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Original Research Article

Formulation and Evaluation of Fast Dissolving Tablet of Pantoprazole Using Natural Sweetener

Amit Sharma [1], Yogesh Kumar Garg [2], Mayank Bansal [3], Ashutosh Sharma [4], Vikas [5]

[1]Research Scholar, Department of Pharmaceutics, Jaipur College of Pharmacy, Jaipur.
[2] Associate Professor, Department of Pharmaceutics, Jaipur College of Pharmacy, Jaipur.
[3] Professor & Principal, Department of Pharmaceutics, Jaipur College of Pharmacy, Jaipur.
[4] Associate Professor, Department of Pharmaceutics, Jaipur College of Pharmacy, Jaipur
[5] Research Associate (R&D) Synbioties Pharmalab Pvt. Ltd., Indore.

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Corresponding author: Amit Sharma
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Abstract:

Fast dissolving tablets represent a significant advancement in pharmaceutical technology, particularly benefiting patients with swallowing difficulties. Their rapid dissolution, ease of administration, and improved bioavailability make them a popular choice in many therapeutic areas, offering an alternative to traditional tablets and capsules. The current study developed Pantoprazole fast-dissolving tablets with better medication release. Superdisintegrants like Crosscarmellose sodium and sodium starch glycolate were used to make fast-dissolving tablets. Magnesium Stearate lubricates, mannitol dilutes. The direct-compression tablets passed all pharmacopoeia testing. This formulation uses stevia (Stevia rebidiana) leaf powder as a natural sweetener. The current research shows that natural sweetener may disguise Pantoprazole's harsh taste. Formulations F1, F5, and F9 discharged 84.59, 82.39, and 80.46% of medication after 10 minutes. F1, made with Sodium Starch Glycolate (8%) and pantoprazole, released the most medication after 10 minutes. F1 performs better than other formulas.

Keywords: Fast dissolving tablets, Pantoprazole, bioavailability, Stevia rebidiana.

Introduction

Fast dissolving tablets (FDTs), also known as orally disintegrating tablets (ODTs), are a type of pharmaceutical dosage form designed to disintegrate and dissolve quickly in the mouth, without the need for water. They are particularly useful for patients who have difficulty swallowing traditional tablets or capsules, such as children, elderly individuals, and those with certain medical conditions. [1]

The objective of the design, development, and evaluation of fast-dissolving tablets of Pantoprazole is to improve the therapeutic efficacy and patient compliance of the medication by utilising a novel pharmaceutical dosage form. The objective of fast-dissolving tablets is to offer a convenient and efficient oral drug delivery system for Pantoprazole, a proton pump inhibitor that is frequently prescribed for the treatment of gastro-esophageal reflux disease (GERD) and other acid-related disorders. [2,3]

Evaluation Of Fast Dissolving Tablets:

Hardness test:

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in kg/cm2. Three tablets were randomly picked and hardness of the same tablets from each formulation was determined. The mean and standard deviation values were also calculated. [4]

Weight variation:

20 tablets were selected randomly from each formulation batches (F1 to F9) and weighed individually to check for weight variation. The Indian Pharmacopoeia allows a little variation in the weight of a tablet. The following percentage deviation in weight variation is allowed [56]:

Friability Test:

Sample of 20 whole tablets was taken. Dedust the tablets carefully and weighed accurately the required number of tablets. Place the tablets in the drum and rotate it 100 times. Remove the tablets, remove any loose dust from them and weighed them accurately. A maximum loss of weight not greater than 1% for most of tablets. Percentage friability was calculated by the following formula:[5,6]

$$\%Friability = \frac{Initial\ weight - Final\ weight}{Initial\ weight} \times 100$$

Drug Content

Ten tablets were powered and the blend equivalent to 10 mg of Pantoprazole was weight and dissolved in suitable quantity of pH 1.2 buffer solutions. Solution was filtered and diluted and drug content analyzed spectrophotometrically at 292 nm.

Wetting Time:

The method was applied to measure tablet wetting time. A piece of tissue paper folded twice was placed in a small Petri dish containing 6 ml of buffer pH 1.2 Tablet was put on the paper and the time for complete wetting was measured. Three trials for each batch were performed and standard deviation was also determined. [7]

Water Absorption Ratio:

A piece of tissue paper folded twice was placed in a small Petridish containing 6 ml of distilled water. A tablet was put on the paper and time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio, R was determined using equation [8]

R=100x Wa-Wb/Wb

Where, Wb = weight of the tablet before water absorption

Wa = weight of the tablet after water absorption

Three tablets from each formulation were performed and standard deviation was also determined.

In vitro Disintegration Time

In vitro disintegration time was performed by apparatus specified in IP at 50 rpm. Phosphate buffer pH 1.2, 900 ml was used as disintegration medium, and the temperature of which maintained at 37 ± 0.5°C and the time in second taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured in seconds. [9]

In vitro Dissolution Studies

An in vitro release study was carried out using dissolution test apparatus USP Type II (Paddle Method). The following procedure was followed throughout the study that is shown in table no. 3.9 to determine the in vitro dissolution rate for the formulations. [10,11].

Result and discussion

Table 1: Evaluation of Fast Dissolving Tablet of Pantoprazole (Hardness, Weight variation, Friability and Wetting time)

Formulation Code	Hardness (Kg/cm^2)	Weight Variation (mg)	Friability (%)	Wetting time (s)
F1	3±0.25	198±0.81	0.54±0.01	21.33±0.12
F2	3.4±0.31	197±1.12	0.49±0.02	25.22±0.32
F3	3.8±0.36	208±1.01	0.35±0.01	13.22±0.27
F4	3.6±0.22	199±1.05	0.37±0.01	12.45±0.12
F5	2.8±0.28	199±0.88	0.52±0.02	13.55±0.43
F6	3.2±0.26	197±1.02	0.42±0.02	14.55±0.43
F7	4.0±0.09	203±0.95	0.39±0.02	14.55±0.43
F8	4.2±0.33	208±1.01	0.42±0.02	15.55±0.43
F9	3.2±0.20	205±1.08	0.58±0.02	17.55±0.43

Table 2: Drug content, Water absorption ratio, In-vitro Dispersion & Disintegration Time of Formulation Code (F1 to F9).

Formulation Code	Drug Content (%)	Water absorption ratio (%)	In vitro Dispersion Time (sec.)	In vitro Disintegration Time (sec.)
F1	99.30±0.73	29.23±0.18	15 ± 1.20	20 ± 0.96
F2	98.75±1.09	24.56±0.21	35 ± 0.60	24 ± 0.20
F3	97.60±0.56	25.25±0.24	30 ± 0.80	25 ± 0.50
F4	98.45±1.29	21.65±0.18	32 ± 0.50	34 ± 0.30
F5	98.38±0.32	23.43±0.31	20 ± 0.30	21 ± 0.20
F6	97.45±0.95	28.73±0.31	34 ± 0.30	22 ± 0.20
F7	98.30±0.67	20.53±0.31	29 ± 0.30	23 ± 0.26
F8	97.30±0.59	22.63±0.31	26 ± 0.30	30 ± 0.23
F9	98.30±0.86	28.73±0.31	22 ± 0.30	26 ± 0.20

The values of Hardness were found to be in the range of 3.0 kg/cm2 to 4.2 kg/cm2. All formulations showed the Friability within in the approved range (<1%).

All the tablets passed weight variation test as per the Indian Pharmacopoeial limits of ±10 %. It was found to be from 97±1.01 to 99±0.88 mg. The weight of all the tablets was found to be uniform.

The content uniformity was performed for all the 9 formulations and results are shown in Table 2. Five trials from each formulation were analyzed spectrophotometrically. The mean value and standard deviation of all the formulations were calculated. The drug content of the tablets was found between 97 to 99 % of Pantoprazole. The results indicated that in all the formulations the drug content was uniform.

The minimum in-vitro disintegration & dispersion time of was found to be 22 & 15 Seconds respectively for formulation code F1. On the basis of above discussion, the tablet formulated by the combination of Sodium Starch Glycolate (SSG) shown less disintegration & dispersion time in comparison to others formulations.

Drug Release Kinetics Studies

Table 3: *In-vitro* dissolution profile of Pantoprazole tablet formulation (F1-F9)

Time (Min)	% Cumulative Drug Release								
	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9
0	0	0	0	0	0	0	0	0	0
10	84.59	75.69	69.57	66.46	82.39	56.59	45.69	29.57	80.46
20	90.21	79.89	72.98	68.26	89.62	62.21	57.89	38.98	82.26
30	92.82	80.69	79.16	78.26	91.23	74.82	62.69	61.16	89.08
40	94.24	86.87	81.66	79.07	92.56	75.03	79.45	69.56	91.32
50	96.26	89.57	85.38	81.97	93.54	85.76	81.46	72.56	93.46
60	98.36	91.38	88.43	84.62	95.26	88.35	86.54	77.2	96.64

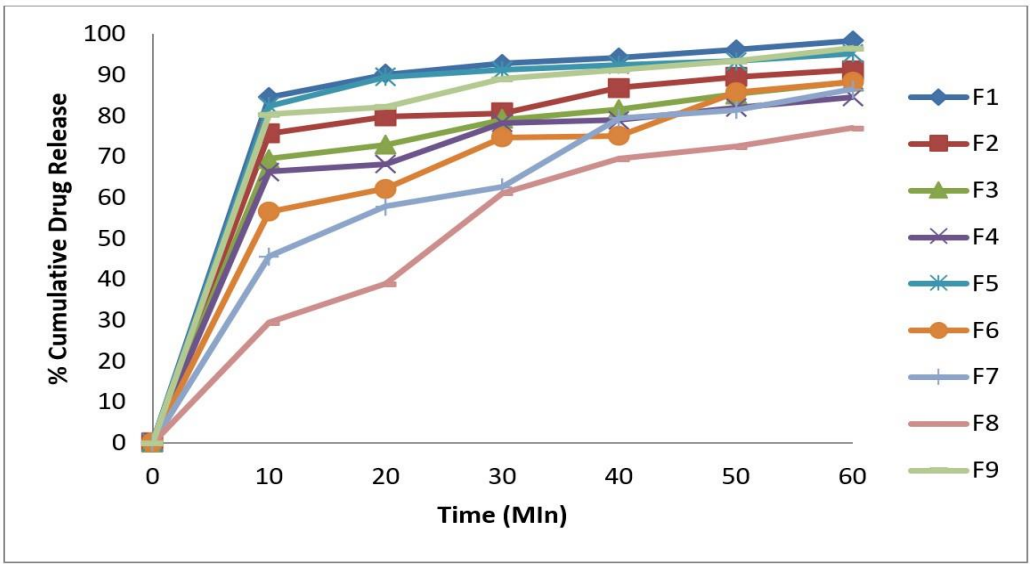

Figure 1: Zero order Release of Pantoprazole Fast Dissolving Tablet from Formulation batches (F_1 To F_9)

All the 9 formulations were subjected for the in vitro dissolution studies using dissolution test apparatus USP Type II (Paddle Method). The samples were withdrawn at different time intervals and analyzed at 273 nm. Percentage Cumulative drug release was calculated on the basis of mean amount of Pantoprazole present in the respective tablet. The results obtained in the in vitro drug release for the formulations F1 to F9 are tabulated in Table 3.

Formulation F1, F5 and F9 released about 84.59 %, 82.39 %, and 80.46% of drug after 10 minutes respectively. The results are shown in figure 1 indicate that the formulation, F1 which was prepared by the Sodium Starch Glycolate (8%) with Pantoprazole showed maximum drug release after 10 minutes. Thus, the formulation (F1) has better result as comparison to others formulations.

The dissolution profile of all the formulations was fitted in to zero-order, first-order, Higuchi and Korsmeyer-peppas models to ascertain the kinetic modeling of drug release.

Conclusion

Pantoprazole was the drug candidate selected to improve its solubility and dissolution. The present investigation

successfully formulated fast-dissolving tablets of Pantoprazole with improved drug release profile. Two different were Crosscarmellose sodium, sodium starch glycolate as a superdisintegrants, employed for the formulation of fast dissolving tablets. Among different excipients used, mannitol as a diluent, magnesium Stearate as a lubricant. The tablets prepared by direct compression method and passed all the pharmacopeia tests. In this formulation use a plant stevia (Stevia rebidiana) leaves powder as a natural sweetener. From the present study it can concluded that the bitter taste of the Pantoprazole can be successfully masked by using natural sweetener. Formulation F1, F5 and F9 released 84.59 %, 82.39 %, and 80.46% about of drug after 10 minutes respectively. Indicate that the formulation, F1 which was prepared by the Sodium Starch Glycolate (8%) with pantoprazole showed maximum drug release after 10 minutes. Thus, the formulation (F1) has better result as comparison to others formulations.

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