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"FORMULATION AND EVALUATION OF FLOATING TABLET OF RANITIDINE HCl"

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ABSTRACT: -Tara gum, Hydroxypropyl methylcellulose K4M (HPMC K4M), carbopol 934, sodium bicarbonate, tartaric acid, and ranitidine HCL to create a new multiple-unit oral floating dosage form (I). To guarantee homogeneity and consistency, the formulation was extensively characterised using Fourier transform infrared spectroscopy (FTIR) and FTIR spectrophotometric analysis. The research verified that the drug content was more than 90%. We assessed the overall floating length and Floating Lag time for each of the eight formulations (F1–F8) and discovered that the medicine content was constant throughout the batches. With a greater concentration of Tara Gum and HPMC, batch F6's floating tablets stood out for their improved swelling index and longer floating duration. According to these findings, employing floating tablets for medicine administration improves therapeutic effectiveness and patient compliance. A floating drug delivery method that uses the right polymers to accomplish sustained and prolonged drug release is very promising.

KEYWORDS: - Floating dosage form, Ranitidine HCL, Tara gum, Hydroxypropyl methylcellulose K4M (HPMC K4M), Sustained drug release

• INTRODUCTION

The ease of use and adoption of these technologies by patients provide additional benefits. The majority of pharmaceutical experts working today are focused on creating the ideal DDS. One dosage should be given to the patient over the whole course of therapy, and the active medication may be delivered to a specific location. Researchers have effectively created a mechanism that motivates researchers to create release control systems [1]. Migratory Motor Complex [MMC] is organized as alternating cycles of activity and quiescence, which may be subdivided into basic (phase 1), pre-burst (phase 2) and burst (phase 3) intervals [2].

a. **Phase I (basal phase):** During the 30- to 60-minute resting phase, there is no secretion and no electrical or contractile activity.

b. **Phase II (pre burst phase):** An erratic effect that lasts for 20–40 minutes and is characterized by a rise in contraction movement frequency and magnitude. At this point, bile enters the duodenum, and gastric mucus discharges during the later portion of the

second stage and the whole third stage [3].

c. **Phase III:** Its enormous, frequent, forceful contractions known as "housekeeping waves," which can last anywhere from ten to twenty minutes and eliminate undigested food.

d. **Phase IV:** Clinical trials might include a 0–5-minute break between phase III and phase I studies. Every two to three hours, this sequence of electrical events repeats itself from the foregut to the tip of the ileum in a highly fasting state [1,2].

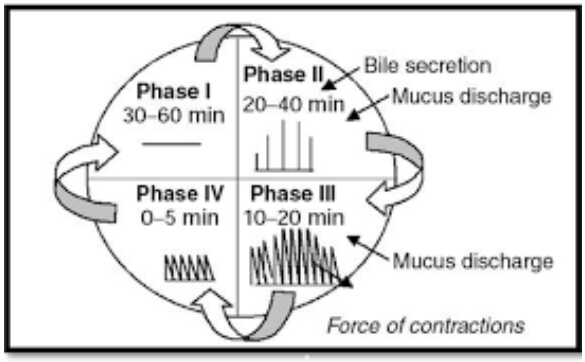


Fig No 1: Gastrointestinal motility pattern

Consequently, during the swallowing condition, the sphincter muscle resists the constant emptying of the stomach. This suggests that GRDDS has to respond rapidly after delivery and be prepared to withstand physiological events in the allotted amount of time. Issues with gastric emptying are widely recognized. For both human and veterinary purposes, the stomach can be utilized as a reservoir for long-term dosage forms· Consequently, there exists a need for controlled-release solutions that demonstrate extended gastrointestinal retention and drug-release characteristics that are not contingent on patient-related factors. The hormone gastrin is secreted by G cells. The contraction of the stomach's smooth muscle serves two primary purposes. Food is ingested and is ground, combined, and liquefied. Gastric emptying is the process by which the wedge is pushed through the pyloric canal and into the small intestine. When the stomach is empty, the mucous membrane lining is thrown in longitudinal folds or rugae, and when it is full, the rugae are ignored and the surface has a smooth, velvety appearance. The nervous system supplies the celiac plexus provides the majority of the sympathetic and vagus nerves provides the parasympathetic feed to the stomach. Venous drainage into the portal vein and branches of the celiac artery provide the stomach with arterial blood [5].

The composition of gastric juice: Certain cells in the mucosa secrete two to three liters of gastric juice per day. roughly 4 mol of hydrogen ions per hour in around 60 ml.

➢

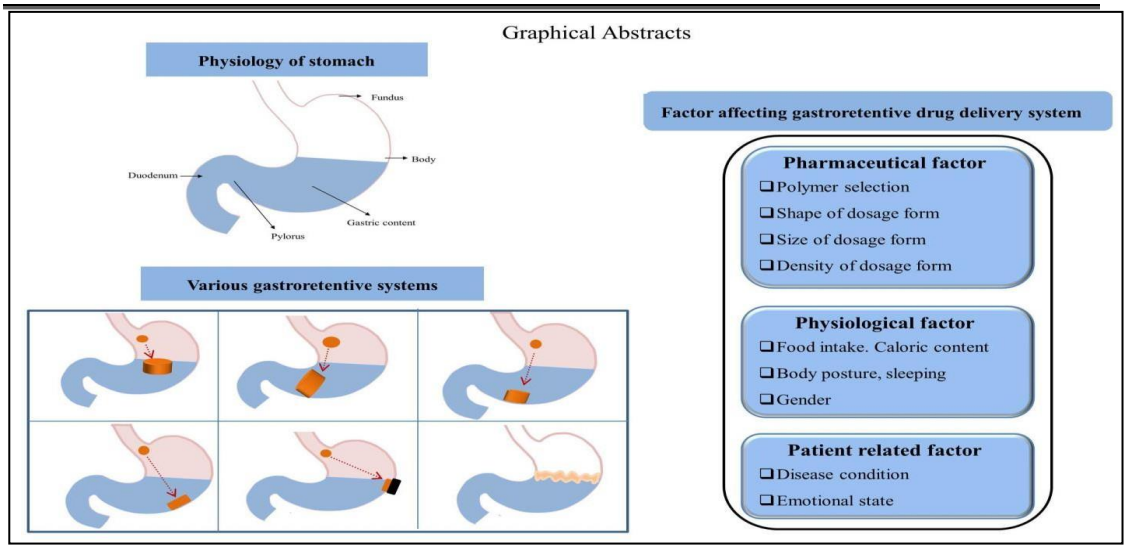


Figure No. 02: Gastric motility of the stomach

- **Criteria for selection of drug for floating drug delivery systems in the stomach**

a. Medications with localized stomach activity, for instance. For example, antacids, misoprostol, and shortly

b. The limited window of absorption for drugs chosen for FDDS in the gastrointestinal tract (GIT) precursor. Levodopa, furosemide, riboflavin, para-amino benzoic acid, and other medications;

c. Antibiotics that interfere with Helicobacter pylori and other common colon germs.

d. Certain medications, such as verapamil HCl, chlordiazepoxide, and diazepam, have poor solubility at high pH levels [3].

- **Floating Drug Delivery System: -** The floating mechanism, which Davis originally reported in 1968, keeps the stomach buoyant for a considerable amount of time because its bulk density is lower than that of gastric liquid.

  As a result, there is a rise in TRB and improved management of drug concentration variations in plasma. There are two types of floating systems: effervescent and non-effervescent.[6]

  The slow dissolution of the plug causes the inflatable chamber to release gas and collapse after a predetermined amount of time, allowing the inflatable system to be expelled from the stomach [7]

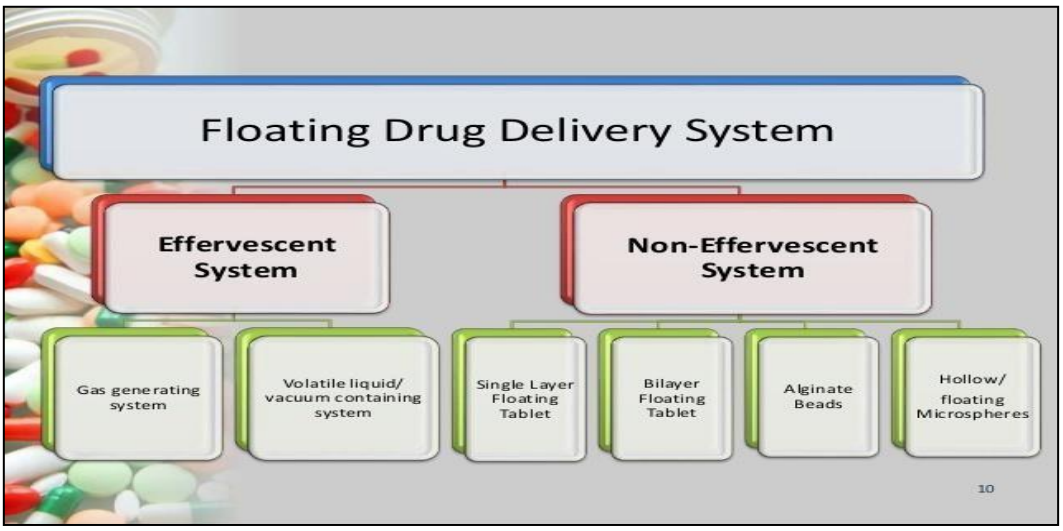


Fig No. 03: Types of Floating drug delivery system

A. Gas generation system: - These floating conveying systems work by releasing CO2 through the foaming reaction of carbonate and bicarbonate with citric acid/tartaric acid. The CO2 is then trapped in the system's gelatinous hydrocolloid layer, reducing its specific gravity and causing it to float on ring 1,18.

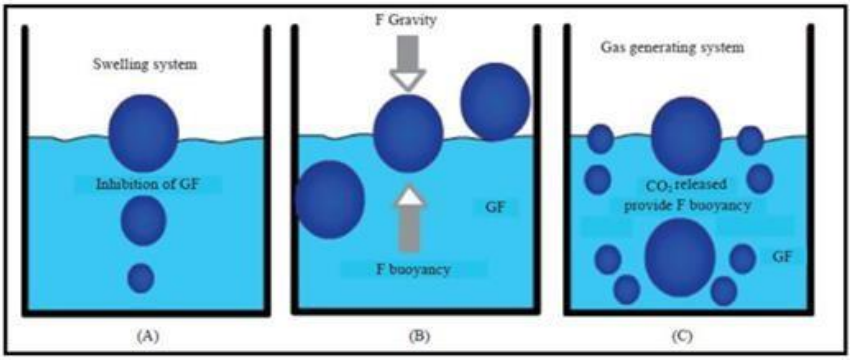


Fig No. 04: The mechanism of the floating system

- **Non-effervescent system**

A. Colloidal gel barrier system: -This combination creates extremely swellable cellulose by combining a high concentration of one or more gels. Gel-forming hydrocolloids are included in the medications in this system, which are used to keep the stomach contents buoyant.

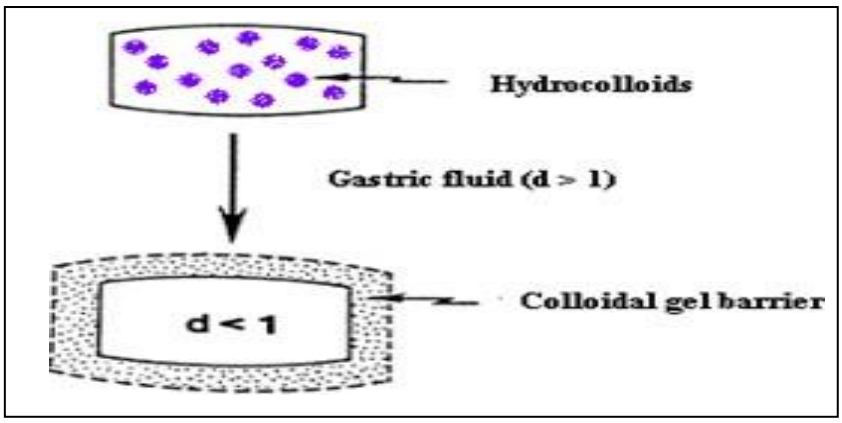


Fig No. 05: Mechanism of colloidal gel barrier system

B. Alginate Microbeads: - Created a range of calcium alginate freeze-dried unit floating dosage forms. Round beads with a diameter of around 2.5 mm can be made by adding the sodium alginate solution to the calcium chloride aqueous solution, which will precipitate the calcium alginate. After the beads are quickly separated, frozen in liquid nitrogen, and lyophilized for 24 hours at -40 °C, a porous system that can sustain buoyancy for 12 hours is formed [8]. With their stomach retentive behavior and several advantages in medication administration, floating dosage systems are an essential technical advancement in drug delivery. Among these benefits are:

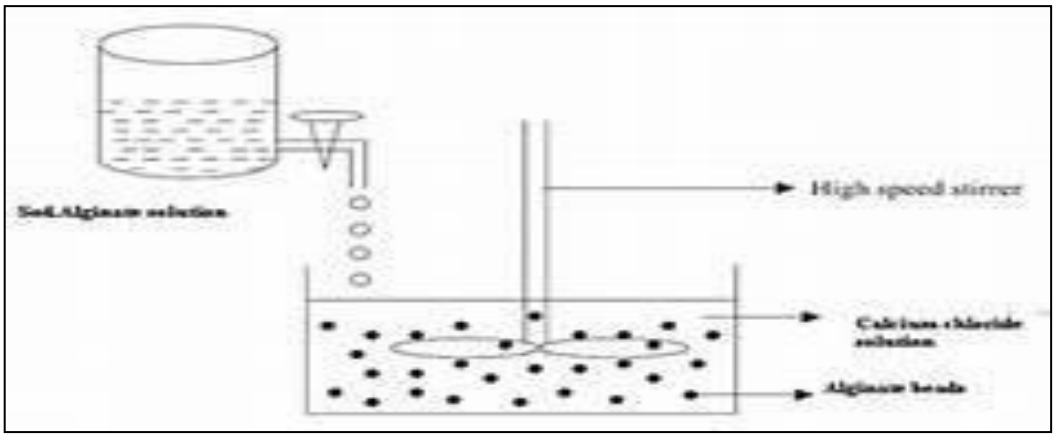


Fig No. 06: Mechanism of Alginate microbeads

C. Hollow Microspheres: - It's made using a novel emulsion-solvent diffusion technique that uses hollow microspheres, or "micro balloons," to hold ibuprofen in the polymer's outer layer. Add the ethanol, the drug's dichloromethane solution, and enteric acrylic polymer to the agitated aqueous PVA solution, which has a 40 °C temperature limit. Drugs and polymers. For almost 12 hours in vitro, the micro balloons remain suspended on the surface

of the acidic dissolving media that contains surfactants [23].

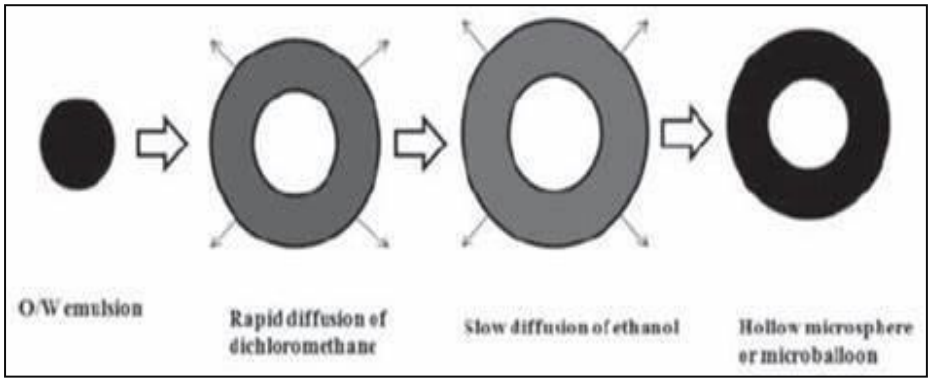


Figure No. 07: Mechanism of Hollow Microspheres

D. The Gastric Retention / Gastric Specific Delivery: - Many techniques for extending the time that oral dose forms remain in the stomach have been abandoned, including high-density and other delayed gastric emptying devices, flotation systems, modified form systems, swelling and expansion systems, and others. (Super-porous, biodegradable hydrogel system, magnet system) [6–7]

E. High-density system: - This approach entails creating a dose form with a density greater than that of the typical contents of the stomach (1.004 g/cm3). The preparations were made by either coating the medication on the heavy core or mixing it with innocuous substances like titanium oxide, iron powder, barium sulfate, and zinc oxide. The density is increased to 1.5–2.4 g/cm3 by this substance. appearance of a medication delivery device that is mucoadhesive or bio adhesive and has density [13].

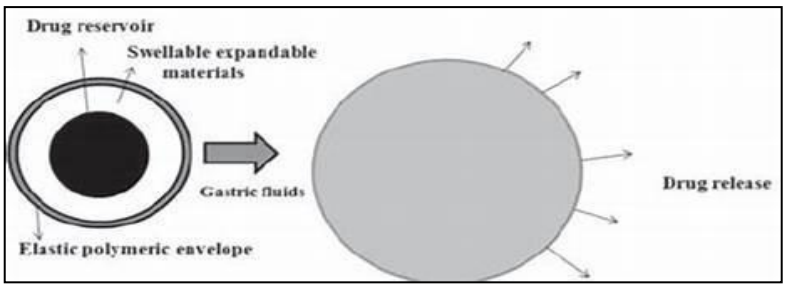


Figure No. 08: Drug release from Swellable system

➢ **Factors affecting gastric retention**

- **Density: -** The stomach emptying rate is directly impacted by the drug system's density. Less than the stomach content (1.004 grams per milliliter) is expected. The drug's density dictates how much space it will occupy in the stomach.

- **Size and Shape: -** When compared to dosage form units with a diameter of 9.9 mm, dosage form units having a diameter greater than 7.5 mm are said to have a higher GRT. When compared to other types of dosage forms, the tetrahedral and ring-shaped dosage forms with flexural moduli of 48 and 22.5 kiloponds per square inch (KSI) respectively are said to have excellent GIT in 24 hours, ≅90% to 100%.[11]
- **Fed state or unfed state: -** In general, the presence of food lengthens the period that the dose is retained in the stomach and gastrointestinal system. Under fasting conditions, the myoelectric complex (MMC) migrates every 1.5 to 2 hours, indicating significant motor activity during intestinal peristalsis. Undigested material is removed from the stomach by MMC. [12].
- **The nature of meals: -** Consuming polymers of nondigestible fatty acid salts might cause the stomach to enter a feeding state, which slows down the pace at which the stomach empties and extends the duration of the drug's release [14].
- **Calorie high-protein: -** Four to ten hours after consuming a meal heavy in fat and protein, GRT can enlarge. Gastric emptying time is slowed down by an increase in calorie content.

➢ **Evaluation of specific gastric systems**

a. Assessment of the impact of different factors on the stomach residence duration of distinct formulations is necessary. The following categories can be used to group these guidelines. a. Galenic: matrix density, ultimate weight flexibility, and diameter size (also known as “cut size").

b. Control: brittleness, hardness (tablet), specific gravity, float time, solubility, and content homogeneity.

c. Shape and geometry.

d. Physiology: bio adhesion, nutrition, posture, sex, and age [11].

- **Physiological parameters: -** Age, sex, posture, feeding, adhesion, health of the subject, and gastrointestinal status [22,26]
- **The diameter: -** Flexibility and density of the Galenic parameter matrix.
- **Control parameters: -** Float time, specific gravity, solubility, uniformity of content, hardness, and brittleness [26].
- **Specific gravity: -** In vitro measurement tools have been made available by Final Weight to ascertain the floating dosage form's true buoyancy over time. The Fourier F it uses to function is the same as the Fourier F needed to submerge the item entirely in the fluid. The fourth approach may be used to assess an object's ability to float or float

by calculating its ultimate weight when submerged in water. The Victorian total of buoyancy and gravity acting on the item is represented by the following equation, which also indicates the size and direction of force as well as the weight generated:

F = F buoyancy- F gravity
F= dfgv-dfgv = (DF-DS)gv

where g is the acceleration brought on by gravity, DF is the fluid's density, DS is the object's density, and F is the total vertical Fourier or the object's total weight. V is the object's volume, and it is the object's mass [12].

- **Types of floating matrix: -**

1. **New Double Layer Floating Compressed Matrix**

The first layer of the tablets is primarily consisting of a hydrodynamic polymer and a combination that produces carbon dioxide. The tablet rises and stays buoyant due to the carbon dioxide that is trapped in the vaporized hydrocolloid and released by the gastric medium. Excavations that are discharged gradually and under control are found in the hydrophilic matrix outer layer.

2. **New multi-unit oral floating dosage form**

According to the reported data, the human stomach is in a nourished condition and takes one to six hours to empty. Consequently, it is occasionally impossible to achieve adequate bioavailability and prolonging of effective plasma levels when sustained release dose forms are taken orally, particularly for medications with restricted intestinal absorption sites. Recent research has shown that some formulations—like floating dosage systems and bioadhesive systems—have longer GETs (gas emptying times).

A sustained-release pill containing the drug and a double-layer drug surrounding the pill are the components of the system; the external layer is an effervescent layer consisting of sodium bicarbonate, and the internal layer is an effervescent layer consisting of sodium bicarbonate. The swellable film is divided into two sub-layers to allow for direct contact between sodium bicarbonate and tartaric acid on the outside. Nevertheless, since the majority of floating dose systems are single unit preparations, a single unit type can be transferred to the small intestine in a short amount of time, regardless of floatation capacity].

3. **Sustained Release Floating Granules**

The active components of the main medication are contained in pharmaceutical granules that are kept in the stomach and are covered in a swellable film. Dextromethorphan hydrochloride (20%) was the medication utilized. Particles based on chitosan exhibit

varying buoyancies in neutral and acidic solutions and may constantly release prednisolone. When using standard capsules, the plasma concentration peaks one hour after the medication is administered; however, when using particles containing a 1:2 blend of drug and chitosan, the chitosan creates a drug level that is sustained throughout time [32].

- **METHODS**

1. **Direct compression** - Powdered materials are compressed straight into tablets without changing the materials' physical composition. When a crystalline material has good physical properties—such as flow property and compressibility—direct compression is typically used. The primary benefits of direct compression are its low cost, minimal operating risk, and time-consuming nature.
2. **Wet granulation –** This is the most popular technique for making tablets. In this method, powders are adhered to one another by a suitable binder. The binder is added by diluting it with a suitable solvent before it is added to the blend powders, resulting in wet granules. These granules are then dried appropriately to remove the solvent, creating dried granules. The production of the first granules is mainly caused by surface tension forces and capillary pressure. The primary benefit is that, although being multistage and time-consuming, it satisfies all requirements for tablet formation [15].

- **EXPERIMENTAL WORK**

Table No. 1: List of Instrument used

S. No.	Instrument used	Make/Model Name
1.	UV spectrophotometer	Shimandzu 1800
2.	Melting point apparatus	Rolex
3.	Dissolution test apparatus	DBA company
4.	Hardness tester	Monsanto tester & pfizer
5.	Friability apparatus	Roche friabilator
6.	Tablet compression machine	Hardik pharma
7.	Weighing balance	Citizen
8.	pH meter	MK VI
9.	Bulk density apparatus	Scientech Pvt. Ltd.
10.	Hot Air Oven	S. M. scientific instrument Ltd.

- **Extraction and purification of Tara gum:-** 8 kg of fresh pods from C. Spinosa dried

under air flow in the solar oven at 35ºC.Ground down and obtain 0.9 kg of plant material. The plant material was extracted with ethanol (96% 4.5L) in a recirculation percolator (2 times per day) over 10 days. The ethanol crude extract (8gm) was concentrated under vacuum trapped on silica gel and removed excess humidity at 25ºC. Afterward, 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.

- **Physiochemical characterization of Tara gum: -** The purified and dried extracted gum powder was evaluated for its solubility, swelling index and loss on drying.
- **Solubility study**: Solubility of Tara gum powder was determined in aqueous medium and organic solvent.
- **Swelling index: -** The study was carried out by using a 100ml stoppered graduated cylinder. The initial bulk volume of 1gm of Tara gum was noted. Water was added in sufficient quantity to ensure 25ml of uniform dispersion by vigorously shaking every 10min for 1hr and then allowed to stand for 24hrs.The dispersion solution was stored at room temperature and the sediment volume of the swollen mass was measured after 24hr.

$$\textbf{Swelling Index} = 100[(v2-v1)/v1]$$

where, Initial volume v1 of material before hydration

v2= Volume of hydrated material

- **Loss on drying: The loss** on drying technique is used to determine high level of moisture or solvents present in the sample. The material sample was weighed(w1) and heated in an oven for 2h at a temperature of $40^0C \pm 2^0C$. It was cooled in the dry atmosphere of desiccators and then finally weighed(w2).

$$\textbf{\% Loss on Drying} = [(w1-w2)\ w1]100$$

Where W1= Initial weight of the powder W2=Final weight of the powder

- **PREFORMULATION STUDY**

- **Authentication of drug sample by using FTI: -** A pure sample's Fourier transform infrared spectroscopy (FTIR) spectrum was captured and used in the KBr pellet technique of FTIR spectroscopy analysis. 10 mg of ranitidine HCL combined with the same weight of potassium bromide. Throughout the frequency range of 4000-400cm-1, the spectra were scanned.[16]

- **Determination of Melting point:** The melting point was established by using a melting point instrument. The medication sample was extracted and put into a capillary tube with a thin wall. The tube measured 10–12 cm in length, 1 mm in diameter, and had a closed end. After heating the capillary in a melting point device and melting the drug sample, the melting point of the powdered sample was noted.
- **Preparation of Calibration curve: -** Using a Shimadzu 1800 UV visible spectrophotometer, the calibration curve for ranitidine HCL was created in a 0.1 N HCL solution. A 50ml volumetric flask containing 50mg of ranitidine HCL was precisely weighed, and the volume was increased by adding 0.1 N HCL to create a 1000µg/ml stock solution of the drug. From the stock solution 1ml was taken and transferred into a 10ml volumetric flask and the rest of the volume was made up with solvent to obtain a 100µg/ml solution from which further dilutions were prepared [16]
- **Determination of solubility: -** Water, ethanol, chloroform, and NaOH were among the several solutions that were used. The drug material was added to the aforesaid solution until the combination became supersaturated. The mixture was then agitated for 10 minutes to 2 hours. After 24 to 72 hours, the mixture was filtered to extract the filtrate, which was then measured for absorbance to determine the drug's concentration in various solutions [17].
- **Drug Excipients Compatibility Study: -** Physically observation of sample was done visually at every week for any change in the sample for 4 weeks [31].

Table No. 2: Selection of Excipients

S. No.	Excipients	Purpose
1.	HPMC K4M	Rate controlling agent
2.	Carbapol 934	Binder
3.	Sodium bicarbonate	Gas generating agent
4.	Tartaric acid	Gas generating agent
5.	Tara gum	Rate controlling agent
6.	Magnesium stearate	Lubricant
7.	Talc	Glidant

➢ **FORMULATION AND DEVELOPMENT: -**

- **Preparation of floating tablet of Ranitidine HCL by direct compression method** Weighed the all ingredient as per the quantities defined in below given table No.04. Pass all the ingredient through the sieve no. 80 and collected individuals in polybegs. Mixed

measure quantity of Hydroxy propyl methyl cellulose K4M, Carbopol 934, Sodium bi Carbonate, Tartaric acid, and Tara gum, have been blended well in a pestle and mortar in a try to get a uniform pill blend. Finally, the well-received combination has been combined with talc and magnesium stearate. The chemical was crushed using a rotary punch tablet machine to create spherical pills. Table No. 3[56] may provide the formulas for the uncommon formulations grouped as F1–F8.

Table No. 3: Composition of Ranitidine HCL floating table

Sr. No.	INGREDIENTS	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.	NaHCO3	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 state	10	10	10	10	10	10	10	10
8.	Talc	10	10	10	10	10	10	10	10
TOTAL WEIGHT		450	450	450	450	450	450	450	450

- **EVALUATION PARAMETER**

- **Angle of repose: -** The angle of repose of the powder blend was determined by the funnel method. The accurately weighed powder blend was taken in funnel. That is height of the funnel was maintained in the funnel touches the heap of powder blend. The powder blend was to flow through the funnel freely onto the surface. The diameter of the powder cone was determined and angle of repose was calculated used the following equation**.**

$$\theta = \tan^{-1}(h/r)$$

Where h= height of the cone r= radius of the con

- **Bulk Density:** – Bulk density is the ratio of the mass of an untapped powder and its volume, including the inter-particulate void volume contribution. It is expressed in gm/cm^3 is given by

$$BD = M/Vo$$

Where BD= bulk density M= weight of the sample in gm Vo= volume of the blend in ml

- **Tapped Density: -** It is a ratio of tapped mass to tapped volume of powder. Tapping the powder blend for fifty times measured the volume. Then the tapping was done for fifty times and the tapped volume was noted down. Via using Tapped density formula calculated tapped density.

TD = M/Vt

Where TD= tapped densityM= weight of sample in gmVt= tapped volume of blend in ml

4. **Compressibility index –** Carr´s index is calculated using the following formula

Carr´s Index (%) = (TD-BD)/TD ×100

➢ Evaluation of post compression parameter of tablets

1. **Thickness: -** Randomly selected the twenty tablets from the formulation and thickness was measured individually by screw gauge. The result was expressed in millimeter.
2. **Hardness: -** The tablet's hardness reveals how well it can tolerate mechanical shocks during handling, packing, and shipping. The tablet's hardness was ascertained by using the Monsanto hardness tester. The tablet was put on the bottom plunger of the hardness tester, and the Monsanto tester scale's zero reading was obtained. The Monsanto hardness tester's standard range is 0 to 20 kg. The screw knob was turned forward until a random reading was taken on each formulation batch's tablet and the average was noted. It is stated as kg/cm^2. The tablet's maximum hardness ranges from 5 to 8 kg/cm2 [25].
3. **Weight Variation: -** Twenty tablets were randomly selected from each batch and the weight of their average weight was determined. Then individual weight of tablets was compared with average weight of tablets. The weight was measured using digital weighing balance.

Table No. 4: Criteria for percent deviation from average weight as per IP

Dosage Form	Average Weight	% Deviation
Floating tablet or uncoated tablet	80 mg or less	10%
	More than 80 but less than 250mg	7.5%
	250mg or more	5%

4. **Friability: -** Initially weighed the ten tablets and transferred them into the friability. The friability was operated at 25rpm for 4min. after 4min the tablets were weighed again. The Friability was calculated by using the formula, general acceptance limit is 0.5-1% [54]

$$\% \text{ Friability} = \frac{\text{Initial weight- final weight X 100}}{\text{Initial weight}}$$

5. **Drug content:** Weighing 30 tablets allowed us to determine their average weight. ten pills mashed in a mortar as well. After dissolving 100 mg of ranitidine in 100 milliliters

of 0.1 N HCL, the mixture was agitated for 20 minutes. The solution was filtered, and 5 milliliters of the filtrate were used to dilute 100 milliliters of 0.1 N HCl acid. The resulting solution's absorbance was measured. use 0.1 N HCl acid as a blank at 310 nm. It was computed how much medication was in each pill [21].

- **In vitro drug release study: -** Using a paddle-type apparatus, 900 ml of media is taken into the flask at 50 rpm and 37 oC±0.5 C at different times intervals. The sink condition is maintained, 5 ml of sample is removed, and all samples are filtered. A 1 ml solution is pipetted out, and the volume is made with the appropriate solvent. The samples are then analyzed using a UV visible spectrophotometer at a lambda max of 310 nm [24]

- **Swelling index:** First, the tablets, and kept in 100ml of 0.1N HCL acid solution and were drawn out of the solution to determine time points, dried and their weights were taken [21].

$$\% SI = \frac{(W2 - W1)}{W1} \times 100$$

- **Floating lag time**: Three individual tablets from each formulation were put in an individual flask containing 400ml of 0.1 N HCL acid solution. Then note time in minutes for each tablet to go from the bottom to the top of the flask is called floating lag time was measured [25].

Figure No. 9: Mechanism of Floating Lag time

- **Floating Time**: Three individual tablets from each formulation were put in an individual flask containing 400ml of 0.1N HCL acid solution. Then note the time for which tablets float on the surface of water [23]

- **RESULT AND DISCUSSION:**

- **Extraction and purification of Tara Gum:** The Tara gum was extracted from Tara seed.
- **Characterization of Tara gum:** The purified and dried extracted powder was evaluated for its micromeritic properties preformulation studies, solubility studies, swelling index,

and loss on drying shown in table no.0

Table No. 5: 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	20º.52
9.	Percentage yield	20%

- **PREFORMULATION PARAMETER:**

- **Organoleptic properties: -** The sample of Ranitidine was identified for color, odor, and taste which were found to be the same as the standard parameter.

Table No. 6: Organoleptic properties of Ranitidine HCl

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

- **Identification and Drug Characterization**

- **Determination of maximum wavelength using UV spectroscopy: -**The maximum wavelength of Ranitidine HCL was found to be 310nm which matches the reported wavelength.

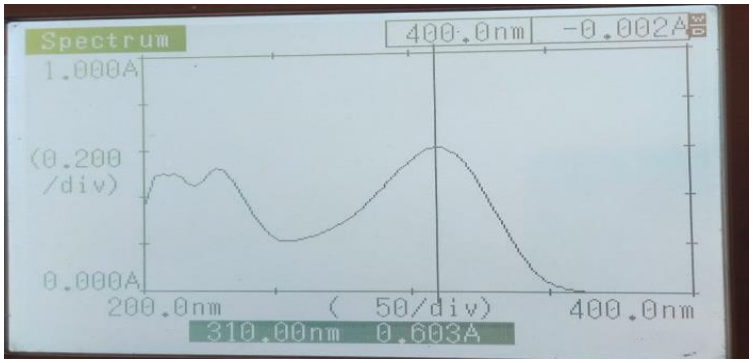


Fig No. 10: Ranitidine HCL spectrum by UV Spectroscopy

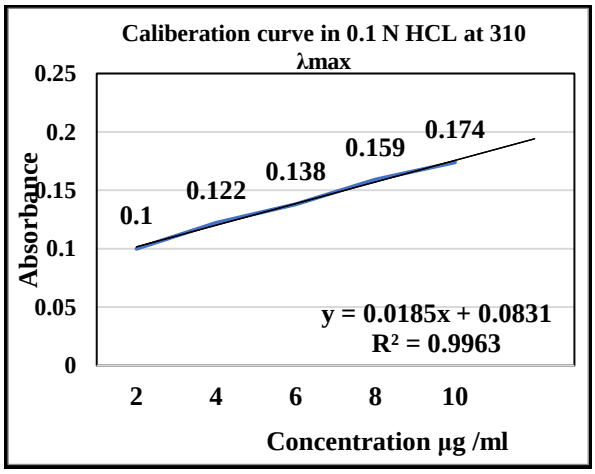
- **Melting point: -** The melting point of Ranitidine HCl was found to be 134°C and the drug was found to be in the pure form.

Table No.7: Melting point of Ranitidine HCl

S.NO.	Range	Melting point
1	134-135	134°C±0.25°C

- **Preparation of calibration curve: -** The calibration curve of Ranitidine HCL in 0.1N HCL was prepared which is shown in below table no**.** 12

Fig. 16: Calibration graph & Absorbance data of Ranitidine in 0.1 N HCL Solution



S.NO.	Concentration (ug/ml)	Absorbance
1	0	0
2	2	0.100
3	4	0.122
4	6	0.138
5	8	0.159
6	10	0.174

Table No.8: Absorbance data of Ranitidine HCL 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

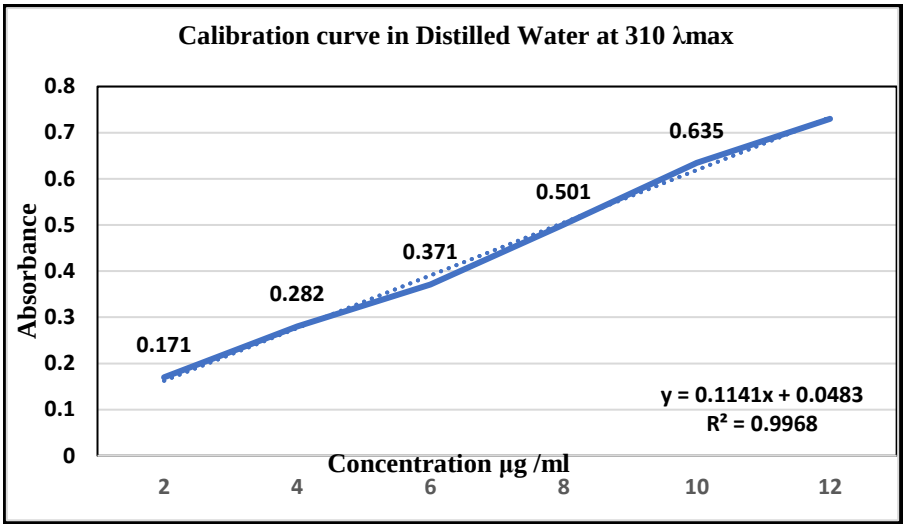


Fig No. 11: Calibration graph of Ranitidine in Distilled water

- **Drug- Excipient interactions: -** Drug- Excipient interactions play a vital role with esteem to release of drug from the formulation between others. FTIR formulation has been used here to study the physical and chemical interaction between drug and excipients used. In the recent study, it has been shownthat there is no chemical interaction between RHCL and the polymers used. Drug has given peaks due to furan ring, secondary diamine, alkenes and two peaks due to nitro functional groups. Form the figure it was shown that there were no changes in these main peaks in IR spectra of mixture of drug and polymers, which show there were no physical compatibility because of some bond formation between drug and polymers [49].

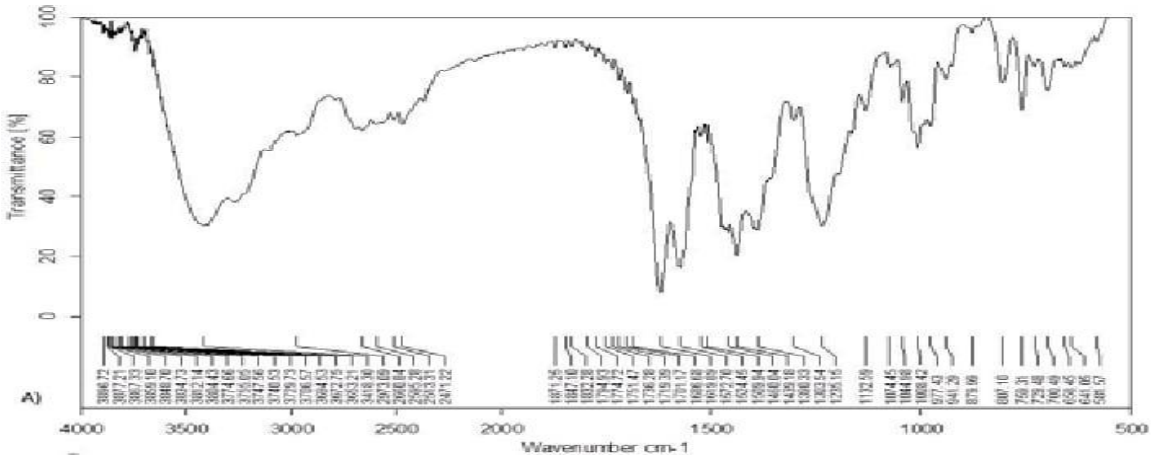


Fig No.12: IR spectrum of floating tablet of Ranitidine HCl FT-IR spectra

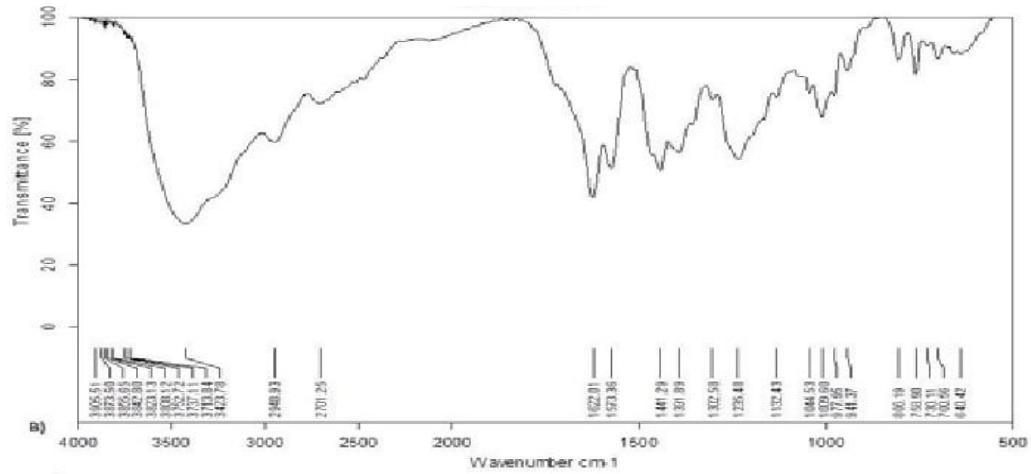


Fig No.13: IR spectrum of floating tablet of Ranitidine HCl with HPMC K4M

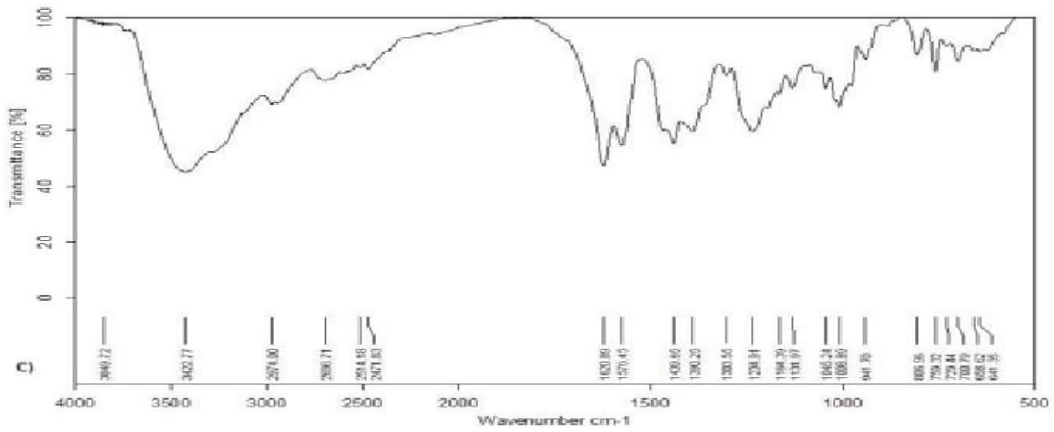


Fig No.14: IR spectrum of floating tablet of Ranitidine HCl with Tara gum

- **Determination of flow properties**:

- **Pre-compression parameters: -**Table 10 displays the metrics, including tapped density, bulk density, Hausner's ratio, Carr's index, and angle of repose, that were determined and reported. After being tabulated, the bulk density and tapped density were discovered to be, respectively, 0.31±0.18 to 0.51±0.13 and 0.36±0.01 to 0.56±0.0. The values of Carr's index and Hausner's ratio were determined to be 15.50% to 16% and 1.14±0.05 to 1.16±0.19, respectively. Less than 25 was the angle of repose for all formulations, indicating good particle flow characteristics. The results showed that the values ranged from 25.30±0.21 to 35.78±0.06. Every result shows that the powder has enough properties. \

- **POST COMPRESSION PARAMETERS**

  The properties of tablets such as thickness, hardness, friability, weight variation, Floating Lag time (min), Floating time, and drug content uniformity for the formulations F1-F8 were determined, and the result

Table No.9: Pre-compression research

F-code	Angle of repose (°) ±S.E.M	Bulk density (g/cm²) ±S.E.M	Tapped density (g/cm²) ± 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. 10: Post-compression parameters of Ranitidine HCL floating tablets

F Code	Thickness (mm) ±S.E.M	Hardness (Kgcm-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	1 min	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	2 min 56 sec	4.5
F4	3.97 ±0.17	6.5±0.05	0.66±0.06	452±0.25	78.12±0.03	2 min	4
F5	3.94 ± 0.19	6.5±0.05	0.53±0.08	450±0.25	86.16±0.02	1.5 min	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 83 sec	5
F8	3.90 ±0.17	9.6±0.05	0.4±0.05	452±0.33	85.23±0.02	min	4

- **Results are presented in mean ±S.E.M=9n=3)**

It was found that the tablets' thickness ranged from 3.91±019 mm to 3.96±0.06. The U.S.P. weight variation test indicates that tablets weighing more than 324 mg have a percentage variance of ±10%. Every pill formulation met the specified weight criteria. Across several formulations, there was good consistency in the drug content, with over 90% of the medication present. It was discovered that the tablets' hardness ranged from 6.5 to 7.3 kg/cm2. Tablet hardness isn't always a reliable measure of power. Friability is another way to gauge a tablet's strength.

Conventional compressed tablets that lose less than 1% of their weight are generally considered acceptable. In the present study, the friability for all the formulations was below 1% indicating that friability was within the prescribed limit

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
01	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
02	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
03	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
04	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
05	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
06	90.5	91.8	88.56	94.2	89.5	74.3	86.12	88.65

USP apparatus 2, a paddle-type six-bucket dissolution apparatus, was used for the dissolving process. Formulation tablets (F1, F2, F3, F4, F5, F6, F7, F8) were fastened with sinkers and placed in the dissolving apparatus's buckets, which were filled with water up to 900 ml and kept at 37±0.5°C with a 50-rpm paddle rotation speed. At 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330, and 360-minute intervals, samples were taken out and subjected to UV spectrophotometer analysis with a lambda max of 314 nm. The quantity of medication released was calculated using the acquired absorbance values.

- **Swelling Index: -** In the current study, tablets of batch f6, which contained a higher amount of Tara gum and HPMC combined, showed a higher swelling index and, overall, a longer total floating time. The swelling index of the tablets from each formulation, F1 to F8, was evaluated, and the results were shown in Table 12. It was between 6.0 and 6.5 hours. Due to the synergistic effects of tarra gum, F6 had a total floating duration of six hours. Increased polymer content caused the dosage form to inflate to its greatest extent, making it very buoyant.

Table No. 12: - Swelling index for floating tablet

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

- **CONCLUSION: -** An antihistaminic (antiulcer) medication, ranitidine HCL is used to treat stomach in patients with active duodenal ulcers, stomach ulcers, erosive esophagitis, Zollinger-Ellison syndrome, and gastroesophageal reflux disease, it is frequently administered. It was created as a floating tablet by combining several excipients, such as tartaric acid and sodium bicarbonate as a gas-producing agent, Tara Gum, and synthetic and natural polymer HPMC K4M with Carbopol 940 as a film formation. Melting point analysis and spectrophotometric analysis were used to characterize the drug sample. The numbers described in the literature were the same as all of the observations and recorded data. A Shimadzu 1800 double-beam UV-visible spectrophotometer was used to create calibration curves for ranitidine HCL in 0.1 N HCL. The administration finds it simple to finance, and by administering it less frequently, patients comply and tolerate it better. Thus, it was deemed worthwhile to develop an oral dosage form—a floating tablet—using an appropriate polymer to deliver the drug with sustained and prolonged release. The drug's bioavailability was enhanced before it exited the absorption window, and the combination of natural and synthetic polymers reduced side effects—such as dizziness, constipation, and vomiting—that are associated with commercial tablet preparations.

Formulation F6 is discovered to have a better impact than the other batches. Therefore, it can be said that the medication administered as a floating tablet offers a more efficient method of therapy and improved patient compliance.

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