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FORMULATION AND EVALUATION OF FLOATING TABLET OF RANITIDINE HCL USING NATURAL GUM

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Abstract

The aim of this research is to develop a floating sustained release ranitidine hydrochloride drug delivery system tablets. Floating tablets of drug Ranitidine hydrochloride have been prepared to prolong the residence time in the stomach and thereby increase its bioavailability. Floating matrix tablets of ranitidine hydrochloride was prepared by direct compression technique employing a combination of hydroxyl propyl methyl cellulose K4M (HPMCK4M) and karaya gum as an polymers and sodium bicarbonate is used as generating agent. The floating tablets have been assessed for weight variation test hardness thickness , friability ,swelling index, in vitro floating ability floating lag time. This natural karaya gum which is swellable hydrophilic polymer is used to control drug release.The results showed that the optimized formulation F3 containing 24% karaya gum 40 mg and 20% HPMC 70 mg had good floating property and shorter floating lag time and sustained drug release for 12 hours.

Keywords: Ranitidine hydrochloride, karaya gum, HPMC floating tablet, Release kinetics

Introduction

Tablets are the most commonly used dosage forms due to their suitability for self-administration, compactness easy to handle and ease of manufacture. However, oral administration has limited use for important drugs from several pharmacological categories that have poor oral bioavailability due to partial absorption. or degradation in the gastrointestinal (GI) tract [1]. Some of these drugs are considered to have a narrow absorption window in the upper gastrointestinal tract. Rapid and erratic gastrointestinal transit could result in incomplete release of the drug from the device above the absorption zone, leading to a reduction in the effectiveness of the administered dose." Gastroretention dosage forms (GRDFs) can be developed to increase the retention time of drugs in the stomach. These systems remain in the field of stomach for several hours and can therefore significantly increase the residence time of drugs in the stomach[2,3]. Prolonged retention in the stomach improves bioavailability, reduces drug waste, and improves the solubility of drugs that are less soluble in the high pH environment of the small intestine[4]. Ranitidine hydrochloride (RHCI) is a histamine H-receptor antagonist. It is widely prescribed for active duodenal ulcers, gastric ulcers, Zollinger-Ellison syndrome, gastroesophageal
reflux disease and erosive esophagitis. The recommended oral dose of ranitidine for adults is 150 mg twice daily or 300 mg once daily. Effective treatment of erosive esophagitis requires the administration of 150 mg of ranitidine 4 times a day. The usual dose of 150 mg can inhibit gastric acid secretion for up to 5 hours, but not for up to 10 hours. An alternative dose of 300 mg leads to plasma fluctuations;

therefore, an extended release dosage form of RHCI is desirable. The short biological half-life of the drug (-2.5 to 3 hours) also favors the development of an extended-release formulation[5, 6].

A traditional sustained-release oral formulation releases most of the drug in the colon, so the drug should have an absorption window either in the colon or throughout the gastrointestinal tract. Ranitidine is absorbed only in the initial part of the small intestine and has 50% absolute bioavailability. In addition, metabolism of ranitidine in the colon is partly responsible for the poor bioavailability of ranitidine from the colon[7]. These properties of RHCI do not favor the traditional sustained-release delivery approach. Thus, clinically acceptable sustained release dosage forms of RHCI prepared by conventional technology may not be successful[8],

Oral treatment of gastric disorders with a H2-receptor antagonist such as ranitidine or famotidine used in combination with antacids has also been reported to promote local delivery of these drugs to the parietal cell wall receptor[9]. Topical administration also increases the bioavailability of the gastric wall receptor site and increases the effectiveness of acid-reducing drugs. This principle can be used to improve both systemic and local delivery of RHCI, which would effectively reduce gastric acid secretion.

Several approaches are presently used to increase gastric retention time. These include floating drug delivery systems, which is also known as hydrodynamically balanced systems, swelling and expanding systems, polymeric bioadhesive systems, modified shape systems, high density systems, and other delayed gastric emptying devices[10, 11,12].

The main objective of the current investigation was to develop a unit floating gastric drug delivery system using karaya gum and hydroxypropyl methyl cellulose (HPMC) as polymers[13]. The feasibility of karaya gum was used to control the drug release rate in the development of a floating drug delivery system, evaluation of the prepared dosage forms for their sustained release, in vitro buoyancy, swellingindex, drug content and in vitro drug release[14].

Materials and methods

1. Materials

Ranitidine hydrochloride was received as a gift sample from zydus candila Healthcare Ltd, Ahmedabad,India. Hpmc k4m, karaya gum, sodium bicarbonate, magnesium stearate, talc was purchased from .....

2. Pre-compression parameters of powder mixtures

For each formulation (F1-F8), drug and polymer were taken, sodium bicarbonate together with other diluents were mixed homogeneously for 5 minutes, then magnesium stearate and talc were added.

Different ratios of karaya gum were selected together with hpmc. The powder mixture was mixed in a motor and the resulting mixtures were evaluated for precompression parameters such as bulk density, compaction density, angle of compaction, Hauser ratio and Carr index, angle of compaction was determined by the funnel method, bulk density and compaction density were determined by the cylinder tapping method and Carr's index was calculated using the following formula

Carrs index=[(Df-D0)×100]\Df

Where Df is bulk density and D0 is tapped density

Preparation of ranitidine floating tablet

The floating tablets of ranitidine were prepared direct compression technique . each tablet formulation contains drug,hpmc ,karaya gum,Sodium bicarbonate talc, magnesium sterate and magnesium sterate. The total weight of tablet is 350 mg. The concentration of HPMC k4m used was 80-100mg and different concentration of karaya gum ranging from 20-40 mg was used. 9-12 % of Sodium bicarbonate that is 36- 48 mg was used. The resultant mixture was compressed into tablets using karnavati tablet machineusing 10 mm flat punches.

Post compression parameters

Thickness:

Thickness was measured using a calibrated digital caliper. Ten tablets of the controlled release floating tablets of Ranitidine HCL formulation were picked randomly and thickness was measured individually.

Hardness:

The tablet hardness is defined as the force required breaking a tablet in a diametric compression test. To perform this test, a tablet is placed between two anvils, force is applied to the anvils & the crushing strength that just causes the tablet to break is recorded. The hardness was measured using Monsanto tester. It is expressed in Kg/cm^2.

Friability:

The friability of the tablets was determined using Roche friabilator. It is expressed in percentage (%). Approximately 20 dedusted tablets (W0) were subjected to 100 free falls of 6 inches in a rotating drum & are then reweighed (W). The friability, f, is given by:

$f = 100 \times (1 - W0/W)$

Weight variation test:

Twenty tablets were weighed individually, average weight was calculated & individual tablet weights were compared to the average weight. The tablets meet the USP test if not more than 2 tablets are outside the percentage limit & if no tablet differs by more than two times the percentage limit[15,16.]

Drug content:

Ten tablets were weighed and average weight was calculated. All the 10 tablets were crushed in mortar. The powder equivalent to 10 mg was accurately weighed, dissolved in 100 ml 0.1 N HCl. The volumetric flask was then shaken for approximately 20 minutes. The solution was filtered & 1 ml of filtrate was diluted to 10 ml using 0.1 N HCl. Absorbance was measured at 315 nm using 0.1 N HCl as a blank. The amount of drug present in one tablet was calculated.

The drug content uniformity was calculated using following formula.Drug content = Absorbance × Dilution Factor Slope

In-vitro buoyancy study:

The in vitro buoyancy was determined by the floating lag time. The tablets were placed in a 100 ml beaker containing 0.1 N HCl. The time required for the tablet to rise to the surface for floating was determined as the floating lag time[17].

Determination of swelling index:

The swelling studies were carried out using USP XXIII dissolution apparatus. No rotation was applied. The pre-weighted tablets were immersed in 900 mL of 0.1N HCL and maintained for 8 h at 37.0±0.5
°C. At predetermined time intervals (0, 0.5, 2, 4, 6, 8 and 12 h), the swollen tablets were removed from the solution, immediately wiped with a paper towel to remove surface droplets, and weighed. The swelling index (Sw) was calculated according the following equation:

Sw (%) = Weight of the swollen tablet − initial weight of the tablet X 100Initial weight of the tablet

In-vitro dissolution studies for floating tablets of Ranitidine HCl :

Dissolution of the tablets was carried out with USP XXIII dissolution type II apparatus (paddle) using 900 ml of pH 1.2 buffer (0.1N HCl) as dissolution medium was filled in a dissolution vessel and the temperature of the medium was set at 37 ±0.50 C. The rotational speed of the paddle was set at 75 rpm. 2 ml of sample was withdrawn at predetermined time interval of 1 hr upto 12 hr and same volume of fresh medium was replaced. The withdrawn samples were filtered and analyzed on UV spectrophotometer at 315 nm using 0.1 N HCL as a blank. Percentage cumulative drug release was calculated[18].

Data analysis for controlled release floating tablet of Ranitidine HCL:

To analyze the mechanism of release and release rate kinetics of the dosage form, the data obtained were fitted into Zero order, First order, Higuchi matrix, Peppas and Hixson Crowell model. Based on the r2- value, the best-fit model was selected.

Zero order kinetics:

Drug dissolution from pharmaceutical dosage forms that do not disaggregate and release the drug slowly, assuming that the area does not change and no equilibrium conditions are obtained can be represented by the following equation,
$Q_t = Q_o + K_o t$

Where Q_t = amount of drug dissolved in time t.
Q_o = initial amount of the drug in the solution andK_o = zero order release constant.

First order kinetics:

To study the first order release rate kinetics, the release rate data were fitted to the following equation,$\log Q_t = \log Q_o + K_1 t/2.303$
Where Qt is the amount of drug released in time t, Qo is the initial amount of drug in the solution andK_1 is the first order release constant.

Higuchi model:

Higuchi developed several theoretical models to study the release of water soluble and low soluble drugs incorporated in semisolids and/or solid matrices. Mathematical expressions were obtained for drug particles dispersed in a uniform matrix behaving as the diffusion media. And the equation is,
$Qt = KH \cdot t1/2$

Where Qt = amount of drug released in time t,KH = Higuchi dissolution constant.

Krosmeyer and Peppas release model:

To study this model the release rate data are fitted to the following equation,$Mt / M = K \cdot t^n$
Where Mt / M □ is the fraction of drug release, K is the release constant, t is the release time and n isthe diffusional coefficient for the drug release that is dependent on the shape of the matrix dosage form [19,20].

Formulation Table

Table No:- 1 Formulation table

Sr. No.	Ingredient (mg)	F1	F2	F3	F4	F5	F6	F7	F8
1	Ranitidine HCl	150	150	150	150	150	150	150	150
2	HPMCK4M	70	70	70	70	84	84	84	84
3	Karaya gum	20	20	40	40	20	20	40	40
4	Sodium bicarbonate	35	42	35	42	35	42	35	42
5	MCC	67	60	47	40	53	42	33	26
6	Talc	6	6	6	6	6	6	6	6
7	Magnesium stearate	2	2	2	2	2	2	2	2
	Total	350	350	350	350	350	350	350	350

RESULTS & DISCUSSION

Precompression Parameters

The Micromeritic properties (bulk density, tapped density, hausner's ratio, compressibility index andangle of repose) of the formulated powder blends are tabulated in Table No. 2.

Bulk density and tapped density
Bulk density and tapped density for all formulations varied from 0.442 to 0.616 gm/ml and 0.512 to 0.713 gm/ml respectively. The obtained figures lie within acceptable range and a large difference does not exist between the bulk density and tapped density.

Hausner's ratio
Hausner's ratio was determined from bulk density and tapped density. The Hausner's ratios lie between 1.13 to 1.22. According to USP specifications all formulation blends showed good flow properties.

Compressibility index
The percentage compressibility of powder was determined using Carr's compressibility index. Compressibility index values determined were within 11.94 to 16.16 demonstrating good compressibility.

Angle of repose
The values for angle of repose for formulations F1,F2,F3,F5 and F6 showed angle of repose below 30°indicating good flow property.

Table no :-2 Precompression Parameters

Formulation Code	Bulk Density ($g/cm^{3)}$	Tapped Density(g/cm^3)	Compressibility Index (%)	Hausner's Ratio	Angle of Repose (θ)
F1	0.4426±0.005	0.5126±0.009	13.65±1.21	1.158±0.02	26.93±0.23
F2	0.4986±0.008	0.5814±0.004	14.24±1.32	1.166±0.05	25.74±0.24
F3	0.5234±0.005	0.6243±0.008	16.16±1.27	1.193±0.04	26.94±0.17
F4	0.4813±0.009	0.5446±0.005	11.94±1.34	1.131±0.09	32.81±0.14
F5	0.5418±0.008	0.6183±0.001	12.36±1.04	1.141±0.03	28.67±0.36
F6	0.6168±0.009	0.7136±0.007	13.56±1.02	1.156±0.08	27.08±0.16
F7	0.4576±0.004	0.5228±0.008	12.47±1.21	1.142±0.03	30.61±0.64
F8	0.4754±0.003	0.5845±0.006	15.24±1.03	1.229±0.02	31.54±1.07

FTIR Spectra

The drug-polymer interactions were examined by Fourier Transformation Infra-Red Spectroscopy(FTIR) studies. FTIR analysis of pure drug Ranitidine HCL and physical mixture are shown in Figureno:- 1 , and Figure no:- 2 respectively. The FTIR spectrum of pure drug Ranitidine HCL wascharacterized by absorption peaks at 3249 cm-1 (NH stretch), 3069 cm-1 (CH Furane stretch), 2950cm-1 (CH aliphatic stretch), 1376 cm-1 (NO2 stretch), 1221 cm-1 (CN stretch), 757 cm-1 (CH stretch).Physical mixture showed major peaks at 3253 cm-1 (NH stretch), 3002 cm-1 (CH Furan), 2945 cm-1(CH aliphatic stretch), 1390 cm-1 (NO2 stretch), 1239 cm-1 (CN stretch) and 756 cm-1 (CH stretch). Careful examination of IR spectrum of pure drug Ranitidine HCL and physical mixture it could be concluded that no physical interaction existing between pure drug Ranitidine HCL and physical mixturewith no new peak, indicting an absence of any chemical interaction between them.

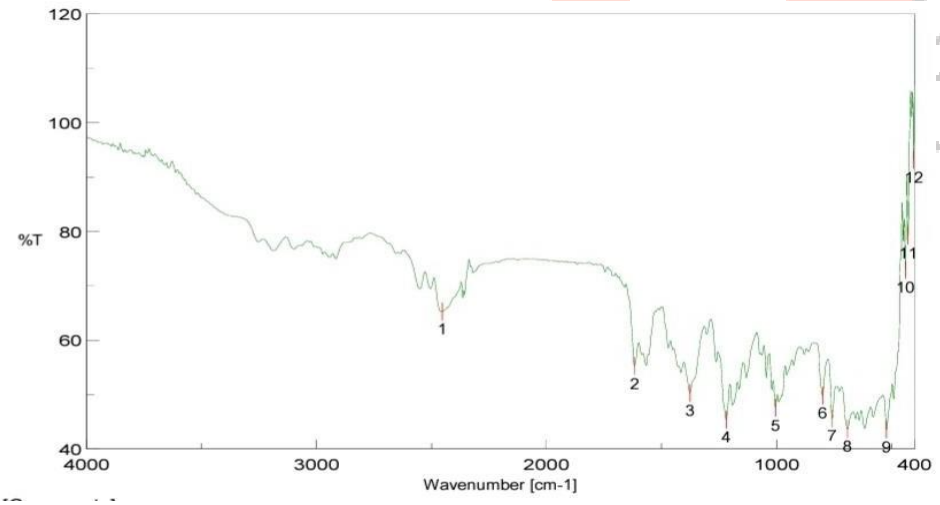

Figure no :-1 IR Spectrum of pure drug Ranitidine HCl

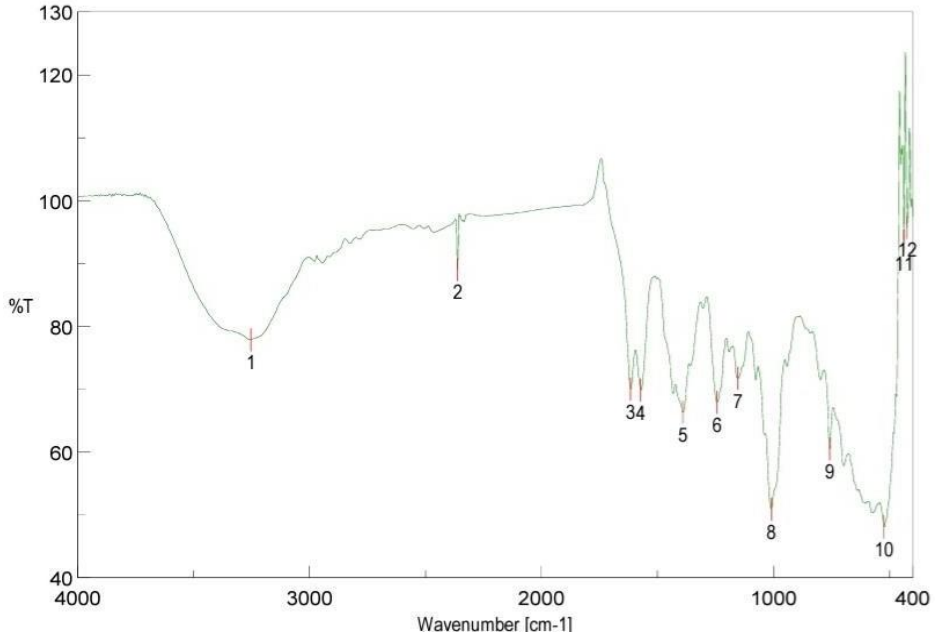

Figure no :-2 IR Spectrum of physical mixture

Post Compression Parameters

Thickness

The test for uniformity of thickness was performed and the results of thickness are tabulated in Table No 3. Tablet mean thickness (n=10) was uniform and the values ranged from 4.60±0.02 to 4.66±0.07 mm.

Weight variation test

The test for weight variation was performed and their results are tabulated in Table No 3 . Weight variation (n=20) was uniform and the values ranged from 0.349±0.09 to 0.353±0.01 respectively. The results indicated that the formulations were within specified range.

Hardness test

The values of hardness for tablet ranged from 4.4±0.1 to 4.8±0.2 kg/cm2. The hardness values of the formulations indicated good mechanical strength. The mean values of hardness of the prepared formulations are tabulated in Table No 3.

Friability test

The friability values of the prepared formulations are tabulated in Table No 3. The values ranged from 0.17 to 0.35 % . The values being < 1% indicated good compactness of the tablets.

Content uniformity test

The results of content uniformity are tabulated in Table No 3. The percent drug content of Ranitidine HCL tablets was between 96.17 to 99.10 . The percent drug content for all the prepared formulations were between specified limits. The formulations therefore passed the test for Content Uniformity.

Table No:- 3 Post compression Parameters

Formulationcode	Thickness ± S.D. (mm)(n = 10)	Hardness ± S.D. (kg/cm^2)(n = 5)	Friability(%)	Averageweight ± S.D. (n=20)	Drug content (%)
F1	4.65±0.064	4.4±0.1	0.351	0.351±0.015	99.10
F2	4.63±0.056	4.5±0.2	0.256	0.349±0.013	97.44
F3	4.61±0.033	4.4±0.5	0.346	0.351±0.015	98.16
F4	4.66±0.055	4.6±0.4	0.206	0.352±0.012	97.58
F5	4.62±0.042	4.8±0.6	0.182	0.351±0.010	96.17
F6	4.64±0.040	4.7±0.5	0.198	0.353±0.013	96.24
F7	4.61±0.049	4.8±0.2	0.176	0.348±0.019	98.92
F8	4.60±0.027	4.7±0.3	0.201	0.349±0.009	98.71

Swelling index

The swelling of the polymers can be determined by water uptake by the tablet. The complete swelling of the tablet was achieved at the end of 12h, so percentage swelling was determined at end of 12 h for all tablet formulations. the maximum percentage of swelling was found in F7 as compared to others formulations, and least percentage of swelling was found in F2 . There is rapid increase in percentage swelling in case of F4,F5,F6,F7,F8 this is because of increase in concentration of polymer that is karaya gum and HPMC. The swelling index was ranging in between 36.67 to 84.34 % as shown in Table No
4. High concentration of Karaya gum showed highest water uptake, showed maximum swelling property.

Table no:-4 Swelling Index (F1-F8)

Formulation code	Swelling Index ± S.D.
F1	39.04 ± 0.5
F2	36.67 ± 0.3
F3	42.76 ± 0.2
F4	45.39 ± 0.4
F5	79.96 ±0.5
F6	72.69 ±0.1
F7	84.34 ±0.4
F8	78.87 ±0.3

In vitro Buoyancy study of Ranitidine HCl

In-vitro floating studies were performed by placing tablet in USP dissolution apparatus-II containing 0.1N HCl, maintained at temperature of 37±0.5°C. The floating lag time and floating time was noted visually and was found to be in the range of 26+0.6 sec to 62+0.4 sec and floating time greater than 12 h (Table No. 5). The floating lag time was found to be more in the formulations which contain low

concentration of gas generating agent (sodium bicarbonate) and high concentration of swelling agent(Karaya gum) in the GRFDDS formulations.

Table no:- 5 *In vitro* buoyancy of Ranitidine floating tablets (F1-F8)

Formulation code	Floating lag time (sec)	Total floating time (h)
F1	26±0.6	>12
F2	28±0.4	>12
F3	27±0.3	>12
F4	31±0.5	>12
F5	49±0.1	>12
F6	56±0.5	>12
F7	45±0.6	>12
F8	62±0.4	>12

% CDR

In Vitro

Drug Release study of Ranitidine HCl Floating Tablet

Dissolution studies on all the eight formulations of Ranitidine HCl floating tablets were carried out using a dissolution apparatus Type II 0.1N HCl (pH 1.2) was used as the dissolution medium. The in- vitro drug release data of different formulations are shown in Table no 6 and Figure No 3. The cumulative percent drug release after 12 hours was found to be in the range of 83.57+0.7, 85.10+0.7, 92.93+0.9, 87.14+0.8% for the formulations F1, F2, F3 and F4 respectively whereas cumulative percent drug release after 12 hours was 82.28+0.6, 71.62+0.6, 75.82+0.8, 62.61+0.5 for formulations F5 to F8 respectively. The cumulative drug release significantly decreased with increase in polymer concentration. The increased density of the polymer matrix at higher concentrations results in an increased diffusional path length. This may decrease the overall drug release from the polymer matrix. F3 formulation showed 92.93% drug release at end of 12 hours so it is considered as best formulation.

Table no:- 6 % CDR of Ranitidine HCl floating tablet

		Cumulative Percentage Drug Release							
Sr. No	**Time**	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**
1	0	0	0	0	0	0	0	0	0
2	1	6.02+0.5	4.28+0.2	2.65+0.4	2.65+0.2	1.05+0.5	1.25+0.5	1.36+0.3	1.52+0.2
3	2	14.04+0.6	11.65+0.6	14.91+0.4	8.17+0.3	7.96+0.5	2.66+0.4	4.08+0.3	4.38+0.5
4	3	19.15+0.2	19.85+0.5	19.87+0.5	16.57+0.2	16.06+0.4	9.68+0.6	16.83+0.2	8.89+0.4
5	4	26.74+0.4	28.54+0.4	31.32+0.4	21.63+0.5	24.44+0.4	16.49+0.4	23.03+0.5	14.71+0.5
6	5	29.12+0.6	29.62+0.3	37.31+0.6	30.31+0.6	31.64+0.6	22.29+0.5	32.74+0.4	19.55+0.6
7	6	43.04+0.7	46.88+0.8	46.82+0.3	39.13+0.5	37.81+0.5	28.33+0.2	28.72+0.5	26.09+0.7
8	7	47.86+0.4	53.68+0.9	62.17+0.5	49.56+0.3	46.08+0.4	33.58+0.2	37.87+0.3	28.39+0.8
9	8	54.86+0.6	57.81+0.6	63.37+0.4	60.65+0.4	51.44+0.7	36.83+0.3	48.24+0.4	35.75+0.5
10	9	59.58+0.2	63.32+0.5	68.47+0.6	63.66+0.6	57.48+0.7	44.07+0.4	55.13+0.5	41.89+0.6
11	10	72.17+0.1	73.45+0.6	73.79+0.7	71.96+0.5	60.48+0.6	48.22+0.3	59.96+0.6	46.32+0.7
12	11	79.78+0.6	81.58+0.6	77.30+0.9	81.99+0.6	69.48+0.5	59.12+0.4	68.64+0.4	54.18+0.6
13	12	83.57+0.7	85.10+0.7	92.93+0.9	87.14+0.8	82.28+0.6	71.62+0.6	75.82+0.8	62.61+0.5

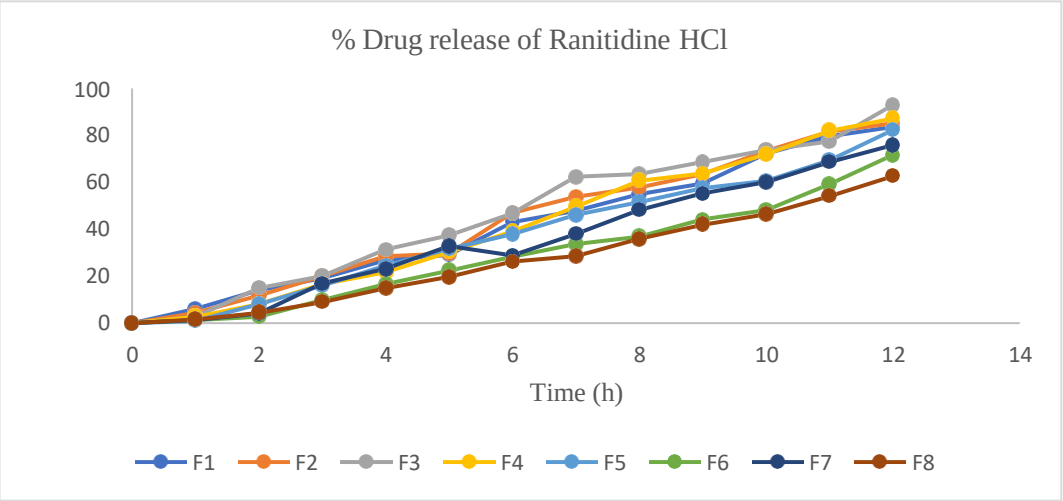

Figure no:- 3 % Cumulative Drug Release Profile of Ranitidine HCl (F1-F8)Comparison of optimized batch with marketed formulation

Marketed formulation of ranitidine (Aciloc 150) dissolution test was performed and it was compared with optimized batch (F3) of ranitidine floating tablet as shown in figure 4. The marketed conventional tablet release 98.11% of drug in 2 hours where as floating tablet of ranitidine release 92.93% of drug in 12h. so optimized batch (F3) was found effective than conventional ranitidine tablet. It was observed that the marketed tablet follow immediate release and developed novel ranitidine floating tablet show sustained release. Karaya gum successfully retained the drug and release slowly through the optimizedbatch of the formulation (F3).

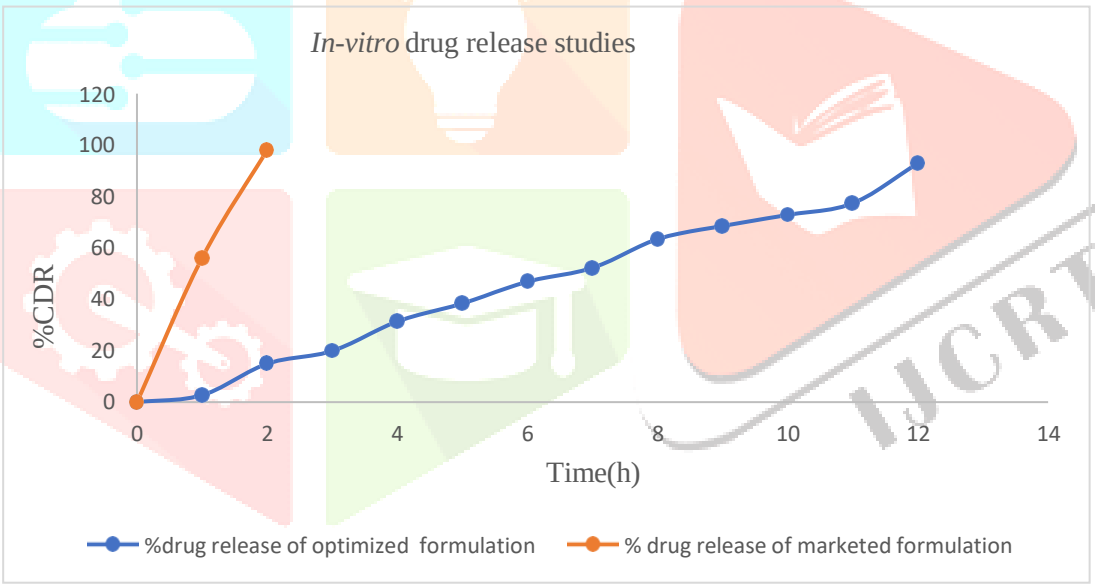

Figure no:- 4 Comparative study of optimized batch (F3) and Marketed formulation

Kinetic data for various models for release study

The in-vitro drug release data of all formulations were analysed for determining kinetics of drug release. The obtained data were fitted to zero order kinetics, first order kinetics and Higuchi model as shown in Table no 7. The highest correlation coefficient (r^2) obtained from these method gives an idea about model best fitted to the release data. From the results of kinetic studies, the examination of correlation coefficient "r^2" indicated that the drug release followed Zero order release kinetics. It was found that the value of "r^2" for zero order ranged from 0.9786-0.9990, which is near to 1 when compared to Higuchi square root ranged from 0.8457-0.9834 and First order ranged from 0.8551-0.9514. It was found that the value of "r^2" for Hixon crowell ranged from 0.9390-0.9726. Further, to understand the drug release mechanism, the data were fitted into Korsmeyer Peppas exponential model Mt / Ma = Ktn. Where Mt / Ma is the fraction of drug released after time 't' and 'k' is kinetic constant and 'n' release exponent which characterizes the drug transport mechanism. The release exponent (n) ranges in between 0.59-0.83. For all the formulations F1 to F8 the values for 'n' ranged indicates that all the formulations followed non-fickian release mechanism. The relative complexity of the prepared formulations may indicate that the drug release mechanism was possibly controlled by the combination of diffusion and erosion.

Table no:-7 Kinetic data for various models for release study

Formulation code	Zeroorder	Firstorder	Higuchi	Peppas		Hixon Crowell	Best fitting model
	R^2	R^2	R^2	R^2	n	R^2	
F1	0.9936	0.9192	0.9012	0.8843	0.64	0.9556	Zero order
F2	0.9956	0.9407	0.9077	0.9903	0.83	0.9712	Zero order
F3	0.9920	0.8551	0.9191	0.9167	0.59	0.9390	Zero order
F4	0.9911	0.9144	0.8818	0.9556	0.60	0.9578	Zero order
F5	0.9925	0.9142	0.9834	0.9911	0.60	0.9556	Zero order
F6	0.9786	0.9054	0.8457	0.9779	0.59	0.9392	Zero order
F7	0.9990	0.9514	0.9344	0.9585	0.61	0.9726	Zero order
F8	0.9947	0.9429	0.8515	0.9869	0.67	0.9581	Zero order

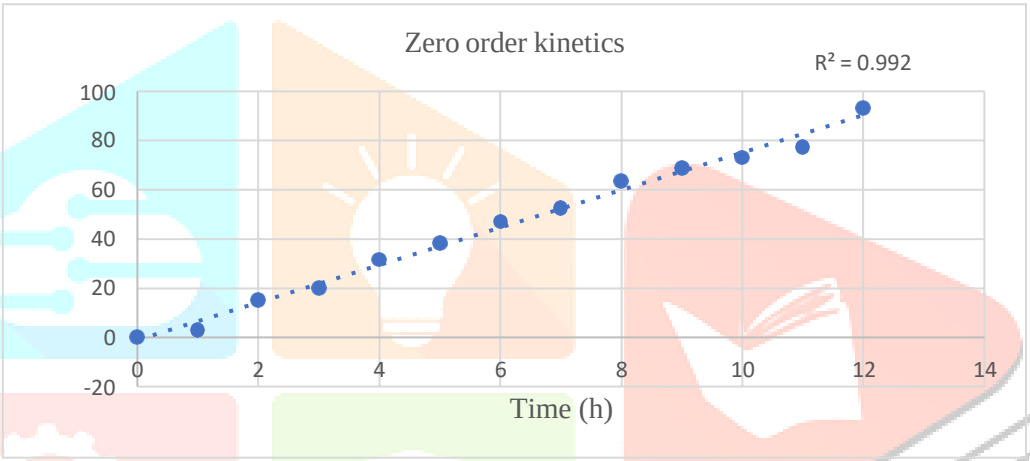

Figure no:- 5 Zero order release kinetics for optimized batch (F3)

CONCLUSION

The objective of the present study was to prepare gastroretentive tablet of Ranitidine HCl by using karaya gum which is a natural polymer. The following conclusions can be drawn from the result obtained. The pre-formulation studies like angle of repose, bulk density, tapped density Haunser's ratio and Carr's index of all formulations were found to be within the standard limits. FTIR studies revealed that there was no chemical interaction between drug and other excipients. The powder mixtures were compressed into tablet and evaluated for post-compression parameters like weight variation, thickness, hardness, friability and drug content. All the formulation batches showed acceptable results. An increment in the concentration of the swelling agent /matrix forming agent lead to the decrease in the drug release this is attributed to an increasing tortuosity and the length of the diffusion path through the matrix as the polymer content increases. An increment in the swelling agent/ matrix forming agent lead to the increment in the floating lag time this could be explained with regard to the rate of the test medium penetration into these matrices and consequently the time required for gel formation increases with the increase in the concentration of the swelling agent. Sodium bi carbonate had influence on both drug release and the floating lag time. This phenomenon might be due to the generation of larger amounts of effervescence with higher NaHCO3 percentages. This would lead to an increase in the rate of pore formation and consequently rapid hydration of the tablets' matrices. In-vitro release profile indicates that sustained release of the drug is possible.

It was confirmed that Karaya Gum successfully retained the ranitidine in optimized batch and indicates sustained release of ranitidine HCl.

REFERENCES

1. Roshan Ahire, Gauri Bhivshet, Rohan Barse, Vijay Jagtap The Quick Review on Floating drug delivery systems: International Journal of All Research Education and Scientific Methods June 2023,1913-1917.
2. GSN Koteswara Rao, KV Ramana Murthy, Aayisha Begum, B Roja Rani, Ch Ragha Naveen, B Raj Kumar, et al. Formulation and Evaluation of Floating Drug Delivery Systems of Propranolol HCl using Modified Pulsincap Technique. International Journal of Pharma Research & Review, Sept 2014; 3(9):15-22.
3. Avaru Geetha Dutt, Ande Pratyusha, Uma Maheshwar Rao, Motor Leela Keerthi, Kalakuntla Sai Krishna, Ashok Morsu. Formulation and Evaluation of Gastro Retentive Drug Delivery System of Tizanidine Hydrochloride: A Review. International Journal of Pharma Research & Review,Oct 2014; 3(10):34-45.
4. Hirtz J. The git absorption of drugs in man: a review of current concepts and methods of investigation.Br J Clin Pharmacol. 1985; 19:77SY83S.
5. Rouge N, Buri P, Doelker E. Drug absorption sites in the gastrointestinal tract and dosage forms forsite specific delivery. Int J Pharm 1996; 136:117-139.
6. Fix JA, Cargill R, Engle K. Controlled gastric emptying. III. Gastric residence time of a non-disintegrating geometric shape in human volunteers. Pharm Res. 1993; 10:1087Y1089.
7. Kedzierewicz F, Thouvenot P, Lemut J, Etienne A, Hoffman M, Maincent P. Evaluation of peroralsilicone dosage forms in human's bygamma-scintigraphy. J Control Release. 1999; 58:195Y205
8. Tortora GJ, Grabowski SR. Principles of anatomy and physiology. 10th ed. USA: John Wiley andSons Inc; 2002.
9. Ashford M, In: Aulton ME, editor. Pharmaceutics: The science of dosage form design. 2nd ed. NewYork: Churchill Livingstone; 2002.
10. Wilson KJ, Waugh A. Anatony and physiology in health and illness. 8th ed. USA: ChurchillLivingstone; 1996.
11. Allen LV, Popovich NG, Ansel HC. Ansel's pharmaceutical dosage forms and drug delivery system.8th ed. New Delhi: B I Publications Pvt Ltd; 2005.
12. Garg S, Sharma S. Gastro-retentive drug delivery system. Pharm Tech 2003;27:50-68.
13. Robinson JR, Lee VH. Controlled drug delivery, fundamentals and applications. 2 nd ed. New York:Marcel Dekker Inc; 1987.
14. Sangekar, S., Evaluation of effect of food and specific gravity of the tablets on gastric retentiontime. Int.J.Pharm, 35: 34-53. 1985.
15. Singh BN, Kim, KH. Floating drug delivery systems: an approach to oral controlled drug deliveryvia gastric retention. J Control Release 2000, 63.
16. Yie W. Chein "Novel Drug Delivery System" 2nd ed. Marcel jekker Inc., New York. 1992, 1-3.
17. Yyas, S. P. and Roop, K. K., Controlled Drug Delivery Concepts and Advances, First Edition, NewDelhi, 196-217. 2002.
18. Vedha hari b.n.et al, the recent developments on gas-tric floating drug delivery systems: an overviewint.j. pharmtech res.2010,2(1), 524- 534.
19. Shweta Arora, Floating Drug Delivery Systems: A Re-view, AAPS PharmSciTech 2005; 6 (3)Article 47, E.372-390.
20. Moursy NM, Afifi NN, Ghorab DM, El- Saharty Y. Formulation and evaluation of sustained releasefloating capsules of Nicardipine hydrochloride. Pharmazie. 2003;58:38-43.