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Comparative *in vitro* evaluation of commercially available rabeprazole tablets

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ABSTRACT

The main aim of present investigation was to study some physico-chemical properties(thickness ,hardness, weight variation, friability and disintegration) and in vitro dissolution of most commercially available formulations of rebeprazole (encoded with RPZ-1, RPZ-2,RPZ-3) in Bangladesh and two multinational companies(encoded with RPZ-4 & RPZ-5).All the brands were within the pharmacopoeial limit when tested for thickness, weight variation, hardness, friability and disintegration.However, RPZ-3 showed the fastest disintegration. Moreover, the comparison of percentage drug release of these companies on the basis of dissolution study demonstrated that RPZ-2 (90 % drug release) complied best while RPZ-4 (74.58% drug release) does not comply with above specification.

Key words: *In vitro* dissolution, market preparations, rabeprazole sodium, physico-chemical properties.

INTRODUCTION

Rabeprazole sodium, a substituted benzimidazole that inhibits gastric acid secretion. Rabeprazole sodium is known chemically as 2-[[[4-(3methoxypropoxy)-3-methyl-2-pyridinyl]-methyl]sulfinyl]-1H–benzimidazole sodium salt[1]. Rabeprazole works by inhibiting the action of the proton pumps[2] which reduces the production of stomach acid.

Tablets with same drug content do not give same therapeutic response as the differences of formulation additives in the tablet, physical form of the drug and varying of manufacturing process which is responsible for variation in the observed dissolution profile and therapeutic effect in different manufacturer company[3]. The *in vitro* dissolution of the drug from the tablet matrix depends on many factors, which includes not only the physiochemical properties of drug but also the nature of formulation and the process of manufacturing[4].So our objective is to evaluate different brands of commercially available rabeprazole enteric coated tablets[5] to get awareness about the pharmaceutical company that gives appropriate active ingredient present in dosage forms released into the market.

MATERIALS AND METHODS

Sample: Marketed rabeprazole tablets encoded with RPZ-1, RPZ-2, RPZ-3,RPZ-4 & RPZ-5 were procured from the retail pharmacy (Dhaka,Bangladesh).

Chemicals: Standard rabeprazole was donated by square pharmaceutical ltd and all other reagents were of analytical grade and procured commercially.

Reagent: 0.1N HCl and phosphate buffer (pH 6.8) were used.

Equipments: For the analysis of rabeprazole content in the dosage forms,UV-VIS Spectrophotometer Model Shimadzu-1800 with 1cm matched quartz cells were used. Other equipments used are USP disintegration apparatus, USP Type-II dissolution apparatus, Roche friabilator, High precision balance and pH meter.

IN VITRO EVALUATION

Weight Variation

20 tablets were selected randomly and weighed individually. The average weight was calculated and individual weight was compared to the average weight. The tablet passes the test if not more than two of the individual weights deviate from the average weight by more than ± 7.5% and none deviated by twice ± 7.5% [6].

Hardness Test

The hardness test was carried out for 10 tablets using Monsanto hardness tester. The average hardness of the tablets was obtained.

Friability test

The % friability of the tables of each brand was calculated by the use of Roche friabilator. It should be less than 1%. Twenty tablets of each brand were selected randomly and weighed individually, then placed in the friability test apparatus.

Disintegration Test:

The disintegration test was performed according to USP procedure. Six tablets from each formulation were weighed and placed in the baskets. The apparatus was operated using 0.1N HCl as immersion fluid at 37± 2 °C for 1 hour. Then after, tablets were observed for any sign of disintegration, cracking or softening. Then, immediately tablets were taken outside and the immersion fluid was replaced with phosphate buffer, pH 6.8 and apparatus was operated on same condition for 1hour. The specification for the disintegration of enteric coated tablet in phosphate buffer (pH 6.8) is 1 hour according to U.S.P[6].

Dissolution Test

Drug release studies were carried out using a USP type II dissolution test apparatus at 100 rpm for 1 hr in simulated gastric fluid (0.1N HCl) and after that for 1hr in intestinal fluid (phosphate buffer, pH-6.8) as dissolution medium at 37°C ± 0.5°C. After 5, 10, 15, 30, 45 and 60 minutes, 10 ml of the samples were taken out and 10 ml Volume of fresh phosphate buffer pH 6.8 was added to kept volume of dissolution medium constant. Then sample was analyzed using UV spectrophotometer at 284 nm and percent drug release was calculated.

Assay

The enteric coated tablets of rabeprazole sodium were tested for their drug content. Twenty tablets of each brand were weighed and finely powdered. 40 mg of rabeprazole sodium equivalent to rabeprazole was weighed and dissolved in phosphate buffer, the solution was filtered. 1 ml of sample was taken and dissolved 50 ml volumetric flask. Absorbance was measured at 284nm using a UV-Vis double beam spectrophotometer and percent purity was determined.

RESULTS AND DISCUSSION

Detail result about in vitro evaluations of rabeprazole tablets for all the brands (hardness, friability, weight variation, disintegration, and assay) is given in Table 1 and the dissolution study is given in Table 2 and figure 1.

All the brands exhibited good hardness strength (4.5± 0.43 to 6.1 ± 1.23) and less friability value (0.23% to 0.71%), which is required for safe handling and transportation. Weigh variation of each brand was calculated and was found within the limit (2.7 to 4.8%). The content of rabeprazole in each tablet of all brands was within the limits prescribed by U.S.P.

Disintegration test was done using 0.1N HCl and phosphate buffer (pH 6.8). Neither of the tested tablets disintegrated up to 2 hrs in 0.1N HCl nor there was any sign of cracking or softening. But in phosphate buffer (pH 6.8), all tablets disintegrated at different time.

The percentage drug release was analyzed in both 0.1 N HCl and in phosphate buffer (pH 6.8) and shown in fig 1. The percent drug release from all brands in 0.1 N HCl were less than 5% and were in range of 0.95% to 4.2%.

In phosphate buffer, the percent drug release was significantly higher. The percent drug release from RPZ-1, RPZ-2, RPZ-3 & RPZ-5 was 83.85±1.46, 82.0±1.02, 83.97±0.86 and 90.02±3.17 respectively which are within the limit. But the percent drug release from RPZ-4 was 78.07±1.23 which is out of limit.

All the brands of rabeprazole tablets passed the dissolution test as prescribed by U.S.P except one brand RPZ-4.

The possible reason for the difference in dissolution rate from brand to brand may be due to difference in particle or surface area of the drug particles[7].

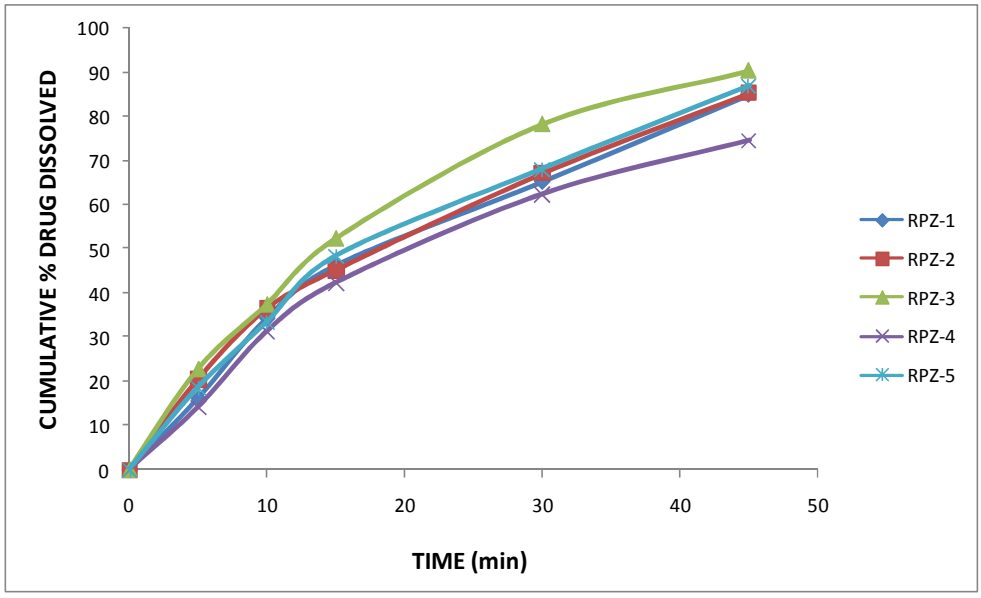
Table 1: Physical evaluation of different brands of rabeprazole tablets

Testing Parameters	RPZ-1	RPZ-2	RPZ-3	RPZ-4	RPZ-5
Weight Variation Test	3.4%	5.6%	3.7%	1.9%	4.3%
Hardness (kg/cm2)	4.5± 0.43	5.4 ± 0.33	3.7± 0.89	6.1 ± 1.23	3.6± 0.76
Friability test (%)	0.35%	0.71%,	0.23%	0.66%	0.57%
Disintegration time:					
a) In 0.1 N HCl (gastric fluid)	No evidence of disintegration for 1hr	No evidence of disintegration for 1hr	No evidence of disintegration for 1hr	No evidence of disintegration for 1hr	No evidence of disintegration for 1hr
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	Complete disintegration in 2 hrs
% Purity	94.12%	95.51%	96.12%	95.43%	93.42%

Table 2: Dissolution profile for different brands in pH 6.8 phosphate buffer

Time (min)	Cumulative % drug dissolved				
	RPZ-1	RPZ-2	RPZ-3	RPZ-4	RPZ-5
0	0	0	0	0	0
5	16.15 ± 0.18	20.45 ± 0.13	22.78 ± 0.14	14.15 ± 0.17	18.62 ± 0.11
10	34.32 ± 0.14	36.54 ± 0.15	37.42 ± 0.17	31.35 ± 0.18	33.42 ± 0.16
15	46.3 ± 0.18	45.25 ± 0.13	52.36 ± 0.14	42.34 ± 0.18	48.35 ± 0.16
30	65.25 ± 0.13	67.14 ± 0.12	78.24 ± 0.16	62.41 ± 0.15	68.12 ± 0.14
45	84.95 ± 0.16	85.34 ± 0.17	90.34 ± 0.15	74.58 ± 0.17	86.88 ± 0.16

Figure 1: Dissolution Profile for different brands 'RPZ' In Ph 6.8 Phosphate Buffer



CONCLUSION

The comparison of dissolution study demonstrates that RPZ-3 (90 % drug release) complied best while RPZ-4 (74.58 % drug release) does not comply with USP specification. Almost all the brands except one have passed all the official tests prescribed by USP. The variation in that dissolution study may be due to different formulation additives, physical form of the drug in the tablet and varying of manufacturing processes from manufacturer to manufacturer.

We strongly recommend the manufacturers to overcome the problem to meet the requirements of the rabeprazole enteric coated tablets.

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