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COMPARITIVE *IN VITRO* EVALUATION OF DIFFERENT COMMERCIALLY AVAILABLE BRANDS OF PANTOPRAZOLE TABLETS

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ABSTRACT

The present study is concerned to investigate and compare physico-chemical properties(thickness, hardness, weight variation, friability and disintegration), invitro dissolution of the drug along with drug content(assay) for different brands of tablets containing pantoprazole (40mg, 20mg) 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 amount of drug obtained and percentage purity is less when compared to that of labeled claim. Among the four brands, both 40 mg(B) and 20 mg(b), brand 1 i.e. B1 and b1 was found to have more amount of the drug and brand 2 i.e. B2 and b2 was found to have less amount of the drug. 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.

INTRODUCTION: Pantoprazole Sodium is chemically sodium 5- (diflouro methoxy)-2- [(3, 4-dimethoxy-2-pyridyl) Methyl] sulphinyl] 1H- benzimidazole sesqui-hydrate [1] which has been widely used in the treatment of peptic ulcer. A wide varieties of Pantoprazole tablets are available in the market. Pantoprazole sodium comes under the class of proton pump inhibitor [2].

The main purpose of an oral tablet is to deliver a certain and defined amount of drug to the human body through GI system. Studies on bioavailability of drugs from a given study showed that in many situations tablets with same drug and drug content did not give the same therapeutic response.

Formulation additives in the tablet, physical form of the drug used in the tablet and manufacturing process vary from manufacturer to manufacturer, which is responsible for variation in the observed dissolution profile and therapeutic effect.

Pantoprazole tablets are available as enteric coated tablets. Enteric coatings [2] are those which remain intact in the stomach but will dissolve and release the contents once it reaches the small intestine. Their prime intension is to delay the release of drugs which are inactivated by the stomach contents or may cause nausea or bleeding by irritation in gastric mucosa.

The main objective of present study was to evaluate and compare the physicochemical bioequivalence of pantoprazole sodium tablets of different brands available in the market.

Pantoprazole tablets are available in 40mg and 20mg doses in the market. In the present study we are comparing 40mg and 20mg tablets of different brands available in the market. The physical parameters weight variation, thickness, hardness, friability, disintegration, dissolution and assay were considered during the present study.

MATERIALS AND METHODS:

Instrumentation: For the analysis of pantoprazole content in their dosage form EI Double beam UV-VIS spectrophotometer model no: 1372 with 1cm matched quartz cells were used. Other equipments used are USP disintegration apparatus, USP type-II dissolution apparatus, Roche friabilator, High precision balance, pH meter.

Materials & Reagents: Reference pantoprazole tablet is a gift sample from Dr. Reddy's Laboratories limited. Four brands were obtained from retail pharmacy.

Physicochemical Parameters:

Uniformity of weight: The test was carried out on 20 tablets as per the procedure specified in USP. 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 USP 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 $37^{o}C \pm 1^{o}C$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. After that it was transferred to pH 6.8 phosphate buffer and dissolution was carried out for 60min at 100rpm. The samples were collected for every 5min. and are analyzed by UV at 289nm using phosphate buffer as blank.

Assay: The tablets were powdered and average weight of powder equivalent to 35mg was taken and dissolved in about 20ml of ethanol. The solution was filtered and the volume is made to 35ml with ethanol. 1ml of sample was taken and dilutions were made as required to produce 10µg/ml concentration. Absorbance was measured at 289nm and % purity was determined.

RESULTS AND DISCUSSION: All the brands exhibited good hardness strength, which is required for safe handling and transportation. Brand 1 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 U.S.P. All the brands of tablets passed the weight variation test.

According to USP, if the tablets are uniform in weight, it is likely that the tablets will be uniform in drug content also. Hence, USP 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 U.S.P 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 prescribed by U.S.P. Even though all brands passed the dissolution test as prescribed by U.S.P., there was variation in Pantoprazole dissolution rate from brand to brand.

TABLE 1: PHYSICAL EVALUATION OF DIFFERENT 'B' BRANDS OF PANTOPRAZOLE TABLETS

PHYSICAL PARAMETER	B1	B2	B3	B4
Weight variation	2.4%	4.6%	3.7%	1.9%
Thickness	3.6mm	3.7mm	3.7mm	3.8mm
Hardness	3 Kg/sq.cm	2.5kg/sq.cm	2.5 kg/sq.cm	2.5 kg/sq.cm
Friability	0.62%	0.49%	0.18%	0.33%
Disintegration time				
a) In 0.1 N HCl (gastric fluid)	No evidence of disintegration for 1 hr	No evidence of disintegration for 1 hr	No evidence of disintegration for 1 hr	No evidence of disintegration for 1 hr
b) In 6.8 pH phosphate buffer (intestinal fluid)	Complete disintigration in 2 hrs	Complete disintigration in 2 hrs	Complete disintigration in 2 hrs	Complete disintigration in 2 hrs
Purity %	96	90	92	93

TABLE 2: PHYSICAL EVALUATION OF DIFFERENT 'B' BRANDS OF PANTOPRAZOLE TABLETS

PHYSICAL PARAMETER	b1	b2	b3	b4
Weight variation	2%	3.8%	1.96%	2.2%
Thickness	3.6mm	3.7mm	3.7mm	3.8mm
Hardness	3 kg/sq.cm	2.5 kg/sq.cm	2.5 kg/sq.cm	2.5 kg/sq.cm
Friability	0.26%	0.33%	0.48%	0.54%
Disintegration time				
a) In 0.1 N HCl (gastric fluid)	No evidence of disintegration for 1 hr	No evidence of disintegration for 1 hr	No evidence of disintegration for 1 hr	No evidence of disintegration for 1 hr
b) In 6.8 pH phosphate buffer (intestinal fluid)	Complete disintegration in 2 hrs	Complete disintegration in 2 hrs	Complete disintegration in 2 hrs	Complete disintegration in 2 hrs
Purity %	96.5	91	91	93

TABLE 3: DISSOLUTION PROFILE FOR BRAND B IN 0.1 N HCl

Time(hrs)	B1	B2	B3	B4
2	0.12±0.06	0.43±0.04	0.36±0.08	0.22±0.07

TABLE 4: DISSOLUTION PROFILE FOR BRAND 'B' IN pH 6.8 PHOSPHATE BUFFER

Time (min)	CUMULATIVE % DRUG DISSOLVED			
	B1	B2	B3	B4
0	0	0	0	0
5	20 ± 0.12	14 ± 0.17	16 ± 0.19	18 ± 0.11
10	34 ± 0.14	36 ± 0.16	31 ± 0.17	34 ± 0.18
15	46.3 ± 0.18	52 ± 0.14	52 ± 0.13	48 ± 0.16
30	65.25 ± 0.13	71 ± 0.12	63.62 ± 0.14	68 ± 0.14
45	82.95 ± 0.16	82 ± 0.19	78.34 ± 0.17	84 ± 0.12
60	95 ± 0.15	91 ± 0.15	92 ± 0.16	93 ± 0.15

TABLE 5: DISSOLUTION PROFILE FOR BRAND 'B' IN 0.1 N HCl

Time (hrs)	b1	b2	b3	b4
2	0.12±0.04	0.46±0.08	0.32±0.03	0.21±0.05

TABLE 6: DISSOLUTION PROFILE FOR BRAND 'B' IN pH 6.8 PHOSPHATE BUFFER

Time (min)	CUMULATIVE % DRUG DISSOLVED			
	B1	B2	B3	B4
0	0	0	0	0
5	18 ± 0.11	15 ± 0.14	16.55 ± 0.16	16.25 ± 0.11
10	33 ± 0.12	32 ± 0.18	41.8 ± 0.15	33.6 ± 0.16
15	41.5 ± 0.19	53 ± 0.16	53.9 ± 0.18	55 ± 0.17
30	66.5 ± 0.16	76 ± 0.15	59.5 ± 0.13	78.5 ± 0.14
45	82.5 ± 0.13	81 ± 0.19	70.3 ± 0.17	82 ± 0.12
60	96.5 ± 0.18	90 ± 0.13	91 ± 0.12	93 ± 0.15

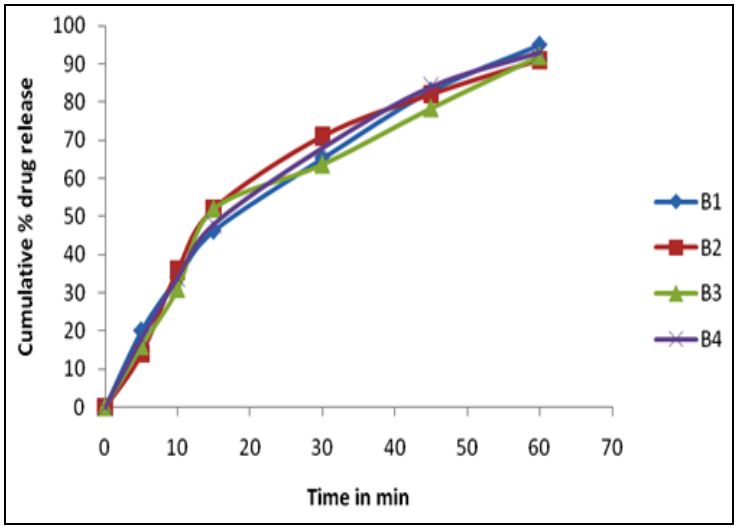

FIG. 1: DISSOLUTION PROFILE FOR BRAND 'B' IN pH 6.8 PHOSPHATE BUFFER

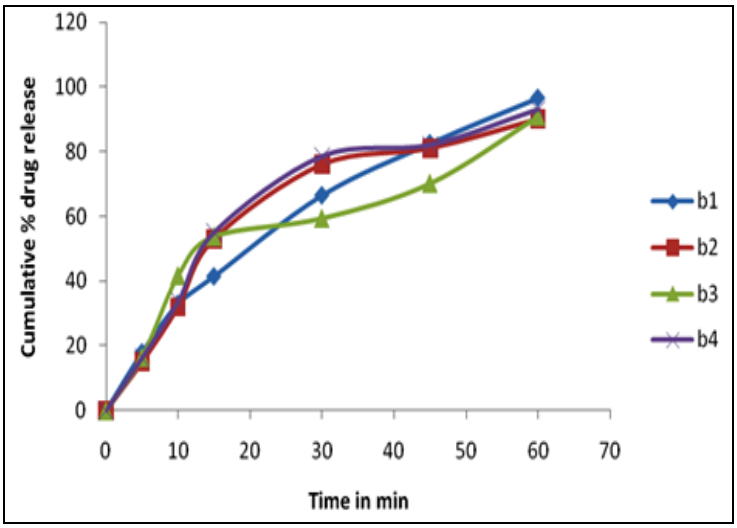

FIG. 2: DISSOLUTION PROFILE FOR BRAND 'B' IN pH 6.8 PHOSPHATE BUFFER

CONCLUSION: Almost all the brands have passed all the official tests prescribed by USP. 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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