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Research on Comparative Quality Analysis of Four Different Marketed Brands of Proton Pump Inhibitors (Pantoprazole) Tablets

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Haileyesus Beyecha Geleta*[1], Vijender Singh[2], Chhaya Chauhan[3]

1M.Sc. Student, Department of Allied Health Sciences, Sharda University, Greater Noida, India

2Professor & Dean, Department of School of pharmacy, Sharda University, Greater Noida, India

3Assistant Professor, Department of School of pharmacy, Sharda University, Greater Noida, India

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ABSTRACT

Aim and Objective: Proton pump inhibitors are used for the treatment of acid-related diseases. This study aimed with comparative evaluation of different brands of pantoprazole tablets available around Greater Noida city of India. The selected brands of tablets are evaluated according to the methods and procedures of pharmaceutical control tests. **Method used**: The investigation of this study was performed by using methods like hardness, friability, *in-vitro* drug release studies, disintegration, weight variation test, and assay of drug content. **Result:** Each brand of pantoprazole tablets was evaluated using known methods and procedures to assess the pharmaceutical quality characteristics. According to the specification and standards of Indian pharmacopeia, the test results of weight variation of mean deviation was lies within ± 0.22 and ± 5.45 and shows satisfactory results. The thickness also ranges from 3.12 to 4.00mm. PAN-3 exhibits a minimum (5.00 ± 0.58kg/cm2) hardness and PAN-4 exhibited maximum (5.60 ± 0.91kg/cm2) hardness. The friability % result was lies between 0.05 and 0.183. This shows less than 1.0% and acceptable result. There is no any disintegration result in 0.1N HCl acidic medium within 2 hrs. but, disintegrated in phosphate buffer within 10.01 and 10.80 min. The *in-vitro* drug release study displayed that all tablets released in buffer medium within the range of 84.89% and 87.80%, this shows all brands release drug above 80% within 45 min. and also release 96.72% to 99.89 within 1 hr. but in 0.1N HCL (pH 1.2) medium the release is below 10% or not significant. Assay value was also ranged between 98.13 to 101.28% by PAN-4 and PAN-3 respectively and lies within the limit of 90% to 110% according to the monograph on Pharmacopoeial Standards. **Conclusion**: These comparatives *in-vitro* evaluation study was conforming all of the tested brands of the pantoprazole enteric-coated tablet fulfilled the criteria set for the official monograph of *in-vitro* quality control tests and manufacturers are produced their products as good pharmaceutical quality

INTRODUCTION

Proton pump inhibitors (PPIs) are widely used and mostly prescribed medicines by physicians for the treatment of gastroesophageal reflux disease (GERD) and peptic ulcer *(Kantor ED,1999 – 2012).* Proton pump inhibitors drugs are ranked in the top of 10 national health-related drug expenditures in the United States since 2015 *(Schumock GT,2016).*

PPIs used to block acid production in the stomach by irreversibly inhibiting H+/K+ adenosine triphosphatase in the level of gastric parietal cells. As such, they are often the treatment of choice for acid-related disorders. Omeprazole is the first class of drugs produced in (1989) and followed by lansoprazole (1995), rabeprazole (1999), pantoprazole (2000) and, esomeprazole (2001). Over the past several decades, PPIs have become one of the most commonly prescribed medications in the United States with use in non-hospitalized patients doubling between 1999 and 2012 and accounting for more than $11 billion in expenditures annually *(Forgacs I, 2008).*

Pantoprazole tablets

Pantoprazole is a drug administered by oral routes categorized under proton pump inhibitor (PPIs) and finalized its activities in the gastric cells by diminishing the secretion of gastric acids according to the availability of doses. Not only this it is also working as anti-bacterial characters which protect the effect of Helicobacter pylori bacteria in the stomach. Many experiences show pantoprazole tablets show effective and well-tolerated drugs in the world for the treatments of gastric and duodenal ulcers and gastro-esophageal reflux disease (GERD) including management of acid-related disorders, control and treatment of ulcer on the gastroduodenal due to Non-steroidal anti-inflammatory Diseases (NSAID). Pantoprazole also replaced benzimidazole, for blocking of H+/K+ ATPase enzyme by means of parietal cells and thereby inhibits the secretion of gastric acid *(Bashar A et al.,2017*

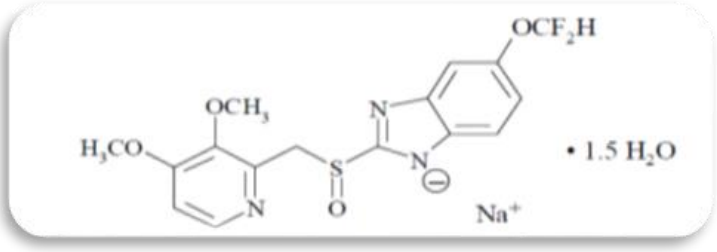

Figure 1: Chemical structure of Pantoprazole

Chemical name: -5-difluoro methoxy-2-({3,4-dimethoxy-2-pyridinyl.Methyl-sulfinyl]-1Hbenzimidazole.

Formula: $C_{16}H_{15}F_2N_3NaO_4S$ x 1.5 H_2O

M. weight: 432.4

Appearance: White to off-white powder.

Properties: Freely soluble in water. *(Indian Pharmacopoeia,2014).*

MATERIALS AND METHODS

MATERIALS

Four respective brands of pantoprazole sodium tablets (encoded as PAN-1, PAN-2, PAN-3 and PAN-4 for tablets PAN-40, Pantosec, Pantop, and pantoBERT, 40mg) respectively and also standard for Pantoprazole sodium.

Sampling techniques

Used random sampling techniques, for Pantoprazole tablets which is from different pharmacy of India.

Instruments

The devices used to accomplish the study was Hardness tester (MONSANTO), Dissolution tester, Friabilator apparatus (ROCHE FRIBLATOR), Disintegration apparatus, UV Visible spectrophotometer, Digital weight balance (KERRO BL3003KE), Vernier caliper (MITUTOYO), pH detector**,** Volumetric or conical flask, funnel, Beakers, Mortar and pestle, and Measuring cylinder.

Chemicals

Analytical grade and freshly prepared distilled water, disodium hydrogen phosphate, HCl, Potassium dihydrogen phosphate and Mehta-nole.

METHODS

Description (Shape and Color)

Color and shape of tablets was analyzed with naked eye for identifying the uniformity of the tablets. Some companies are put groves on the surface for identifying their brands. All this indication is determined by visual inspection.

Hardness

Hardness is expressed as the resistance of the product/tablet against the exerted force till its breakdowns. Tablet strength can withstand the shock and pressure during manufacturing process, packing and transportation, and also handled by the patient. To test the hardness of the tablets was determined by using an instrument of Monsanto Tester. The unit of hardness is expressed by kg/cm^2 (*Dharmaraj D et al., 2014)* and lie between 5-10kg/cm^2 win in limit of ± 5% (*(Chaturvedi H et al.,201*

Thickness

The thickness of specific tablets may be measured by an instrument called Vernier caliper, which indicate accurate measurements and provides information of the variation between tablets *(Lachman L et al.,1986).*

Weight Variation

Weight variation test is performed to check and ensure that the manufactured pharmaceutical products (tablets) have a uniform weight. The test was done by weighing randomly selected 20 tablets of pantoprazole individually and calculating the average weight and comparing the individual weight to the average weight. Not more than two of the individual weights of the tablets deviate from the average weight by more than the percentage give in the pharmacopoeia and none deviates by more than twice that percentage.

Percent of deviation (PD) = Wo Wa/Wa*100

Where Wo = Initial weight

Wa = Average weight

Indian pharmacopeia (IP) limits for tablet weight variation is given below (*IP,2014).*

Table 1: Limits of weight variation as per I.P

R. No	Max % difference allowed	IP
01	80mg > or less	±10%
02	80mg - 250mg	± 7.5%
03	250mg < or more	± 5%

Friability

Friability defined as the phenomenon where the surface of the tablet is damage due to mechanical shock. The test can be performed to evaluate the ability of physical strength of the tablets to survive scratch in packing handling and transporting. It is tested by using Roche friability apparatus. The tablets should be carefully weighed accurately before test performing, and the plastic drum fixed with a machine is rotated 25 rpm or 100 revolutions at 4 minutes with responsible care, lastly remove the tablets from the drum de-dusted carefully and weigh accurately. The percentage limit of friability or a maximum mean weight loss from the three samples should be not more than 1.0%, and also acceptable in most pharmaceutics of tablets (*IP, 2014).*

$$\text{Percentage friability (\%)} = W_1 - W_2 / W_1 * 100$$

Where, W_1 = Tablet weights before testing.

W_2 = Tablets weights after testing.

Disintegration

Disintegration is the first physical change observed for a drug when enters into the body. And helps in knowing the API solubility in the gastric fluids of the digestive system. As per USP, the disintegration apparatus consists of 6 glass tubes. The disintegration environment which is maintained at 37 ± 2ºC, in 1-liter vessel. The rack contained the tablets move up and down in the medium containing vessel through a distance of 5 to 6 cm at a frequency of 28 to 32 cycles per minute.*(Chaturvedi H et al.,2017)*. The assembled beaker containing 900 ml of 0.1N HCl (pH 1.2) maintained at 37°C ± 2°C and operated for 2 hours. And replaced by phosphate buffer pH 6.8. A disc was added to each tube and operated further for 60 minutes *(Senthil K et al., 2010)*.

Table 2: Disintegration time for different brands of pantoprazole tablets

Types of Tablets	Disintegration Time (DT)
Uncoated Tablet	15 Minute (B.P/I.P)
Film Coated	30 Minute (B.P/I.P)
Sugar Coated	60 Minute (B.P/I.P)
Enteric Coated/ Gastric Resistant Tablet	0.1N HCl for 2 hrs. and phosphate buffer 6.8 for 1 hr. (B.P/I.P) OR The test is carried out first in distilled water (at room temperature for 5 min. Than stimulated gastric fluid 1 hour.

Dissolution

The rate and extent of drug release form of tablets is estimated by dissolution test. The dissolution medium was 900 ml of acidic buffer of pH 1.2 for 2 hrs and phosphate buffer of pH 6.8 for 1 hr. The tablet will be kept into the basket. The temperature will be maintained at 37 ± 0.5°C and stirring at the rate of 100 rpm. Samples were withdrawn at regular time intervals and equal volume replaced with fresh dissolution medium. Samples were measured by UV Spectrophotometer at 283nm for pH1.2 and 288nm for pH 6.8. (*Sumit C et al.,2009*).

Content of Active Ingredients (Assay)

Content uniformity testing of drugs includes the content/potency assay to determine the content of active ingredients contained in multiple different samples collected throughout the pantoprazole brands. Drug content or content uniformity is determined using U.V apparatus.

Procedure: As per the label claim of each brand, 20 tablets were crushed and a quantity equivalent to the average weight of the tablets was weighed accurately and transferred to a 100 ml volumetric flask. Add 60 ml of methanol and dilute vigorously. After sonication, the volume was then made up to the 100 ml mark with methanol. This solution was filtered using a Whatman filter paper 40 and a clear solution was obtained. Take 1ml of the stock solution and diluted to 10 ml with methanol. Withdraw 5ml of this solution and diluted to 10ml with methanol and check the absorbance of solutions. The absorbance was measured at 289 nm using UV- Spectrophotometer (*Dharmaraj D et al., 2014).* And then the amount of drug present in the tablet was then calculated using the following formula:

Calculation Formula

Assay=ASp/ASd*Swt/100*100/SpWt*P/100* AWt/LC*MWt.P/MWt.PS*100

Where;

P = Purity

LC = Label Claim

ASp = Absorbance of sample,

ASd = Absorbance of standard,

MWt P = Molecular weight of pantoprazole,

MWt PS = Molecular weight of pantoprazole sodium

RESULTS AND DISCUSSION

Preparation of standard graph

Standard graph for the drug pantoprazole was done separately in 0.1N HCL (pH 1.2) acidic buffer and pH 6.8 phosphate buffer. Table 3 shows that the concentrations of pantoprazole tablets in pH 1.2 acidic and pH 6.8 phosphate buffers with the respective absorbance. Figure 2 and 3 also show graph of calibration curves of pantoprazole in pH 1.2 acidic buffer and also pH 6.8 phosphate buffer medium respectively.

Table 3: Standard calibration curve of pantoprazole in 0.1N HCL and buffer pH 6.8 solution

Sr. No	0.1N HCL acidic Solution at 283 nm			Phosphate buffer pH 6.8 Solution at 288nm		
	Solution (ml)	Concentrat-ion (µg/ml)	Absorption (nm)	Solution (ml)	Concentrat-ion (µg/ml)	Absorption (nm)
1	0	0	0	0	0	0
2	1	2	0.079 ± 0.012	1	2	0.105 ± 0.001
3	2	4	0.174 ± 0.033	2	4	0.235 ± 0.003
4	3	6	0.270 ± 0.049	3	6	0.354 ± 0.001
5	4	8	0.346 ± 0.011	4	8	0.455 ± 0.005
6	5	10	0.432 ± 0.028	5	10	0.567 ± 0.001
7	6	12	0.518 ± 0.023	6	12	0.655 ± 0.003

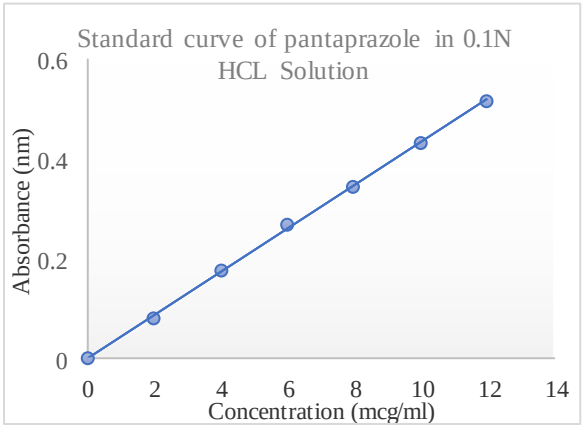

Figure 2: Standard Curve with 0.1N HCL

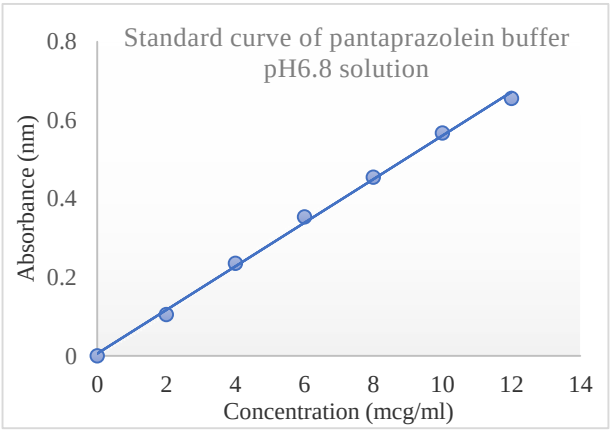

Figure 3 Standard Curve with Phosphate

Description (Shape and Color)

All randomly selected brands of enteric-coated pantoprazole tablets for study were looking good, non-sticky, clean and each tablet was packed correctly in the packaging materials including with necessary and important information on every strip. All visual inspection was analyzed with naked eye and the written information's are well prepared as shown in table 4 and 5 below.

Table 4: Product information for various brands of Pantoprazole tablets studied

Code Assigned	Brand Name	Dosage (mg)	Date of Manufacture	Expiry date	Batch No	Country Origin
PAN-1	PAN-40	40	Nov, 2018	Apr, 2021	8443157	India
PAN-2	Pantosec	40	Oct, 2018	Sep, 2020	AFB8D65	India
PAN-3	Pantop	40	Oct,2018	Mar, 2021	B171K018	India
PAN-4	pantoBERT	40	Aug,2018	July, 2020	DD18136	India

Table 5: Results of description assessment of different brands of pantoprazole tablets studied

Assigned Code	Color	Shape	Packing material	Dosage form
PAN-1	Red brown	Convex round	Aluminum foil blister	Enteric-coated tablet
PAN-2	Slight yellow	Convex round	Aluminum foil blister	Enteric-coated tablet
PAN-3	Bright yellow	Convex round	Aluminum foil blister	Enteric-coated tablet
PAN-4	Grey	Convex round	Aluminum foil blister	Enteric-coated tablet

Weight Variation Tests

Weight variation test is performed to check ensure that the manufactured pharmaceutical tablets have a uniform weight and also an indicative of the proper manufacturing practices followed by the drug manufacturers. *(Jakaria M et al., 2016).* Indian pharmacopeia (IP) states that the individual weights of each sample deviated from the mean weight should be within 7.5% for the tablets lie between 80 and 250mg. So, this study showed that the maximum and minimum deviation from the mean of each brand was ± 3.25, and ±0.22%, ± 5.45 and ± 0.61%, ± 3.24 and ± 0.25%, and ± 3.90 and ± 0.49% exhibited respectively by PAN-1, PAN-

2, PAN-3, and PAN-4. So, all the tablets investigated are falls within the acceptable weight variation range of ± 7.5% and pass the test according to Indian pharmacopeia. The mean weight variation result of each brands under investigation of this study was shown in table 9 below.

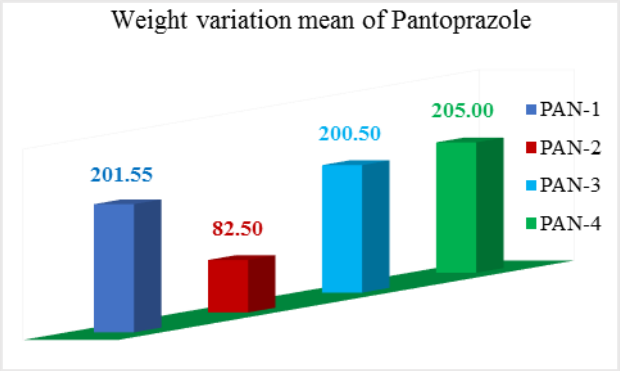

Figure 4: Weight Variation of Pantoprazole

Hardness Tests

Hardness test is essential for a tablet evaluation because the structural integrity of the tablet should be maintained throughout the whole process from manufacturing till the patient.

Currently the study or evaluation performed shows that (*Okoye EI and I wuagwu MA, 2010)*the mean was ranges from ±0. 32% to ±0.91% and also, the average was found within the range 5.00 ± 0.58 to 5.60 ± 0.91 Kg /cm^2. PAN-4 tablet is hardened and exhibits 5.60± 0.91Kg/cm^2. while PAN-3 brand is not as such hardened and may be crushed easily. Generally, the study reveals all brands showed optimum hardness with the standard limit of 4-6kg/cm^2 for proper packaging, storing, handling and transporting (*Dulla O et al., 2018.)*

Figure 5: Hardness test of Pantoprazole

Thickness Test

The uniformity in thickness of tablets is necessary for consumer requirement as well as packaging of the products. The 5% deviation of all brands of tablet were within the range of ± 0.16 % and ± 0.20% and complies the limit. Mean of each brand performed on thickness were found to be satisfactory that lies in between 3.12± 0.11 and 4.00 ± 0.09mm. PAN-2 brand was the thinnest while PAN-1 is the thickest brands.

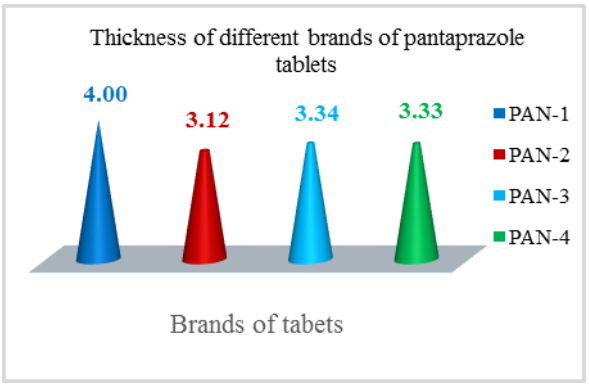

Figure 6: Thickness of Pantoprazole tablets

Friability Tests

Friability test can be performed to evaluate the ability of the tablets to withstand abrasion and cracking during packing, storing, handling and transporting. As per Indian Pharmacopeia, the loss of weight less than 1.0 % are acceptable. The mean percent deviation of the friability investigated was lies between 0.050% and 0.183%. The maximum result of friability percent was exhibited by the brand PAN-2 (0.183) and the minimum result of the friability percent exhibits by brand PAN-3 (0.050. This indicated the samples were lies in the range of permitted limit of IP less than 1.0% loss and pass the test. Friability results are summarized in Table 6. below.

Table 6: Results of friability tests

Code of Tablet Brands	Friability results *
PAN-1	201.55 ± 3.68
PAN-2	82.50 ± 2.28
PAN-3	200.50 ± 3.38
PAN-4	205.00 ± 4.47

Disintegration Tests

Disintegration refers the breaking of a tablet into smaller particles and it is an important process for dissolution. The disintegration test is used to determine the time elapsed for tablets to disintegrate into smaller particles that will pass through a 10-mesh screen. The study indicated that all the pantoprazole tablet brands did not show any signs of physical change during immersed in acidic medium of 0.1N HCl for 2 hrs. (Table.7). But, after the samples were exposed to phosphate buffer (pH 6.8) all brands we're starting to disintegrate. So, according to the test performed all brands are passed the disintegration test as well and completely disintegrated in the buffer medium less than 1hr. Specifically, the result of disintegration time shows, 10.80 ± 0.46, 10.58 ± 0.23, 10.46 ± 0.37 and 10.43 ± 0.58 min. for PAN-4, PAN-1, PAN-2 and PAN-3 respectively according to maximum to minimum disintegration time recorded. Generally, PAN-3 disintegrated faster (10.43min) whereas PAN-4 relatively delayed disintegration time (10:80min) when compared with other pantoprazole brand products. See table 7 below.

Table 7: Disintegration of pantoprazole tablets in 0.1N HCL and phosphate buffer pH 6.8.

Tablet Codes	Disintegration time(min)*			
	Time Limit	In 0.1N HCL medium	Time Limit	Buffer pH 6.8 medium*
PAN - 1	120	0.00	60	10.58 ± 0.23
PAN - 2	120	0.00	60	10.46 ± 0.37
PAN - 3	120	0.00	60	10.43 ± 0. 58
PAN - 4	120	0.00	60	10.80 ± 0.46

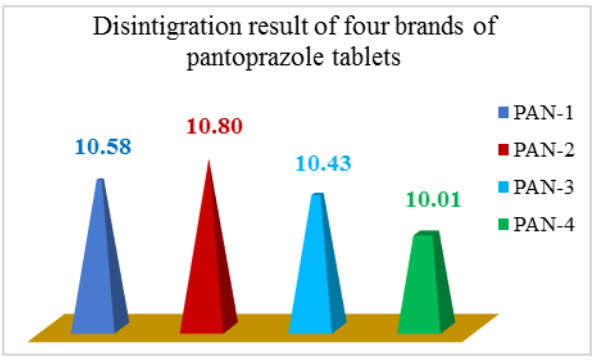

Figure 7: Disintegration of Pantoprazole

***In-Vitro* drug release Tests**

Dissolution is directly related to the absorption and bioavailability of the drug. The dissolution profile is determined by sampling the medium containing the dissolved drug at appropriate time points.

The results of *in-vitro* drug release study were revealed that the drug release in 0.1NHCL (pH1.2) were not significant and below 10% (PAN-3, 8.73%) within 2 hrs. and drug release was started after the tablets are exposed to phosphate buffer pH 6.8 medium. The variation in the dissolution profile of selected brand of tablets was ranges from 84.89 to 87.80% within 165min that score above 80%. Generally, drug release started after 2 hrs., and PAN-1 PAN-2, PAN-3 and PAN-4 reached 98.61%, 97.53%, 99.89%, and 96.72% within in one hour in phosphate buffer pH 6.8. The release of Pantoprazole sodium from the tablets was shown in Table 8 and Figure 8.

Table 8: Dissolution test in 0.1N HCL and Phosphate buffer pH6.8 Solution.

***In-vitro* (dissolution) test (%)**					
	Time	PAN-1	PAN-2	PAN-3	PAN-4
0.1N HCL, Medium	60	0.00	0.00	0.00	0.00
	90	0.23	0.36	2.46	0.00
	120	3.48	3.21	8.73	0.32
Phosphate buffer pH 6.8	120	0.00	0.00	0.00	0.00
	125	7.80	10.50	9.55	4.55
	130	25.84	28.34	27.12	22.73
	135	40.30	42.53	42.66	36.51
	150	68.41	70.91	66.99	67.32
	165	87.39	87.66	87.80	84.89
	180	98.61	97.53	99.89	96.72

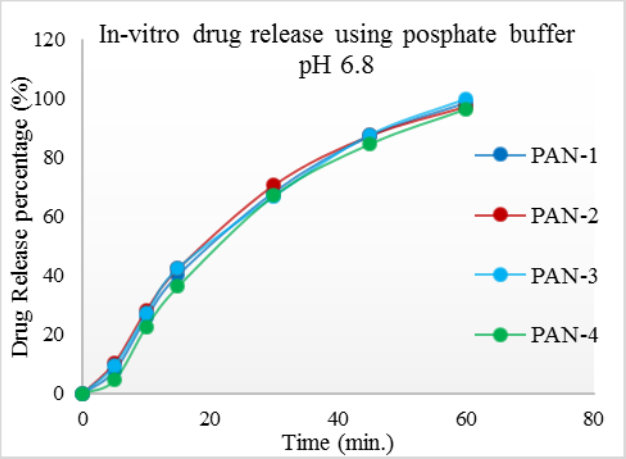

Figure 8: Dissolution profile of pantoprazole

Content of active ingredient (Assay)

The randomly selected brands of pantoprazole sodium tablets of each brand were tested for their drug content. The result of this study shows that the drug content of studied tablets was found to be between 98.13 and 101.28% for each brand of pantoprazole drugs according to Pharmacopoeias. Generally, all studied brands are meet specification monograph 90 – 110% as Pharmacopoeial standards.

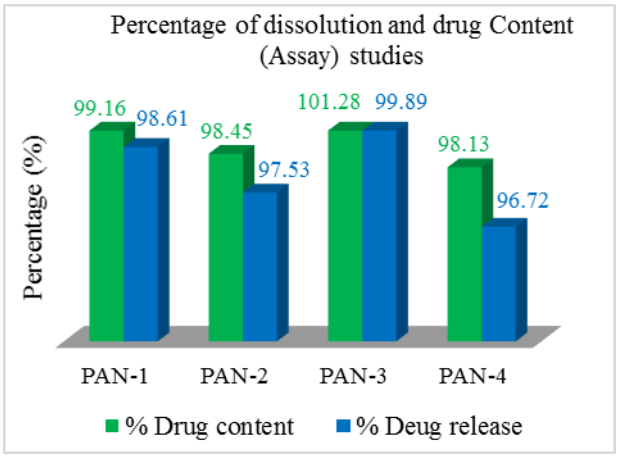

Figure 9: Percent of assay and dissolution

Table 9: Summary results of Post evaluation of studied pantoprazole brand

Tablets Code	Post Evaluation of pantoprazole tablets						
	Weight variation (mg)*	**Hardness test (Kg/cm^2) ***	**Thickness test (mm)***	**Friability test (%)**	**Disintegration (min.) ***	**Dissolu-tion (%)**	**Drug Content (%)**
PAN-1	201.55 ± 3.68	5.40 ± 0.46	4.00 ± 0.09	0.075	10.58	98.61	99.16
PAN-2	82.50 ± 2.28	5.10 ± 0.32	3.12 ± 0.11	0.183	10.46	97.53	98.45
PAN-3	200.50 ± 3.38	5.00 ± 0.58	3.34 ± 0.05	0.050	10.43	99.89	101.28
PAN-4	205.00 ± 4.47	5.60 ± 0.91	3.33 ± 0.02	0.073	10.80	96.72	98.13

***Mean ± SD, n = 10,20

CONCLUSION

These comparatives *in-vitro* evaluation study of various brands indicate the usefulness and effectiveness of different pantoprazole brand tablets. Generally, the present study results revealed that all of the tested brands of the pantoprazole sodium enteric-coated tablets fulfilled the criteria set in the official monograph for *in vitro* quality-control tests and manufacturers are produced their products as good pharmaceutical quality and the control of government is well organized.

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