DIU Journal of Health and Life Sciences Volume 02, No. 01 & 02, 2015
https://doi.org/10.36481/diuhls.v02i1-2.w7bnt074

COMPARATIVE STUDY OF DIFFERENT BRANDS OF RANITIDINE TABLETS IN BANGLADESH

Mahfuza Sultana , Jeasmin Akter and *Md. Al-Faruk

Department of Pharmacy, Daffodil International University, Dhaka 1207.

Abstract: *Ranitidine is a H_2- receptor blocker, which is widely used for the treatment of peptic ulcer disease. Present was designed to assess the therapeutic properties of different branded ranitidine hydrochloride tablets available in retail pharmacies of Bangladesh. Ranitidine HCl tablets manufactured by five different brands following USP specifications were collected from local retail Pharmacy located in Dhaka. Various parameters such as weight variation, thickness, hardness, disintegration, dissolution, potency etc. were analyzed according to the official (BP/USP[8]) pharmacopoeia methods to evaluate their quality. The result showed that four brands of Ranitidine HCl tablets complied USP specification of potency and the remaining one was more potent. Four brands showed a good result for weight variation, hardness, disintegration time and dissolution rate. One brand of tablets showed minor deviation in dissolution rate as compared to USP specification. It is evident from the study that most of the brands tested showed good results. Though this study was performed on a limited scale but the data reported here can help the Drug Control Authority to get an idea about the quality status of the marketed Ranitidine HCl preparations in Bangladesh.*

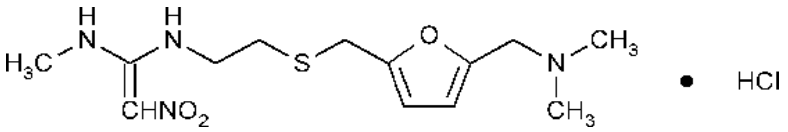
Keywords: *Ranitidine tablets, hardness, disintegration time, dissolution rate, quality evaluation.*

Introduction

Ranitidine is a competitive, reversible inhibitor of the action of histamine at H_2-receptors, including receptors on gastric cells with a minimal effect on H_1 receptors. It is one of the drugs of choice for the treatment of active duodenal ulcers, gastric ulcers, Zollinger Ellison syndrome, gastroesophageal reflux disease, and erosive esophagitis. The indicated oral dosage of ranitidine is 150 mg twice daily. In the treatment of endoscopically diagnosed erosive esophagitis, the dosage is 150 mg ranitidine 4 times a day[1].

Ranitidine HCl is chemically familiar as N-[2-[[[5-[(dimethylamino) methyl]-2-furanyl]methyl]thio]ethyl]-N'-methyl-2-nitro-1,1-ethenediamine, hydrochloride. It is a white to pale yellow, crystalline powder and highly soluble in water. It has a slightly bitter taste and sulfur-like odor [4]. It has the following structural formula:

***Corresponding Author:** Md. AL- Faruk**,** Lecturer, Department of Pharmacy**,** Daffodil International University, Dhaka 1207, Bangladesh, E-mail: maruppharm@daffodilvarsity.edu.bd, Contact No.: +8801737296319



Structure of Ranitidine HCl

Generally each tablet, for oral dosage contains 168 mg or 336 mg of ranitidine hydrochloride equivalent to 150 mg or 300 mg of ranitidine respectively.

Sub-standard or spurious drugs could endanger patient's life. After the implementation of National Drug Policy in 1982 the quality of marketed drug, no doubt, improved, but cross-checking is required. For this reason, market preparations of Ranitidine HCl were evaluated.

Materials and methods

The investigation was performed in Pharmaceutics Laboratory of the department of Pharmacy of Daffodil International University.

Five brands of Ranitidine HCl tablets were obtained from different retail pharmacy shop. All tablets were of same manufacturing year. The samples were identified as brand 1, brand 2, brand 3, brand 4 and brand 5. Standard Ranitidine sample was used to prepare the standard calibration curve. All the solutions were prepared using distilled water.

Appearance of tablets

Physical appearances e.g. color; size, shape and surface texture of all tablets were observed

Weight Variation

The weight variations of five brands Ranitidine HCl were determined and the observed results are shown in the Table 1. The USP specification of weight variation: ±7.5 for 130 to 324 mg average weight of tablet and ± 5% for more than 324 mg of average weight of tablet. It was observed that all of the brands meet the USP specification[2].

Preparation of standard curve of Ranitidine

A standard solution of Ranitidine was prepared in aqueous medium. 100 mg of standard Ranitidine was weighed and placed in 100 ml volumetric flask and the required volume was made with distilled water. The solution was then diluted to achieve a concentration of 100 µg/ml by adding distilled water. A series of standard solutions e.g., 2 µg/ml, 4 µg/ml, 5 µg/ml, 6 µg/ml, 8 µg/ml, 10 µg/ml, 12 µg/ml, 14 µg/ml etc. were prepared by proper dilution using distilled water.

The absorbance of each ranitidine solution was measured at 314 nm against a blank using UV-spectrophotometer (Shimadzu). The measured absorbance was plotted against the respective concentration of the standard solutions which provided a straight line[9].

Weight variation procedure

Ten tablets were taken and weighed individually by an analytical balance. The average weight of the tablets was calculated. Then % of weight variation is calculated by using the following formula:

$$\% \text{ of weight variation} = \frac{Individual weight - average weight}{average weight} \times 100 \quad (1)$$

Then RSD% was calculated.

Hardness test Procedure

The hardness of five brands of Ranitidine HCl (10 tablets from each brands) were measured by following-

A calibrated load cell measures the force applied. Results are expressed in Newton (N) or Kilopound (kp)

Disintegration test procedure

About 700 ml distilled water was taken in 1000 ml beaker and the beaker was placed into the device. One ranitidine was placed in each tube of basket rack and plastic disk was placed over each tablet and the basket rack is accurately positioned into the beaker. The temperature was maintained as 73 ± 0.5°C. A motor driven device helped to move the basket up and down through a distance of 5-6 cm at a rate of 28-32 cycles per minutes. The time at which all the ranitidine tablets passed through the sieve was the disintegration time[3].

In-vitro dissolution test procedure

About 900 ml of distilled water was filled into 1000 ml beaker of dissolution apparatus. One ranitidine tablet was placed into each beaker. The dissolution medium was heated up to 37±0.5 C by an auto heater and 50 rpm was adjusted. 10 ml solution was withdrawn from beaker at 10 minutes interval which was replaced with 10 ml distilled water and then withdrawn solution was filtered through filter paper. The withdrawn solution of the sample was suitably diluted and absorbance was measured at 314 nm by using UV-visible spectrophotometer. Finally the percent release of ranitidine tablet was determined[5].

Assay of Potency

Average weights of five tablets were determined. Five tablets were crushed. Tablet powder equivalent to 100mg of ranitidine was taken. It was dissolved in distilled water. Then it was shaken for 30 minutes. The solution was filtered. The filtrate was suitably diluted. Absorbance was taken at 314 nm by using UV-visible spectrophotometer. Finally the potency of ranitidine tablet was determined.

Results

Table 1: Weight variation of different branded ranitidine tablets

Serial No	Tablets	No of Tablet	Highest Weight Variation (%)	Lowest Weight Variation (%)	RSD %
1	Brand 1	20	2.22	0.148	0.790
2	Brand 2	20	2.57	0.161	0.690
3	Brand 3	20	2.759	0.403	0.912
4	Brand 4	20	5.3	2.327	1.393
5	Brand 5	20	1.96	0.11	0.642

The hardness of five brands of Ranitidine HCl (10 tablets from each brands) were measured and observed results are shown in Table 2. According to BP/USP specification, hardness of tablet is not more than 7.0 kp. It was seen from the result none of the marketed ranitidine HCl sample exceeded the specification and therefore it can be said that all the brands complied with the specification for hardness.

The potency of five Brands of Ranitidine HCl tablets was determined. The obtained results were shown in the Table 2. According to USP, ranitidine tablets contain an amount of Ranitidine HCl equivalent to not less than 90.0 percent and not more than 110 percent of the labeled amount of Ranitidine. From the result, it is evident that 4 out of five brands of Ranitidine HCl tablet meet the specification of potency whereas only Brand 5 was more potent than the USP range [8].

Table 2: Hardness and potency of 5 brands of Ranitidine HCl tablets

Serial no.	Marketed sample	Average Hardness (kp)	Potency (%)
1	Brand 1	5.25	104.2
2	Brand 2	4.37	98.4
3	Brand 3	5.09	99.06
4	Brand 4	6.79	92.7
5	Brand 5	5.66	114.02

The disintegration time of five brands of Ranitidine HCI are shown in Figure 1. The specification of disintegration time is 5 to 30 minutes. It was seen from result that none of the marketed Ranitidine HCl sample exceeded the specification and therefore it can be said that all the Brands complied with the specification for tablet disintegration time.

The dissolution rate of five brands of Ranitidine HCl tablets was determined. The observed results were shown in Figure 2. The percentage of drug release was plotted against the times, which give dissolution curve. It was observed that not less than 80% of the labeled amount of Ranitidine to be dissolved in 45 minutes. It is shown from the result that the Brand 4 showed 86.37 % release after 50 minutes. The remaining four Brands of Ranitidine HCl tablets meet the specification[6, 7].

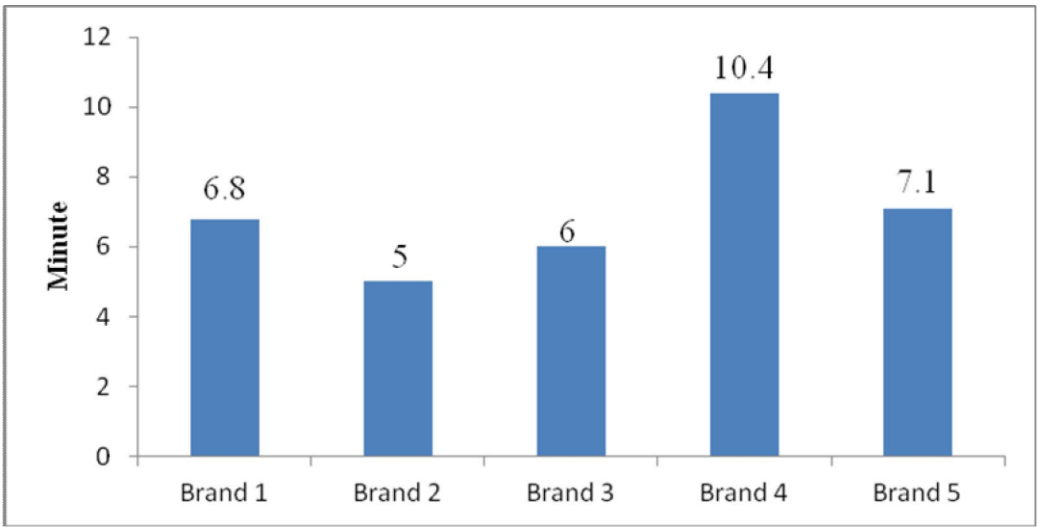


Figure 1: Bar diagram of average disintegration time (min) of different marketed sample

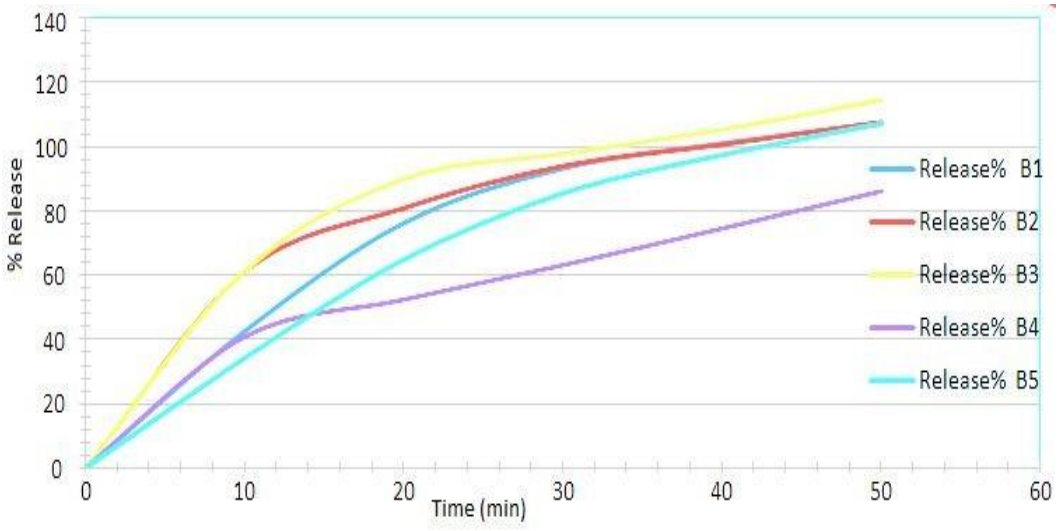


Figure 2: Comparative release curve of different branded Ranitidine HCl

Discussion

All the samples used for the study were within their shelf life at the time of investigation. All brands showed acceptable uniformity of weight as none had percent deviation in weight greater than 5% as stipulated by the USP[8]. The significance of this test is to ensure that the tablets in each lot are within the appropriate weight range.

The crushing strength of the tablets is an essential criterion in the determination of the ability of the tablets to resist chipping, abrasion or breakage under conditions of storage, transportation and handling. It was seen from the result that none of the marketed Ranitidine HCl sample exceeded the specification and therefore it can be said that all the brands comply with the specification for hardness. Ranitidine tablets contain an amount of Ranitidine HCl equivalent to not less than 90 percent and not more than 110 percent of the labeled amount of Ranitidine[8].

From the result, it is evident that 4 out of five brands of Ranitidine HCl tablet meet the specification of potency whereas only Brand 5 was slightly more potent than the USP[8] range. The obtained results were shown in Table 2.

Disintegration is a process which causes the tablet to break rapidly so as to increase the surface area of the tablet fragment and promote rapid release of drug. The disintegration test measures the time required for tablets to disintegrate into particles. This is a necessary condition for dissolution and could be the rate –determining step in the process of drug absorption. It was seen from result that none of the marketed Ranitidine HCl sample exceeded the specification and therefore it can be said that all marketed sample complied with the specification for tablet disintegration time.

The dissolution test is a measure of the amount of the drug released into the dissolution medium with time. According to USP[8], there should not less than 80% of the labeled amount of Ranitidine to be dissolved in 45 minutes. It is observed from the results USP Brand 4 showed 86.37 % release after 45 minutes. And the remaining four Brands of Ranitidine HCl tablets meet the specification.

Conclusion

Ranitidine HCl tablets have been analyzed to find their correct quality status. The present study, although performed on a limited scale yet on the basis of professional judgment the data reported in this study can help the Drug Control Authority to get an idea about the quality status of the marketed ranitidine HCl preparations in Bangladesh. Further In-vivo study can be done to make judicious comparison between brands.

References

1. *McCarty-Dawson, Sue SO. Ranitidine versus cimetidine in the healing of erosive esophagitis. Clin.Ther. 1996, 18: 1150-1160.*

2. *Dhivya S, Nishanthi M, Jyostna M, Gobalakrishnan P, Vijayakumar B. "Formulation and invitro evaluation of ranitidine hydrochloride floating tablets." International Journal of Biological & Pharmaceutical Research. 2012; 3(4): 513-517.*

3. *Mannur VS, Karki SS, Ramani KB. "Formulation and Characterization of Ranitidine Hydrochloride Fast Disintegrating Tablets". International Journal of Chem. Tech Research, CODEN (USA): IJCRGG, 2 (2), 1163-1169.*

4. *Cappola ML. "A better dissolution method for ranitidine tablets USP". Pharm. Dev. Technol. 2001; 6(1): 11-17.*

5. *Wagner JG. Biopharmaceutics and relevant Pharmacokinetics, Drug Intelligence Publications, Hamilton, IL, 1971, 64.*

6. *Banker GS and Rhodes CT. Principles of Drug absorption. Modern Pharmaceutics.2nd Edt. New York: Marcel Dekker Inc; 1990, 23.*

7. *Indian Pharmacopoeia. Ministry of Health and welfare, Delhi, Controller of publication; 1996, (II), 659-661.*

8. *The United States Pharmacopoeia 24, NF 19, united state pharmacopoeial convention, Rockville, M.D. Asian Edi., 2000: 1462-5, 1913-1914.*

9. *Sarfaraz S and Reddy CVR. "Method development, validation and dissolution studies of ranitidine in its pharmaceutical dosage under different conditions by spectrophotometry". Journal of Chemical and Pharmaceutical Research, 2014, 6(3):1228-1232.*