



## COMPARATIVE IN-VITRO CHARACTERIZATION OF DIFFERENT COMMERCIALY AVAILABLE BRANDS OF PANTOPRAZOLE SODIUM TABLETS

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### ABSTRACT

The present study is concerned to characterize and compare the various physico-chemical properties like thickness, hardness, weight variation, friability and disintegration time, in-vitro dissolution profile of the pantoprazole sodium for different brands of tablets containing (40mg) prepared by various pharmaceutical industries under different trade names. All the brands passed all the official tests as prescribed by the Pharmacopoeia. All the brands were within the limit when tested for Thickness, Weight variation, Hardness, Friability and Disintegration. The four brands of pantoprazole sodium 40 mg (B<sub>1</sub>, B<sub>2</sub>, B<sub>3</sub>, B<sub>4</sub>) was found to have ideal disintegration time as well as dissolution time. The

U.V. Spectrophotometric method for the assay of Pantoprazole tablets used in this study is simple, inexpensive, reproducible and easy to use and could be used in routine monitoring of the quality of the pantoprazole sodium tablets, especially in the absence of high technology equipment.

**KEY WORDS:** Pantoprazole Sodium, Enteric coated tablets, Pharmacopoeia, Comparative *In-Vitro* evaluation.

## INTRODUCTION

Tablets are most widely preferred solid oral dosage forms since they offer safe and convenient way of drug administration and also provide means of accurate dosing.<sup>[1]</sup> Enteric coated tablets are the tablets that are coated with an enteric coating polymer which acts as a barrier that controls the location of oral medication in the digestive system where they are absorbed. Enteric coating is done to protect active pharmaceutical ingredient from the acidic environment of the stomach, to prevent gastric distress from a drug due to irritation, for the delivery of drugs that are optimally absorbed in the small intestine.<sup>[2]</sup> Pantoprazole is a substituted benzimidazole derivative that belongs to the category of proton pump inhibitors (PPI's) and is used as an anti-ulcerant. It binds irreversibly to the proton pump  $H^+K^+ATPase$  in the gastric parietal cell and inhibits gastric acid secretion.<sup>[3]</sup> Pantoprazole is available in market in the form of enteric coated tablets and i.v. injections. It is an acid-labile drug which gets degraded in the gastric fluid of the stomach and therefore must be delivered to the intestine. Hence, a delayed release formulation of pantoprazole as an enteric coated tablet may solve the stability problem of drug in the stomach and release the drug in the intestine.

## MATERIALS AND METHODS

### Instrumentation

For the analysis of pantoprazole content in their dosage form Shimadzu Double beam UV-VIS spectrophotometer model no: 1700 with 1cm matched quartz cells were used. Other equipments used are USP disintegration apparatus, USP type-II dissolution apparatus, Roche friabilator, High precision balance, Digital pH meter.

### Materials

Pantoprazole sodium standard drug was obtained from elder pharmaceuticals, navi Mumbai. Different brands of pantoprazole sodium tablets are purchased from local retail pharmacy.

### Experimental Methods

#### Preparation of standard graph for pantopraole using pH 1.2 acidic buffer

Calibration curve of pantoprazole sodium was prepared in 0.1 N HCl. 10 mg of the drug was dissolved in 100 ml of 0.1N HCl to obtain a stock solution of concentration 100  $\mu\text{g/ml}$ . This solution was then serially diluted with 0.1 N HCl to give solutions of concentration ranging from 5  $\mu\text{g/ml}$  to 25  $\mu\text{g/ml}$ . The absorbance of these solutions was measured at 283 nm using 0.1N HCl as blank and the standard curve was plotted to get the linearity and regression equation (Figure: 1).

**Physicochemical Parameters<sup>[4-6]</sup>**

**Uniformity of weight:** The test was carried out on 20 tablets as per the procedure specified in IP. Average weight and maximum % deviation was calculated.

**Hardness test:** The hardness was carried for 5 tablets using Monsanto hardness tester .The average hardness of the tablets was obtained.

**Friability test:** Friability test was carried out as per IP and % friability of each brands were calculated.

**Disintegration test:** The disintegration test was carried out according to USP procedure on six tablets using disintegration test apparatus with disc in distilled water medium at  $37\text{oC}\pm 1^{\circ}\text{C}$  and average disintegration time was calculated.

**Dissolution test:** The dissolution test was carried out on two stages in USP type-II dissolution apparatus. In acid stage dissolution was carried out in pH 1.2 (0.1N HCl) buffer at 100rpm for 2 hrs. The samples were collected for every 5min. and are analyzed by UV at 283nm using phosphate buffer as blank.

**RESULTS AND DISCUSSION**

All the brands exhibited good hardness strength, which is required for safe handling and transportation. B<sub>1</sub> exhibited maximum hardness while all the other brands exhibited similar hardness.

All the brands had a friability of less than 1%. Tablets having fewer tendencies to generate powder on handling and transportation will have low friability values. The content of Pantoprazole in each tablet brand was within the limits prescribed by the I.P. All the brands of tablets passed the weight variation test.

According to I.P., if the tablets are uniform in weight, it is likely that the tablets will be uniform in drug content also. Hence, I.P. prescribes only weight variation test on tablets when the drug forms the major bulk of the tablet. As all the brands passed the weight variation test, it is concluded that all the tablets are uniform in drug content also.

All the brands of tablets passed the I.P. disintegration test indicating that they will completely disintegrate in the intestine within 2 hours.

All the brands of Pantoprazole tablets passed the dissolution test as prescribed by I.P. Even though all brands passed the dissolution test as prescribed by I.P., there was variation in Pantoprazole dissolution rate of different brands.

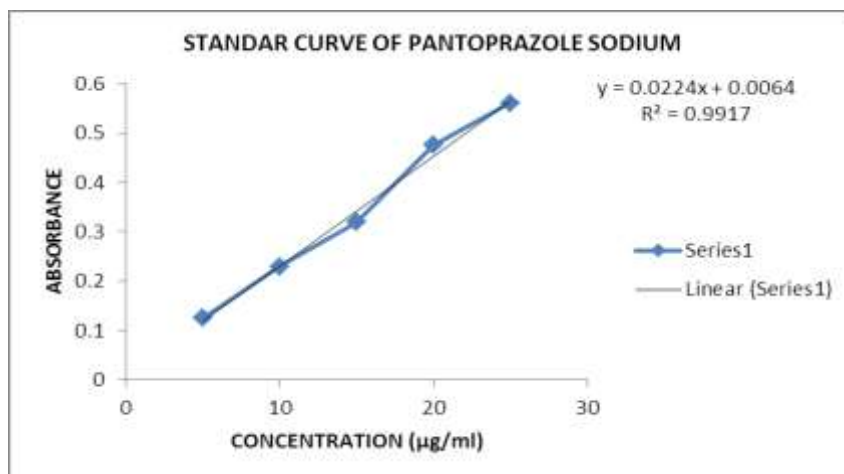


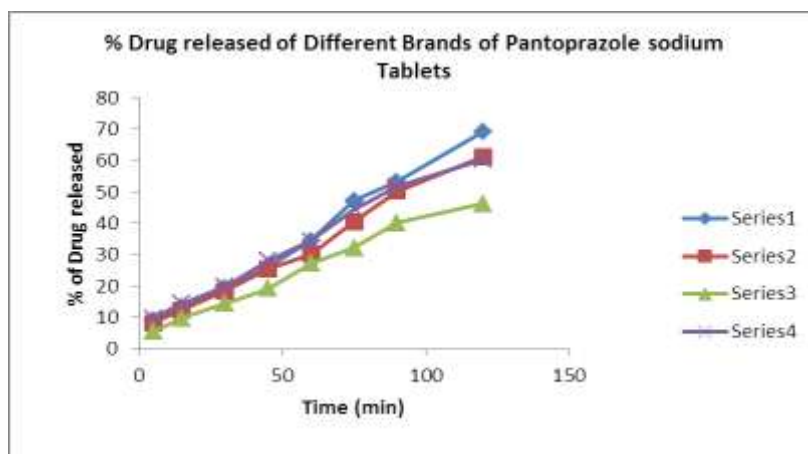
Figure 1: Standard Curve of Pantoprazole Sodium.

Table 1: Physical Evaluation of Different Brands of Pantoprazole Tablets.

Batch number	Weight Variation (%)	Thickness (mm)	Hardness (Kg/sq.cm)	Friability (%)	Disintegration Time (Mins)
B <sub>1</sub>	3.6	3.4	3.5	0.19	78
B <sub>2</sub>	2.8	3.6	3.0	0.63	85
B <sub>3</sub>	3.2	3.5	2.5	0.39	110
B <sub>4</sub>	1.9	3.6	2.5	0.32	92

Table 2: Dissolution Profile for Different Brands of Pantoprazole Sodium Tablets in 0.1 N HCl.

Time (Mins)	% DR OF B <sub>1</sub>	% DR OF B <sub>2</sub>	% DR OF B <sub>3</sub>	% DR OF B <sub>4</sub>
5	9.11±0.15	8.22±0.12	5.51±0.11	9.92±0.11
15	13.29±0.16	12.34±0.13	9.83±0.16	14.47±0.14
30	19.20±0.12	18.45±0.17	14.42±0.13	19.92±0.19
45	26.22±0.16	25.52±0.15	19.21±0.14	28.25±0.12
60	34.40±0.11	30.13±0.11	27.23±0.13	34.47±0.13
75	47.28±0.19	40.46±0.18	32.15±0.16	44.48±0.17
90	53.26±0.13	50.29±0.15	40.11±0.15	51.63±0.17
120	69.20±0.17	61.19±0.18	46.26±0.12	60.28±0.14



**Figure 2: Dissolution Profile for Different Brands in 0.1N HCl.**

## CONCLUSION

Almost all the brands have passed all the official tests prescribed by I.P. 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 determine 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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## REFERENCES

1. N. Rama Rao, M. Eswar Gupta, Comparative *In- Vitro* Evaluation of Commercial Paracetamol Tablets, Journal Of Pharmaceutical Technology and Research, 2009; 1(2): 47-50.
2. OA Adegbolagun, OA Olalade and SE Osumah, Comparative evaluation of the biopharmaceutical and chemical equivalence of some commercially available brands of ciprofloxacin hydrochloride tablets, Tropical Journal Of Pharmaceutical Research, 2007; 6(3): 737-745.
3. Chakraborty S, Sarkar S, Debnath SK, Formulation Development and Evaluation of Pantoprazole Enteric Coated Tablets, International Journal of Chem Tech Research, 2009; 1: 663-666.

4. Campos DR, Klein S, Zoller T, Vieria NR, Barros FA, Meurer EC et al., Evaluation of pantoprazole formulations in different dissolution apparatus using biorelevant medium, *Arzneimittelforschung*, 2010; 60(1): 42-7.
5. Bushra M. U. Et al, Comparative in vitro evaluation of commercially available rabeprazole tablets, *Der Pharmacia Sinica*, 2013; 4(6): 28-31.
6. Anroop N., Rachna G., Rachna K., Shery J. and Mahesh A., Formulation and Evaluation of Enteric Coated Tablets of Proton Pump Inhibitor, *Journal of Basic and Clinical Pharmacy*, 2010; 1(4).
7. Senthil K, Ashok Kumar S and Ezhilmuthu R.P., Formulation and evaluation of didanosine enteric coated sustained release tablet; *Journal of Biomedical Science and Research*, 2010; 2(3): 126-131.