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In vitro proportional investigation of different Pantoprazole sodium brands of gastro-resistant tablets

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Abstract

The present work is a comparative exploration of some of the physicochemical possessions like weight change, thickness, diameter, hardness, disintegration time, *in vitro* drug discharge, and analysis studies of various commercially available Pantoprazole sodium tablets (PST) containing 40 mg of drug. The hardness, loss on friability, dissolution test, disintegration test, and uniformity of drug content were evaluated. All the brands meet the requirements as per the pharmacopoeial standards. The dissolution profile study revealed that PST-1 was faster, while PST-2 was slower. The dissolution information was kinetically treated.

Keywords: Brand; evolution; kinetics; Pantoprazole.

1. Introduction

Gastric passage and pH outlines are important factors for predicting and controlling drug discharge recital of enteric-coated tablets (ECT). Proton pump inhibitors (PPIs) are widely prescribed for the controlling of the peptic ulcer (Tirpude & Puranik, 2011), gastro esophageal reflux disorder (GERD), and Zollinger-Ellison syndrome (Mishra *et al*., 2011). PPIs overwhelm gastric acid secreted by constraining the pumping of the proton (H+). Enteric-coated tablets bypass the stomach with its acid-resistant coating and discharges in intestinal alkaline pH (Thomson *et al*., 2010). The ECT of Pantoprazole Sodium (PS) allows drugs through the stomach into the intestine for healthier dissolution and absorption and for avoiding the irritating effect on the gastric mucosa for greater patient compliance (Fukui *et al*., 2000). Generic drugs have lesser expansion costs; therefore, they are low-priced compared to the original innovative formulations. Although generic drugs encompass similar active ingredients, they have shown differences in quality and efficacy due to differences in formulation techniques and excipients used. The Indian market is augmented with various generic brands of PS (40 mg) gastro-resistant tablets. The objective of this exploration was to evaluate and compare the quality of dissimilar marques of PS 40 mg ECT available in India.

2. Materials and methods

2.1. Materials

Resources necessary in this study are listed in table 1.

Table 1. Resources essential in this assessment and source.

Pantoprazole sodium-40 Enteric-coated tablet brands	**Manufacturer**
PEPGERD (PST-1)	Sigman
PANTOSEC (PST-2)	Cipla
PANTODAC (PST-3)	Zydus Cadila
PROTONIX (PST-4)	Pfizer
PRAZOTO (PST-5)	Solace
PANTOP (PST-6)	Aristo
Name of the Chemical	**Supplier**
Phosphate buffer solution (pH 6.8)	Lab made
Pantoprazole sodium (pure sample)	Walkman Selman Pharmaceuticals, Pvt. Ltd., Anantapur
Name of the instrument	**Made**
Digital weighing balance	Shimadzu ELB 300
Monsanto hardness tester	Labotech
Roche friabilator	HMK Tablet 1601
Disintegration device	Lab India (DT-2901)
USP-II dissolution test device	Lab India (DS-8000)

2.2. Methods

Various brands were considered for the official and unofficial tests as declared below (Ahad *et al*., 2010; Liberman and Lachman 1991; Reddy *et al*., 2011; Hindustan *et al*., 2012).

2.2.1. Weight uniformity

The test was achieved by weighing twenty tablets individually, and its mean weight was calculated. The weight deviation percentage of each tablet was calculated to the mean weight. The test results were found satisfactory as the deviation in weight is within the limits (±5%) as specified in Indian Pharmacopoeia.

2.2.2. Thickness

The thickness of the PST was calculated with Vernier digital calibrators, and mean values were premeditated.

2.2.3. Hardness

The tablet to be tested was detained amid a static jaw and a cell phone by Monsanto Hardness Tester. The mean understandings were intended and expressed in kg/cm^2.

2.2.4. Friability

The friability test can be accomplished to assess the ability of the tablets to withstand abrasion in packaging, handling, and transport. Preweighed tablets were positioned in the rotation compartment and revolved for 4 min (100 rpm). Acceptable weight loss limits should not exceed 1%. The loss in friability was calculated using the formula

$$\% \text{ friability } = \frac{\text{Weight Final}}{\text{Weight Initial}} \text{X } 100$$

2.2.5. Disintegration time

The disintegration tests of the enteric-coated PS tablets were done by the USP disintegration apparatus. A tablet has been inserted into each tube of the basket frame assembly without a disc. The group was placed in the beaker containing 0.1 N HC1 (pH 1.2), maintained at 37±2°C, and operated for 2h. After 2h, HC1 0.1 N was replaced with a phosphate buffer of pH 6.8. One disc was kept in each tube and run for another 60 min. Then, the disintegration time of each tablet was recorded (Alsulays *et al.*, 2017).

2.2.6. Dissolution study

The dissolution test was accepted in two phases in the dissolution apparatus of the type II USP. In the initial step, the setup was performed in a buffer of pH 1.2 (0.1 N HCl) at 100 rpm for 2h. Subsequently, it was moved to the phosphate buffer at pH 6.8, and the dissolution was carried out for 60 min at 100 rpm. The samples were withdrawn on each 5 min and analysed by UV spectrophotometer using the phosphate buffer as a solution (Haritha, 2017).

2.2.7. Uniformity of content test

5 tablets were accurately weighed and minced into a powder. The powder equivalent to 40 mg of PS was carefully weighed and solubilized in about 40 ml of ethanol. 1 ml of the sample was taken and diluted to get 10 mg/ml. Absorbance was restrained at 289 nm, and purity was determined (Tribedi *et al*., 2013).

3. Results and discussion

It was found that the weight variation of all brands was < 5%, and all brands approved the test. All brands have shown good resistance to hardness, necessary for safe handling and transport (table 2). The PST-2 presented the extreme hardness, while all the other brands displayed identical hardness. It was established that the loss on the friability of all the brands was < 1%. All the brands of tablets have passed the disintegration test, which indicates that they will disintegrate completely in the intestine in 2h, without disintegrating in the stomach. All these tenets were itemized in Figure 1, table 2. The whole brands of PST passed the dissolution test as per the Indian Pharmacopoeia. The PST-1 has maximum % cumulative PS discharge, i.e., 97.84%, while PST-2 has the least (90.25%), and other brands are above the range (table 3; Figure 1).

Table 2. Physicochemical physiognomies of PS tablets.

Parameters	PST-1	PST-2	PST-3	PST-4	PST-5	PST-6
Weight of the tablet (mg)	325±2.89	386±1.25	370±2.36	390±4.25	364±1.94	351±0.85
Thickness (mm)	5.50±0.10	5.40±0.20	5.30±0.30	5.20±0.20	5.30±0.40	5.20±0.20
Hardness (kg/cm2)	7.20±0.50	9.80±0.70	6.80±0.30	7.00±0.40	5.80±0.35	8.30±0.25
Friability (%)	0.58±0.01	0.36±0.02	0.44±0.03	0.54±0.04	0.18±0.01	0.22±0.01
Drug content (%)	97.84±2.54	90.25±5.67	91.58±2.25	96.38±4.51	95.21±5.25	94.65±4.58
Disintegration time *a) In 0.1 N HCl (for 1h)*	NED	NED	NED	NED	NED	NED
b) In 6.8 pH (PBS) (for next 120 min)	68±0.10	45±0.20	62 ±0.30	77±0.20	60±0.50	58±0.20

NED- No evidence of disintegration; values in mean ±SD; trails (n)=3

Table 3. *In vitro* drug discharge profile of PST (1-6) in 0.1N HCl for the first 2h and 6.8 pH PBS for the next 1h at 289 nm

Time (min)	Cumulative drug release (%)					
	PST-1	PST-2	PST-3	PST-4	PST-5	PST-6
0	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00
15	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00
30	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00
45	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00
60	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00
70	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00
80	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00
90	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00
100	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00
110	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00
120	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00	00.00±0.00
130	34.68±0.91	28.27±0.65	31.89±0.54	27.84±0.54	32.30±0.77	32.41±0.34
140	45.27±0.35	45.33±0.98	42.34±0.68	41.37±0.87	42.86±0.69	43.20±0.30
150	68.75±0.29	54.41±0.25	59.46±0.18	55.82±0.56	61.74±0.37	65.40±1.25
160	82.46±0.39	78.72±0.75	80.57±0.52	78.75±0.30	80.96±0.58	80.90±0.85
170	88.67±0.34	82.76±0.48	85.78±0.48	82.48±0.39	85.32±0.01	87.52±0.46
180	97.84±0.65	90.25±0.66	92.59±0.61	93.63±0.82	95.87±0.28	94.59±0.68

Values in mean ±SD; trails (n)=3

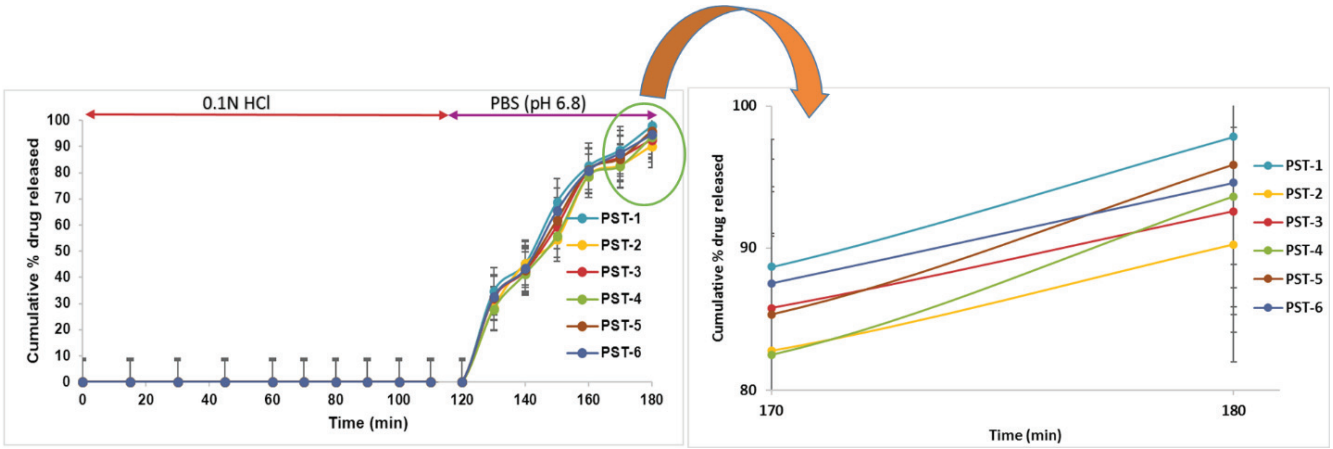

Fig .1. *In vitro* drug discharge profile of PST; final % drug released in inset is zoomed.

4. Conclusion

All the brands were found to be smooth and elegant in appearance. PS tablets were consistent in diameter, thickness, and weight. PST-1 to PST-6 demonstrated a passable mechanical forte to repel the fracture and erosion. Furthermore, these brands disclosed tolerable disintegration time, PS discharge pattern, and uniformity in PS content. Hence, it was concluded that the swapping among these brands would not affect effectiveness.

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