IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Formulation And Evaluation Of Floating Tablets Of Pantoprazole For Gastroretentive Drug Delivery In Peptic Ulcer Treatment

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Abstract: Floating drug delivery systems (FDDS) are designed with a lower bulk density than gastric fluids, enabling them to remain buoyant in the stomach for extended periods without affecting the gastric emptying rate. While floating on the stomach's contents, these systems release medication in a controlled and sustained manner. Once the drug is fully released, the system disintegrates or is emptied from the stomach. This mechanism increases the Gastric Residence Time (GRT), leading to improved control over fluctuations in plasma drug concentration. To achieve this, FDDS must possess sufficient structural integrity to form a cohesive gel barrier and release the drug gradually while maintaining a density lower than that of gastric fluids. These systems are typically developed using effervescent and non-effervescent approaches that rely on buoyancy mechanisms. Such methodologies are particularly beneficial for delivering drugs with a narrow therapeutic window.

Our review aims to provide detailed insights into the pharmaceutical principles guiding the design, classification, and preparation of FDDS. It also explores factors influencing their performance, their advantages, applications, limitations, and potential future advancements in this innovative drug delivery system.

Keywords: Floating drug delivery system, Pantoprazole, Polymer, Gastroretentive system, Prolonged Gastric Retention

INTRODUCTION

A floating tablet is a gastroretentive drug delivery system (GRDDS) designed to remain buoyant in gastric fluid for an extended period, allowing controlled drug release and prolonged gastric retention time. Buoyancy is achieved using low-density polymers or gas-generating agents that react with gastric fluids to maintain the tablet's position in the stomach.[1]

FDDS are low viscosity systems that remain buoyant over the gastric contents without disturbing the gastric evacuating rate for a prolonged period.[2] These are useful for medicines that are inadequately answerable or unstable in intestinal fluids. When the system is floating on the gastric contents, the medicine is released at a controlled rate from the system and is voided from the stomach after the release of the medicine results in bettered gastric retention time had control of the oscillations in tube medicine attention, achieve lesser remedial benefit of the medicine substance. For illustration, medicines that are absorbed in the proximal part of the gastrointestinal tract (GIT) and medicines that are inadequately answerable in or degraded by the alkaline pH may profit from prolonged gastric retention. In addition, for original and sustained delivery of medicine to the stomach and proximal small intestine is used to treat certain conditions, dragged gastric

retention of their medial half may offer very numerous advantages including bettered bio availability and remedial efficacy and possible reduction of cure size.[3]

Pantoprazole is a protein pump inhibitor (PPI) used to treat acute duodenal ulcers, acute benign gastric ulcers, gastroesophageal reflux disease (GERD), and as a preventative measure for duodenal ulcer. It has a local effect on the stomach and works by competitively inhibiting the enzyme H+/K+ ATPase, which is found in the gastric parietal cells. For acute duodenal ulcers, acute benign gastric ulcers, and gastroesophageal reflux disease (GERD), the usual oral dosage recommendation is 45 mg, and it is taken for 8–12 weeks. The drug is suitable for FDDS due to short biological half-life (1-2 hrs) and local activity in stomach.[4]

Pharmacokinetics:

Pantoprazole sodium is made as an enteric-coated tablet to guarantee that the medication is only absorbed after it has left the stomach. The area under the serum concentration-time curve (AUC) and peak serum concentration (Cmax) increase proportionately to oral and intravenous dosages from 10 mg to 80 mg. The pharmacokinetics and accumulation potential of pantoprazole are unaffected by multiple daily dosages. When taken with meals, the maximum amount of pantoprazole increases significantly and varies greatly.

Absorption:

After oral treatment, pantoprazole is quickly absorbed; peak plasma concentrations of 1.1 to 3.1 mg/L are reached 2 to 4 hours after an enteric-coated tablet is consumed. The medication has a 77% estimated absolute oral bioavailability and is susceptible to low first-pass hepatic extraction. Bioavailability is unaffected by concurrent meal consumption. The mean plasma terminal elimination half-life of pantoprazole is short (t1/2=0.9 to 1.9 hours). Once achieved, however, the suppression of acid secretion lasts for a long time after the medication has been removed from the bloodstream.

Distribution:

Its apparent volume of distribution is comparatively small (mean 0.16 1.1 kg at steady-state). Plasma pantoprazole concentrations decrease monophasically after an initial distribution phase, with an apparent mean t1/2 of 0.9 to 1.9 hours.

Metabolism:

The liver substantially metabolizes pantoprazole via the cytochrome P450 (CYP) system. Whether pantoprazole is administered orally or intravenously has no effect on how it is metabolized. The main metabolic process involves CYP2C19 demethylation and sulfation. Another metabolic route is CYP3A4. With a once-daily dosing, these slow pantoprazole metabolizer subpopulations accumulate very little (23%) despite having elimination half-lives of 3.5 to 10 hours.

Excretion:

Following a single oral or intravenous dose, approximately 71% of pantoprazole was excreted in the urine and 18% in the feces due to biliary excretion in healthy, properly metabolizing volunteers. The unchanged drug pantoprazole was not eliminated by kidneys.

Drug Interactions:

Using pantoprazole with atazanavir, indinavir, and nelfinavir may decrease plasma concentrations. It is not recommended to take atazanavir concurrently. Avoid using ketoconazole and itraconazole together if at all feasible because they may alter plasma levels. Proton pump inhibitors may cause an increase in digoxin serum levels. Zinc and pantoprazole cannot be taken together.

MATERIALS AND METHODS

MATERIALS

All the materials used in the formulation and evaluation of floating tablets of pantoprazole are listed below, distilled water was used for all preparations.

Table 1: List of materials used

Sr. No	Name of the material	Grade	Manufacturer
	Pantoprazole	Pharma Grade	Dhamtec Pharma and Consultants, Navi Mumbai
	HPMC K4M	LR	Research-lab Fine Chem Industries, Mumbai
	Ethyl Cellulose	LR	Research-lab Fine Chem Industries, Mumbai
	β-Cyclodextrin	LR	Research-lab Fine Chem Industries, Mumbai
	Micro Crystalline Cellulose	LR	Research-lab Fine Chem Industries, Mumbai
	Citric Acid	LR	Research-lab Fine Chem Industries, Mumbai
	Sodium Bicarbonate	LR	Research-lab Fine Chem Industries, Mumbai
	Talc	LR	Research-lab Fine Chem Industries, Mumbai
	Magnesium Stearate	LR	Research-lab Fine Chem Industries, Mumbai

PRE FORMULATION STUDIES OF PANTOPRAZOLE

Solubility

Solubility of Pantoprazole was determined by taking 1gm Pantoprazole in 10ml solvent. Pantoprazole was found to be soluble in phosphate buffer, freely soluble in water and ethanol and practically insoluble in n-hexane.

Melting Point

Melting point is one of the important parameter to identify the purity of the drug. Melting point also helps in understanding crystallinity. Melting point of Pantoprazole was determined by open capillary tube method. Pantoprazole was placed in capillary tube closed at one end and was attached with thermometer. The whole assembly was kept in oil bath and heated, progress in temperature was monitored, the point at which drug started melting was noted. The experiment was repeated three times. The mean melting point was considered as the melting point of drug.

UV Spectroscopy

Determination of λmax for pure Drug Pantoprazole

1. **Preparation of stock solution:**
   The standard solution of pantoprazole 1000 µg/ml was prepared by weighing 100mg of pure pantoprazole using an analytical scale, transferred into a 100 ml volumetric flask, then partially added 0.IN HCI, shaken, then the volume was made up to 100ml with 0.1N HCL.
2. **Determination of λmax:**
   Pantoprazole stock solution was diluted by measuring 10ml of the solution into 100ml volumetric flask and diluted it with solvent upto the boundary mark, then homogenize solution of 100 µg/ml was obtained. Measure the absorbance in the wavelength range 200-400 nm with the UV-Visible spectrophotometer to obtain the maximum wavelength of the pantoprazole. 0.1 N HCL was used as blank.

3. Preparation of calibration curve for Pantoprazole:

Five series of pantoprazole solution prepared with concentration of 2µg/ml, 4µg/ml, 6µg/ml, 8µg/ml, 10µg/ml were used for the determination of calibration curves.

First 10ml of the standard stock solution of pantoprazole solution was pipetted into 100 ml standard flask and volume was made up to 100ml which gave a conc. of 100µg/ml (Secondary Stock Solution).

Again, from secondary stock solution(100µg/ml) different dilutions were made by pipetting 2ml, 4ml, 6ml, 8ml and 10 ml into 10 ml volumetric flask and the volume was made upto the mark by using 0.1N HCL. This gave the concentrations of 2µg/ml, 4µg/ml, 6µg/ml, 8µg/ml, 10µg/ml respectively. Measure the absorbance with UV-Vis Spectrophotometry at the wavelength of 285nm. The calibration curve was then plotted taking concentration on X-axis and absorbance on Y-axis

FORMULATION DEVELOPMENT

Floating tablets containing Pantoprazole were prepared by direct compression technique using Karnavati Rimek punch machine. The drug, polymer, sodium bicarbonate and citric acid were weighed accurately and passed through mesh and blended for 10 min. Then sieved materials were mixed with lubricant (magnesium stearate and talc) for 5 min and mixed geometrically and compressed using Karnavati Rimek machine. Before tablet preparation the mixture blend of all formulations were subjected to pre-compression studies like bulk density, tapped density, compressibility index(%), Hausner's ratio and angle of repose.

Table 2: Composition of floating tablet of Pantoprazole

Sr.No	Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1.	Pantoprazole	20	20	20	20	20	20	20	20	20
2.	HPMC K4M	20	25	30	-	-	-	20	25	30
3.	Ethyl Cellulose	20	25	30	20	25	30	10	15	20
4.	β-Cyclodextrin	-	-	-	20	25	30	10	10	10
5.	Micro Crystalline Cellulose	35	30	25	35	30	25	35	30	25
6.	Citric Acid	03	03	03	03	03	03	03	03	03
7.	Sodium Bicarbonate	02	02	02	02	02	02	02	02	02
8.	Talc	45	40	35	45	40	35	45	40	35
9.	Magnesium Stearate	05	05	05	05	05	05	05	05	05
	Total Weight	150	150	150	150	150	150	150	150	150

EVALUATION PARAMETERS

PRE-COMPRESSION EVALUATION PARAMETERS:

1. **Angle of repose:**

The fixed funnel and free-standing cone approach both make use of a funnel with its tip fixed at a specific height, h, which was maintained above graph paper that was laid out on a level horizontal surface. The following equation can be used to calculate the angle of repose, where r is the radius of the conical pile.

$$\theta = Tan - 1(h/r)$$

Where, θ is the angle of repose, h is height of pile, r is radius of base of the pile

Table 3: Angle of Repose

Angle of repose (θ) degree	Flow
≤ 25	Excellent
25-30	Good
30-40	Passable
≥ 40	Poor

2. **Bulk Density:**

Bulk density is the apparent density of powder under defined condition. It is the untapped powder volume and expressed as (g/cm^3). Bulk density of powder is determined using

Bulk density = weight of sample in gram / volume occupied by the sample

3. **Tapped Density:**

Tapped density is the apparent density of powder obtained by standard conditions. It is the volume of powder obtained after mechanical tapping. Tapped density of powder is determined using

Tapped density = weight of sample in gram/ Tapped Volume

4. **Carr's index and Hausner's ratio:**

The compressibility index of the granules was determined by Carr's compressibility index

$$\text{Compressibility Index} = \frac{\text{Bulk Density - Tapped Density}}{\text{Tapped Density}} \times 100$$

Hausner's ratio is indicated by numbers useful in industries for correlating the flowability of powder.

Hausner's ratio = Tapped density / bulk density

Table 4: Relationship between % Compressibility and Flowability

Sr. No.	% Compressibility	Flowability	Hausner Ratio
1.	1-10	Excellent	1.00-1.11
2.	11-15	Good	1.12-1.18
3.	16-20	Fair	1.19-1.25
4.	21-25	Passable	1.26-1.34
5.	26-31	Poor	1.35-1.45
6.	32-37	Very Poor	1.46-1.59
7.	≥ 38	Very Very Poor	≥ 1.60

POST-COMPRESSION EVALUATION PARAMETERS:

1. **Shape of the tablet:**
   Tablets from each formulation batch were examined and revealed to have a round shape without any cracks.

2. **Thickness:**
   The crown thickness of each tablet was measured by a Vernier caliper.

3. **Hardness:**
   Pfizer Hardness tester was used for determining the hardness of tablet and it is the capacity of tablet to resist the mechanical shock. The hardness is expressed in Kg/cm^2. Randomly 5-10 tablets were taken from each batch and tested for hardness and the values were recorded.

4. **Weight variation:**
   10 tablets of each formulation were taken for the weight variation test. Each of the tablet were weighed individually using the electronic balance and average weight was calculated and the deviation was recorded by comparing with the average tablet weight. The weight variation limit should not exceed ±7.50.

5. **Friability:**
   Friability of the tablets was determined using a Labline LTII apparatus. This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm, dropping the tablets from a height of 6 inch these on each revolution. A pre weighed sample of tablets was placed in the friabilator and subjected to 100 revolutions. Tablets were de- dusted using a soft muslin cloth and reweighed.

6. **Drug content uniformity:**
   Each formulation's five pills were weighed, then they were ground up in a mortar and combined. 10mg of the substance was taken in 100ml volumetric flask. The pantoprazole concentration in ug/ml was determined by using a standard calibration curve of the drug. The drug was allowed to dissolve in the solvent (0.1N HCL), the solution was filtered, 1ml of the filtrate was taken in 50ml of volumetric flask, diluted up to 50ml mark with 0.1N HCL, and then analyzed spectrophotometrically at 289nm.[5].

7. **In vitro dissolution studies:**
   Dissolution test was carried out using USP II (Labline) rotating paddle method (apparatus 2). The stirring rate was 50rpm. 0.1 N hydrochloric acid was used as dissolution medium 900 ml and was maintained at 37±0.5°C. Samples of 5ml were withdrawn at predetermined time intervals, filtered and replaced with 5ml of fresh dissolution medium. The collected samples were suitably diluted with dissolution fluid, wherever necessary and were analyzed at 289nm by using a double beam UV spectrophotometer. To calculate the release profile, the cumulative percentage of drug release was plotted against time.[6]

8. **In-vitro buoyancy:**
   The in vitro buoyancy was determined by floating lag time method the tablets were placed in 100ml beaker containing 0.1 N HCl. The tablets were dropped into the dissolution medium, which is 0.1N HCL, and the time required for the tablets to rise to the surface and float was determined as floating lag time. The time between introduction of dosage form and its buoyancy in 0.1 N HCl and the time during which the dosage form remain buoyant were measured.[7,8]

9. **Release Kinetics of drug:**
   All the formulations were subjected to study the release kinetics. The drug release profile of all the batches were fitted to
   • Zero order kinetics
   • First order kinetics
   • Higuchi model
   To ascertain the kinetic modeling of drug release and the model with the higher correlation coefficient was considered to be the best fit model.

RESULTS AND DISCUSSION

The main goal of this research was to create novel floating pantoprazole tablets that would float in the stomach for a long duration, increasing their oral bioavailability by extending their gastric residence time.

Pre-formulation Studies:

Appearance: Physical appearance of the drug was found to be brownish colour powder.

Solubility: Pantoprazole was found to be soluble in phosphate buffer, freely soluble in water and ethanol and practically insoluble in n-hexane.

Melting Point: Melting point of Pantoprazole was found to be 151˚C

Calibration Curve of Pantoprazole

The drug sample when subjected to UV spectrophotometric analysis, showed absorption maxima (max) at a wavelength of 289nm. The obtained peak was as per the reference value given in literature.

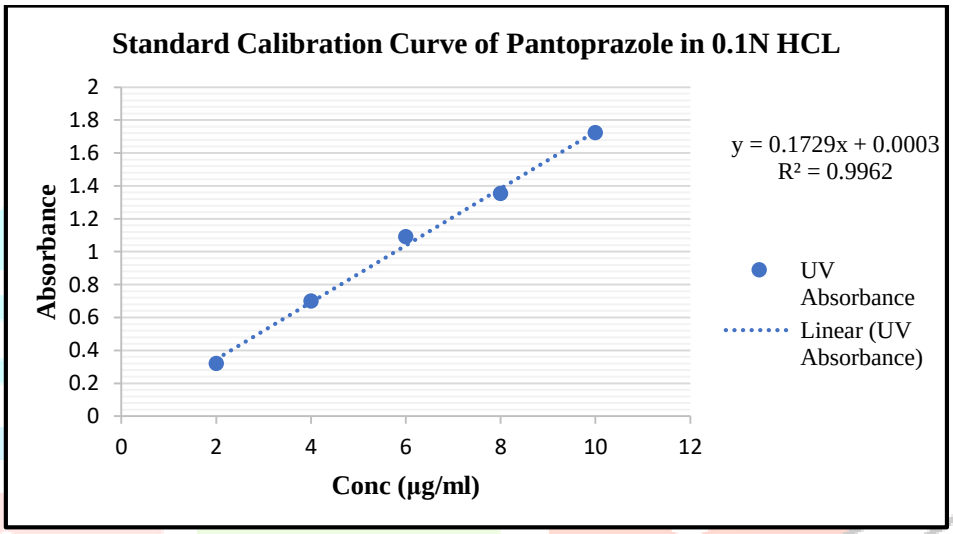

Fig 1: Calibration Curve of Pantoprazole

Pre-Compression Evaluation of Pantoprazole:

The angle of repose of formulation blend was in the range of 24.51˚- 28.70˚ which indicates good flow properties of the different blends. The Carr's index and Hausner's ratio were found in the range of 3.61-19.83 and 1.04-1.25 indicating good flowability.

Table 5: Evaluation of Pre-compression parameters of pantoprazole

Formulation	Angle of Repose	Bulk density	Tapped density	Carr's index	Hausner's ratio
F1	28.70±0.6	0.588 ± 0.02	0.610 ± 0.1	3.61±0.02	1.04 ± 0.05
F2	27.83±0.1	0.466 ± 0.01	0.551 ± 0.03	15.43±0.1	1.18 ± 0.02
F3	25.73±0.05	0.543 ± 0.02	0.630 ± 0.15	13.81±0.01	1.16 ± 0.01
F4	25.83±0.2	0.436 ± 0.02	0.510 ± 0.02	14.51±0.01	1.17 ± 0.02
F5	28.67±0.5	0.473 ± 0.01	0.590 ± 0.02	19.83±0.01	1.25 ± 0.01
F6	25.17±0.2	0.473 ± 0.02	0.550 ± 0.02	14.00±0.01	1.16 ± 0.04
F7	26.83±0.05	0.456 ± 0.02	0.500 ± 0.02	8.80±0.01	1.10 ± 0.02
F8	24.51±0.05	0.413 ± 0.02	0.480 ± 0.02	13.96±0.01	1.16 ± 0.01
F9	25.23±0.05	0.456 ± 0.01	0.510 ± 0.1	10.59±0.01	1.12 ± 0.02

Post-Compression Evaluation of Pantoprazole Floating Tablets:

Table 6: Evaluation of Post-compression parameters of pantoprazole

Formulation	Thickness (mm)	Hardness (kg/cm^2)	Weight Variation (mg)	Friability (%)	Drug content (%)	Floating Time (hrs)	Floating Lag time (sec)
F1	2.5±0.04	3.5±0.08	150.2±0.4	0.20±0.005	97.10	11	49
F2	2.51±0.03	3.15±0.05	150.4±0.9	0.5±0.01	92.56	10	46
F3	2.5±0.0	3.54±0.09	150.5±0.9	0.41±0.01	94.86	9	45
F4	2.5±0.03	3.55±0.07	150.5±0.9	0.34±0.02	94.40	12	47
F5	2.51±0.03	3.12±0.3	150.4±0.6	0.41±0.01	90.26	10	45
F6	2.56±0.09	3.18±0.2	150.3±0.4	0.38±0.01	95.33	12	48
F7	2.5±0.04	3.52±0.03	150.5±0.9	0.35±0.01	93.80	10	45
F8	2.49±0.03	4.12±0.3	150.2±0.4	0.41±0.01	94.16	11	44
F9	2.4±0.04	3.54±0.09	150.1±0.3	0.51±0.01	96.23	10	43

In-Vitro Drug Release Data batch F1-F9

Table 7: Invitro Drug release

Time (hrs)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	4.77± 0.01	4.85±0 .02	5.91± 0.01	6.86± 0.01	5.58± 0.06	7.06± 0.02	6.54±0 .02	10.12± 0.01	4.25±0 .06
2	10.43±0 .02	9.28±0 .03	19.26± 0.02	11.65± 0.02	9.21± 0.02	16.14± 0.02	9.27±0 .01	15.75± 0.06	10.21± 0.02
3	14.52±0 .03	15.98± 0.01	23.82± 0.01	17.24± 0.01	16.24± 0.01	23.54± 0.01	17.25± 0.05	23.56± 0.02	15.1± 0.03
4	21.76±0 .02	23.42± 0.06	37.48± 0.03	24.56± 0.02	15.31± 0.01	29.21± 0.02	24.28± 0.03	34.58± 0.03	21.43± 0.01
5	30.24±0 .02	24.35± 0.01	39.73± 0.01	25.25± 0.01	32.15± 0.01	31.25± 0.01	25.97± 0.02	43.05± 0.02	24.21± 0.03
6	34.54±0 .02	31.85± 0.06	62.47± 0.05	32.12± 0.01	33.54± 0.03	40.21± 0.01	30.58± 0.03	57.23± 0.02	31.9± 0.01
7	44.31±0 .04	45.05± 0.02	69.29± 0.01	45.37± 0.01	43.15± 0.04	50.36± 0.02	46.21± 0.01	72.12± 0.01	45.04± 0.04
8	53.78±0 .02	58.21± 0.03	71.56± 0.01	54.86± 0.02	59.12± 0.01	61.21± 0.01	57.31± 0.03	85.15± 0.01	59.25± 0.05
9	66.47±0 .03	70.98± 0.02	75.85± 0.02	70.21± 0.01	67.21± 0.01	73.58± 0.02	69.84± 0.02	92.95± 0.01	72.46± 0.01
10	80.56±0 .01	85.56± 0.02	88.13± 0.01	85.21± 0.02	87.32± 0.03	92.48± 0.02	82.21± 0.02	96.25± 0.03	92.53± 0.01

Release Kinetics of batch F1-F9

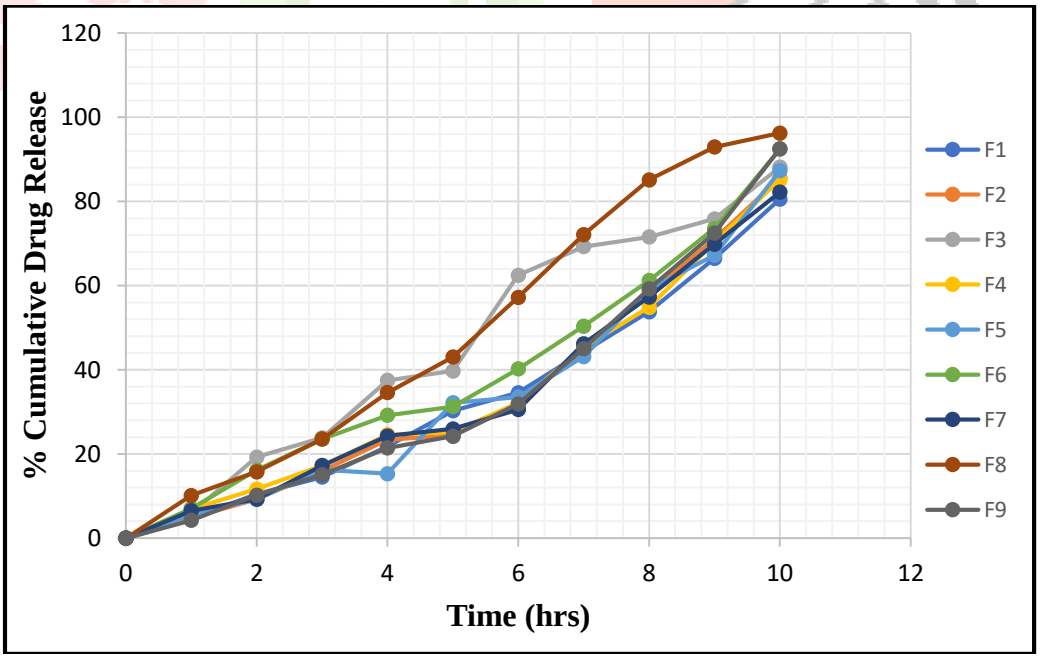

Fig 2: Comparative In-vitro Release Profile According to Zero Order Kinetics for formulations F1-F9

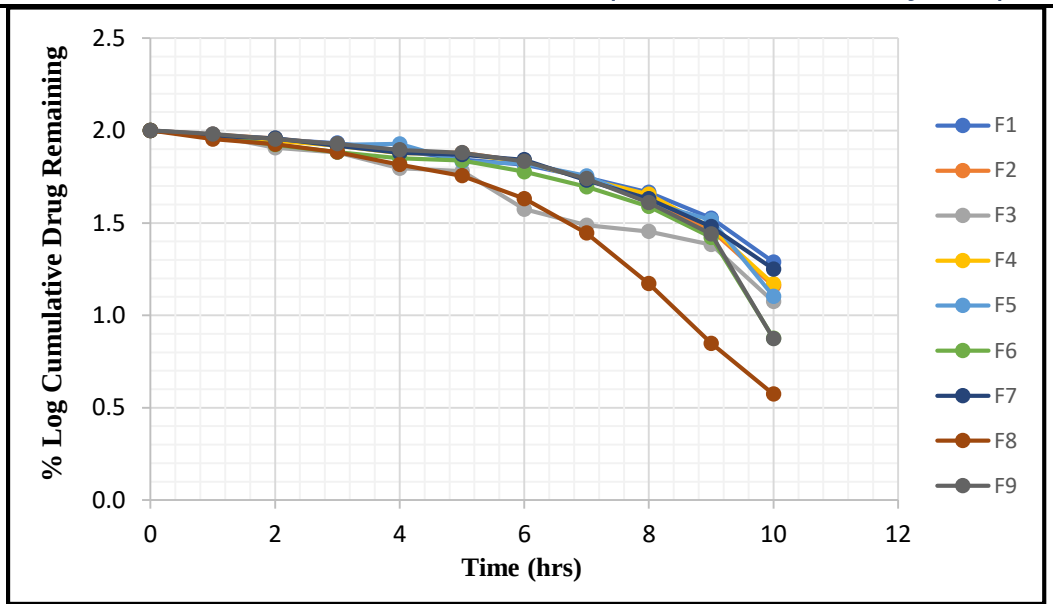

Fig 3: Comparative In-vitro Release Profile According to First Order Kinetics for formulations F1-F9

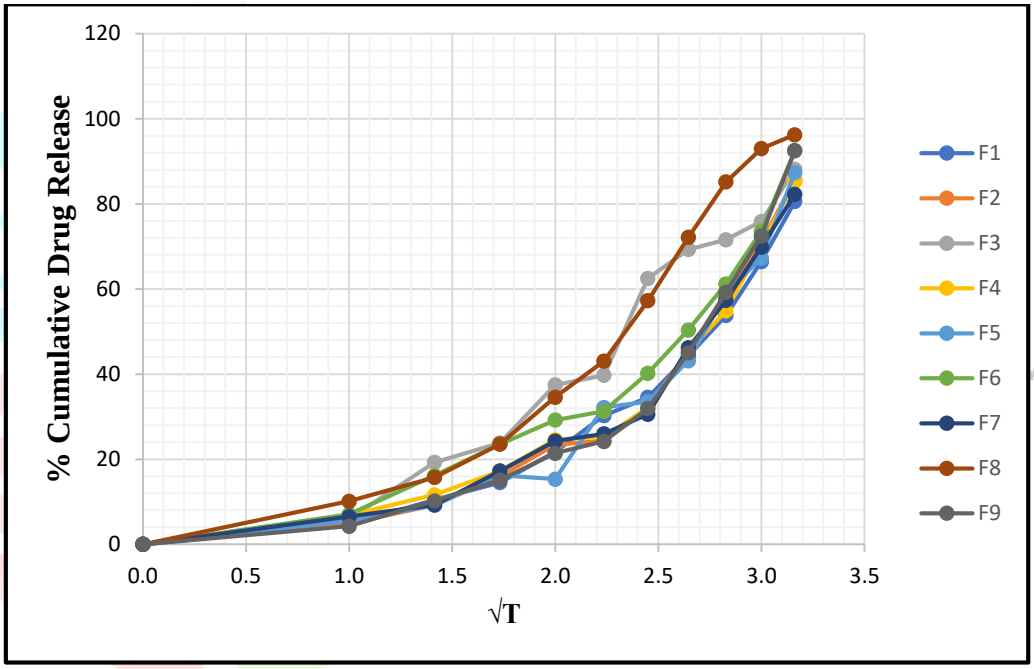

Fig 4: Comparative In-vitro Release Profile According to Higuchi Model Kinetics for formulations F1-F9

CONCLUSION

In the current investigation, an effort was made to keep the dosage form in the stomach for longer. By creating floating drug delivery systems, this can be accomplished. These tablets were made primarily by cutting down on lag time, which may also boost bioavailability. Beta-cyclodextrin was utilized as a polymer for the creation of floating tablets. HPMC K4M,Ethyl cellulose, microcrystalline cellulose, Talc, citric acid (a gas generating agent), sodium bicarbonate, magnesium stearate were also utilized. The prepared floating tablets underwent tests to determine their stiffness, weight fluctuation, thickness, friability, homogeneity of the drug content, buoyancy lag time, total floating time and in vitro dissolution investigations. The 9 formulations F1, F2, F4, F6, F7, F8 and F9 all exhibited strong floating characteristics, whereas F3 & F5 displayed moderate floating. Studies on stability were done for all the formulations, and F8 and F9 demonstrated good stability. It was shown that the highest drug release from F8 & F9 was up to 96.25% and 92.53 within 10 hours. The following three models were tested: zero order, first order and Higuchi model. It was discovered that medication release and floating ability were significantly influenced by the concentration of polymers and gas-generating agents. Thus, it may be concluded that a stable dose form for pantoprazole with controlled release can be created.

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