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Formulation and Evaluation of Floating Tablet of Pantoprazole Sodium

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ABSTRACT: The Present research work focuses on the formulation and evaluation of Floating tablet of Pantoprazole sodium. Floating tablets were prepared by direct compression method. 40mg of Pantoprazole was taken in a single tablet of 250mg. Floating tablet of pantoprazole sodium increase the gastric residence time as well as bioavailability and thereby showed increased therapeutic efficacy. The addition of gel forming polymer (HPMC) and gas generating agent sodium bicarbonate and citric acid was essential to achieve In vitro buoyancy. Preformulation studies were conducted to select suitable excipient,
Combination of different excipient was used to formulate pantoprazole floating tablets. The evaluation parameter such as Weight variation, Thickness, Hardness, Friability, disintegration time, In-vitro drug release studies was conducted. The results were within the limit and were compared with marketed formulation.

Key words –Pantoprazole Sodium, Floating tablet, Gastric residence time, HPMC

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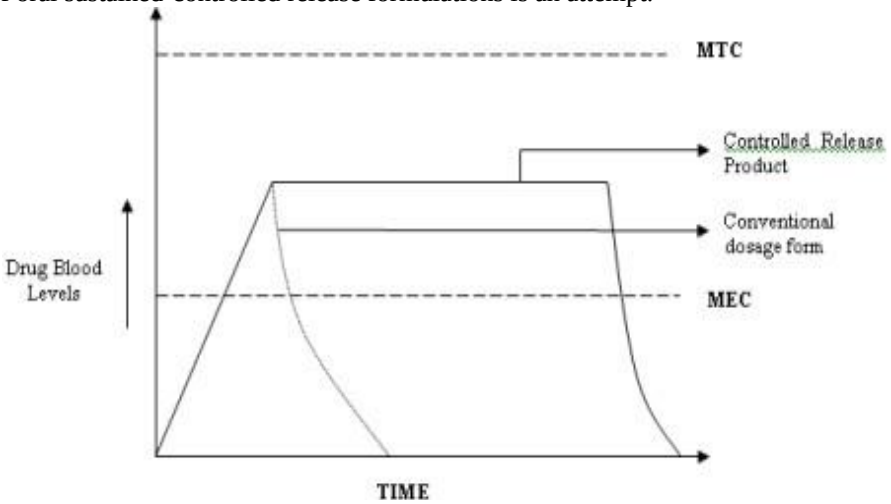
I. INTRODUCTION

Floating drug delivery system is such a system that provides long gastric retention time (GRT) and gastric emptying time (GET) Drugs that have a short half-life require frequent dosing. Conventional drug delivery - the short gastric retention time (GRT) and gastric emptying time (GET) to avoid this limitation, the development of oral sustained-controlled release formulations is an attempt.



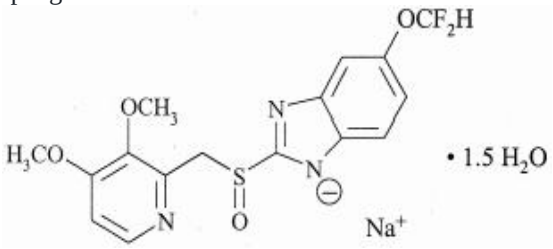
(**Fig 1.**Typical plasma concentration-time profile of floating dosage form)

Aim & Objective

The motive of research work is to select a drug of pantoprazole sodium which is suitable for floating dosage form and optimize the formulation using different excipient like sodium bicarbonate, citric acid, tartaric acid and Hydroxypropyl methylcellulose (HPMC), prepare Floating tablet by using direct compression method and evaluate prepared floating tablet on the basis of floating time, drug content, drug polymer interaction and in-vitro release study.

Drug Profile

Pantoprazole Sodium is a proton pump inhibitor drug used for treatment of erosion and ulceration of the esophagus caused by gastro esophageal reflux disease.



(Chemical Structure of Pantoprazole Sodium)

Table no1: Formulation Table

COMPOSITION	F1	F2	F3	F4	F5	F6
Pantoprazole sodium	40mg	40mg	40mg	40mg	40mg	40mg
Microcrystalline cellulose	93.82mg	93.64mg	91.56mg	91.41mg	91.66mg	89.96mg
Talc	2mg	2mg	2mg	2mg	2mg	2mg
Citric acid	21.87mg	21.87mg	21.87mg	21.87mg	21.87mg	21.87mg
Sodium bicarbonate	43.7mg	43.5mg	45.2mg	44.5mg	44.9mg	43.8mg
carbapol	15.62mg	15.62mg	16mg	16.35mg	16mg	16.5mg
Pvp	9.37mg	9.37mg	9.37mg	9.37mg	9.37mg	9.37mg
Hpmc	15.62mg	16mg	16mg	16.35mg	16mg	16.5mg
Magnesium stearate	6.25mg	6.25mg	6.25mg	6.25mg	6.25mg	6.25mg
	250mg	250mg	250mg	250mg	250mg	250mg

II. MATERIAL AND METHODS

Direct compression method

Milling of drug and excepient
Mixing of drug and excepient
Tablet compression

Standard calibration curve

Preparation of standard stock solution Stock solution was prepared by diluting 10 mg of each drug in sufficient quantity of double distilled water in separate volumetric flask and volume was made up to 100 ml to get the concentrations of 100 µg/ml for each drug. Dilutions from stock solution were 3-15 µg/ml for Pantoprazole .

Derivative spectrophotometry offers a useful approach for the analysis of in tablet dosage form using the zero-crossing technique. The measurements were carried out at wavelengths of 238.5 and 288 nm for Pantoprazole Sodium. The method was found to be linear (*r*2 - 0.9991) in the range of 3-15 µg/ml for Pantoprazole Sodium In this study a first order derivative spectrophotometric method is applied for the simultaneous determination of Pantoprazole Sodium) 4 µg/ml of Pantoprazole Sodium at 288 nm. The method was successfully used for simultaneous determination of Pantoprazole Sodium

Pre-compression parameters

Angle of Repose

The granules were allowed to flow through the funnel fixed to a stand at definite height (h). The angle of repose was then calculated by measuring the height and radius of the heap of granules formed.

tan □ = h/r

□ = tan-1 (h/r)

Where, □ = angle of repose

h = height of the heap

r = radius of the heap

Relationship between angle of repose and powder flow Angle of repose Powder flow

< 25	Excellent
25-30	Good
30-40	Passable
> 40	Very poor

Compressibility Index
Compressibility index (%) = ρt – ρo x 100
ρt
Where **ρo** = Bulk density g/ml002E
ρt = Tapped density g/ml.
he **Hausner ratio** is a number that is correlated to the flow ability of a powder or granular material. It is named after the engineer Henry H. Hausner (1900–1995).
The Hausner ratio is calculated by the formula

$$H = \frac{\rho_T}{\rho_B}$$

Where, ρ_B is the freely settled bulk density of the powder, and ρ_T is the tapped bulk density of the powder. The Hausner ratio is not an absolute property of a material; its value can vary depending on the methodology used to determine it.

Post-compression parameters
Hardness Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. Thehardness of the tablets was determined using Monsanto hardness tester. It was expressed in kg/cm2. Three tablets were randomly picked and hardness of the tablets was determined.
Friability
The friability of tablets was determined by using Roche Friabilator. It was expressed in percentage (%). Ten tablets were initially weighed (W initial) and transferred into friabilator. The friabilator was operated at 25rpm for 4 minutes or run up to 100 revolutions. The tablets were weighed again (Wfinal). The % friability was then calculated by –
%F = 100 (1-W0/W)
% Friability of tablets less than 1% was considered
Acceptable.

Weight Variation

130 or less	10
130-324	7.5
324 or more	5.0

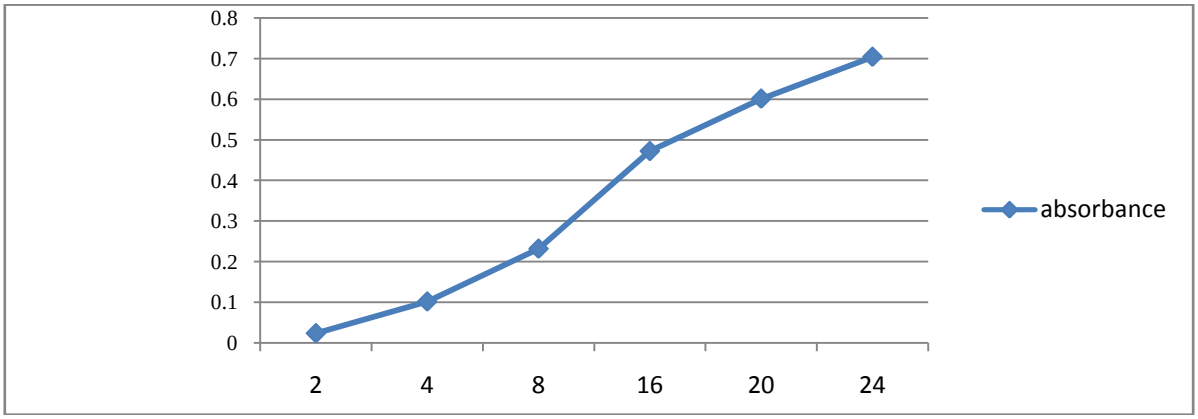
Buoyancy / Floating Test
The time between introduction of dosage form and its buoyancy on the simulated gastric fluid and the time during which the dosage form remain buoyant were measured. The time taken for dosage form to emerge on surface of medium called Floating Lag Time (FLT) or Buoyancy Lag Time (BLT) and total duration of time by which dosage form remain buoyant is called Total Floating Time (TFT).

In vitro drug release studies
In vitro drug release study of the floating tablet Pantoprazole Sodium is conducted.

III. RESULT

Table 2: Standard calibration curve

concentration	absorbance
0.2 mg/ml	0.024
0.4 mg/ml	0.102
0.8 mg/ml	0.232
1.6 mg/ml	0.472
2 mg/ml	0.601
2.4 mg/ml	0.704



(Fig 1.standard calibration curve)

Table 3: Pre-compression parameters

formulations	angle of repose	bulk density	tapped density	carr's index	hausner's ratio
F1	24.41	0.458	0.589	16.33	1.23
F2	25.58	0.469	0.698	17.12	1.49
F3	28.15	0.502	0.756	18.96	1.25
F4	27.65	0.468	0.603	19.43	0.14
F5	29.64	0.437	0.623	28.78	0.12
F6	24.90	0.456	0.603	18.02	1.16

Table 4: Post Compression Properties of Pantoprazole floating Tablets

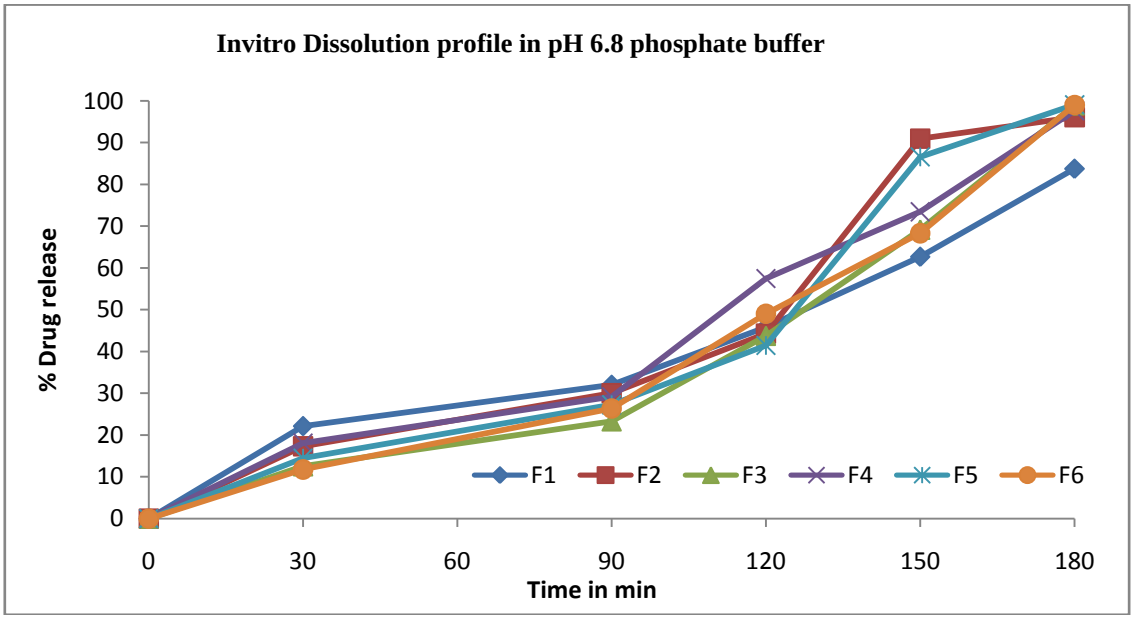
formulation	hardness kg/cm2	weight variation	Friability (%)	drug content	disintegration time (min)
F1	5.80	240/2.04	0.69	96.28	10.6
F2	5.56	242/2.42	0.51	97.62	8.26
F3	5.83	248/0.40	0.48	99.51	5.38
F4	6.00	250/-2.04	0.68	98.50	11.48
F5	5.12	250/0.00	0.54	99.08	9.12
F6	5.66	247/1.21	0.49	100.34	6.02

Table 5: Buoyancy / Floating Test

formulation	Buoyancy lag time (sec)	Total floating time (hrs)
F1	3	12
F2	4	12
F3	4.5	10
F4	3.5	10
F5	5	12
F6	5	14

Table 6: In-vitro dissolution table

	F1	F2	F3	F4	F5	F6
30	22.15	17.31	12.52	18.09	14.44	11.76
1hr 30mins	32.08	30.04	23.27	29.17	27.23	26.35
2hrs	45.82	44.29	43.78	57.46	41.65	49.03
2hrs 30 mins	62.67	90.98	69.15	73.46	86.62	68.33
3hrs	83.75	96.10	98.94	97.65	99.09	99.00



(**Fig 1.2** in-vitro dissolution graph)

IV. DISCUSSION

Series of experiments were performed during preformulation studies to select suitable excipient .Combination of different excipient were used to formulate pantoprazole floating tablets. Various Percentage of the excipient was also used to get best formulations with high bioavailability. Evaluation experiments such as friability, hardness, contentuniformity,thickness, weight variation, disintegration time were carried out and found that the results were satisfactory. Dissolution method was developed and validated. Dissolution of three batches of pantoparazole enteric coated tablet were carried out and found that RSD(Relative standard deviation) is below 2% including good reproducibility from batch to batch.

V.CONCLUSION

In accordance with present study it was concluded that, floating tablet of pantoprazole sodium increase the gastric residence time as well as bioavailability and thereby shows increased therapeutic efficacy.The addition of gel forming polymer (HPMC) and gas generating agent sodium bicarbonate and citric acid was essential to achieve In vitro buoyancy. Method of preparation is simple, cost effective and scalable. Results of evaluation experiments were compared with marketed formulation.

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