ISSN (O): 2349-5332
CODEN: IRJPHY

FABRICATION AND OPTIMIZATION OF PANTOPRAZOLE SODIUM FLOATING TABLETS USING TAMARIND GUM AS A NATURAL POLYMER.

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Submitted on: 28.09.2021; **Revised on:** 12.10.2021; **Accepted on:** 15.10.2021

ABSTRACT

In the present study, the formulations were designed to retain in the stomach for a long time for better treatment and management of erosion and ulceration. Formulations (F1 – F9) were prepared by using various proportions of polymer like hydroxy propyl methyl cellulose ($HPMC_{50cps}$) and tamarind gum containing pantoprazole sodium as a model drug due to its low half-life (1hr). Tamarind gum is a plant polysaccharide extracted from seed endosperm of the plant, *Tamarindus indica Linn*. (Family: Fabaceae) by aqueous based solvent evaporation technique. Tamarind gum polymer has boundless applications utilizing in the pharmaceutical industry as well as in biomedical field. In the research, we prepared the Pantoprazole floating tablet utilizing the tamarind gum as a natural polymer. The physicochemical compatibility of the drug with the extracted polymers is identified by using infrared spectroscopy and differential scanning calorimetry. The floating tablet was prepared by wet granulation technique using $HPMC_{50cps}$ and Tamarind gum (extracted from natural origin) as polymer along with sodium bicarbonate ($NaHCO_3$) as gas generating agent and evaluated for various physical properties including floating ability and Kinetic release profiles were assessed. All the parameters complied with pharmacopeia's limits. Finally, it was confirmed that the prepared formulations containing tamarind gum have shown floating ability as well as improved in-vitro release properties. The present research work outlines a systematized proposal for design and development of Tamarind gum loaded floating tablets of Pantoprazole sodium to enhance the bioavailability and therapeutic efficacy of the drug.

KEYWORDS: Pantoprazole sodium, Tamarind gum, Hydroxy propyl methyl cellulose ($HPMC_{50cps}$), Floating ability, Immediate Release profile.

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Indian Research Journal of Pharmacy and Science; 29(2021)2549-2562;
Journal Home Page: https://www.irjps.in
DOI: 10.21276/irjps.2021.8.3.3

INTRODUCTION

The oral route of drug administration is the most important method of administering the drugs to the systemic effects. Oral Solid indefinite quantity forms (Tablets and Capsules) are a number of the foremost fashionable and convenient ways of drug delivery.[1] Oral controlled release drug delivery system (OCRDDS) facilitates the continuous oral delivery of drugs at predictable and reproducible rates throughout the course of their GI transit. The major goal of OCRDDS is to achieve more predictable and better bioavailability of drugs. Over the last three decades, a variety of approaches have been used to enhance the retention of an oral dosage form in the stomach, including floating systems, swelling and expanding, bio adhesive, modified shape systems, high density systems, concomitant administration of pharmacological agents that delay gastric emptying, raft forming systems and other delayed gastric emptying devices.[2,3] Under certain circumstances, prolonging the gastric retention of a delivery system is desirable to achieving greater therapeutic benefit for the drug substances with poor bioavailability because of narrow absorption window in GIT. The standard gastric emptying time is 2 to 3 hours through the stomach and upper part of intestine that assists to decrease the drug release from the matrix leading to insufficient therapeutic efficacy.[4]

Gastro retentive systems can remain in the gastric region for several hours and hence significantly prolong the gastric residence time of drugs. Prolonged gastric retention improves bioavailability, reduces drug waste, and improves solubility for drugs that are less soluble in a high pH environment. Floating drug delivery systems (FDDSs) are the systems having a bulk density less than gastric fluids. They remain buoyant in the stomach for a prolonged period of time and defy the gastric emptying rate. The floating of dosage form on the gastric contents allows the drug to be released slowly at the desired rate from the system. Once the drug is released, the residual system is emptied from the stomach. It causes an increased gastric residence time (GRT) and a better control of fluctuations in plasma drug concentration. It has applications also for local drug delivery to the stomach and proximal small intestines. Gastro retention helps to provide better availability of new products with new therapeutic possibilities and substantial benefits for patients.[5,6] Pantoprazole Sodium, first sold under the brand name Protonix, is used for short-term treatment of erosive esophagitis associated with gastroesophageal reflux disease (GERD), maintenance of healing of erosive esophagitis, and pathological hyper secretory conditions including Zollinger–Ellison syndrome. Pantoprazole is a proton pump inhibitor drug that inhibits gastric acid secretion. It works on gastric parietal cells to irreversibly inhibit (H+/K+)-ATPase functions and suppresses the production of gastric acid. The drug has short biological half life, 1 to 2 hours has low bioavailability (77%). Due to its low half life and low bioavailability, it's preferable route of administration is the intravenous route but multiple unit dosage form like floating microsphere or floating tablet can also be given for non-invasive therapy through oral route of administration that expeditiously reduces the dosing frequency.[4,7]

Natural polymers usually have distinctive properties that differentiate them from synthetic polymers, and tamarind gum polysaccharide (TGP) is one of them. TGP has a wide range of favourable properties that makes it a suitable excipient for

various solicitations like diluents, binder, and disintegrating agent in tablet formulation, thickeners in oral liquids, protective colloids in suspensions, gelling agents in gels, and bases in suppository formulation. Tamarind (*Tamarindus Indica L.*) gum is obtained from endosperm of seeds of the tamarind tree, Fabaceae family, which is a seed gum with potential industrial applications.[8] It is also known as "Indian Date" which is a fresh ingredient used in the production of tamarind kernel powder (TKP) polysaccharide (jellose), adhesive and tannin. Chemically tamarind kernel powder is highly branched carbohydrate polymer shown in Fig. 1.[9] The pH of gum was found to be almost neutral i.e., 6.70 ± 0.01. Surface tension of tamarind seed polymer decreases with an increase in temperature. Swelling index reveals that the gum swells well in water was found to be 87%. Tamarind kernel powder disperses and hydrates quickly in cold water but does not reach maximum viscosity unless it is heated for 20-30 mins. The powder is evaluated for its suitability as a carrier to improve the dissolution rate of poorly water-soluble drug. It is used as potential polysaccharide or suitable polymer for immediate release formulation as well as controlled release formulations.[10]

Generally the colour of tamarind gum is light brownish. The polymer was soluble in hot water, swell to form a gel in cold water and insoluble in methanol, ethanol, benzene, ether and acetone but when it is completely dissolve in hot water at a temperature of about above 85°C , it forms a highly viscous colloidal solution or a viscous gel.[11] It is advantageous than other polymer due to its neutral, non-ionic nature and branched polysaccharide having hydrophilic in nature, gel-forming, and mucoadhesive properties. In addition, extracted tamarind gum is also biodegradable, biocompatible and non-irritant. So, objective of the present investigation is to extract the natural polymer from the seed polysaccharides (*Tamarindus indica)* and to employ the extracted gum as a potential biopolymer in the fields of Pantoprazole Sodium Floating Tablets which is helpful in pharmaceutical, cosmetic, and food applications.[8,9,11]

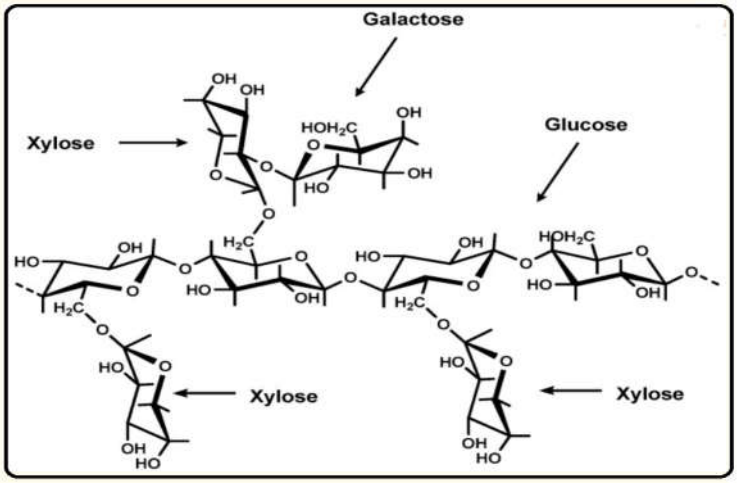

Fig. 1: Structure of Tamarind Seed Polysaccharide [8,9]

METHODOLOGY

MATERIALS

Pantoprazole Sodium was procured from Rajasthan Antibiotics Pvt Ltd. Di-calcium phosphate and light magnesium carbonate from Central drug house Pvt Ltd., Hydroxy propyl methyl cellulose ($HPMC_{50cps}$) from Emami ltd, Kolkata and all other chemicals used were of analytical grade.

EXTRACTION PROCESS OF TAMARIND SEEDS:

The seeds of *Tamarindus indica* was dried in a hot air oven for 20 min at 40^0C and removed by simply crushing the seeds from aside. The crushed seeds were soaked in water for 24hrs, boiled for 1 hrs, and kept aside for 2 hrs for release of gum into water. The soaked seeds were taken and squeezed in a muslin bag to remove marc from the filtrate. Then, to the filtrate, equal quantity of absolute ethyl alcohol was added to precipitate the gum. The gum was separated by filtration. The marc was not discarded but it was sent for multiple extractions with decreasing quantity of extracting solvent, i.e. water with the increase of number of extraction. The isolation was continued until the material was free of gum. The separated gum was dried in hot air oven at temperature 40°C. The dried gum was powdered and stored in airtight containers at room temperature for further studies.[12,13] The flow chart of total extraction process of Tamarind gum was presented on Fig. 2.

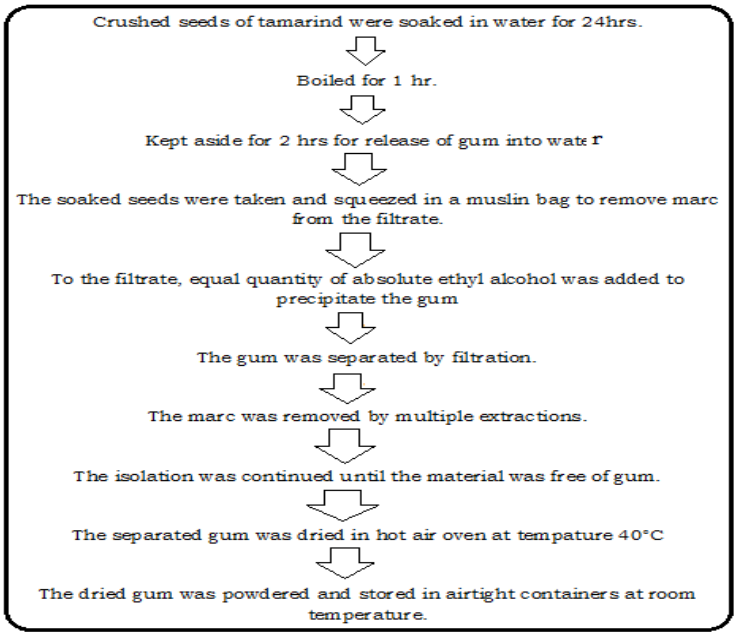

Fig. 2:- Extraction process flow chart of tamarind seed

PREFORMULATION STUDIES:

The preformulation study which is a backbone of various physicochemical properties of the sample is a study to develop a constructive and secure dosage from. The different parameters like angle of repose, bulk density, tapped density, compressibility or carr's index, hausner's ratio were evaluated.[14-17]

PREPARATION OF DRUG LOADED FLOATING TABLETS:

Floating tablets of Pantoprazole sodium were prepared by wet granulation method. The formulation codes were F1 to F9 as shown in Table 1. Here, we are scrutinizing the different ratio of $HPMC_{50cps}$ and extracted gum by alternative ratio

method where the formulation F1 was the preparation only with $HPMC_{50cps}$ and F9 formulation was only with extracted polymer. Other formulations (F2 – F8) were the combination of two polymers in different ratio. All the ingredients including drug, polymers, diluents, and gas-generating agent were weighed accurately and blended for 20 min. polyvinyl pyrrolidone K30 (PVP_{K30}) as binder in isopropyl alcohol as granulating fluid was added to form cohesive mass. The cohesive mass was screened through sieve #12 to get the granules. The granules were dried and dry screened through sieve #16. The granules were lubricated and compressed at predetermined hardness (5-6 kg/cm^2) on a rotary tableting machine using 9 mm flat punches.[18-21]

Table 1: Composition of drug loaded floating tablets

Formulation code	Drug: TG	Drug: $HPMC_{50cps}$	DCP	PVP_{K30}	Light magnesium carbonate	$NaHCO_3$	Citric acid	Magnesium stearate	Talc
F1	4:0	4:8	3%	5%	1%	4%	2%	0.5%	0.5%
F2	4:1	4:7	3%	5%	1%	4%	2%	0.5%	0.5%
F3	4:2	4:6	3%	5%	1%	4%	2%	0.5%	0.5%
F4	4:3	4:5	3%	5%	1%	4%	2%	0.5%	0.5%
F5	4:4	4:4	3%	5%	1%	4%	2%	0.5%	0.5%
F6	4:5	4:3	3%	5%	1%	4%	2%	0.5%	0.5%
F7	4:6	4:2	3%	5%	1%	4%	2%	0.5%	0.5%
F8	4:7	4:1	3%	5%	1%	4%	2%	0.5%	0.5%
F9	4:8	4:0	3%	5%	1%	4%	2%	0.5%	0.5%

***All quantities are given in molar ratio and %; TG- Tamarind gum; DCP- Di-calcium phosphate.**

CHARACTERIZATION OF PANTOPRAZOLE SODIUM TABLET

FT-IR study:

Compatibility studies were performed by FT-IR spectrophotometer. The IR spectrum of pure drug and physical mixture of drug and polymer were studied by using a KBr pellet technique. The spectrum of pantoprazole and drug with different polymers physical mixtures were recorded using spectroscopy (Shimadzu 8400S, Japan, India) and the spectra was recorded over the wave number range of 4000 to 400cm−1.[22-24]

Differential scanning colorimetry (DSC) study:

The drug polymer interaction was confirmed by investigating differential scanning calorimetry study or DSC study. Both the sample and reference are maintained at nearly the same temperature throughout the experiment. Generally, the temperature program for a DSC analysis is designed such that the sample holder temperature increases linearly as a function of time. The thermogram of pure pantoprazole and pantoprazole loaded floating tablet was obtained by using calibrated DSC. [22-24]

Weight variation Test:

The procedure described in United State Pharmacopoeia (USP) was employed to determine the weight variation of the tablets. Weight variation test was done by weighing 20 tablets individually, calculating the average weight and comparing the individual tablet weight to the average weight.

The % deviation of every tablets weight against the typical weight was calculated. Not more than 2 of

the individual weights deviate from the average weight by more than percentage and none deviates by more than twice that percentage. Weight variation IP limits just in case of consideration of tablets more than 80 mg however more than 250 mg is ± 5%.[16,25,26]

Tablet thickness:

The thickness of three tablets randomly selected from the each formulated batches was determined using a digital Vernier callipers and the mean of these readings was taken as the mean tablet thickness. Tablet thickness should have to be controlled at intervals at ± 5th variation of standard worth. [16,25]

Diameter of prepared tablets:

The diameter of the tablets was determined by using Vernier callipers. Randomly selected three tablets from each formulation were used and average values were calculated.[16,25]

Hardness of prepared tablets:

The resistance of tablets to capping, abrasion or breakage under conditions of storage, transportation and handling before usage depends on its hardness. Use Monsanto type, to measures the diametrically applied force required to break the tablet. Randomly three tablets are usually selected from the each batch of formulation and average hardness of a tablet of each batch was calculated and recorded. [16,25,26]

Friability test:

Friability indicates the ability of a tablet to withstand mechanical shocks while handling. The friability of the tablets was determined using the Roche friabilator. Randomly selected ten (10) tablets from each batch were weighed (W_I) and placed in the apparatus where they are exposed to rolling and repeated shocks as they fall 6 inches in each turn within the apparatus. After four minutes of this treatment or 100 revolutions, the tablets are reweighed (W_F) and the weight compared with the initial weight. The loss due to abrasion is a measure of the tablet friability, using the following formula:

$$\% \text{ of Friability} = [(W_I - W_F)/ W_I] \text{ X } 100$$

Friability below 1% was considered acceptable. If friability is more than this limit, batch does not pass this test. In case capping is observed, the batch is not suitable for commercial use even if % of friability is within the limit.[16,26]

***In-vitro* buoyancy studies:**

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 tablets were placed in a 100 ml beaker containing the medium of 0.1 (N) HCl. The time required for the tablet to appear on the surface of medium called Floating Lag Time (FLT) or Buoyancy Lag Time (BLT) and the total duration of the time the tablet constantly floats on the medium was noted as Total Floating Time (TFT) respectively.[4,27,29]

Determination of swelling index:

The swelling index of tablets was determined in 0.1 N HCL (pH 1.2) at room temperature for 8 hours. The randomly selected tablets from each batch were weighed (W_0) and placed in a petridish containing the buffer solution. After each predetermined time interval, the tablets were taken out from the petridish and weighed again (W_t) after excess water removed carefully if needed. The percentage of swelling Index (SI) was calculated by the following formula. [4,27,29]

$$SI = [(W_t - W_0) / W_0] \text{ x } 100$$

Where, SI = swelling index, W_t = weight of tablet at time t, W_O = weight of tablet before immersion.

***In-vitro* release studies:**

In-vitro dissolution tests were conducted in 900 ml 0.1 N HCl at 37 ± 0.5°C using USPXXII tablet dissolution apparatus for 6 h. The speed of rotation was maintained at 50 rpm. At predetermined time intervals, 5 ml sample was withdrawn and diluted. The samples were analyzed for drug release by measuring the absorbance at 292 nm using Spectrophotometric method (UV-1800, Shimadzu, Japan). To predict and correlate the *in-vitro* release behaviour of all formulations of Pantoprazole sodium floating tablets, the release data were fitted into suitable mathematical models such as zero order, first order, Higuchi, and Korsmeyer–Peppas model. [27,28,30]

***In-vitro* release kinetics:**

Drug release data were fitted to the kinetic model including the zero order, first order, Higuchi matrix, Korsmeyer-Peppas release equations to find out the equation with the best fit. Different 'n' values of Korsmeyer-Peppas equation indicate different mechanism of drug release. If the 'n' value is around 0.5 then Fickian diffusion is apparent, if the n value ranges from 0.5 to 1.0 it represents anomalous diffusion transport and if the n value reaches 1 and above then case II and Super case II transport is indicated which shows that the release is following Zero order.[25,31]

RESULT AND DISCUSSION:

Batches of Pantoprazole sodium tablets were prepared according to Table 1 using $HPMC_{50cps}$, tamarind gum by wet granulation method. The pre-compression & post-compression parameters were within prescribed limits of IP. All batches of tablets were found to standard floating lag times in minutes and formulation F9 showed higher swelling index as compared to others.

FT-IR study:

The compatibility between drug and polymer under the experimental condition was confirmed with FTIR study. The Pantoprazole sodium showed the characteristics peaks at 3485.2 cm^{-1} for N-H stretching, 2944 cm^{-1} for C-H bending, 1377cm-¹ for C-N stretching and 1038.9 cm^{-1} for C-H bending. All the predictable peaks of pure drug were found to be similar IR spectra of the physical mixture of drug and polymer showed that there was no significant interaction between them and was suitability of the polymers used for the preparation of floating tablet shown in Fig. 3 and Fig. 4.

DSC study:

The DSC thermogram analysis of Pantoprazole sodium and the physical mixtures shows that there was no significant interaction between drug and polymers physical mixture as shown in Fig. 5.

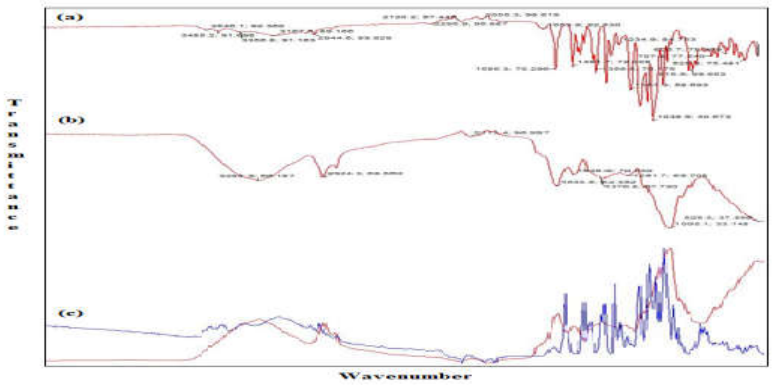

Fig. 3: IR spectra of (a) pure drug (Pantoprazole Sodium) (b) extracted Tamarind gum (c) Physical mixture of drug with natural polymer, Tamarind gum

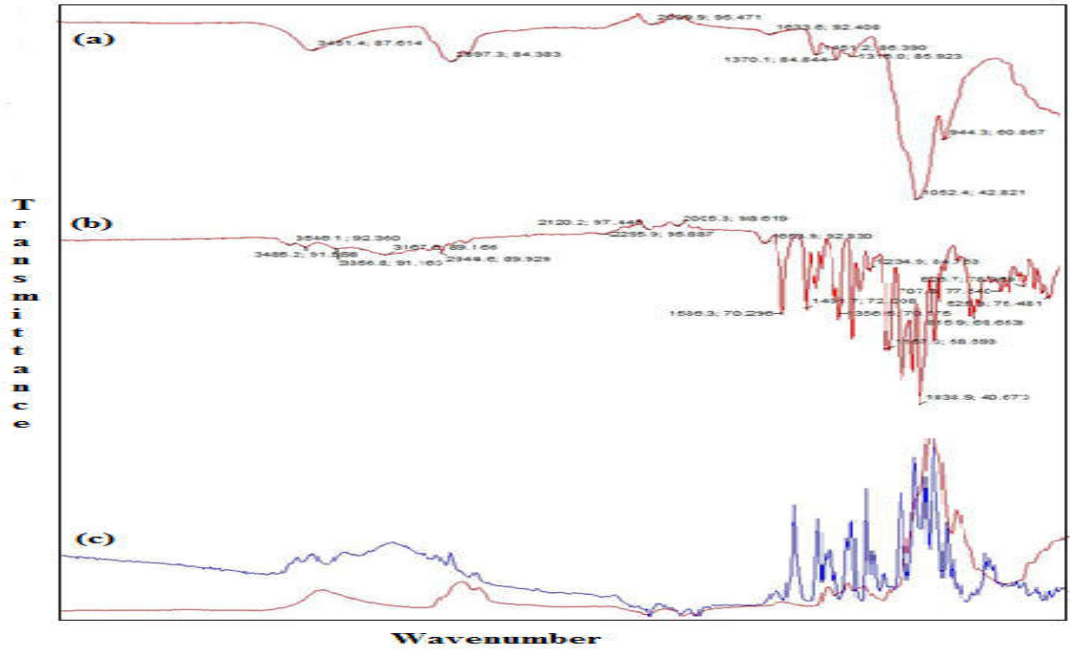

Fig. 4: IR spectra of (a) synthetic polymer, HPMC (b) pure drug, Pantoprazole Sodium (c) Physical mixture of drug with synthetic polymer, HPMC

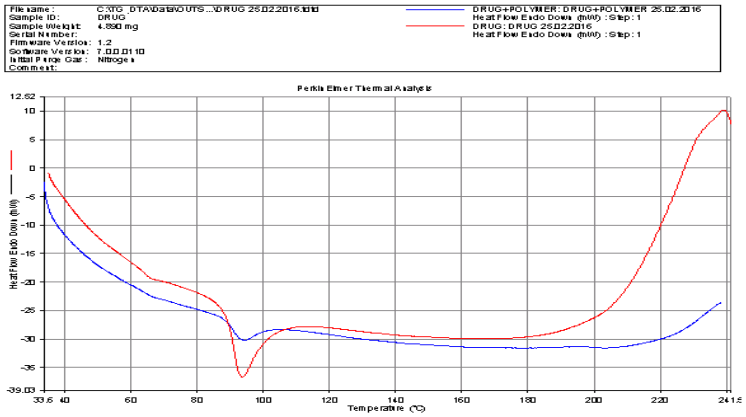

Fig. 5: DSC thermogram of drug with polymer, tamarind gum.

Pre-compression studies:

All the powder mixers of different formulations were analyzed for their physical properties and results were reported in Table 2. The value of angle of repose of formulation within the range of 30˚ indicates good flow properties for the granules. The tapped density values ranged between 0.5 ± 0.08 to 0.57 ± 0.04 g/ cm^3 and the bulk density values ranged between 0.41 ± 0.03 to 0.47 ± 0.07 g/ cm^3. The result of carr's index and hausner's ratio were found to be in the range of 11 ±0.86 to 24 ± 1.95 % and 1.19 ± 0.01 to1.12 ± 0.09 %. All the results of powder blend containing tamarind gum indicate that the powder was having good flowing properties and compressibility that allow to be directly compressed into tablets properly.

Table 2: Evaluation parameters of pre-compression studies

Formulation Code	Angle of repose	Bulk density (g/cc)	Tapped density(g/cc)	Carr's index (%)	Hausner ratio
F1	30.5	0.45	0.55	18.18	1.22
F2	29.45	0.42	0.5	16	1.19
F3	28.56	0.41	0.52	21	1.26
F4	30.45	0.47	0.56	16.07	1.19
F5	29.56	0.45	0.55	18.18	1.22
F6	31.00	0.42	0.53	20.75	1.26
F7	29.00	0.41	0.54	24.07	1.31
F8	30.00	0.42	0.55	23.63	1.30
F9	28.10	0.47	0.53	11.32	1.12

Table 3: Post compression study of prepared floating tablets

Formulation code	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	Weight Variation(mg)
F1	3.36	5.55	.33	±2
F2	3.36	5.50	.33	±1
F3	3.33	5.51	.34	±2
F4	3.33	5.52	.69	±1
F5	3.28	5.53	.68	±2
F6	3.31	5.54	.67	±1
F7	3.32	5.45	.66	±1
F8	3.34	5.40	.65	±2
F9	3.31	4.50	.66	±1

Post compression study:

The thickness (mm), weight variation (%), hardness (kg/cm^2), friability (%) was calculated and the result are shown in Table 3. The thickness of the matrix tablet was found to be in range of 3.28 ± 0.44 to 3.33 ± 0.070. The hardness of the matrix tablet was found to be in the range of 4.50 ± 0.16 to 5.55 ± 0.28 kg/cm^2 which indicated good mechanical strength. The weight variation test was done by randomly selected 20 tablets from each batch and performed the study. The weight variation of floating tablets was found to in the range of 1 to 2%. The friability test was performed by taking 10 tablets from each batch. The friability of the floating tablets was found to be in range of 0.33 to 0.66%. It was found to comply with in the limits specified which was a maximum loss in weight was less than 1%. This reveals good adhesion of tablet ingredients. Hence the tablets containing tamarind gum possessed good physical strength which helps to withstand handling stress during packaging and travelling.

***In-vitro* buoyancy study:** *In-vitro* buoyancy was determined by the measurement of floating lag time (FLT) and total floating time (TFT) shown in Table 4 and the photocopy of floating time at different time interval was shown in Fig. 6. Tablet was

placed in a 100 ml beaker containing 0.1 N. HCL. Time required for tablet to rise on the surface of medium and float was determined as "FLT." It is expressed in seconds or minutes. The duration of time by which tablet constantly emerges on the surface of medium was determined as the "TFT." It is expressed in hrs. As shown table 4, the floating lag time for all the formulation (F1-F9) was found to be in the range of 3 to 3.55 mins and total floating time were build up from 2 to 2.30 hrs. But the formulation containing maximum amount of tamarind gum (F9) was showing the highest swelling index when compared to the other formulations. The formulation containing maximum concentration of tamarind gum (F9) was showing the highest swelling index when compared to the other formulations.

Table 4: Floating characteristics of prepared floating tablet

Formulation code	Floating lag time (min)	Total floating time (hr)	Swelling Index
F1	3.10	2.10	194
F2	3.55	2.30	252
F3	3.20	2.20	226
F4	4	2.30	231
F5	3.50	2.10	163
F6	3.43	2.15	123
F7	3.50	2.30	103
F8	3.57	2.40	126
F9	3.48	2.30	238

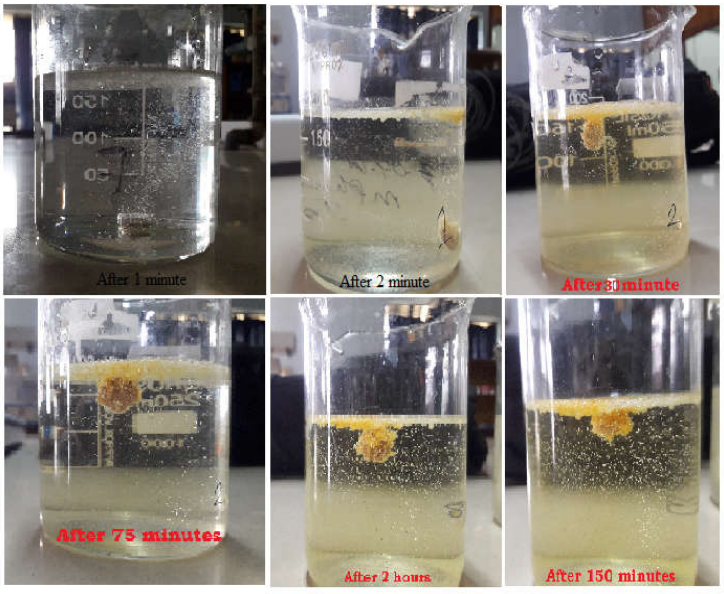

Fig. 6: Photograph of prepared floated tablet at different time interval

In-vitro* release study*:

It includes the dissolution of the matrix type tablet formulations study of all the formulations by fitting the data obtained from dissolution study. *In vitro* release study was carried out for all the formulations in 0.1 N HCL for 6 hours. Drug release data were fitted to different types of kinetic model shown in Fig. 7 and In-Vitro drug release kinetics parameter of different models for prepared Pantoprazole sodium loaded floating tablet was given in table 5. Among the formulations, the formulation containing tamarind gum (F9) shown the R2 value 0.993 which follow the zero order release kinetics and krosmeyer peppas value (n) was found to be 0.82 which indicate the no fickian transport.

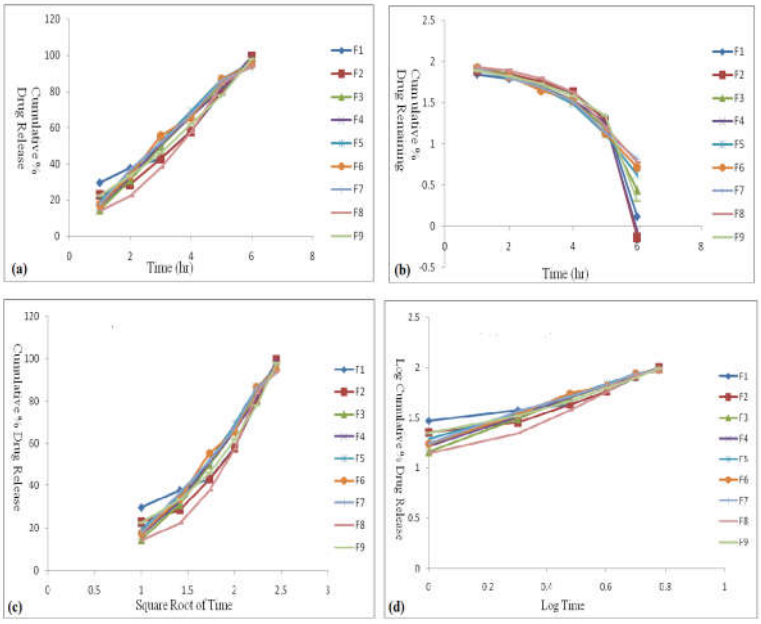

Fig. 7: Release kinetics model fitted to the formulations (a) zero order release kinetics (b) first order release kinetics (c) higuchi release kinetics (d) krosmeyer peppas release kinetics

Table 5: *In-vitro* release kinetic for prepared floating tablet

	First Order Model		Zero-order Model		Higuchi Model		Korsmeyer – peppas Model	
Formulation	**R^2**	**K_1**	**R^2**	**K_0**	**R^2**	**K_h**	**R^2**	**n**
F1	0.682	-0.29	0.947	13.85	0.882	46.54	0.895	0.65
F2	0.68	-0.34	0.971	15.80	0.916	53.41	0.935	0.84
F3	0.849	-0.27	0.985	16.85	0.988	58.39	0.991	1.07
F4	0.987	-0.33	0.996	16.44	0.985	56.82	0.993	0.99
F5	0.994	-0.24	0.994	15.80	0.988	54.84	0.879	0.91
F6	0.987	-0.23	0.987	15.86	0.988	55.84	0.994	0.94
F7	0.936	-0.21	0.990	15.51	0.991	54.86	0.890	0.93
F8	0.875	-0.22	0.977	17.26	0.938	58.47	0.972	1.119
F9	0.737	0.27	0.993	15.09	0.949	51.47	0.977	0.82

CONCLUSION

The present study was to prepared the floating tablet of pantoprazole sodium with different polymers namely hydroxy propyl methyl cellulose ($HPMC_{50cps}$) and natural polymer like tamarind gum. The natural polymer was extracted by water based extraction process from the tamarind seeds which was collected from the local areas. The extracted natural gum has revealed that the floating retention time of the formulation had increased significantly in comparison to non-floating formulation. Moreover, tamarind gum has shown a greater increase of floating retention time. The present study is immensely important in the sense that such floating formulations for the treatment and management of erosion and ulceration will be available in the stomach for long time. Thus, it will provide better formulations for the treatment of various stomach and gastric problems. In future study, it will be helpful to formulate sustained release delivery system for improving the patient compliance and decrease dosing frequency. More over the method of preparation is simple, cost effective and scalable.

ACKNOWLEDGEMENT

Authors are thankful to Calcutta Institute of Pharmaceutical Technology & AHS, uluberia, howrah for providing the necessery planning permission to achieving the research work.

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CONFLICT OF INTEREST REPORTED: NIL; SOURCE OF FUNDING: NONE REPORTED