IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Human Journals
Research Article
June 2017 Vol.:9, Issue:3

Evaluation of Different Marketed Brands of Pantoprazole Sodium Tablets: A Comparative Study

IJPPR
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An official Publication of Human Journals
ISSN 2349-7203
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Abul Bashar*[1], Pulak Deb[1]

[1]*Girijananda Chowdhury Institute of Pharmaceutical Science (GIPS) Azara, Guwahati, Assam-781017*

Submission: 7 June 2017
Accepted: 12 June 2017
Published: 25 June 2017

www.ijppr.humanjournals.com

Keywords: Pantoprazole, Proton Pump Inhibitors (PPI's), Comparative studies, physicochemical parameters.

ABSTRACT

Aim and Objective: The present investigation was to study some physiochemical properties such as weight variation, thickness, diameter, hardness, disintegration time, *in-vitro* drug release studies and assay of different commercially available formulations of pantoprazole (40 mg). **Method used:** Hardness test, Friability test, Dissolution test, Disintegration test, Weight variation test, Uniformity of Drug content. **Result:** All the brands met the requirements as per specifications of Indian Pharmacopoeia for tablet formulation. Assay value was also found to be within the limit of 90% to 110% of drug content, weight variation 0.76% to 1.53%, hardness 3.5kg/cm^2 to 5.5kg/cm^2 and the friability was also found less than 1%. The study on dissolution profile revealed that the BRAND-1 had faster dissolution rate while BRAND-2 had the slowest dissolution rate. The drug release rate followed first order release kinetics. **Conclusion:** These comparative *in-vitro* evaluation studies of various brands indicate the usefulness, effectiveness and idealness of any commercial product. The data obtained may be useful for further formulation development studies.

INTRODUCTION:

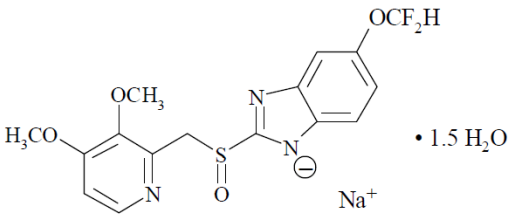
Pantoprazole is a Proton Pump Inhibitor (PPI), which inactivates the final step in the gastric acid secretion pathway in gastric parietal cells in a dose-dependent manner. Pantoprazole also exhibits antibacterial activity against *Helicobacter pylori in-vitro.* Seventeen years of clinical experiences, worldwide have shown pantoprazole to be an effective and well-tolerated treatment option in the management of acid-related disorders, including gastric and duodenal ulcers and Gastro-oesophageal reflux disease (GERD) and the treatment or prevention of gastroduodenal lesions induced by NSAID'S. Pantoprazole also effective in combination with different regimens for *H. pylori* eradication and is included in the first-line PPI-based options for this purpose. Pantoprazole is a substituted benzimidazole, which blocks the H+/K+ - adenosine triphosphate enzyme system of parietal cells and thereby inhibits the basal and stimulated gastric acid secretion.(1)

Proton pump inhibitors (PPIs):

Proton pump inhibitors (PPIs) suppress gastric acid secretion by specific inhibition of the H+/K+- ATPase in the gastric parietal cell. This process starts with absorption of the PPI in the parietal cell. PPIs are weak bases, so protonation takes place in the acidic region of the secretory canaliculus of the parietal cell. In the secretory canaliculus, the methylsulfinyl group shifts to a highly reactive sulfenamide. The final step is covalent binding of the reactive sulfenamide to 2 cysteine moieties of the catalytic subunit of the H+/K+- ATPase of the proton pump. This results in inhibition of the acid secretion, followed by elevation of the intragastric pH. (2)

Drug profile:

Chemical structure:



Formula: C16H14F2N3NaO4S x 1.5 H2O

Molecular weight: 432.4

Chemical name: 5-(difluoromethoxy) -2-[[(3,4-dimethoxy-2-pyridinyl) methyl]sulfinyl]-1H-benzimidazole Sesquihydrate.

Appearance: White to off-white powder.

Properties: Freely soluble in water. (3)

MATERIALS AND METHODS:

Materials:

From four different companies 4 different brands of pantoprazole tablets (such as PAN40, PANTOSEC, PANTODAC 40, etc.) are collected and the quality control tests were carried out.

Chemicals:

Phosphate buffer solution pH 6.8, 0.1 N Hydrochloric acid, pure pantoprazole powder.

Instruments:

Monsanto Hardness tester, Dissolution test apparatus (type-2), Roche friabilator and Disintegration apparatus.

Method:

1. Uniformity of weight: The test was carried out by weighing individually twenty tablets and their average weight was calculated. The percent deviation of each tablets weight against the average weight was calculated. The test requirements are met if not more than 5%.(4)

2. Thickness: The thickness of the tablets was determined by using Digital Vernier calipers. Five tablets were used, and average values were calculated.

3. Hardness: Hardness can be defined as the strength of the tablet to withstand the pressure

applied. The tablet to be tested was held between a fixed and a moving jaw of Monsanto Hardness Tester**.** The average values were calculated and expressed in kg/cm^2.(5)

4. Friability: Friability test can be performed to evaluate the ability of the tablets to withstand abrasion in packing, handling and transporting. The Friabulator consists of a plastic chamber divided into two parts and revolves at 25 rpm. A fixed number of tablets are weighed, placed in the tumbling chamber and rotated for four minutes of 100 revolutions. The acceptable limits of weight loss should not be more than 1%. The percentage weight loss (friability) was calculated using the formula:

$$\% \text{ Friability} = (\text{Loss in weight} / \text{Initial weight}) \times 100$$

5. Disintegration time: Disintegration testing of the enteric coated tablets was carried out using USP disintegration apparatus. One tablet was introduced into each tube of the basket rack assembly without disc. The assembly was positioned in the beaker containing 0.1N HCl (pH 1.2) maintained at 37°C ± 2°C and operated for 2 hours. After 2 hours the 0.1N HCl was replaced with phosphate buffer pH 6.8. A disc was added to each tube and operated further for 60 minutes. The disintegration time of each tablet was then recorded.(6)

6. Dissolution Study: The dissolution test was carried out in two stages in USP type-II dissolution apparatus. In first stage, the dissolution was carried out in pH 1.2(0.1 N HCl) buffer at 100 rpm for 2 hours. After that, it was transferred to pH 6.8 phosphate buffer and dissolution was carried out for 60 min at 100rpm. The samples were collected for every 5min and are analyzed by UV Spectrophotometer using phosphate buffer as blank.

7. Content of Active Ingredient (Assay): Five tablets were weight accurately and ground into fine powder. Powder equivalent to 40 mg of pantoprazole was weighed accurately and dissolved in about 40 ml of ethanol. 1ml of the sample was taken dilution were made as 10mg/ml concentration. Absorbance was measured at 287nm and % purity was determined.(7)

RESULTS AND DISCUSSION:

Weight variation of all brands was found to be less than 5% and as per IP hence all brands passed the weight variation test. According to IP, if the tablets are uniform in weight it is likely

that the tablets will be uniform in drug content also. All the brands exhibited good hardness strength, which is required for safe handling and transportation as well as the release of drug. Brand 2 exhibited the maximum hardness while all the other brands exhibited similar hardness.

Friability of all brand was found to be less than 1% which is required as per IP and all brands passed the test. All the brands of tablets passed the disintegration test indicating that they will completely disintegrate in the intestine within 2 hours but no disintegration takes place in the stomach.

All the brands of pantoprazole tablets passed the dissolution test as per IP. The Brand-1 had maximum % cumulative drug release i.e. 96.60% while Brand-2 has the minimum % cumulative drug release i.e. 91.16 and other brands are in above the range.

Table 1: Physical Evaluation of Different Brands of Pantoprazole Tablets

Physical parameter	**BRAND-1**	**BRAND-2**	**BRAND-3**	**BRAND-4**
Weight variation (%)	0.76	1.53	0.80	0.81
Thickness (m.m.)	4.16	3.53	3.93	3.27
Hardness (Kg/cm^2)	4.2	5.3	3.7	3.3
Friability (%)	0.42	0.23	0.53	0.49
Drug content (%)	97.90	90.87	94.13	107.17
Disintegration time (0.1 N HCl gastric fluid)	No evidence of disintegration for 1 hour.	No evidence of disintegration for 1 hour.	No evidence of disintegration for 1 hour.	No evidence of disintegration for 1 hour.
Disintegration time (In 6.8 pH phosphate buffer)	Complete disintegration in 2 hours.	Complete disintegration in 2 hours.	Complete disintegration in 2 hours.	Complete disintegration in 2 hours.

Table 2: Dissolution profile for different brand in 0.1 N HCl

Time (hours)	BRAND-1 (Cumulative % drug release)	BRAND-2 (Cumulative % drug release)	BRAND-3 (Cumulative % drug release)	BRAND-4 (Cumulative % drug release)
2	0.45	0.34	0.28	0.36

Table 3: Dissolution profile for different brand in PH 6.8 Phosphate Buffer

Time (min)	BRAND-1 (Cumulative % drug release)	BRAND-2 (Cumulative % drug release)	BRAND-3 (Cumulative % drug release)	BRAND-4 (Cumulative % drug release)
0	0	0	0	0
5	19.44	15.68	18.36	16.15
10	32.89	30.68	33.62	31.01
15	46.67	50.66	43.04	44.71
30	67.61	60.35	66.88	64.16
45	82.2	78.57	78.57	80.35
60	96.6	91.16	94.06	92.98

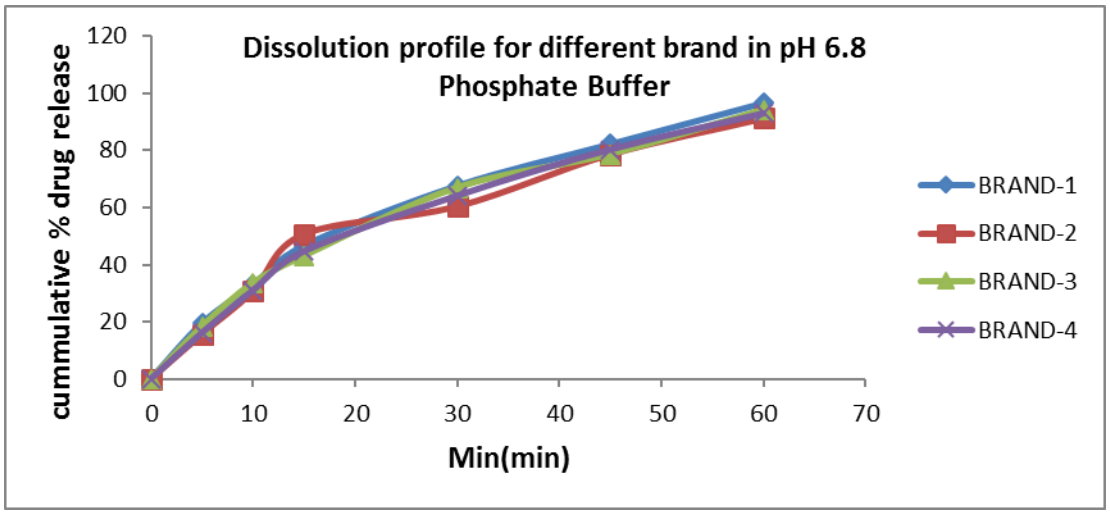


Fig.1: Dissolution profile for different brand in pH 6.8 Phosphate Buffer

CONCLUSION:

All the brands have passed all official tests prescribed by Indian Pharmacopoeia (IP). Formulation additives in the tablet, physical form of the drug used in the tablet and manufacturing processes vary from manufacturer to manufacturer which is responsible for the variation in the observed dissolution profiles. It is an alternative to determining pantoprazole sodium in the pharmaceutical dosage forms that contain it as unique active principle with quite satisfactory results for the specific purposes of its design.

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