sec) V/s hardness (kg/cm^2) plotted and shown in Fig. 5.

In-vitro Dissolution Study and Kinetic modeling of drug release

All the ten formulation of prepared floating tablets of Famotidine were subjected to invitro release studies these studies were carried out using dissolution apparatus, 0.1N HCL (PH 1.2)

The release data obtained for formulations FT1 to FT10 were tabulated in table 9 and fig no.6 shows the plot of cumulative % drug released as a function of time for different formulations.

The invitro release of all ten batches of floating tablets showed the release with an initial effect. In the first hour % drug released were 49.19, 40.30, 37.41, 31.44, 46.66, 34.51, 39.47, 26.66, 30.66 and 27.09 For FT1, FT2, FT3, FT4, FT5, FT6, FT7, FT8, FT9 and FT10 respectively. The values of invitro release were attempted to fit into various mathematical models. Plots of zero order, first order, Higuchi matrix, Peppas and Hixson-Crowell were depicted in fig no 4,5,6,7 and 8 respectively.

The regression coefficients values for formulation FT10 of zero order and first order plotes were found to be 0.9942 and 0. 9850 respectively.

Fig 7 shows the graphical representation of cumulative drug released as a function of square root of time. This Higuchi plot was almost linear with regression coefficient values of 0.9880 for formulation FT10. The linearity suggests that the release of Famotidine from Xanthan gum, HPMC K4M, HPMC K100M was diffusion controlled

Plot of log cumulative percent drug released vs. log time is shown in fig no: 3

Peppas-korsmeyer equation was given as

$$\% R = ktn$$

Where, R= drug release

K=constant

n=slope

t=time

The ‘n’value for FT10 was found to be 0.6725 which is indicates that the release. Approximates non-fickian diffusion mechanism.

Hixson- crowell plot of the formulation were shown in fig-8. The regression coefficient of formulation FT10 was found to be -0.9936. These results indicated that the release rate was limited by the drug particles dissolution rate and erosion of the polymer matrix The in-vitro drug release profile of tablet from each batch (FT1 to FT10) was carried out and results shown in Table 3. % cumulative drug release V/s time (hr) was plotted and shown in Fig.3. From the in-vitro dissolution data it was found that formulation FT1, FT2. FT3, FT4, FT5, FT6, FT7 and FT9 released more than 90% of drug before 8 hr of the study indicating that the polymer amount is not sufficient to control the drug release. While FT8 and FT10 containing Xanthan gum & HPMC K100M released more than 90% of drug with in 8 hr. It concludes F10 had better controlled release than the other formulation. Thus, it may be concluded that the drug release from gastro retentive famotidine tablet is best explained by Zero-order Kinetic model. The values of slope and intercept for Zero-order Kinetic model are 10.120 and 17.177 respectively. # All quantities were in milligrams. # All the batches contained 1% w/w talc and 0.5% w/w magnesium stearate.

Table 2 → Micromeritic properties of powder blend

Powder blend	Angle of Repose (^{0})	Loose Bulk Density (g/ml)	Tapped Bulk Density (g/ml)	Compressibility Index (%)	Total Porosity (%)
FT1	24°.30'	0.130	0.155	16.13	15.78
FT2	26°.77'	0.110	0.130	15.67	20.00
FT3	25°.28'	0.090	0.102	14.48	37.50
FT4	28°.56'	0.105	0.126	16.30	26.31
FT5	29°.88'	0.129	0.146	15.41	27.77
FT6	25°.30'	0.114	0.135	14.30	12.50
FT7	26°.47'	0.132	0.148	12.76	35.00
FT8	24°.28'	0.135	0.154	13.47	13.04
FT9	26°.56'	0.144	0.162	12.34	20.83
FT10	28°.88'	0.106	0.120	15.91	10.00

Table 3→ Evaluation of Physical Parameters of Floating Tablets

Tablets Batch	Weight variation test (%)	Friability (%)	Hardness (kg/cm^2)	Thickness (mm)	Drug content (%)
FT1	± 1.75	0.92	5.6 ±0.47	3.08 ± 0.2	98.02
FT2	±3.52	0.72	4.5 ±0.63	3.16 ±0.010	97.01
FT3	±2.15	0.91	6.4 ±1.27	3.14 ±0.012	99.53
FT4	±1.56	0.86	5.1 ±0.03	3.12 ±0.06	98.01
FT5	±3.54	0.79	4.3 ±0.83	3.16 ±0.011	97.04
FT6	±1.42	0.86	5.1±0.03	3.18 ±0.012	98.40
FT7	±2.11.	0.78	4.3 ±0.83	3.15 ±0.010	97.11
FT8	±1.89	0.81	6.4 ±1.27	3.10 ±0.012	99.55
FT9	±2. 56	0.96	5.1 ±0.03	3.11 ±0.06	99.01
FT10	±2.04	0.75	4.3 ±0.83	3.20±0.011	99.69

All the values are expressed as mean ± SE.

Table 4 → Effect of different polymers on drug release by paddle method										
Cumulative % Drug release										
Time (hrs)	**FT1**	**FT2**	**FT3**	**FT4**	**FT5**	**FT6**	**FT7**	**FT8**	**FT9**	**FT10**
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
1	49.19	40.30	37.41	31.44	46.66	34.51	39.47	26.66	30.66	27.09
2	58.92	52.35	42.36	48.91	69.47	46.85	56.52	36.59	44.31	45.68
3	87.47	65.94	57.71	66.18	76.41	56.61	68.48	51.56	57.96	65.51
4	99.68	76.14	67.49	79.62	81.56	64.17	71.83	67.34	63.49	77.48
5	-	89.57	73.06	83.67	89.58	74.90	91.35	80.11	70.06	81.80
6	-	101.16	80.84	88.04	101.83	82.62	100.16	92.02	81.34	89.07
7	-	-	90.07	100.1	-	89.98	-	100.30	92.07	98.12
8	-	-	97.98	-	-	95.35	-	-	98.18	100.36
FLT (sec.)	175	102	NO	95	136	NO	100	78	190	45
TFT (hrs)	8	8	NO	12	12	NO	>12	6	8	>12

Table 5 → Effect of hardness on Buoyancy Lag Time of formulation FT10	
Hardness in kg/cm^2	**Buoyancy Lag Time (sec)**
4	47
5	58
6	76
7	89
8	186

Time	**Table 6→ Swelling Index of Tablets of Batch FT1 to FT10**									
	FT1	**FT2**	**FT3**	**FT4**	**FT5**	**FT6**	**FT7**	**FT8**	**FT9**	**FT10**
1 hr	32	33	31	40	35	29	36	48	30	42
2 hrs	39	38	38	51	42	36	46	59	41	51
3 hrs	41	43	44	62	49	48	56	65	46	67
4 hrs	49	49	52	73	57	59	64	78	54	76
5 hrs	56	65	68	90	68	62	77	82	60	91

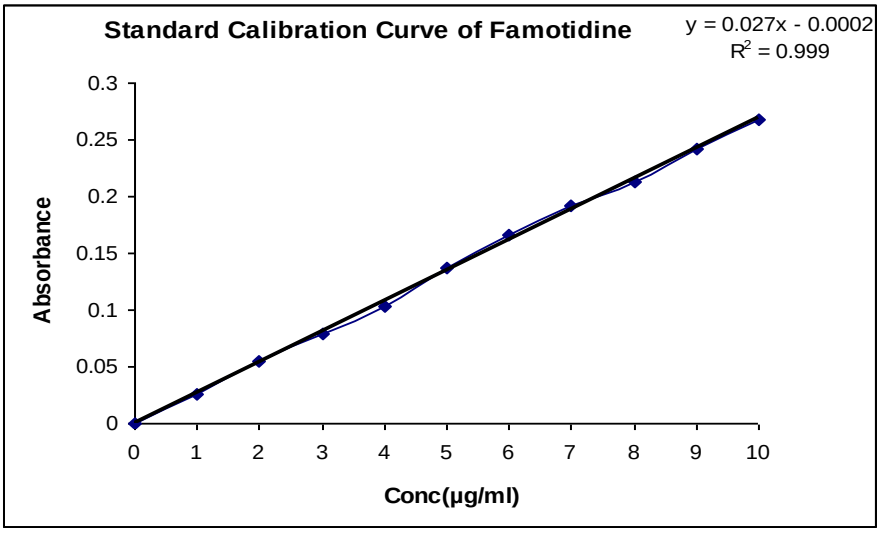


FIG NO: 1 STANDARD CALIBRATION CURVE OF FAMOTIDINE

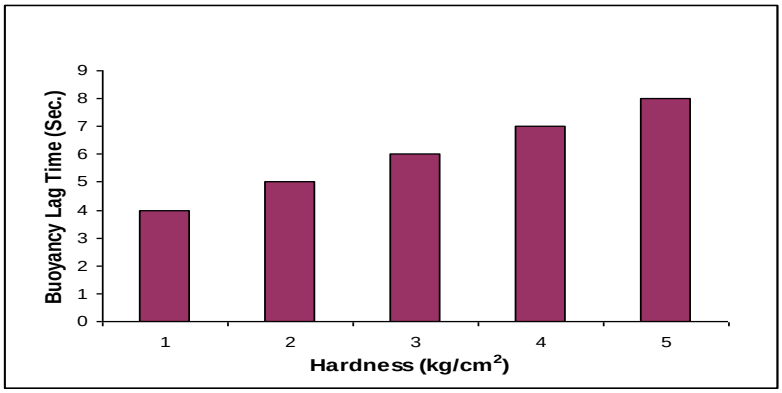


FIG NO: 2 PLOT OF HARDNESS V/S BUOYANCY LAG TIME

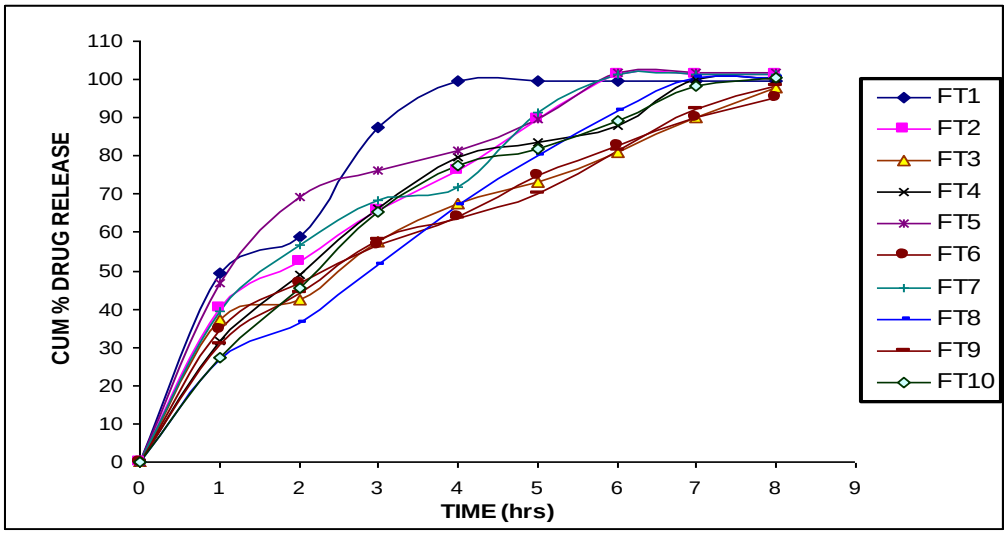


FIG NO 3: IN VITRO DISSOLUTION PROFILE FOR TABLETS OF BATCHES FT1 TO FT10 (USING DISSOLUTION APPARATUS)

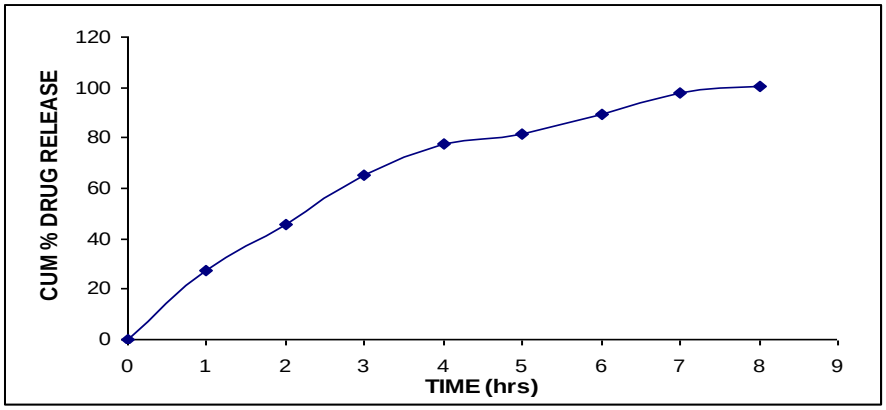


FIG NO:4 INVITRO CUMULATIVE % DRUG RELEASD V/S TIME FOR FORMULATION (FT10) OF FAMOTIDINE [ZERO ORDER RATE]

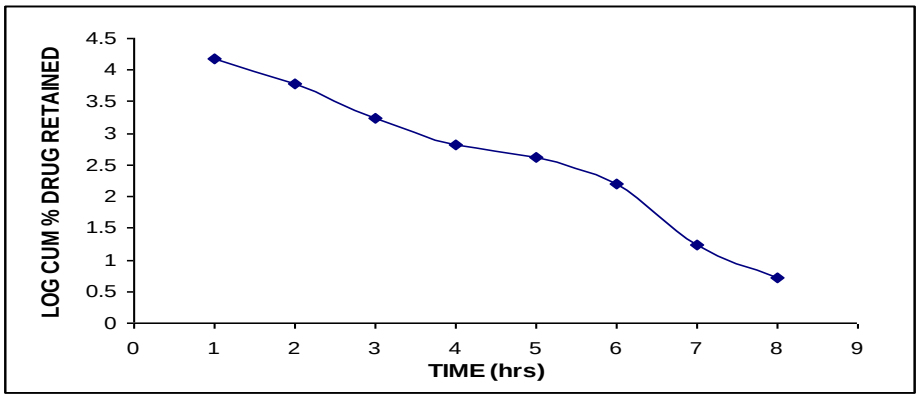


FIG NO:5 LOG CUMULATIVE % DRUG RETAINED V/S TIME FOR FORMULATION (FT10) OF FAMOTIDINE [FIRST ORDER PLOT]

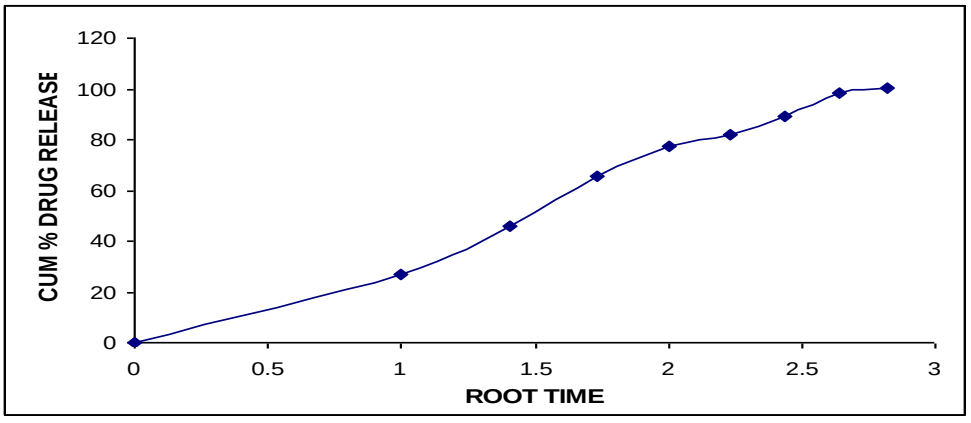


FIG NO: 6 CUMULATIVE % DRUG RELEASED V/S ROOT TIME FOR FORMULATION (FT10) OF FAMOTIDINE [HIGUCHI MATRIX

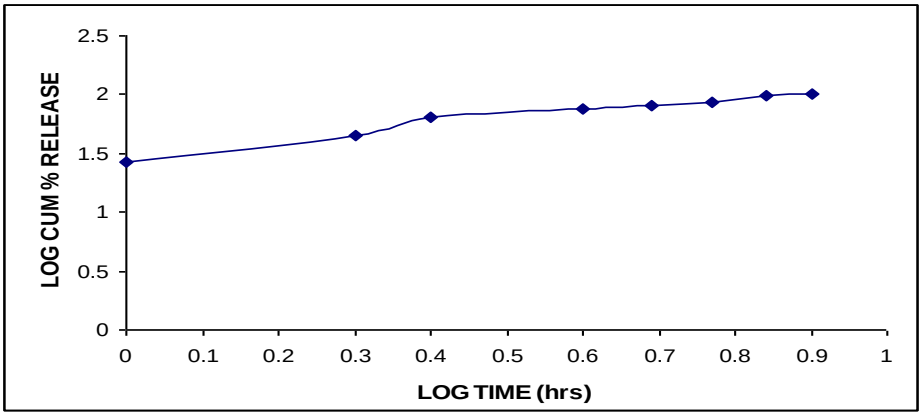


FIG NO: 7 LOG CUMULATIVE % DRUG RELEASED V/S LOG TIME FOR FORMULATION (FT10) OF FAMOTIDINE [PEPPAS]

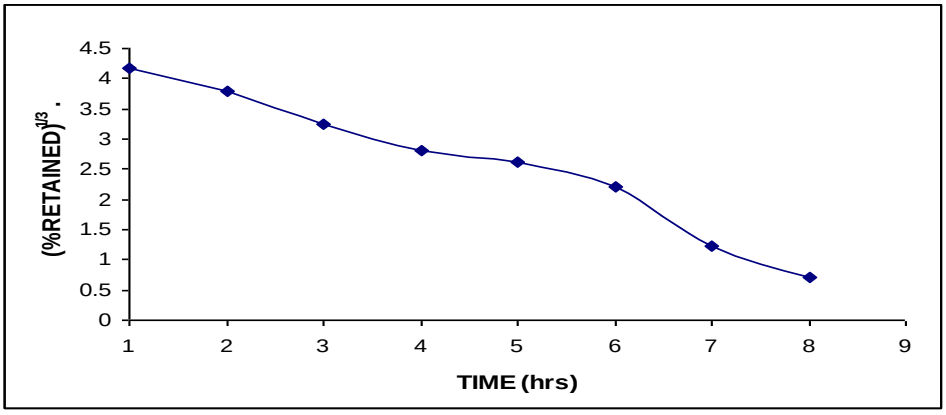
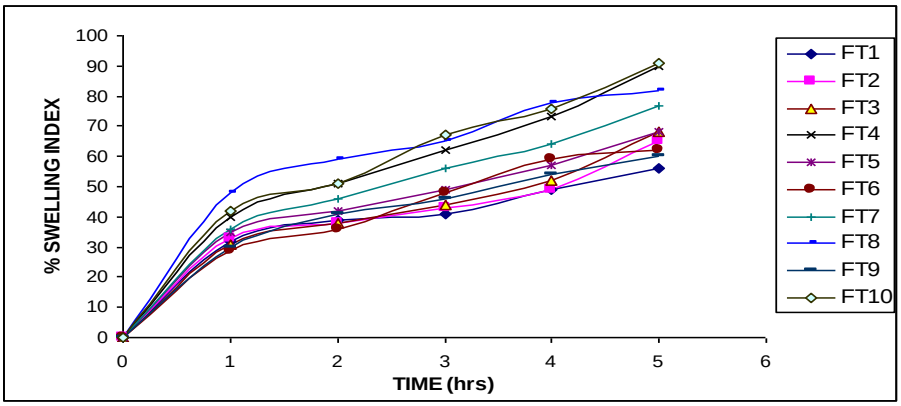


FIG NO: 8 CUBE ROOT OF % DRUG RETAINED V/S TIME FOR FORMULATION (FT10) OF FAMOTIDINE [HIXSON-CROWELL]



CONCLUSION

Gastro retentive (low density) tablets of Famotidine were prepared using polymer which not only imparted buoyancy to the formulations but also reduced floating lag times to a great extend. The use of HPMC K4 M, HPMC K100 M polymer in matrix tablets as density reducing agent has given a different look while Xanthan gum used as release retardant polymer. During the study with the polymer various characteristics of the material were observed; like highly porous spherical structure, good compressibility, good flow property with drug and other polymers, no significant effect on drug release and compatibility with drug and other polymers as seen through IR spectra.

The other most important thing that can be concluded from the study was that the formulation and process variables play some role in the release behavior of the matrices. Faster release of the drug from the hydrophilic matrix was probably due to faster dissolution of the water-soluble drug from the core and its diffusion out of the matrix that fast release of drug retarded by use of Xanthan gum. Formulation F10 has desired release profile by adjusting different parameters that ultimately effect release behavior of the matrices.Thus it is summarized and concluded that HPMC K4M, HPMC K100 M and Xanthan gum can be successfully used in formulation of Famotidine sustained release gastro retentive floating drug delivery system using low density polymer.

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