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Development and Evaluation of Floating Tablets of Pantoprazole

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ABSTRACT

The present study was undertaken with an aim to design, develop and evaluate floating tablet of Pantoprazole, which release the drug in a sustained manner over a period of 12 hours. In this research work used hydroxy propyl methyl cellulose (HPMC K4M), gas generating agent sodium bicarbonate and citric acid. The high level of HPMC K4M and citric acid favors preparation of floating tablet Pantoprazole. The tablets were prepared by direct compression techniques and evaluated thickness, hardness, weight variation, friability, floating lag time and In-vitro drug release studies indicated that the floating dosage form showed slower release as concentration of HPMC K4M increases. Formulation F1 was considered as optimized formulation which shows satisfactory sustained drug release and remained buoyant on the surface of medium for more than 12 hrours. It can also conclude that floating drug delivery system of Pantoprazole can be successfully formulated as an approach to increase gastric residence time and thereby improving its bioavailability.

Keywords : Pantoprazole, Floating Drug Delivery, Citric Acid, Buoyancy, Direct Compress

I. INTRODUCTION

Davis, in 1968 firstly described the concept of floating drug delivery system after experiencing chocking by some person, while swallowing medicinal pills. The researchers suggested that such difficulty could be overcome by pills having density less than 1. 0gm/ml, so that pill will float on water surface. The goal of any drug delivery system is to provide a therapeutics concentration within range and to show pharmacological action with minimum incidence of adverse effects. To achieve this goal one should maintain dosing frequency an suitable route of administration. Various routes that are used this days include oral, parenteral, rectal, topical, nasal, vaginal, ocularetc. Out of this oral route most favored route of drug delivery, because of ease of administrion, flexibility in designing, ease of production and low cost. Oral administration is the most convenient and preferred means of any drug delivery to the systematic circulation. Oral controlled release drug delivery have been recently of increasing interest in pharmaceutical field to achieve improved therapeutic advantages, such as ease of dosing administration, patient compliance and flexibility in formulation. The gastric emptying of dosage forms is an extremely variable process and ability to prolong and control the emptying time is a valuable asset for dosage forms that reside in the stomach for a longer period of time than conventional dosage forms. [3]Gastric emptying of dosage forms is an extremely variable process and ability to prolong and control emptying time is a

valuable asset for dosage forms, which reside in the stomach for a longer period of time than conventional dosage forms. One of such difficulties is the ability to confine the dosage form in the desired area of the gastrointestinal tract. To overcome this physiological problem, several drug delivery systems with prolonged gastric retention time have been investigated. Attempts are being made to develop a controlled drug delivery system that can provide therapeutically effective plasma drug concentration levels for longer durations, thereby reducing the dosing frequency and minimizing fluctuations in plasma drug concentration at steady state by delivering drug in a controlled and reproducible manner that are less soluble in high pH environment. Gastric retention to provide new therapeutic possibilities and substantial benefits from patients. Gastroretentive Dosage Forms (GRDFs) extend significantly the period of time over which the drugs may be released.

II. METHODS AND MATERIAL

List of Materials Used:

Sr. No.	Materials	Procured from
1	Pantoprazole	Sanofi India Ltd Goa.
2	HPMC K4M	Colorcon Asia, Goa. Ltd.
3	Ethyl Cellulose	S.D Fine Chemicals, Mumbai.
4	Carbopol 934P	Colorcon Asia, Goa. Ltd.
5	Sod. Bicarbonate	S.D Fine Chemicals, Mumbai.
6	Citric Acid	S.D Fine Chemicals, Mumbai.
7	Mg stearate	S.D Fine Chemicals, Mumbai.
8	Lactose	S.D Fine Chemicals, Mumbai
9	Talc	S.D Fine Chemicals, Mumbai

DRUG AUTHENTICATION:

Preformulation Studies of Pantoprazole:

It is extensive information to bring out good quality at high standard at which optimal dosage desired. Preformulation studies were performed on the drug, which included melting point determination, solubility and compatibility studies.

Solubility of Pantoprazole:

Solubility of Pantoprazole was determined slightly soluble in phosphate buffer, freely soluble in water and practically insoluble in n-hexane.hanol, solubility studies were performed by taking 1gm Pantoprazole in 10ml solvent.

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:

Preparation of 0.1N HCl:

0.1N HCl was prepared according to IP 1996. A quantity of 8.5 ml of HCl was diluted with fresh distilled water to produce 1000 ml.

Standard Curve of Pantoprazole:

Pantoprazole has been quantitatively analyzed by various techniques. In present studies, Pantoprazole was estimated by UV Spectrophotometry method.

Preparation of Stock Solution in 0.1N HC1.2):-

Stock solution of Pantoprazole(100µg) was prepared in 0.1N HCl. The UV spectrum was recorded at 285 nm. The solution of 2 to 10 µg/ml prepared from

appropriate dilution with 0.1N HCl. The absorbance of each solution was recorded using UV spectrophotometer (Lab India) at wavelength absorption maximum.

Construction of Calibration curve of Pantoprazole in 0.1 N HCl (pH 1.2)

100mg of Pantoprazole accurately weighed and dissolved in pH buffer 1.2 and made a volume up to 100ml, made concentration of 1000µg/ml.1ml of solution was pipette out and dilute with pH 1.2 buffer solution make concentration of 100µg/ml. From stock solution aliquot ranging from0.2to 1ml pipette out and diluted with pH 1.2 buffers to get concentration range 2 to 10 µg/ml. The absorbance measured at 289 nm against blank solution. Standard graph plotted by keeping concentration on x-axis and obtained absorbance on y-axis.

Drug-Excipients Compatibility Studies

Drug-Excipients compatibility studies form an important part of Preformulation studies. The interaction between the drug and excipients are determined after a specific time period by using suitable analytical techniques like IR.

Infrared Absorption Spectroscopy:

To investigate any possible interaction between the drug and polymer used (HPMC K4M, Ethyl cellulose, carbopol, Sodium bicarbonate, lactose, magnesium stearate and talc). Infrared spectra recorded on Bruker infrared spectrophotometer in KBr pellets. IR spectrum of pure drug (Pantoprazole) and its physical mixture was carried out by using FT-IR.

FORMULATION DEVELOPMENT:

Formulation Design:

Formulation Design study is important for selection of appropriate excipients for preparation tablets. The three grades of HPMC namely HPMC K 4M, HPMC K15K, HPMC K100M were used for trial preparation of tablets. The trial batches of tablets were prepared by direct compression technique using other commonly used excipients.

Preparation of Pantoprazole Floating Tablet:

Floating tablets containing Pantoprazole were prepared by direct compression techniqueu using Karnavati Rimek punch machine.The tablet of different concentrations were prepared. The drug, polymer, sodium bicarbonateand citric acid weighed accurately and passed through mesh and blened for 10 min. Then sieved materials were mixed with lubricant (magnesium stearate and talc) for 5 min & mixed geometrically and compressed using Karnavati Rimek machine.The compositions details of floating tablets are given in table.

Before tablet preparation the mixture blend of all formulations are subjected to preformulations studies like bulk density, tapped density, compressibility index(%), Hausner's ratio and angle of repose.

Composition of floating tablets of Pantoprazole

Ingredients(mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Pantoprazole	20	20	20	20	20	20	20	20	20
HPMCK4M	20	25	30						
Ethyl Cellulose				20	25	30			
Carbopol934p							20	25	30

Sodium bicarbonate	2	2	2	2	2	2	2	2	2
Citric acid	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Mg.stearate	5	5	5	5	5	5	5	5	5
Talc	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5
Lactose	50	45	40	50	45	40	50	45	40
Microcrystallinecellulose	49	49	49	49	49	49	49	49	49
Total	**150**	**150**	**150**	**150**	**150**	**150**	**150**	**150**	**150**

EVALUATION PARAMETERS:

Pre-compression evaluation parameters:

- Angle of repose
- Bulk and tapped density
- Compressibility index and Hausner ratio.

Post-compression evaluation parameters:

(Evaluation of compressed tablets)

- Thickness and appearance
- Hardness
- Friability
- Weight variation
- Uniformity of drug content
- In-vitro dissolution studies

Pre-compression evaluation parameters:

Bulk density and Tap density:

Bulk density is calculated by using a formula:

$$\text{Bulk Density (g/ml)} = \frac{\text{weight of sample in gm}}{\text{volume occupied by sample in ml}}$$

The final volume was recorded and the tap density was calculated by the following equation:

$$\text{Tapped Density} = \frac{\text{Weight of powder blend}}{\text{Tapped Volume of the packing}}$$

Compressibility Index and Hausner Ratio:

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

$$\text{Hausner Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

Relationships between % Compressibility and Flow ability

Sr.No	**% Compressibility**	**Flowability**	**Hausner Ratio**
1.	5-15	Excellent	1.00-1.11
2.	12-16	Good	1.12-1.18
3.	18-21	Passable	1.19-1.25
4.	23-35	Fair or Passable	1.26-1.34
5.	33-38	Poor	1.35-1.45
6.	>40	Very poor	1.46-1.59

Sr.No.	**Average mass**	**Percentage deviation**
1.	130mg or less	±10
2.	More than 130 mg and less than 324 mg	±7.5
3.	324 mg or more	±5

Drug Content:

This test is performed to maintain the uniformity of weight of each tablet which should be in the prescribed range according to the Indian Pharmacopoeia. The content uniformity test is mandatory for tablets whose average weight is below 50mg. This test is performed by taking twenty tablets were selected randomly, weighed and powdered. A quantity of powdered tablet equal to 100mg of Pantoprazole was dissolved in 0.1N HCl in 100 ml volumetric flask. The so formed sample was diluted and the absorbance was measured at 289nm using 0.1N HCl as blank.

In-vitro dissolution studies:

Dissolution test was carried out using USP II (electro lab) 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 1ml of fresh dissolution medium. The collected samples were suitably diluted with dissolution fluid, wherever necessary and were analyzed for the Pantoprazole at 289nm by using a double beam UV spectrophotometer.

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 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. 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).[82]

Swelling index of Pantoprazole floating tablets:

The swelling index of tablets was determined by using 0.1 N HCl (pH 1.2) at room temperature. The swollen weight of the tablets was determined at predefined time intervals. The swelling index was calculated by the following equation:

Swelling index (SI) = $\frac{Wt-W0}{W0}$ Where,

Wt = Weight of tablet at time t.

W0 = Initial weight of tablet

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
- Korsmeyer-Peppas 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.

Zero Order Kinetics:

Drug dissolution from pharmaceutical dosage forms that do not disaggregate and release the drug slowly (assuming that area does not change and no equilibrium conditions are obtained) can be represented by the following equation

$$ft = Kt$$

Where, ft = the fraction of drug dissolved in time's

K = Rate Constant

t = Time

This model represents an ideal release profile in order to achieve the prolonged pharmacological action. This is applicable to dosage forms like transdermal systems, as well as matrix tablets with low soluble drugs, coated forms and osmotic systems.

First Order Kinetic:

This model has also been used to describe absorption and/or elimination of some drugs, although it is

difficult to conceptualize this mechanism in theoretical basis.

Log Q_t= log Q_0 + Kt/2.303

Where Q_t = Amount of drug released in time't'.

Q_0 = Initial amount of drug in the solution.

K = Rate Constant.

Higuchi Model:

This model is applicable to study the release of water soluble and low soluble drugs incorporated in semi-solid and/or solid matrices.

$$ft = Kt^{1/2}$$

Where, ft = Amount of drug released in time't'

Koresmayer Peppas Model:

This model is relating exponentially the drug release to the elapsed time (t):

$$ft = at^n$$

Where, a = constant incorporating structural and geometric characteristics of the drug dosage form.

n = Release exponent

This model is widely used; when the release mechanism is not well known or when more than one type of release phenomenon could be involved.

III. RESULTS AND DISCUSSION

Reformulation study of Pantoprazole :- Description:

Colour - white to white off

State - crystalline

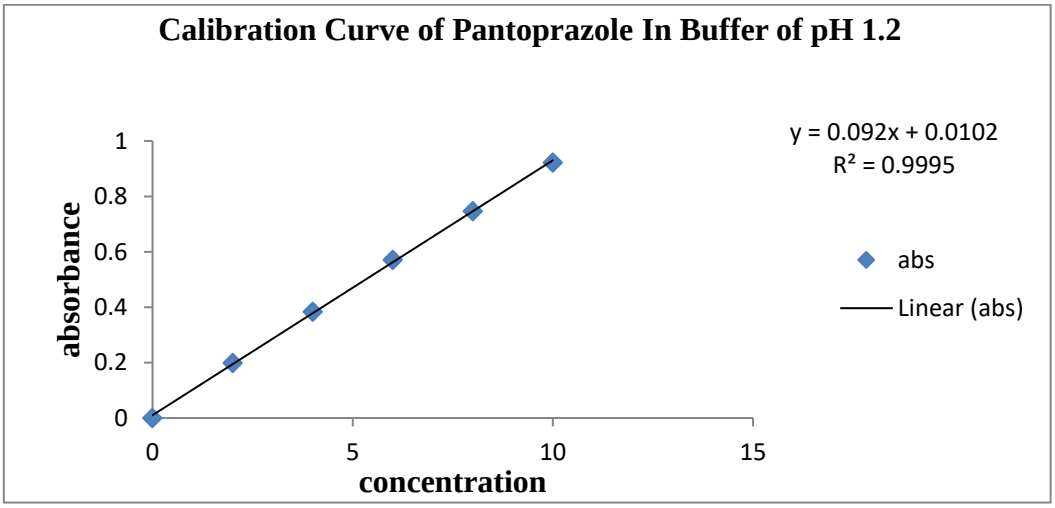
Odour - bitter

Melting point:

Melting point of Pantoprazole was found to be 285^{0}c

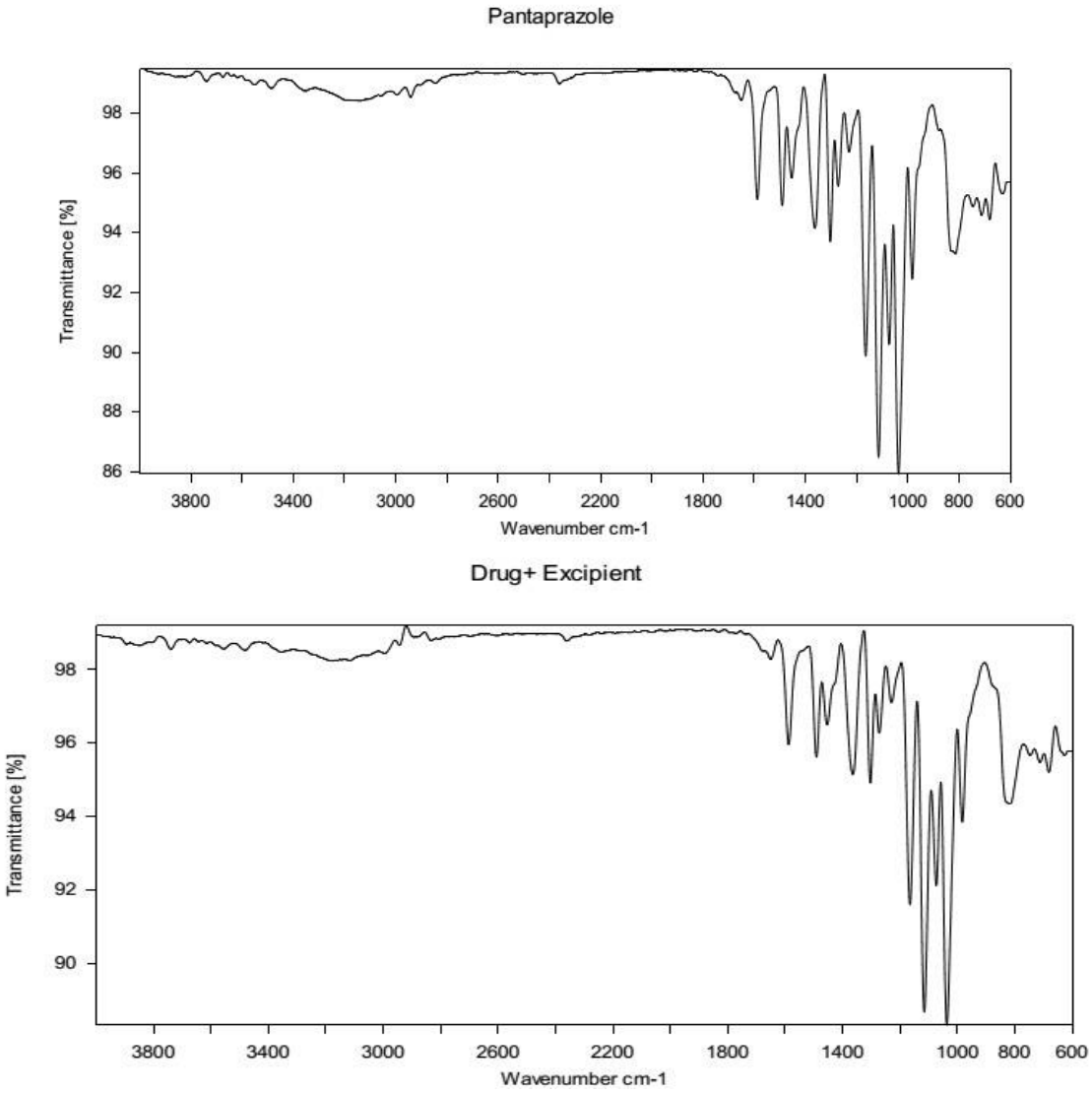
Solublity: It is freely soluble in water, and very slightly soluble in phosphate buffer.

Calibration Curve of Pantoprazole



Excipients Compatibility studies.

a) FTIR Study



FTIR of Drug and Excipient.

Data obtained form IR Spectra:-

Interpretation of IR Spectra:

Sr.No.	Functional Group	StandardValue	Obtained Value
1	N-H and O-H stretch	3600-3250	3373
2	Olifinic and aromatic C-H stretch	3050	2992
3	Asymmetric C-H stretch in methyl and methylene of ethyl and piperazin group.	2950	2920

Pre-Compression evaluations parameters:

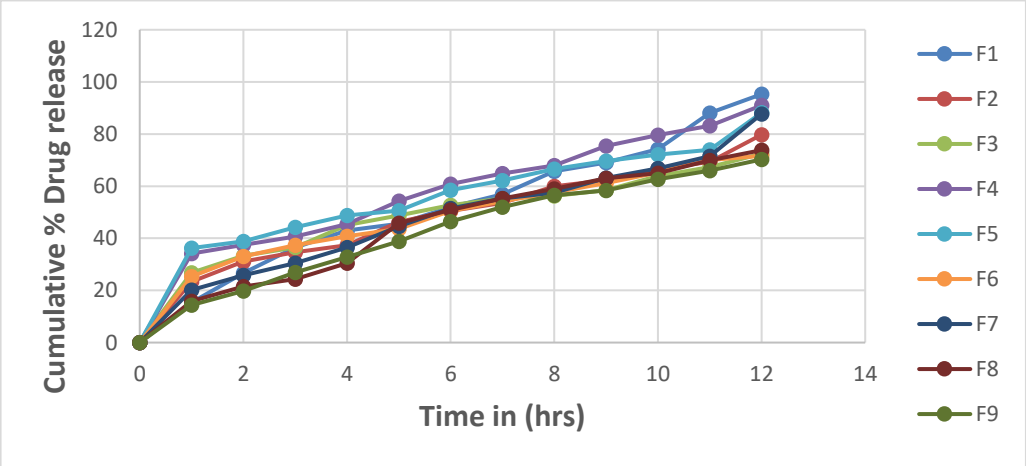
Batch Code	Angle of repose (θ)	Bulk density (gm/cm3)	Tappeddensity (gm/cm3)	Carr'sindex (CI)	Hausner's ratio (HR)
F1	26.2±0.17	0.417±0.67	0.501±0.51	16.05±0.44	1.17±0.27
F2	25.9±0.69	0.415±0.78	0.485±0.61	15.56±0.46	1.16±0.43
F3	25.8±0.45	0.416±0.63	0.495±0.37	15.27±0.35	1.16±0.35
F4	26.4±0.22	0.409±0.37	0.484±0.39	13.71±0.95	1.15±0.75
F5	25.4±0.42	0.405±0.36	0.469±0.71	13.64±0.69	1.18±0.35
F6	26.9±0.23	0.406±0.41	0.444±0.47	13.36.±0.71	1.11±0.74
F7	26.5±0.40	0.415±0.35	0.479±0.27	11.36±0.75	1.15±0.36
F8	27.3±0.27	0.425±0.32	0.487±0.65	12.73±0.35	1.14±0.47
F9	27.7±0.26	0.411±0.42	0.463±0.95	11.23±0.47	1.12±0.87

Post-compression evaluations parameters:

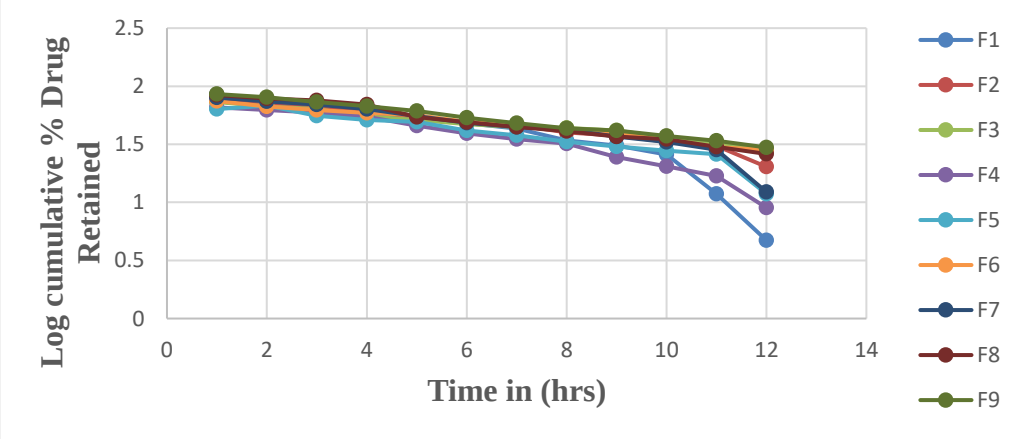
Batch Code	Weight variation Average wt in (mg) ±SD	Hardness (kg/cm2) ±SD	Thickness (mm) ±SD	Friability (%)	Drug Content Uniformity (%)±SD
F1	150±2.64	5.4±0.20	3.2±0.11	0.11	100.33±1.15
F2	150±2.51	5.3±0.20	4.2±0.12	0.21	96.00±1.29
F3	150±1.00	5.7±0.17	3.2±0.06	0.32	98.00±1.00
F4	150±2.00	5.7±0.15	3.3±0.7	0.33	99.00±1.40
F5	150±2.51	5.8±0.11	4.0±0.10	0.52	100.00±1.28
F6	150±4.72	5.8±0.05	3.4±0.11	0.42	98.00±2.64
F7	150±4.16	5.6±0.17	3.4±0.13	0.89	96.33±1.15
F8	150±4.04	5.7±0.19	3.2±0.15	0.22	102.66±2.30
F9	150±3.60	5.7±0.17	4.7±0.19	0.93	98.66±2.08

In-Vitro Drug Release Data batch F1-F9

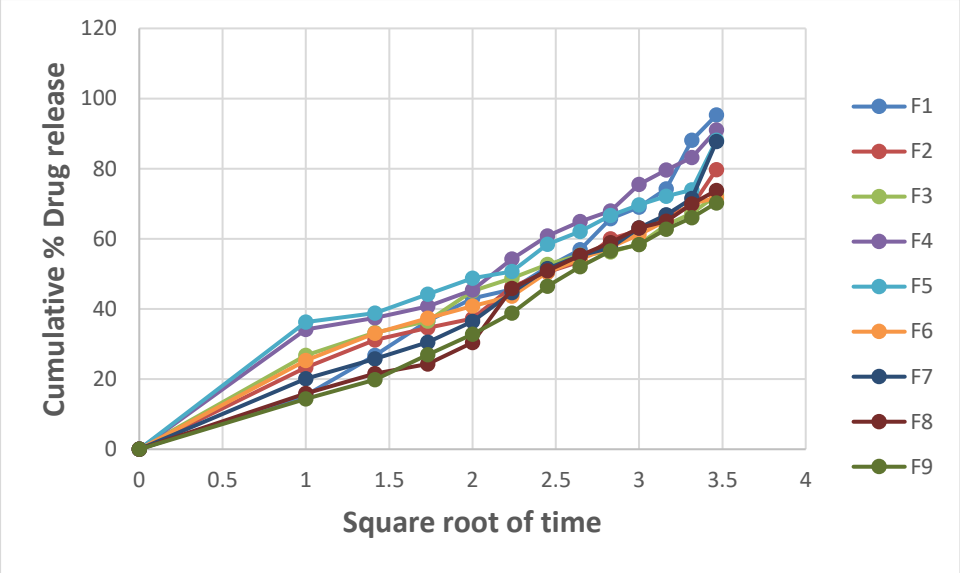
Time(hr)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
1	15.347	23.339	26.769	34.135	36.273	25.331	20.146	15.887	14.391
2	26.726	31.138	33.285	37.463	38.809	33.064	25.755	21.571	19.831
3	36.511	34.635	36.541	40.736	44.217	37.393	30.526	24.318	26.955
4	42.994	37.311	45.149	45.413	48.800	40.857	36.480	30.424	32.835
5	45.619	46.350	48.762	54.275	50.658	43.678	44.637	45.864	38.838
6	51.926	50.551	52.689	60.776	58.466	50.507	51.535	50.904	46.468
7	56.932	53.555	55.333	64.903	62.124	54.182	55.289	55.232	52.023
8	65.777	60.009	56.287	67.956	66.637	57.657	57.470	58.932	56.573
9	69.039	62.336	58.432	75.471	69.703	61.151	63.133	63.085	58.326
10	74.195	66.687	63.929	79.606	72.176	65.241	66.874	65.030	62.704
11	88.128	69.308	67.265	83.173	73.944	70.075	71.501	69.955	66.012
12	95.282	79.753	72.443	90.99	88.153	71.654	87.724	73.825	70.262



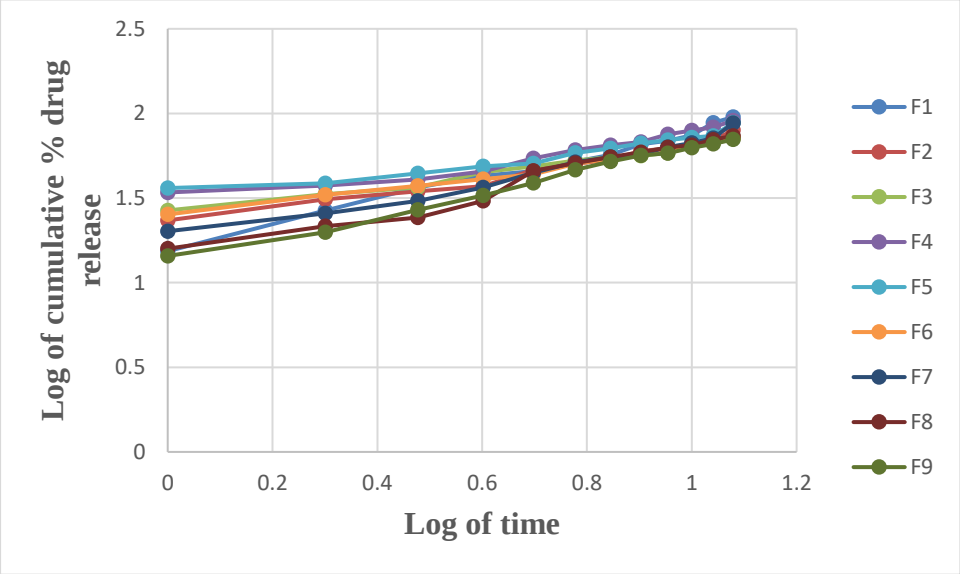
In-vitro Release Profile F1-F9 Formulations



Comparative In-vitro Release Profile According to first order kinetics for formulations F1-F9.



Comparative In-vitro Release Profile According to Higuchi Matrix kinetics for formulations F1-F9.



Comparative In-vitro Release Profile According to Korsmeyer Peppas kinetics for formulations F1-F9.

Kinetic Data:

Drug release kinetic model

Sr. No.	Release exponent	Drug transport mechanism
1	0.5	Fickian diffusion
2	0.5 < n < 1	Anomalous transport
3	1.0	Case II Transport
4	Higher than 1.0	Super case II transport

Interpretation of diffusion release mechanisms.

Formulation	Floating Lag Time (seconds)	Matrix Integrity	Floating Duration (hours)
F1	45	✓	> 12
F2	47	✓	> 12
F3	46	✓	> 12
F4	40	✓	> 12
F5	47	✓	> 12
F6	45	✓	> 12
F7	46	✓	> 12
F8	45	✓	> 12
F9	46	✓	> 12

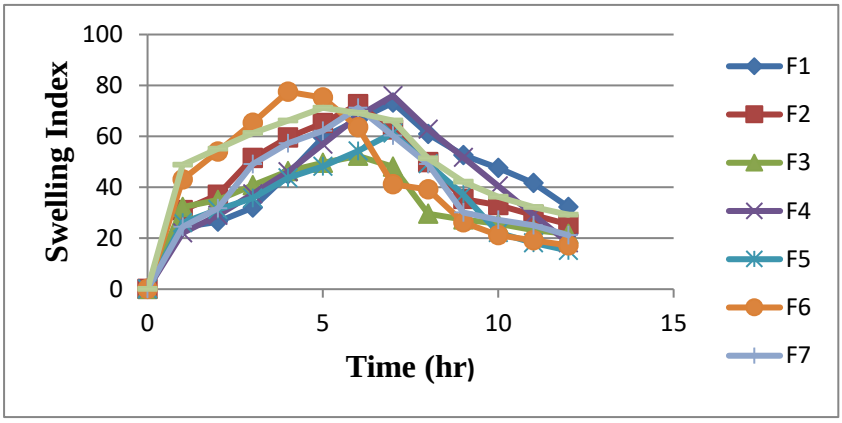
Floating Properties of Pantoprazole tablets.

Swelling Index Study

Swelling Characteristics (water uptake study)

Time(hr)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	25.32	30.04	32.21	23.06	26.03	43.01	24.49	43.65	44.87
2	28.52	39.06	34.95	29.96	31.25	54.05	31.77	55.47	53.11
3	32.05	52.49	40.78	37.38	35.73	65.25	49.15	66.07	61.24
4	45.07	57.55	46.37	46.02	43.66	77.51	57.23	59.22	66.21
5	59.49	65.23	49.65	56.92	48.22	75.23	62.12	74.18	71.22
6	66.51	72.55	52.33	68.95	50.30	63.51	71.23	76.19	69.19
7	73.21	62.70	48.06	75.97	57.32	41.23	60.22	69.23	65.13
8	60.96	49.99	29.60	61.85	47.23	39.12	49.12	57.18	51.41
9	52.66	35.38	27.33	50.78	35.12	26.23	30.12	40.03	39.13
10	47.55	34.96	25.72	40.49	18.21	21.12	27.23	35.28	34.23
11	41.61	30.14	23.13	26.22	16.18	19.12	25.12	27.22	28.24
12	33.20	22.49	21.74	16.21	12.16	17.11	21.21	18.01	23.25

Relationship between swelling index and time.



DISCUSSION

In the present study, FDDS of Pantoprazole were prepared by using polymer hydroxy propyl methyl cellulose (HPMC K4M), and using sodium bicarbonate as gas generating agent and Lactose as binder. FDDS tablets were prepared by direct compression technique. Formulation was optimized by using different ratios of polymers and lactose.

The prepared FDDS tablets were evaluated for its hardness, friability, uniformity of weight, uniformity of drug content, drug-polymer interaction studies, in vitro floating studies, and in vitro dissolution studies.

Reformulation Studies

Melting Point Determination

Melting point of Pantoprazole was determined by capillary method. The melting point of Pantoprazole was found to be in the range 285^{0}C, which complied with IP standards, indicating purity of the drug sample.

Solubility

Pantoprazole freely soluble in water, and very slightly soluble in phosphate buffer.

Compatibility studies

Compatibility studies were performed using IR spectrophotometer. The IR spectrum of pure drug and physical mixture of drug and polymers were studied. Drug-excipients interactions play a vital role with respect to release of drug from the formulation amongst others. FTIR techniques have been used here to study the physical and chemical interaction between drug and excipients used. In the present study, it has been observed that there is no chemical interaction between Pantoprazole and the polymer used. From the figure.6.3and 6.4 It was observed that there were no changes in these main peaks in IR spectra of mixture of drug and polymers, which show there were no physical interactions because of some bond formation between drug and polymers. The peaks obtained in the spectra's of each polymer correlates with the peaks of drug spectrum. This indicates that the drug was compatible with the formulation components.

Standard Calibration Curve of Pantoprazole

The scanning of drug solution in UV region (200–400 nm) to find out the wavelength of maximum absorption (λ max). The λ max was found to be at 285nm. So the Standard calibration curve of Pantoprazole was developed at these wavelengths. The calibration curve was linear between 02-10µg/ml

concentration ranges. The standard calibration curve of Pantoprazole was determined in 0.1N HCl, by plotting absorbance against concentration at 289 nm.. The R^2 were found to be 0.999 in 0.1 N HCl.

Angle of Repose (θ)

The angle of repose for the formulated blend was carried out and the results were shown in table no.6.4. It concludes all the formulations blend was found to be in the range 25.4±0.42 to 26.9±0.23. The lower angle of repose 25.04±0.42 was shown by formulation F5. Formulation containing HPMC K4M showed good angle of repose.

Compressibility Index

Carr's index below 15 % usually shows good flow characteristics, but above 25% indicate poor Flow ability. Compressibility index was carried out, it found between 10.90% and 21.88% indicating the powder blend has the required flow property for compression.

Hausner's Ratio

Hausner's ratio is simple method to evaluate stability of powder column and to estimate flow properties. Low range was observed for Hausner's ratio that indicates good flow ability. Many different types of angular properties have been employed to assess Flowability. The Hausner's ratio was found between 1.11±0.74and 1.18±0.35.All formulation showed acceptable flow properties.

EVALUATION OF TABLETS

Tablet dimensions

The thickness of the tablet is depends upon the diameter of die, the amount of fill permitted to enter the die, the compaction characteristics of the fill material and the force applied during compression.

Hardness and friability

Thus, the tablets found to be of good tensile strength to withstand the handling stress without break. Tablets hardness is a determining factor, with regard to the buoyancy of the tablets. Tablet hardness reflects differences in tablet density and porosity, which are supposed to result in difference release patterns of the drug by affecting the rate of penetration of the dissolution fluid at the surface of the tablet. The hardness of the prepared GFDDS of Pantoprazole was found to be in the range of 5.3±0.2to 5.8±0.1 kg/cm^2.

It ensures that the tablets can withstand mechanical impacts during packing, transportation and other processing operations. The present study of tablets is in within the limit and the slight variation in friability because of the variation in compression force applied and its total weight. The friability of tablets is also depends on moisture contents in it. The friability of all the tablets was to be less than 1% i.e. in the range of 0.11to 0.93 %.

Uniformity of weight

All the prepared GFDDS tablets were evaluated for weight variation and The percent deviation from the average weight was found to be within the prescribed official limits.

Uniformity of drug content

The drug content uniformity was examined as per I.P specification. All the batches of tablets were found to comply with uniformity of content test and Drug content was in range of 96.00±1.29 30 to 102.66± 2.30 in the prepared formulation.

Tablet density

When tablet contacts the test medium, tablet expanded (because of swellable polymers) and there was liberation of CO2 gas (because of effervescent agent NaHCO3). The density decreased due to this expansion and upward force of CO2 gas generation.

This plays an important role in ensuring the floating capability of the dosage form. To provide good floating behavior in the stomach, the density of the tablets should be less than that of the gastric contents the density below (1.004g/cm3) than of gastric fluid. For formulation F1-F9 density were found to be less than that of the gastric content.

In vitro Buoyancy

The gas generated is trapped and protected within the gel, formed by hydration of polymer, thus decreasing the density of the tablet. As the density of the tablet falls below 1, the tablet became buoyant. The results presented in table no 6.9. reveled that HPMC K100M produced tablets with good gel strength, entrapping CO_2 gas and imparting stable and persistent buoyancy. Floating lag time was in range of 45 sec to 47 sec.

Swelling Study

The swelling indexes of batches F1 to F9 are Polymer matrices representing swellable matrix drug delivery systems are porous in nature. When these matrices come in contact with water or aqueous gastrointestinal fluid, the polymer absorbs the water and undergoes swelling or hydration. The rapid formation of a viscous gel layer upon hydration suggests that swelling is associated with polymer chain relaxation with volume expansion. The liquid diffuses through the polymer matrix at a constant velocity, and the rate of diffusion of the liquid and that of macromolecular relaxation of the polymer are almost of the same magnitude or, possibly, the rate of diffusion of the liquid is relatively higher than that of relaxation of the polymer segment.

This mechanism gives the idea regarding the water uptake study of various grades of polymer. This phenomenon is attributes to that the swelling is more due to water uptake and then gradually decreased due to erosion. Swelling measurement was performed separately in order to collect on the basis of weight increase over time. The swelling is due to presence of hydrophilic polymer, which gets wetted and allows water uptake leads to increase in its weight.

The swelling index was calculated with respect to time. As time increase, the swelling index was increased, because weight gain by tablet was increased proportionally with rate of hydration. Later on, it decreased gradually due to dissolution of outermost gelled layer of tablet into dissolution medium. The direct relationship was observed between swelling index and HPMC K4M increase, swelling index was increased.

In vitro dissolution study:

Besides the satisfactory buoyancy, the matrix tablets are required to release Pantoprazole gradually over prolonged period. Hence, they were tested for release kinetics by conducting in-vitro dissolution test.

The results obtaining in In-Vitro release studies were plotted in different model of data treatment as follows:

- Cumulative percent drug released vs. time (zero order kinetics)
- Log Cumulative percent drug retained vs. time (First order rate kinetics)
- Log Cumulative percent drug released vs. square root of time (Higuchi's classical diffusion equation)
- Log Cumulative percent drug released vs. log time (Peppas Exponential equation)

Dissolution data of batch F1 to F9 are as shown in Table no.6.6. From the dissolution study it was concluded that release from the matrix is largely dependent on the polymer swelling, and drug diffusion. It was observed that all the tablets ascended to the upper one third of the dissolution vessels within a short time, and remained floated until the complete of release studies. The drug release study was carried out up to 12 hrs. The percentage drug release from batch F1 to F9 vary from 95.282 to

70.262 % because of increase in concentration of polymer (HPMC K4M). High drug release is observed in F1 batch because of low concentration of polymer (HPMC K4M). Large concentration of high viscosity polymer induces the formation of strong viscous gel layer that slowed down the rate of water diffusion into the tablet matrix, which may result in the retardation or decreases the drug release. Being water soluble polymers, they dissolve and form pores filled liquid in which drug can there after diffuse in dissolution medium. All the formulations were designed as dosage form for 12 hrs.

From the dissolution study it was concluded that release from the matrix is largely dependent on the polymer swelling and drug diffusion

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V. REFERENCES

[1]. Baviskar DT,Jain D K. Textbook of Novel Drug Delivery System.Nirali Prakashan, India:2014 pp.11.1-11.13.

[2]. Audumbar Digambar Mali, Ritesh Suresh Bathe. 2015 A Review on Gastroretentive Floating Drug Delivery System. Amer. J. Pharm. Res; 5(2): 107-132.

[3]. Rohit D.Jondhale, Pallavi S.Gadhave,Ashish A.Mahajan.2015 A Review on Floating Drug Delivery System.World J. of pharmacy and pharma sciences;4(10):562-575.

[4]. Dixit N.2011, Floating drug delivery system. J. Curr Pharma Res;7(1):6-20.

[5]. Wikipedia(http://en;wikipedia.org/wikipedia/Pantoprazole)

[6]. Gupta S K, Gupta U, Omray L K, Yadav, Soni V K. 2010 Preparation and characterization of floating drug delivery system of acyclovir.Int J appl pharm.; 2(3): 7-10.

[7]. Hemant Patil, Bharat Prashar, Abhishek Chandel, Varun Thakur, 2012 Formulation and Evaluation of Pantoprazole Sodium Sesquihydrates. J. Pharma Res.;5(9): 4659-4662.

[8]. Drug bank (http://www.drug bank/D78467.)

[9]. Indian Pharmacopoeia, Government of India, Ministry of Health and Family Welfare.Vol.3 Indian Pharmacopoeia Commission, Ghaziabad;2821.

[10]. Timucin Uğurlu and Uğur Karacgcek.2014 An Overview on Gastroretentive Drug Delivery Systems. J. Medi. Pharma. Inno; 1(4): 5- 11.

[11]. Zulfequar Ahamad Khan,Rahul Tripathi, and Brahmeshwar Mishra,2011Floating Elementary Osmatic Pump Tablet for controlled delivery of diethyl CarbamazepineCitrate;a water solubledrug.APPSPharma.Sci:Tech.;12(4):1312-1323.

[12]. Lachman L, Lieberman H A, Kanig J L1991.The theory and practice of industrial pharmacy: 3rd edition. Varghese publishing house, Mumbai;: 296-302.

[13]. Famotidine Floating Tablets By Lipid Solid Dispersion Spray Drying Technique. Int.J.Of Res In Pharma And Chem. 2012; 2(4): 996-1000.

[14]. Y. Srinivasa Rao, Eswara Ranga Sandeep V, K.P.R. Chowdary.2012 Design and Evaluation of Pioglitazone Hydrochloride Gastroretentive Floating Matrix Tablets Asian.J. Pharma.Cli.Res.;5(4):225-231.

[15]. Nirav Rabadia, Mr. Ajay Tiwari, Gaurang Patel, Vishal Virani.2012 The Floating Drug Delivery System and Its Impact on Calcium Channel Blocker: A Review Article. J. Pharma. Sci. Tech;4(1): 835 - 867.

[16]. Wells J. M. Aulton, 2002 Pharmaceutics: The science of dosage form design. 2nd edition. Edinburgh: Churchill Livingstone Longman group.133-134.

[17]. Audumbar Digambar Mali, Ritesh Suresh Bathe. Design and Optimization of Gastroretentive Floating Matrix Tablets of an Antihypertensive Drug Quinapril HCl. Int. J. Pharm. Tech. 2015; 7(2): 9212-9224.

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