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Formulation and Evaluation of Fast Dissolving Tablets of An Anti Ulcer Drug by Sublimation Method

Arifa Begum Shaik[1]*, Pooja Gundraju[1], Sai Lakshmi Pallampati[1], Jyothi Kota[1], Priyanka Pirudula[1], Padma Latha Kantamaneni[1]
1. Vijaya Institute of Pharmaceutical Sciences for Women, Vijayawada-521108, A.P, India.

ABSTRACT

The purpose of present research was to formulate and develop the patient friendly pantoprazole sodium fast dissolving tablets using sublimation method to achieve rapid dissolution. In this study, an attempt was made to fasten the drug release from the oral tablets by incorporating the superdisintegrants and camphor/ammonium bicarbonate as subliming agents. The prepared fast dissolving tablets were subjected to pre-compression analysis and evaluated for hardness, weight variation, friability, wetting time, water absorption ratio and disintegration time. From the results of *in vitro* drug release studies, the formulation F9 exhibited fast release profile of about 95.21% in 14 min and disintegration time 90 sec when compared with other formulations. For the optimized formulation F9, the initial dissolution rate was 38.82% / 2 min. Fourier transform infrared spectroscopy studies revealed that there was no possibility of interactions between drug and excipients. The present study demonstrated potential for rapid absorption, improved bioavailability, effective therapy and patient compliance.

Keywords: Fast dissolving tablet, pantoprazole sodium, subliming agent, superdisintegrant, proton pump inhibitor.

*Corresponding Author Email: arifashaik2007@gmail.com
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INTRODUCTION

Oral route of drug administration offers wide acceptance up to 50-60% of total dosage forms. Solid dosage forms have gained popularity because of ease of administration, accuracy of dosage, possibility of self-medication and avoidance of pain as well as the patient compliance. Among the solid dosage forms, tablets and capsules are most popular; one major drawback of this dosage forms for some patients, is the difficulty to swallow. Drinking water plays a vital role in the swallowing of oral dosage forms. People experience inconvenience in swallowing conventional dosage forms such as tablet when there is unavailability of water, in case of motion sickness (kinetosis) and sudden episodes of coughing during the common cold, allergic condition and bronchitis[1]. For these reasons, tablets that can dissolve or disintegrate at a faster rate in the oral cavity have attracted a great deal of attention. Such tablets are also suitable for active people. Fast dissolving tablets are also known as mouth-dissolving tablets, melt-in mouth tablets, orodispersible tablets, quick dissolving tablets etc[2].

Pantoprazole sodium is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the enzyme system of hydrogen/ potassium adenosine triphosphatase (H^+/K^+ ATPase) at the secretory surface of the gastric parietal cell. It is used for the treatment or symptomatic relief of gastric disorders such as gastric and duodenal ulcers, gastroesophageal reflux disease and Zollinger - Ellison syndrome. It is freely soluble in water, pH 6.8 and 7.4 phosphate buffer, practically insoluble in n-hexane and chloroform. The systemic bioavailability of pantoprazole sodium is 77%, biological half life is 1 h; short duration of action. Its absorption is dose dependent and upon oral administration undergoes extensive first pass metabolism, thereby making it suitable candidate for fast dissolving tablet dosage forms[3].

There are various approaches to formulate rapidly disintegrating or dissolving tablets. Sublimation is one of these approaches in which a subliming agent and superdisintegrant are included into the formulation to achieve fast disintegration of tablets. Extremely fast disintegration of tablets would be required to increase the release of pantoprazole sodium from tablets for rapid absorption by the oral mucosal blood vessels. Therefore, an attempt to formulate pantoprazole sodium into fast disintegrating tablets for oral administration would have potential for emergency treatment of peptic ulcers. This could be achieved by selecting the suitable pharmaceutical excipients in the correct proportion, in combination with optimal manufacturing techniques[4].

The present research was mainly focused on the development and evaluation of fast dissolving tablets of an antiulcer drug, pantoprazole sodium. Various batches of pantoprazole sodium fast

dissolving tablets were prepared by sublimation method using different subliming agents (camphor & ammonium bicarbonate) and superdisintegrants (crosscarmellose sodium, sodium starch glycolate & Crosspovidone) in different proportions to achieve the rapid release of drug from tablets.

MATERIALS AND METHOD

Pantoprazole sodium was received as a gift sample from Rakshit Pharmaceuticals, India. Sodium starch glycolate (SSG) and Magnesium stearate were obtained from Loba Chemie, Tarapur. Croscarmellose sodium (CCS) and Crospovidone (CP) were obtained as gift samples from Ciron Drugs & Pharmaceuticals, Palghar. Camphor was purchased from Qualikems Fine Chem, Vadodara. Ammonium bicarbonate, Talc and Mannitol were purchased from Finar Chemicals Ltd., Oxford Laboratory, Mumbai and Himedia Laboratory, Nashik respectively. Sodium saccharin and Flavour were kindly gifted by Blue Circle Organics Pvt. Ltd. and Aurobindo Pharma Ltd., Hyderabad respectively.

Preformulation studies

The first step in the rationale development of dosage form is pre-formulation study which involves an investigation of physicochemical properties of a drug substance alone and when combined with excipients[5]. Pre-formulation studies on the obtained sample of drug include colour, taste, solubility analysis, melting point determination and compatibility study.

DRUG - EXCIPIENT COMPATIBILITY STUDIES

Fourier Transformation Infra-Red (FTIR) Analysis

An FT-IR spectrophotometer was used for the infrared analysis of samples[6]. About 4-5 mg of sample was mixed with dry potassium bromide (KBr) and the sample was examined at transmission mode over the wave number range of 4000-400 cm^{-1}.

FORMULATION DEVELOPMENT

Calibration of standard curve of pantoprazole sodium[7]:

100 mg of pantoprazole sodium was weighed accurately and dissolved in 100 ml of phosphate buffer solution, pH 6.8 in 100 ml volumetric flask. From this suitable dilutions were made to get concentrations of 2 µg, 4 µg, 6 µg, 8 µg, 10 µg and 12 µg respectively. The absorbance of each solution was measured by UV-visible spectrophotometer at 288.5 nm using the phosphate buffer solution, pH 6.8 as blank.

Formulation of fast dissolving tablets of pantoprazole sodium by sublimation method

The FDTs of pantoprazole sodium were prepared using camphor/ammonium bicarbonate as subliming agent. CCS, SSG and CP were used as superdisintegrants. Each of the superdisintegrants was used in three different proportions. Mannitol was used as diluent in quantity sufficient; talc as flow promoter and magnesium stearate as lubricant. Sodium saccharin was used as sweetener and banana flavour for good mouth feel. All the ingredients were passed through sieve no. 60 and mixed in geometric order. All the materials were directly compressible. So, this uniformly mixed blend was compressed into tablets using tablet machine Rimek Mini Press (punches flat-faced, 8 mm diameter) to prepare 200 mg tablets. Sublimation was performed from tablets by keeping in hot air oven at 40ºC for 6 h. Total nine formulations were prepared and the composition of formulations was shown in Table 1.

Table 1: Formulation of different batches of pantoprazole sodium

Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)	F7 (mg)	F8 (mg)	F9 (mg)
Pantoprazole sodium	40	40	40	40	40	40	40	40	40
Camphor	15	20	25	--	--	--	15	20	25
Ammonium bicarbonate	--	--	--	15	20	25	--	--	--
CCS	05	10	15	--	--	--	--	--	--
SSG	--	--	--	05	10	15	--	--	--
CP	--	--	--	--	--	--	05	10	15
Sodium saccharin	01	01	01	01	01	01	01	01	01
Banana	02	02	02	02	02	02	02	02	02
Magnesium stearate	01	01	01	01	01	01	01	01	01
Talc	02	02	02	02	02	02	02	02	02
Mannitol	134	124	114	139	129	119	134	124	114
Total (mg)	200	200	200	200	200	200	200	200	200

EVALUVATION OF FDTs OF PANTOPRAZOLE SODIUM:

EVALUATION OF PRE-COMPRESSION PARAMETERS:

Angle of repose:

Determination of angle of repose was done using funnel method. In this method, a funnel was fit vertically to the stand at a height of 6 cm. The open end of funnel was closed with thumb, 5 g of powder was poured into funnel and then the thumb was removed. The maximum cone height (h) was noted down. Radius of the heap (r) was measured and the angle of repose (θ) was computed using the formula[8].

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

Where θ = angle of repose

Bulk density:

Bulk density was determined by pouring the weighed amount of powder (passed through standard sieve # 40) into a measuring cylinder and initial height was noted[9]. This initial volume was known

as the bulk volume. Then, bulk density was calculated according to the below mentioned formula and expressed in g/cm^3.

$D_b = M / V_b$

Where, M is the mass of powder, V_b is the bulk volume of the powder.

Tapped density (d_t):

The measuring cylinder consisting of a known mass of blend (M) was tapped for a fixed time (100 tappings). The minimum volume (V_t) occupied in the cylinder and height of the blend was measured[10]. The tapped density (ρ_t) was calculated using the formula;

$D_t = M / V_t$

Where, M is the mass of powder and V_t is the tapped volume of the powder.

Carr's index or % compressibility[11, 12]:

Carr's index indicates flow properties of powder and calculated as,

$I = (D_t - D_b) / D_t \times 100$

D_t is the tapped density of the powder, D_b is the bulk density of the powder.

Hausner's ratio:

It is an indirect index of ease of powder flow and calculated by using the following formula[13],

Hausner's ratio = D_t / D_b

Where D_t = tapped density, D_b = bulk density

Lower Hausner's ratio (<1.25) indicates better flow properties than higher ones (>1.25).

Table 2: Relationship between % compressibility and flowability

% Compressibility	Flowability
5 – 10	Excellent
12 – 16	Good
18 – 21	Fair passable
23 – 25	Poor
33 – 38	Very poor
< 40	Very very poor

EVALUATION OF POST-COMPRESSION PARAMETERS:

Physical appearance:

The physical appearance of the compressed tablets includes the measurement of a number of attributes like tablet shape, smoothness, chipping, cracks, surface texture, colour, embossing, debossing etc.

Thickness:

Thickness was determined for 20 pre-weighed tablets of each batch using a Vernier calipers and the average thickness was determined in mm**.** The tablet thickness should be within a ± 5%

variation of a standard.

Weight variation:

20 tablets were selected randomly from each formulation and weighed individually to check for weight variation[14]. Weight variation specification as per I.P. was given in Table 3.

Table 3: Weight variation specification as per I.P.

Average weight of tablet	% Deviation
80 mg or less	±10
80 mg to 250 mg	±7.5
250 mg or more	±5

Tablet hardness:

The force applied across the diameter of the tablet in the order to break it is known as tablet hardness. The resistance of the tablet to chipping, abrasion or breakage under conditions of storage, transportation and handling before usage depends on its hardness. Hardness of the tablet of each formulation was determined using Strong Cobb hardness tester[15].

Friability:

Friability test was done using Roche friabilator to assess the effect of friction and shocks, which often lead the tablet to chip, cap or break. The apparatus subjects a number of tablets to the combined effect of abrasion and shock by utilizing a plastic chamber which revolves at 25 rpm dropping the tablets at a distance of 6 inches with each revolution. Pre weighed sample of tablets was placed in the friabilator, which was then operated for 100 revolutions. Tablets were dusted and reweighed. Compressed tablets should not lose more than 1% of their weight.

$$\% F = \text{Initial weight} - \text{Final weight} / \text{Initial weight} \times 100$$

Wetting time & water absorption ratio[16]:

A piece of tissue paper folded twice was placed in a small petri dish (internal diameter = 6.5 cm) containing 6 ml of phosphate buffer solution, pH 6.8. A tablet was placed on the paper and time required for complete wetting was measured using a stop watch. The wetted tablet was then weighed. Water absorption ratio (R) was determined using following equation,

$$R = 100 \times \frac{W_a - W_b}{W_b}$$

W_a = Weight of tablet after water absorption,

W_b = Weight of tablet before water absorption.

Uniformity of drug content:

The prepared pantoprazole sodium tablets were tested for their drug content. Three tablets of each formulation were weighed and finely powdered. About 40 mg equivalent of pantoprazole sodium

was accurately weighed and completely dissolved in phosphate buffer solution, pH 6.8 and the solution was filtered. 1 ml of the filtrate was further diluted to 100 ml with phosphate buffer solution, pH 6.8. Absorbance of the resulting solution was measured by UV-Visible spectrophotometer at 288.5 nm.

***In-vitro* dispersion time:**

To determine *in-vitro* dispersion time, 10 ml measuring cylinder was taken in which 6 ml phosphate buffer solution, pH 6.8 was added and tablet was dropped in it. The time taken for complete dispersion of the tablet was determined.

***In- vitro* disintegration time:**

In-vitro disintegration times for fast dissolving tablets of pantoprazole sodium were determined using USP disintegration test apparatus with 900 ml of phosphate buffer solution, pH 6.8 as medium maintained at a temperature of 37 ± 2°C. The time in seconds taken for complete disintegration of the tablets with no palpable mass remaining in the apparatus was measured.

***In-vitro* dissolution studies:**

Dissolution testing of fast dissolving tablets of pantoprazole sodium was carried out with "Paddle type USP dissolution test apparatus" at 50 rpm and 37±0.5°C temperature in phosphate buffer solution, pH 6.8. At each specified intervals of time, 5 ml sample was withdrawn and replaced by fresh media. The samples were measured by UV- visible spectrophotometer at 288.5 nm against the blank. The % drug release was calculated using an equation obtained from the calibration curve. The release studies were conducted in triplicate and the mean values were plotted versus time.

RESULTS AND DISCUSSION

Pre-formulation studies of pantoprazole sodium:

The drug and the excipients interaction studies were evaluated by checking the physical appearance and by FT-IR analytical methods. The following pre-formulation studies were performed on pantoprazole sodium and excipients.

Analytical report for API:

Table 4: Analytical report for pantoprazole sodium

Preformulation test	Results
Description	Pale yellowish brown, odourless, crystalline powder.
Solubility	Very soluble in water, methanol and ethanol, freely soluble in acetone.
Category	Proton pump inhibitor
Melting Point	274^{o}C

Table 5: Pantoprazole sodium characterization

Test	Result
Particle size (µm)	9.84
Bulk density (g/cm^3)	0.374
Tapped density (g/cm^3)	0.596
Carr's index	9.48
Hausner's ratio	0.742
Angle of repose (^{o})	28.98

Drug - excipients compatibility studies:

The interaction studies were carried out to ascertain any kind of interaction of drug with the excipients used in the preparation of fast dissolving tablets.

Interpretation of Pantoprazole sodium:

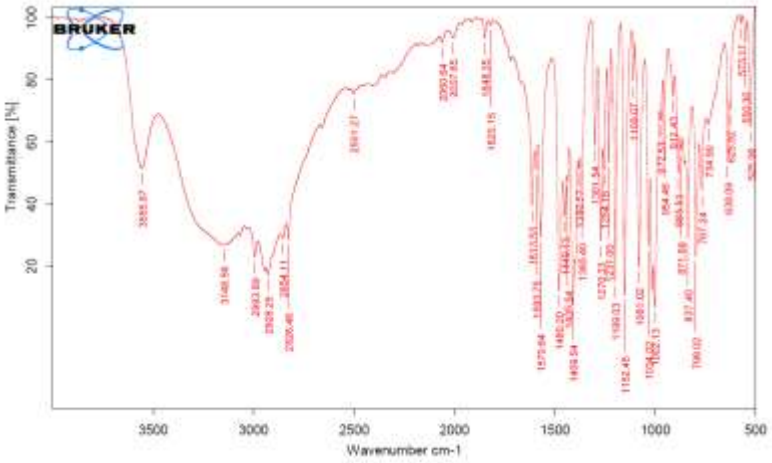

Figure 1: FT-IR Spectra for Pantoprazole sodium

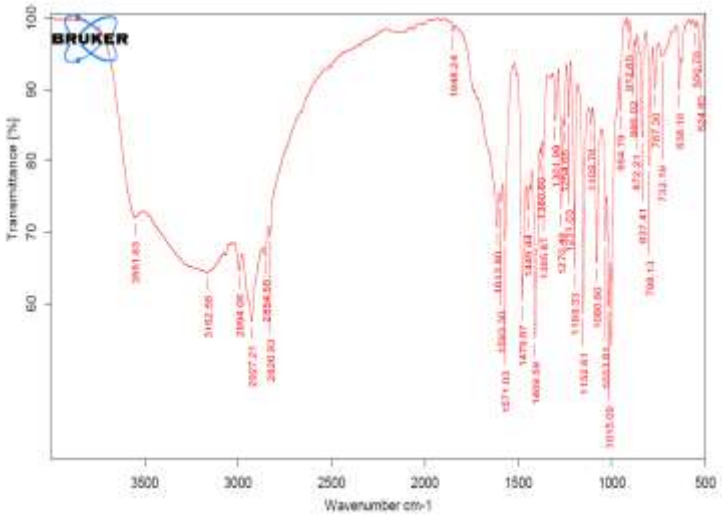

Figure 2: FT-IR Spectra for Pantoprazole sodium + CCS

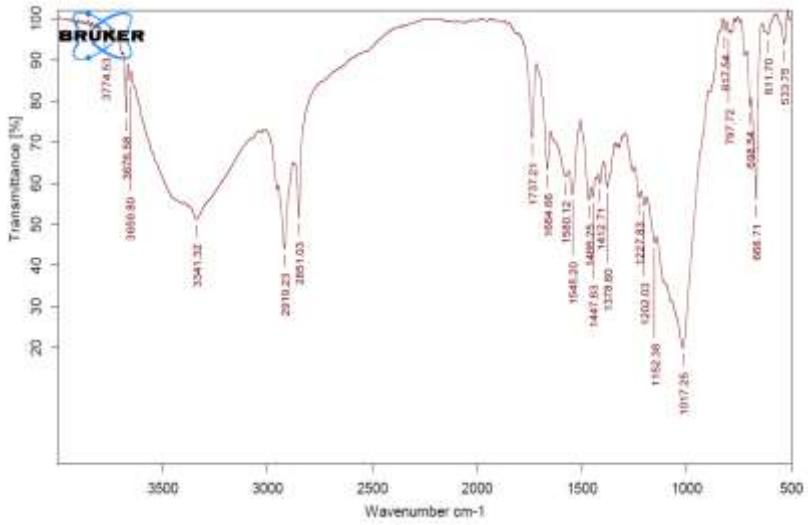

Figure 3: FT-IR Spectra for Pantoprazole sodium + Formulation F3

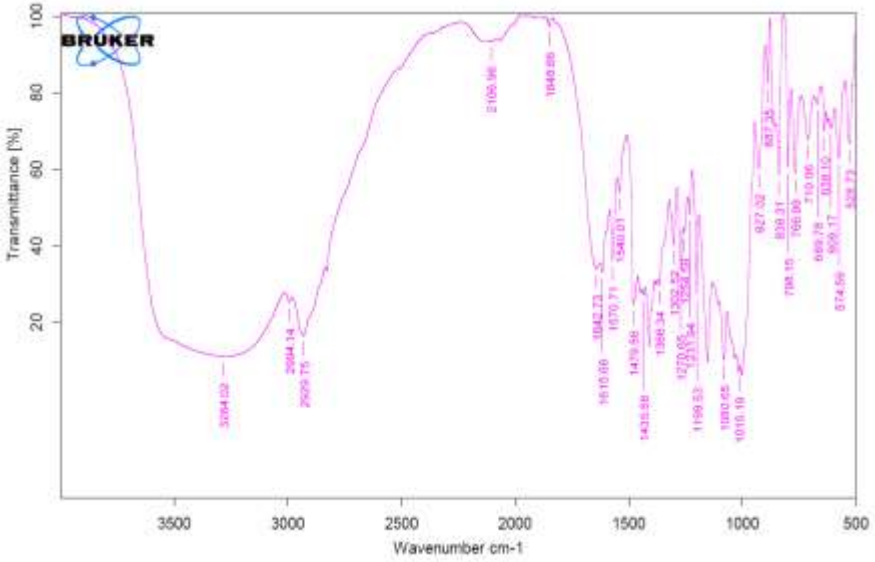

Figure 4: FT-IR Spectra for Pantoprazole sodium + SSG

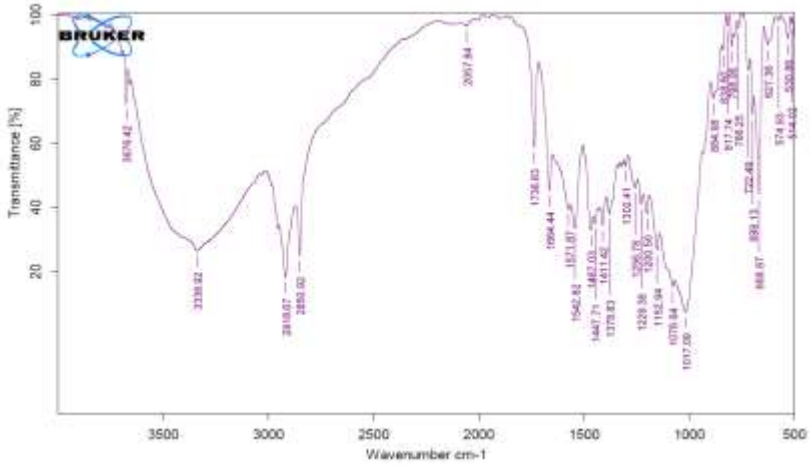

Figure 5: FT-IR Spectra for Pantoprazole sodium + Formulation F6

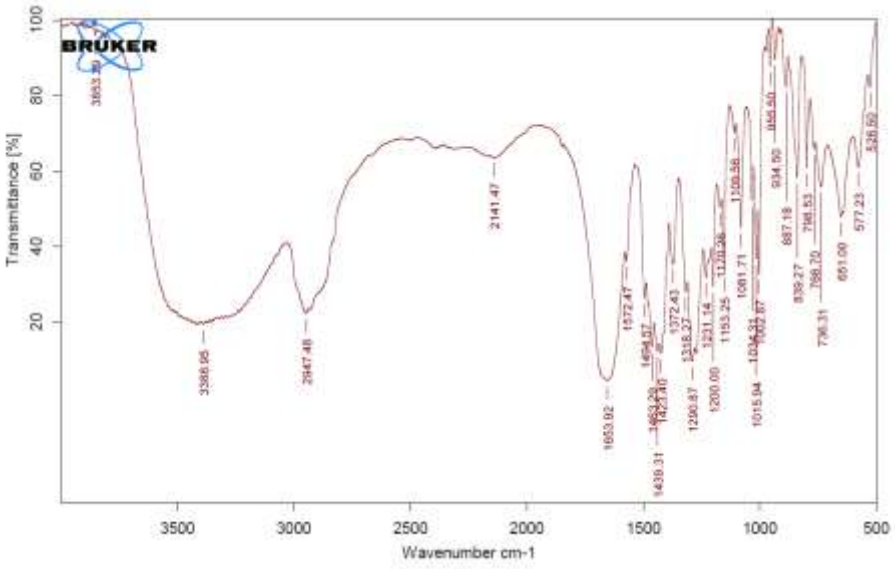

Figure 6: FT-IR Spectra for Pantoprazole sodium + CP

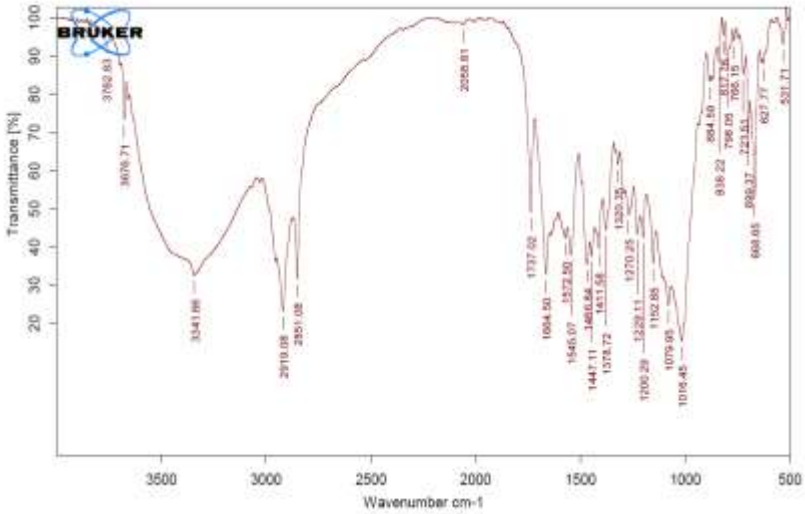

Figure 7: FT-IR Spectra for Pantoprazole sodium + Formulation F9

From the FT-IR spectra, it was revealed that there was no chemical interaction of the pure drug, pantoprazole sodium with superdisintegrants and excipients.

Table 6: FT-IR spectra interpretation of drug

Interpretation	Pure drug
N-H	3555.97
CH_2	3148.56
CH_3	2993.89
C-O	1593.75
C-F	1365.40
S=O	1034.02

Inference:

FT-IR studies were carried out to find out the possible interaction between selected drug

pantoprazole sodium; superdisintegrants CCS, SSG and CP as well as physical mixtures of formulations F3, F6 and F9. FT-IR of pantoprazole sodium showed the following peaks at 3555.97, 3148.56, 2993.89, 1593.75, 1365.40 and 10734.02 cm^{-1} due to N-H, CH_2, CH_3, C-O, C-F and S=O functional groups. The physical mixture of drug with superdisintegrants CCS, SSG and CP as well as physical mixtures of formulations F3, F6 and F9 clearly showed the retention of these characteristic peaks of pantoprazole sodium thus revealing no interaction between the selected drug, superdisintegrants and other excipients.

Formulation development:

Standard curve of pantoprazole sodium:

The standard calibration curve of pantoprazole sodium in phosphate buffer solution (PBS), pH 6.8 was shown in Fig. 8. Drug concentration and absorbance followed linear relationship and the curve obeyed Beer-Lambert's law and the correlation coefficient value (R^2) in phosphate buffer solution, pH 6.8 is 0.999.

Table 7: Standard calibration curve of pantoprazole sodium

Concentration (µg/ml)	Absorbance at 288.5 nm (in phosphate buffer solution, pH 6.8)
0	0.000
2	0.169
4	0.311
6	0.457
8	0.642
10	0.798
12	0.939

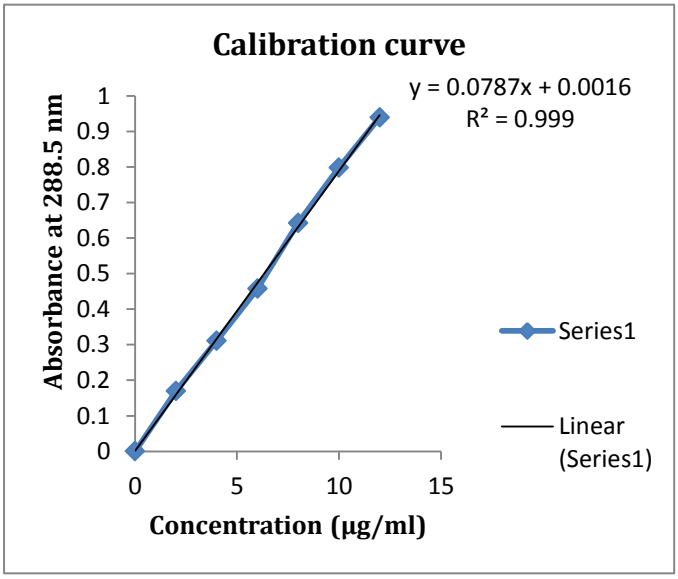

Figure 8: Standard calibration curve of pantoprazole sodium in PBS, pH 6.8

The present study was undertaken to formulate fast dissolving tablets of pantoprazole sodium by sublimation method using croscarmellose sodium, sodium starch glycolate & crospovidone as superdisintegrants; camphor & ammonium bicarbonate as subliming agents. Total nine batches were formulated (F1, F2, F3, F4, F5, F6, F7, F8 and F9). The prepared tablets were evaluated for various pre-compression and post-compression parameters and the results were shown in Table 8 & 9 respectively.

FT-IR studies revealed that there was no interaction between the selected drug, superdisintegrants and other excipients. The angle of repose of all the formulations was within the range of 26.97^{o}±0.31 – 30.88^{o}±0.3. These values indicate that the powder blend exhibited good flow properties. The bulk density was found in the range of 0.38±0.03 - 0.50±0.07 g/cm^3. The tapped density ranged between 0.43±0.09 – 0.66±0.01 g/cm^3. The Carr's index and Hausner's ratio of all the formulations existed in the range of 11.62±0.10 to 30.27±0.05 and 1.13±0.04 to 1.52±0.07 respectively. These values indicate that the prepared powder blend of FDTs exhibited excellent flow properties.

The tablets were evaluated for various post-compression parameters such as physical appearance, diameter, thickness, weight variation, hardness, friability and drug content. The prepared tablets of all the nine formulations were found to be in pale yellowish brown colour, smooth in texture; round and flat in shape. Diameter & thickness values for all the formulations were found to be 0.8±0.1 and 0.4±0.2 respectively. Weight variation values for all the nine formulations were found to be within the limits. Hardness for all the formulations was found to be from 1.5 ± 0.01 to 3.1 ± 0.02 kg/cm^2. The friability was found in the range of 0.24%±0.02-0.75%±0.03 and drug content values in the range of 95.75%±0.01 - 99.38%±0.01. These values indicate that the prepared FDTs passed the tests for friability and drug content.

The wetting time for all nine formulations was found to be in the range of 33 sec to 94 sec. Water absorption ratios of all formulations were in the range of 135 ± 1.87 to 203 ± 1.32. Wetting time, *in vitro* dispersion time and water absorption ratio found to be faster for the formulation F9 containing sublimable agent camphor & superdisintegrant crospovidone as compared to other formulations. According to the Pharmacopoeial standards, the dispersible tablet must disintegrate within 3 min. All formulated batches have shown less disintegration time i.e. 90 to 133 sec indicating suitability of formulation for fast dissolving tablet.

Table 8: Pre compression parameters of various pantoprazole sodium formulations

Formulation	Angle of repose (^{o})	Bulk density (g/cm^3)	Tapped density (g/cm^3)	Carr's Index	Hausner's ratio
F1	29.38±0.15	0.38±0.03	0.43±0.09	11.62±0.10	1.13±0.04
F2	28.40±0.25	0.41±0.06	0.58±0.03	30.27±0.03	1.52±0.07
F3	28.31±0.34	0.41±0.02	0.58±0.02	30.27±0.05	1.52±0.06
F4	29.90±0.24	0.45±0.04	0.55±0.06	18.91±0.04	1.23±0.03
F5	30.26±0.33	0.47±0.02	0.66±0.01	28.78±0.06	1.40±0.08
F6	30.88±0.30	0.50±0.07	0.62±0.03	20.00±1.12	1.25±0.01
F7	27.34±0.32	0.40±0.05	0.55±0.02	27.27±0.04	1.37±0.10
F8	27.63±0.10	0.41±0.06	0.55±0.06	24.45±0.03	1.34±0.04
F9	26.97±0.31	0.40±0.05	0.50±0.07	20.00±1.12	1.25±0.02

Note: Mean ± S.D. of three determinations

Table 9: Post compression parameters of various pantoprazole sodium formulations

Formulation	Hardness (Kg/cm^2)	Friability (%)	Wetting time (sec)	Water absorption ratio	Disintegration time (sec)
F1	2.40±0.15	0.75±0.03	59 ± 1.77	147 ± 1.22	124 ± 1.52
F2	2.90±0.20	0.50±0.01	62 ± 1.98	166 ± 1.45	117 ± 1.00
F3	2.70±0.03	0.24±0.02	52 ± 1.29	135 ± 1.87	115 ± 1.24
F4	3.10±0.02	0.73±0.03	94 ± 1.20	156 ± 1.32	119 ± 2.00
F5	2.30±0.15	0.35±0.07	92 ± 1.96	202 ± 0.25	124 ± 1.78
F6	2.30±0.20	0.47±0.06	89 ± 1.24	156 ± 1.75	133 ± 1.32
F7	1.50±0.01	0.62±0.02	36 ± 1.18	166 ± 2.01	111 ± 1.10
F8	1.90±0.30	0 .53±0.01	34 ± 1.12	166 ± 1.45	96 ± 1.53
F9	2.10±0.04	0.68±0.15	33 ± 1.19	203 ± 1.32	90 ± 1.60

Note: Mean ± S.D. of three determinations

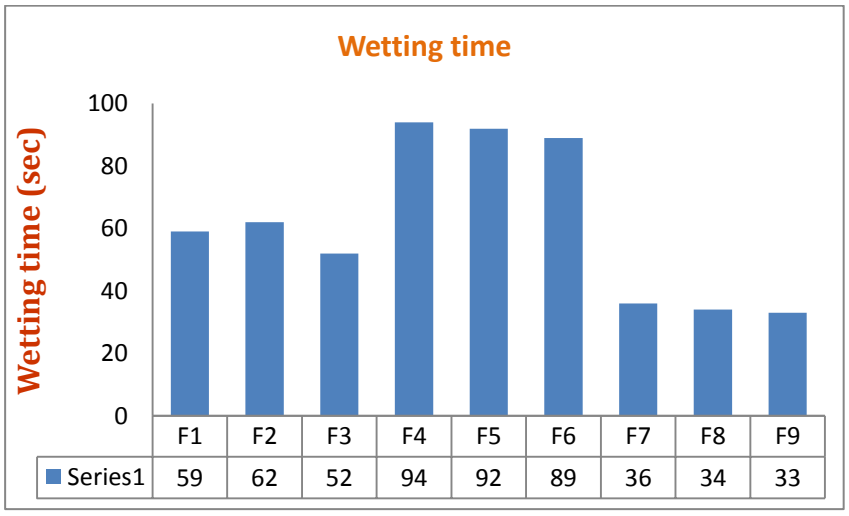

Figure 9: Bar diagram showing wetting time for pantoprazole sodium FDT formulations

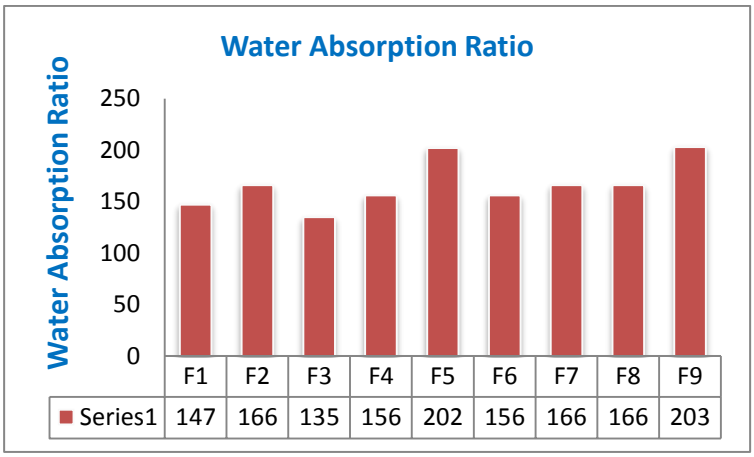

Figure 10: Bar diagram showing water absorption ratio for pantoprazole sodium formulations

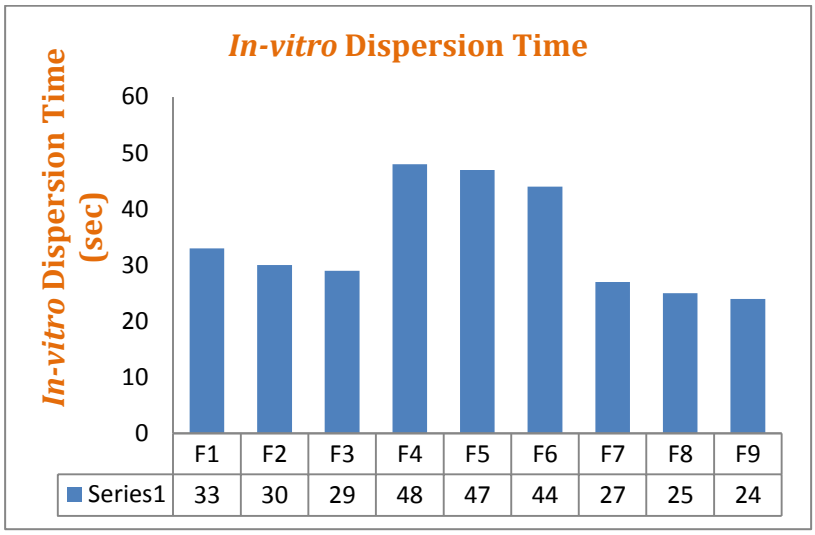

Figure 11: Bar diagram showing in-vitro dispersion time for the FDT formulations of pantoprazole sodium

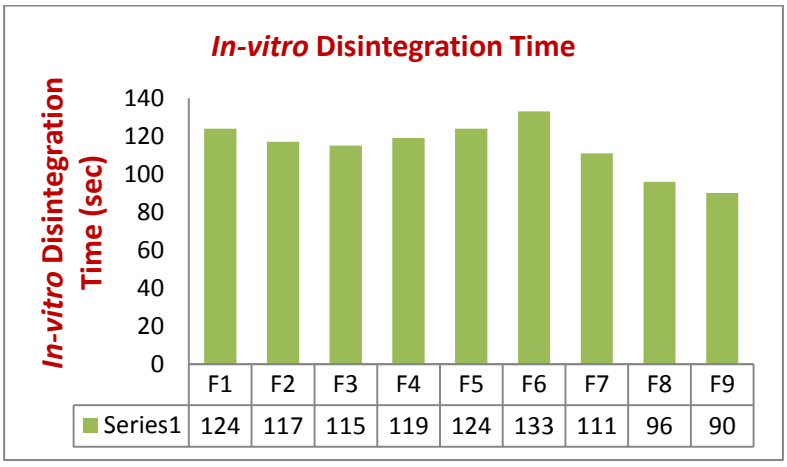

Figure 12: Bar diagram showing in-vitro disintegration time for pantoprazole sodium FDT formulations

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

The dissolution conditions used for studying the drug release from the fast dissolving tablets of pantoprazole sodium were: Dissolution test apparatus: USP type II, speed: 50 rpm, stirrer: paddle type, volume of medium: 900 ml, volume withdrawn: 5 ml, medium used: phosphate buffer solution, pH 6.8, temperature: 37±0.5ºC, λ_{max}: 288.5 nm.

The *in-vitro* dissolution studies of all formulations (F1 to F9) were conducted and the results were presented in Table No. 10 & Figure 13. The amount of drug released from different formulations F1, F2, F3, F4, F5, F6, F7, F8 and F9 at end of 14 min were 82.37%, 84.97%, 86.95%, 64.36%, 83.13%, 85.37%, 91.09%, 92.46% and 95.21% respectively. In case of formulations F1, F2 & F3, croscarmellose sodium was used as the superdisintegrant (2.5%, 5% and 7.5%) & camphor (7.5%, 10% & 12.5%) as the subliming agent. For formulations F4-F6, the superdisintegrant used was sodium starch glycolate (2.5%, 5% and 7.5%) & the subliming agent was ammonium bicarbonate (7.5%, 10% and 12.5%). In formulations F7-F9, crospovidone (2.5%, 5% and 7.5%) was used as the superdisintegrant & camphor (7.5%, 10% and 12.5%) as the subliming agent. The maximum drug release of 95.21% was obtained from formulation F9 (crospovidone 7.5% & camphor 12.5%) and minimum drug release of 64.36% shown by F4 (sodium starch glycolate 2.5% & ammonium bicarbonate 7.5%). Further, the initial dissolution rate for formulation F9 was 38.82% / 2 min. Results showed that the drug release from the formulations increased with increase in the amount of superdisintegrant and subliming agent added in each formulation. Formulation F9 showed faster drug release compared to all formulations due formation of porous structure by sublimation of camphor.

Table 10: *In-vitro* Release Studies of Trial Batches

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
2	21.57	22.86	29.78	14.28	18.55	22.08	20.89	30.34	38.82
4	45.38	43.27	44.65	19.64	29.35	29.72	39.46	43.37	58.45
6	56.23	47.68	57.47	28.73	46.14	37.83	57.51	54.64	63.71
8	62.45	57.89	64.39	40.88	58.49	53.67	66.43	67.38	72.94
10	69.67	66.42	72.87	47.29	62.54	67.82	77.59	72.07	82.52
12	77.95	76.88	80.49	57.98	74.45	75.93	83.62	81.78	87.29
14	82.37	84.97	86.95	64.36	83.13	85.37	91.09	92.46	95.21

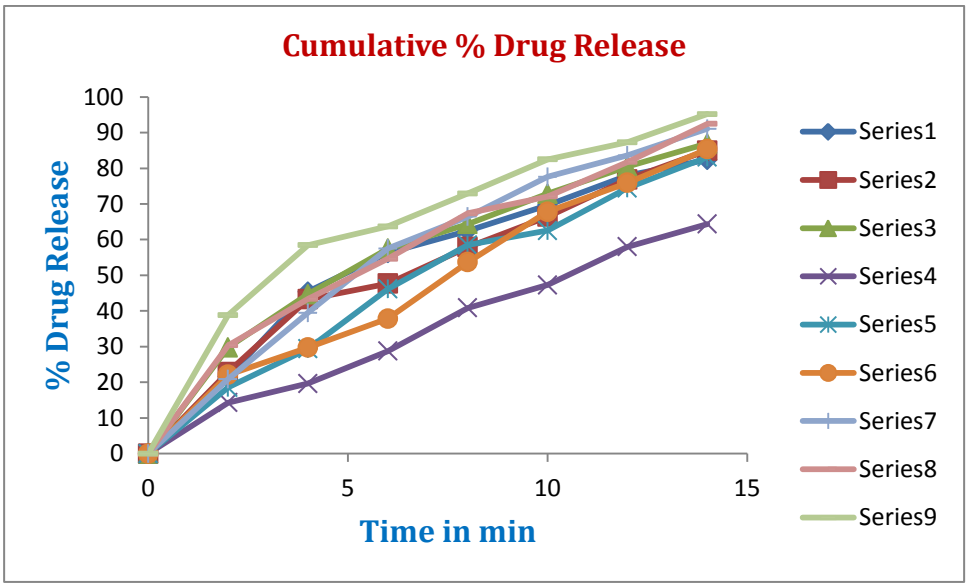

Figure 13: Drug release profiles for pantoprazole sodium FDTs (F1-F9)

CONCLUSION

Fast dissolving tablets of pantoprazole sodium were prepared using different superdisintegrants (croscarmellose sodium, sodium starch glycolate & crospovidone) and subliming agents (camphor & ammonium bicarbonate) by sublimation method. A total of nine formulations were prepared. All the physical characteristics of the formulations were found to be well within the limits of official standards. All the formulations get disintegrated with in a time period of 133 sec, when tested for *in-vitro* disintegration time. Amongst all the formulations, formulation F9 containing crospovidone 7.5% and camphor 12.5% is fulfilling all the parameters satisfactorily and has shown fastest disintegration (90 sec), wetting time (33 sec) and higher % drug release (95.21%) as compared to other formulations. Overall, the results suggest that suitably formulated fast dissolving tablets of pantoprazole sodium containing camphor as a subliming agent (F9) can be achieved. Fast dissolving tablets disintegrated within few seconds without need of water; thereby enhance absorption leading to increased bioavailability. Thus, the present study demonstrated potential for rapid absorption, improved bioavailability, effective therapy and increased patient compliance.

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