

# Effect of Natural Polymer and Excipients on Gastro Retentive Behavior of Floating Ranitidine Tablet

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## ABSTRACT

The current study was designed for the preparation of a gastro-retentive floating tablet of Ranitidine HCL by using combination of natural polymer Tara gum and synthetic polymer hydroxyl propyl methyl cellulose in an attempt to delay its gastric retention time and the side effects which occurs in marketed preparataion. The tablet was manufactured by the direct compression method. The outcome of varying concentrations of HPMC, Tara gum with sodium bicarbonate and citric acid for gas generating agent and magnesium stearate and talc. The preparation was augmented on the basis of adequate tablet qualities, total duration of floating, floating lag time, and in vitro drug release. The prepared tablet was found to have optimal hardness, low friability, consistent weight uniformity, and thickness. Dissolution study and floating lag time result indicated that formulation F6 showed better and controlled release of a drug. The floating lag time was 03min 30second and the total floating time was 6 hours. FTIR spectroscopy studies showed no interaction between the used polymer and the drug. The result indicated that a combination of synthetic and natural polymers reduces side effects and shows the best result[4,5].

**Keywords:** Ranitidine HCL, Tara Gum, HPMC, Floating tablet

## INTRODUCTION

Gastric emptying for dosage forms is a highly variable process, specifically for those dosage forms that have a stomach stay for more than that of conventionally prepared dosage forms. For controlled release, drugs were designed in such dosage form to drug release at the programmed rate for maintaining the particular concentration of drug-specific time period with minimal side effects. The gastric retentive system is so formulated in an attempt to retain GIT for a longer time period ultimately enhancing the retention time of the drugs in the gastric region hence increasing their potential for absorption. Many different approaches are available that protect gastric retention, including a floating drug delivery system. A floating system, a dense density- controlled them, increases the retention time of a drug in GIT. For this, we use several approaches like muco-adhesion, gas generating, high-density, and low-density systems [1,2]. Floating improves the efficacy of tablets by controlling the rate

of drug release and reducing dose frequency. Floating systems can be either non-effervescent or effervescent floating drug delivery systems. The effervescent approach utilizes various polymers in providing the floating drug delivery system Hydroxy propyl methyl cellulose is a cellulose ether polymer of non-ionic nature. It may be fibrous or in granular powder form which is soluble in cold water and is. In soluble in hot water (Higuchi&Hussain,1978). HPMC has been in use as a tablet binder, as a film coater, and also to produce matrix tablets of extended-release. It is also used for the synthesis of the oral controlled drug delivery system. It has excellent characteristics of compression and good swelling properties, which helps in the formation of a gel layer (external) that further control the release of the drug [4]. Floating effervescent tablets of Ranitidine HCl were formulated in this study. Pre-compression parameters such as repose angle, tapped density, bulk density, and compressibility index and after- compression parameters such as thickness, weight variation,

**Relevant conflicts of interest/financial disclosures:** The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.



friability, hardness, drug content, and in vitro drug release were investigated. Dissolution studies were performed in 0.1N HCl solution. Moreover, FTIR was performed to investigate the drug-polymer interaction.

## MATERIALS AND METHOD

- **Chemicals:** Hydroxy propyl methyl cellulose, Tartaric acid, Tara gum, Lactose, Talc (glidant) Magnesium stearate (lubricant) & sodium bicarbonate. Moreover, Hydrochloric acid, and were also procured by Merck, as the drug Ranitidine HCl. All chemicals were of analytical grades.
- **Instruments:** UV spectrophotometer (shimedzu 1800), paddle (Apparatus II) dissolution apparatus, analytical weighing balance, Erweka hardness tester, vernier calipers, Roche Friabillator, and single punch tablet compression machine.

## II. Experimental Work

- **Extraction and purification of Tara Gum:** The Tara gum was extracted from Tara seed.

- **Charaterization of Tara gum:** The purified and dried extracted powder was evaluated for its micromeritis properties preformulation studies, solubility studies, swelling index, and loss on drying shown in table no.01

### Extraction and purification of Tara gum:

- 1.8 kg of fresh pods from C. Spinosa dried under air flow in solar oven at 35°C.
- Ground down and to obtain 0.9 kg of plant material.
- The plant material was extracted with ethanol (96% 4.5L) in recirculation percolator (2 times per days) over 10 days.
- The ethanol crude extract (8gm) was concentrated under vacuum trapped on silica gel and removed excess humidity at 25°C.
- Afterwards, the ethanol extract was fractionated with the following solvents: petroleum ether(150ml); chloroform(200ml) ethanol; (200ml) and water (200ml)
- The pure Tara gum was oven dried

**Table No. 01: Physiochemical Characterization of Tara gum**

S. No.	Parameter	Result{N=3}
1.	Loss on drying	12%
2.	Swelling index	18
3.	Solubility	Soluble in cold and hot water & insoluble in ethanol
4	Bulk density	0.42
5.	Tapped density	0.59
6.	Compressibility index	17.85
7.	Hausner's ratio	1.12
8.	Angle of repose	20°.52
9.	Percentage yield	20%

### 7. 2 Preformulation Parameter:

- **Organoleptic properties**

The sample of Ranitidine was identified for color, odor and taste which were found to be same as that standard parameters.

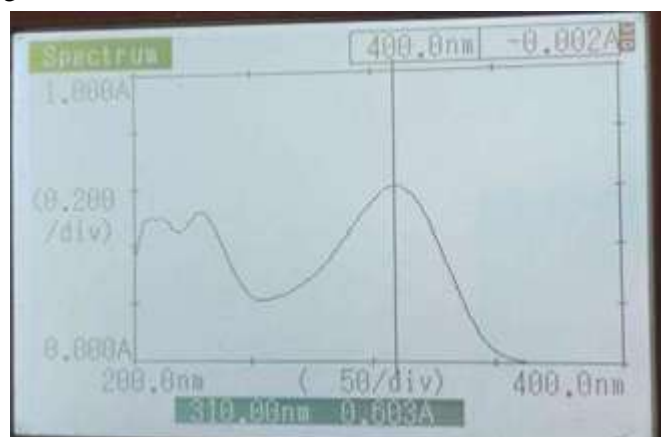
**Table No. 02: Organoleptic properties of Ranitidine HCl**

S. No.	Parameter	Sample
1	Color	Brownish
2	Form	Crystalline powder
3	Odor	Odorless
4	Test	Bitter

### Identification of Drug

➤ **By UV Spectroscopy:** 10 mg drug dissolve in 100 ml of 0.1N HCL it's an obtained stock solution of 100micrograms/ml. Then from the

stock solution, 10 ml of solution is taken and the volume is made up to 100 ml with 0.1 N HCL solution and scanned under UV between 200 to 400 nm wavelength.



**Figure 01: Ranitidine HCL Spectrum by UV Spectroscopy**

➤ **By Melting point determination:**

Melting Point determination is one of the formulation properties in which the temperature at which it changes state from solid to liquid at atmospheric

pressure. During the melting process, the solid and liquid can exist in equilibrium. The Melting point of the Ranitidine HCL drug is determined by using Melting Point Apparatus. [11]

**Table No.3: Melting Point of Ranitidine HCL**

Drug	Observed
Ranitidine HCL	134°C±0.25°

➤ **Calibration curve of Ranitidine HCL**

Measurement of the spectrum of Ranitidine HCL by using UV Visible1800 Shimadzu double beam spectrophotometer. Absorbance was observed at 310nm.

➤ **Dilutions preparation**

From the standard stock solution of Ranitidine HCL different dilutions were prepared. Five different dilutions of 5(µg/ml),10(µg/ml), 15(µg/ml), 20(µg/ml), 25(µg/ml), 30(µg/ml) was prepared from 1000 (µg/ml) standard stock solution.

➤ **Standard stock solution**

An accurately weighed quantity of Ranitidine HCL(10mg) was dissolved in 0.1N HCL to make a10 ml Solution (1000µg/ml).

**Procedure:** After preparation of standard and sample solutions, measurement of the absorbance of different dilutions 5 (µg/ml), 10(µg/ml), 15 (µg/ml), 20(µg/ml), 25(µg/ml) in 1cm cuvette by using UV visible Spectrophotometer.

**Table No.04: Absorbance of Ranitidine HCL in 0.1N HCL at λ 310nm**

S. No.	Concentration. (ug/ml)	Absorbance
1	0	0
2	5	0.161
3	10	0.325
4	15	0.432
5	20	0.572
6	25	0.733

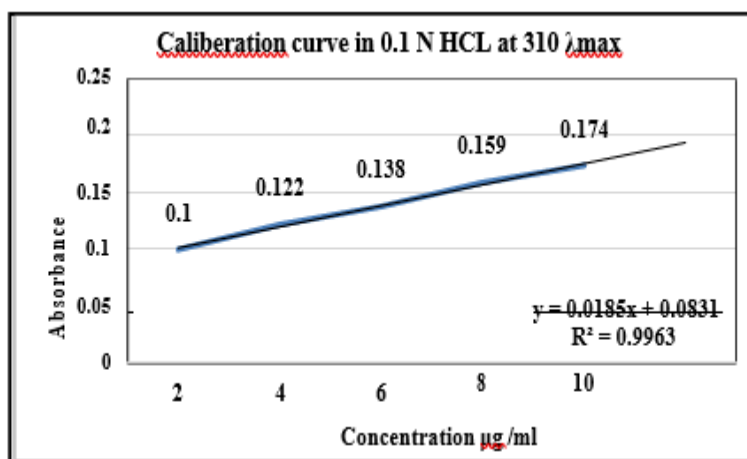


Figure 02: Calibration graph of Ranitidine in 0.1 N HCL Solution

Table No.05: Absorbance of Ranitidine HCL in Distilled Water at λ 310nm

S.NO.	Concentration (ug/ml)	Absorbance
1	0	0
2	2	0.171
3	4	0.282
4	6	0.371
5	8	0.501
6	10	0.635

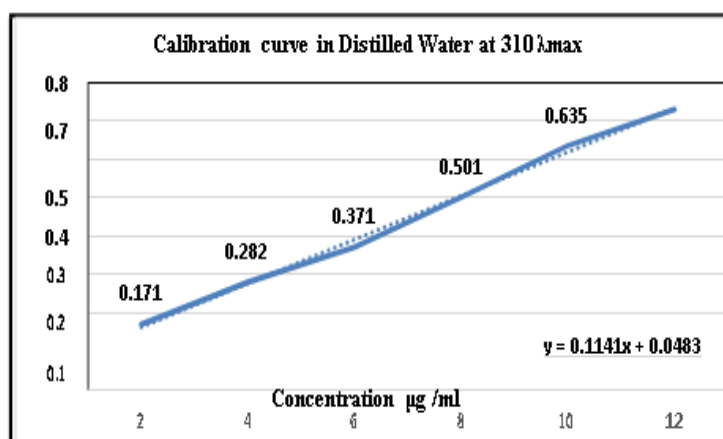


Figure 03: Calibration graph of Ranitidine HCL in Distilled water

➤ **Solubility studies of the drug:**

The Term Solubility is defined as the maximum amount of solute that can be dissolved in a given amount of solvent to form a homogenous system at the specified temperature and Specific

added to the above solutions till Supersaturated Solution from the Mixture is shaken for 10 min till 2hours and after 24 to 72 hrs. Filter the mixture Take Filtrate and Give Absorbance to detect the Concentration of the Drug is Soluble in Different Solutions Pressure from a Saturated Solution.

**Procedure:** To Prepare different solutions Water, HCL, Ethanol, and Chloroform. The drug material is

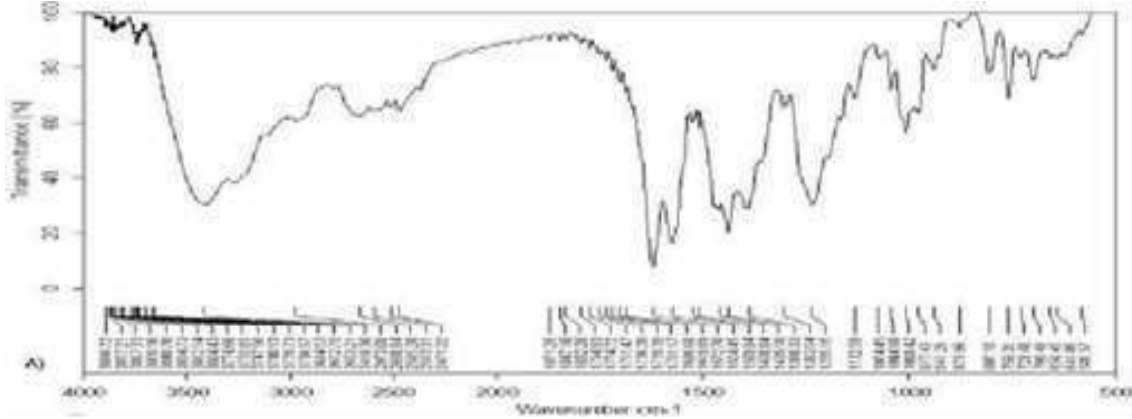
Table No. 06: Determination of solubility of Ranitidine HCL in various solvent:

S. No.	Solvent	Inference
01	Water	Freely soluble
02	Methanol	Soluble
03	Ethanol	Sparingly soluble
04	Chloroform	Very slightly soluble

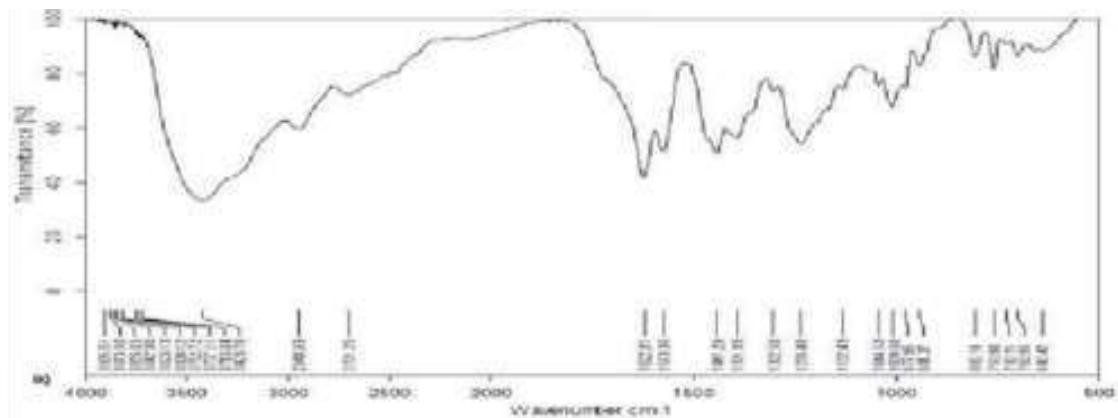
➤ **Drug and Excipient Interaction Studies:**

The raw material pure drug, a physical mixture of excipient, as well as polymer and formulation powder samples, were characterized by FTIR spectroscopy in the range of 4000– 400 cm<sup>-1</sup> using the KBr pellet

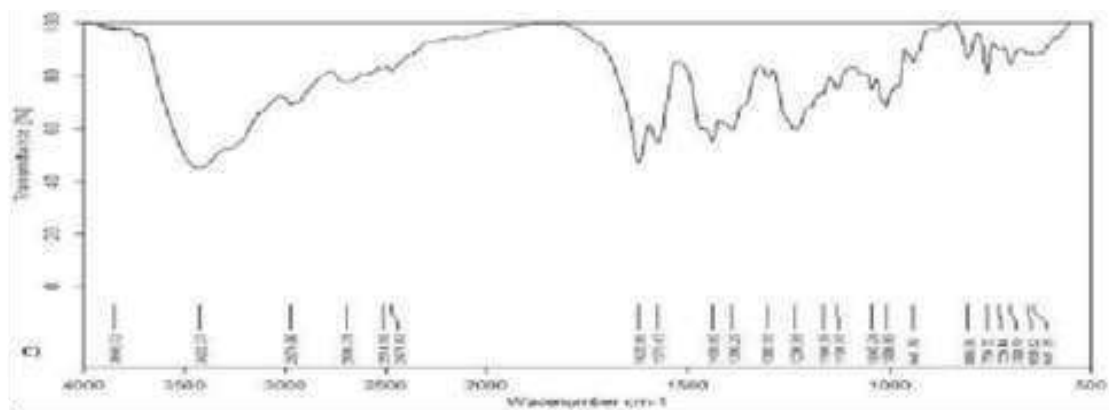
method. The different formulations of Excipients, drug and their physical mixtures were found to be stable under refrigerated conditions, and room temperature. As there were no changes in physical characteristics. Hence it was inferred that the selected excipients are compatible with the drug [7].



**Figure 04: IR spectrum of the Floating Tablet of Ranitidine HCl. FT-IR spectra**



**Figure 05: IR spectrum of the Floating Tablet of Ranitidine HCl. With HPMCK4M**



**Figure 06: IR spectrum of the Floating tablet of Ranitidine HCl With Tara Gum**

➤ **Formulation Code:**

Table No.: 07

S. No	Ingredients in mg	F1	F2	F3	F4	F5	F6	F7	F8
1.	Ranitidine HCL	150	150	150	150	150	150	150	150
2.	HPMC K4M	70	72	74	76	78	80	82	84
3.	Carbapol 934	55	55	55	55	55	55	55	55
4.	NaHCO <sub>3</sub>	45	45	45	45	45	45	45	45
5.	Tartaric acid	30	30	30	30	30	30	30	30
6.	Tara Gum	80	78	76	74	72	70	68	66
7.	Magnesium sterate	10	10	10	10	10	10	10	10
8.	Talc	10	10	10	10	10	10	10	10
<b>Total weight</b>		450	450	450	450	450	450	450	450

### The procedure of floating tablet of Ranitidine HCL

- Firstly, all the elements have been weighed correctly on weighing balance and then pass through sieve No.40.
- The drug HPMC and Carbapol 934, sodium bicarbonate, tartaric acid, and tara gum have been blending a mortar and pestle try to a get uniform pill blend.
- In last talc and magnesium stearate have been blended with the so-received blend.
- The compound turns into compressed into a round pill with the use of a rotator punch machine.

#### ➤ Evaluation of Formulation:

- **Pre-compression studies:** Formulations prepared for compression were subjected to pre-compression parameters to study the flow properties of powders (repose angle, tapped density, bulk density, Hausner's ratio, and compressibility index).

- **The angle of Repose:** To measure the repose angle of weighed powder, the method of the fixed funnel was used. The funnel was stationary with the help of a supporting stand such that the tip of the funnel remained 10cm above the horizontal surface. A circular dish of known radius (r) was positioned on a plane horizontal surface centered beneath the funnel tip, having sharp edges, and the diameter of its cone base was denoted as "D". Powder was filled in the funnel and the funnel tip was obstructed with the thumb which was then immediately removed. The powder was permitted to fall through a funnel over a petridish till the

excess powder slides down at the sides of the petridish. The vertical height (h) of the heap was obtained. The repose angle was calculated by given formula [10].

$$\Theta = \tan^{-1}(2H/D)$$

- **Bulk Density:** Apparent bulk density was evaluated by torrential drug excipients mixture into a graduated cylinder and computing the weight and volume [7]

$$D_b = M/V_b$$

Whereas,  $D_b$  depicts bulk density, M for mass, and  $V_b$  is bulk volume. The unit of bulk density is g/ml

- **Tapped Density:** To find out the tapped density the graduated cylinder the powder sample. The initial powder volume was observed, marked at the graduated cylinder, and tapped onto the hard and smooth impervious surface until the mass or volume changes became constant. The tapped density was determined by the following formula [7].

$$D_t = M/V_t$$

Where as  $D_t$  depicts tapped density, M is for mass and  $V_t$  is for tapped volume.

- **Carr's Compressibility Index:** It was calculated by importing previously received data of bulk and tapped density in to the following equation [7].

$$C.I = (D_t - D_b)/D_t \times 100$$

- **Hausner's Ratio:** It was calculated by inducing values of bulk and tapped density into the following formula:

$$H.R = \frac{D_t}{D_b}$$

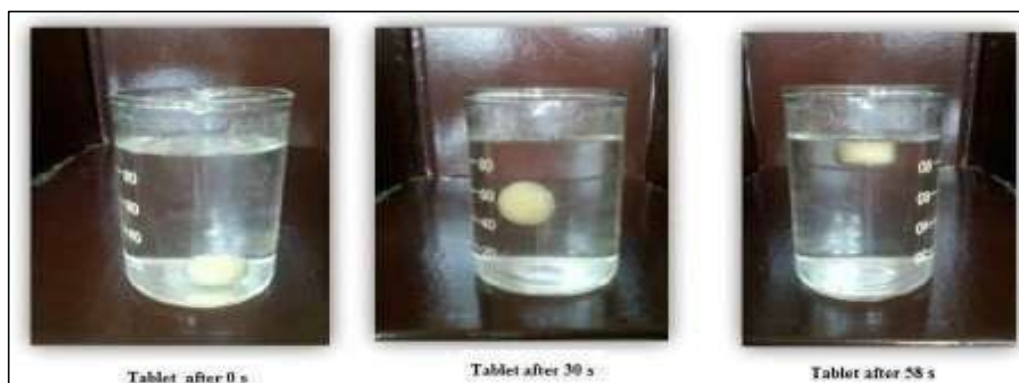
➤ **Post-compression Parameters:**

- **Thickness:** The thickness of the tablet is measured by using a screw gauge. It gives the changes in weight variation of tablets.
- **Hardness:** The hardness of five tablets was determined using Pfizer & eureka hardness tester and average values were calculated
- **Friability:** Friability is the measure of tablet strength. Roche friabilator was used for testing

the friability using the following procedure. Twenty tablets were weighed accurately and placed in the tumbling apparatus that revolve at 25 RPMs were weighed and the percentage loss in tablet. Dropping the tablet through a distance of six inches with each revolution. After 4 min, the tablet was weighed and the percentage loss in tablet weight was determined [12].

$$F = \frac{W_{Initial} - W_{Final}}{W_{Initial}} \times 100$$

- **Floating lag time:** the lag time was carried out in a beaker containing 100ml of 0.1N HCL as a testing medium maintained at 37°C. the time required for the tablet to rise to the surface and float was determined as floating lag time.



- **Floating Time:** floating time is the time, during which the tablet floated in 0.1N HCL dissolution medium (including floating lag time) on immersion in 0.1N HCL solution Ph (1.2) at 37°C, the tablets floated, & remained buoyant without disintegration. Formulation containing HPMC K4M, Tara gum (FM-6) showed good FLT of 3min 30sec [13].
- **Swelling Index Study:** Swelling index study was performed on all the batch (FM-1 to FM- 8). The result of the swelling index was shown. In the present study, a higher swelling index was found for tablet so f batch FM-6 containing a combination of HPMC K4M, and Tara Gum. Thus, the viscosity of the polymer had a major influence on the swelling process, matrix integrity, as well as floating capability, hence from the above results it can be concluded that a linear relationship exists between swelling processes [13].

$$\%SI = \frac{W_2 - W_1}{W_1} \times 100$$

- **Content Uniformity:** it is the amount present in each formulation for formulation (or tablets). Tablets from the formulation were taken and dropped in 100ml 0.1NHCL in a beaker. After 24 hours or when the drug is released completely the same sample was withdrawn (about 1ml) and diluted to 10ml with 0.1N HCL and absorbance was taken at 314nm using a UV spectrometer. From the standard graph % drug release was calculated [14]
- **In vitro Dissolution test:** The rate of release of ranitidine from floating tablets was evaluated by the paddle method from united states pharmacopeia (USP) dissolution apparatus II (paddle method). dissolution test was performed using 0.1 N HCL (900ml) at 37°C ± 0.5 for 6

hours at 50rpm. An Aliquot equal to 5ml was taken at particular time intervals and the samples were substituted with renewed dissolution medium. The samples were filtered and diluted to a suitable concentration with 0.1N HCL. These solutions' absorbance was measured at 310 nm

using a UV spectrophotometer. The cumulative percentage of the release of the drug was determined using the equation obtained from a standard curve [15]

**RESULT:**

**Table No.08: Pre-Compression parameters of the blend.**

Formulation code	Angle of repose (°) ±S.E.M	Bulk density (g/cm <sup>2</sup> ) ±S.E.M	Tapped Density (g/cm <sup>2</sup> ) ± S.E.M	Compressibility index (%)	Hausner's ratio±S.E.M
F1	38.78±0.06	0.51±0.13	0.66±0.05	15.52	1.15±0.19
F2	30.35±0.05	0.43±0.01	0.45±0.08	14.54	1.14±0.18
F3	29.45±0.12	0.31±0.18	0.38±0.10	16.12	1.17±0.06
F4	27.35±0.02	0.40±0.05	0.42±0.18	20.15	1.16±0.12
F5	26.20±0.22	0.44±0.14	0.47±0.14	18.16	1.18±0.05
F6	24.30±0.21	0.18±0.05	0.20±0.15	12.21	1.12±0.10
F7	27.12±0.15	0.32±0.18	0.33±0.12	16.45	1.16±0.12
F8	26.41±0.16	0.25±0.20	0.26±0.10	17.12	1.17±0.19

**Table No.09: Post-compression Parameters of Ranitidine HCl floating tablets.**

Batch	Thickness (mm) ±S.E.M	Hardness (K gcm-2) ±S.E.M	Friability (%) ±S.E.M	Average weight ±S.E.M	Content uniformity (%) ±S.E.M	Floating Lag time(min)	Floating Time (h)
F1	3.98±0.15	5.3±0.15	0.71±0.09	449±0.63	81.46±0.03	1min	3
F2	3.96±0.06	4.8±0.13	0.60±0.10	445±0.26	79.56±0.02	3min	5
F3	3.96±0.03	6.6±0.09	0.50±0.07	451±0.63	80.85±0.01	2min56sec	4.5
F4	3.97±0.17	6.5±0.05	0.66±0.06	452±0.25	78.12±0.03	2min	4
F5	3.94±0.19	6.5±0.05	0.53±0.08	450±0.25	86.16±0.02	1.5min	3
F6	3.91±0.19	6.2±0.19	0.5±0.10	454±0.23	88.63±0.01	3min 30sec	6
F7	3.90±0.18	7.5±0.06	0.45±0.09	450±0.25	76.56±0.02	2min 83sec	5
F8	3.90±0.17	9.6±0.05	0.4±0.05	452±0.33	85.23±0.02	3min	4

**Table No.10: Swelling index:**

Time (Hrs)	F1	F2	F3	F4	F5	F6	F7	F8
1	21±0.50	18±0.33	28±0.34	21±0.21	25±0.66	36±0.12	29±0.12	30±0.66
2	65±0.50	75±0.64	70±0.56	69±0.32	70±0.32	164±0.13	45±0.65	65±0.32
3	80±0.56	120±0.25	80±0.65	130±0.24	120±0.45	212±0.12	120±0.25	90±0.45
4	90±0.60	135±0.24	112±0.33	165±0.34	135±0.12	235±0.15	126±0.23	120±0.12
5	135±0.30	145±0.30	130±0.66	177±0.54	156±0.21	255±0.24	135±0.34	135±0.21
6	166±0.20	165±0.12	145±0.55	185±0.34	170±0.33	265±0.32	145±0.15	165±0.34
7	190±0.30	180±0.12	160±0.66	195±0.12	185±0.33	280±0.22	165±0.22	180±0.32

**Table No.11: Cumulative Drug Release Profile of F1-F8**

Time(h)	F1	F2	F3	F4	F5	F6	F7	F8
0	0	0	0	0	0	0	0	0
0.5	6.54	8.54	7.56	6.54	7.45	6.12	7.56	6.45
1	18.6	11.9	9.74	15.6	12	13.89	14.2	13.65
1.5	26.4	27.4	16.4	25.6	18.6	18.56	19.6	20.65
2	31.5	39.9	25.4	37.5	24.5	24.26	24.67	26.32
2.5	53	58.4	36.45	45	35.12	34.95	35.45	37.65

3	59.4	59.9	50.12	56.7	45.9	40.99	41.23	45.23
3.5	68.2	70.4	56.26	70.5	56.5	45.52	46.25	47.25
4	75.5	80	62.13	78.7	72.6	50.32	51.32	55.45
4.5	79.3	84.6	71.65	86.3	74.5	52.46	56.12	58.56
5	84	85	80.32	88.6	80.5	57.74	58.23	59.36
5.5	89.4	90.2	86.23	93.5	85.6	68.5	70.56	74.35
6	90.5	91.8	88.56	94.2	89.5	74.3	86.12	88.65

## CONCLUSION:

Ranitidine HCL is an antihistaminic drug (antiulcer drug), used for the treatment of gastric. It is widely prescribed in active duodenal ulcers, gastric ulcers, Zollinger- Ellison syndrome, gastroesophageal reflux disease, erosive esophagitis. It was formulated as a floating tablet by using combination of different polymers like synthetic and natural polymer HPMC K4M, Tara Gum, and use of tartaric acid & sodium bicarbonate as a gas-generating agent & Carbopol 940 as a film former in a combination of suitable excipients. The characterization of the drug sample was done by using spectrophotometric analysis and melting point determination. All the observations and recorded data were identical to the values reported in the literature of Ranitidine HCL in 0.1 N HCL, were prepared using a double-beam UV-visible spectrophotometer (Shimadzu 1800). It is easy for the administration to afford and decreased frequency of administration resulting the better patient compliance and acceptance. Therefore, thought worthwhile to develop an oral dosage form, a floating tablet using a suitable polymer to effectively deliver the drug with sustained and prolonged release and the drug before it reaches the absorption window enhanced drug bioavailability and due to the combined polymer of natural & synthetic it reduces the side effect which is found in marketed preparation of tablet, like confusion, constipation, vomiting. It is observed from formulation F6 which shows a better effect than other batches. Thus, it can be concluded that the drug given in the form of a floating tablet provides better patient compliance and an effective mode of treatment.

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