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Appraisement of Ranitidine Hydrochloride Tablet (USP150mg) Preparations from Few Selected Companies in Bangladesh

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Abstract: The study was aimed to evaluate the pharmaceutical properties of few selected generic products of ranitidine hydrochloride tablets available in retail pharmacies of Bangladesh. We collected 10 nationally manufactured generic ranitidine HCl tablets from local Market who followed USP specifications and examined their physical parameters and potency to check their compliance with the USP. The intention was to evaluate the quality of this pharmaceuticals after 20 years of implementing the National Drug Policy in 1982. All tested ranitidine tablet samples (Rt_1-Rt_{10}) were selectively collected from local retail pharmacies in Savar, Dhaka-1344, Bangladesh. Before purchasing the samples, their physical appearance, name of manufacturer, batch number, date of manufacturing, expiry date, manufacturing license number and Maximum Retail Price (MRP) were properly checked. The various parameters of the selected samples such as diameter, shape, size, weight variation, thickness, hardness, disintegration, dissolution and potency have been determined according to the American Pharmacopoeia USP 27 requirements. It was found that all ten selected products met the USP 27 specifications. The differences in hardness among the tablets were significant. Interestingly, dissolution profiles of some tablet products were not weighty different from one another, whereas those of tablets were significantly different. However, all brands complied with USP 27. It could be concluded that the selected ranitidine HCl tablets met the required USP specifications and are considered quality products in terms of the mentioned parameters.

Key words: Ranitidine HCL, Bangladeshi generic drug, quality control, dissolution test

INTRODUCTION

Ranitidine is a histamine H2-receptor antagonist that competitively inhibits gastric acid secretion by parietal cells in the gastric mucosa (Mycek *et al*., 1997). It was introduced in 1981 and was the world's top-selling prescription drug by 1988. It is indicated in the treatment of Peptic Ulcer Disease (PUD) and Gastroesophageal Reflux Disease (GERD). The drug has a short biological half-life of approximately 2.5-3 h, an absolute bioavailability of only 50% in oral forms (Dave *et al*., 2004).

Because of the increasing complexity of modern pharmaceutical manufacturing arising from the diversity of drugs and dosage forms, complex ethical, legal and economic responsibilities have been placed on those concerned with modern pharmaceutical industry. The awareness of these issues is the responsibility of all those involved in the development, manufacture, control and marketing of quality products (Yasmeen *et al*., 2005; Bushra *et al*., 2008).

In low income countries pharmaceuticals account for 30.4% of health care spending compared with 19.7% in high income countries (Ye Lu, 2011). Up to 90% of the population in developing countries purchase medicines through out-of-pocket payments (Cameron *et al*., 2009) making medicines the largest family expenditure item after food. As a result, medicines are unaffordable for large sections of the global population and are a major burden on government budgets. The organization of a country's pharmaceutical sector can have implications for medicine availability, price and affordability.

Since generic drugs are safe, effective and low in cost, they have many advantages from a medical-financial viewpoint. However, there must be a tight governmental supervision system to ensure that generic drugs on the market are quality products, since there is no possibility for the health care professional or consumers to assess the quality of these products by themselves.

The dissolution test is a method of testing the release of active ingredients from oral solid preparations and is aimed at confirming their quality according to a fixed standard which also aids in preventing significant bioequivalence. It is regularly used for stability and quality control of oral dosage forms. Dissolution test can

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be used to waive in vivo bioequivalence study requirements (Anand *et al*., 2011).

The difference in dissolution behavior between innovator and generic ranitidine tablets has been previously tested (Mullaicharam *et al*., 2012). After the implementation of the National Drug Policy in 1982 (Islam, 1984) the quality of marketed drug, no doubt, improved but not as expected (Chowdhury *et al*., 2006). This fact raised the need to evaluate some widespread pharmaceutical preparations available in the market like ranitidine tablets. The major purpose of this study is to investigate the overall quality of the marketed ranitidine (tablets) preparations available in Bangladesh. We hope that the findings of this study will help to make awareness both in physicians and consumers to select quality products. The investigation was performed in "Pharmaceutics Laboratory" Dept. of Pharmacy, Faculty of Health Science, Gono University and Quality control Department of Gono Shastho Pharmaceutical Ltd. Savar, Dhaka-1344, Bangladesh during October 2011-August 2012.

MATERIALS AND METHODS

Sample selection and sample collection: The marketed sample of 10 brands of Ranitidine hydrochloride 150mg tablet were purchased at M.R.P from different Retail pharmacy at Savar, Dhaka-1344 in Bangladesh. The samples were properly checked for their physical appearance, name of manufacturer, batch number, manufacturing date, expiry date, manufacturing license number which mentioned in Table 1. The reference raw sample of ranitidine HCl was collected from Gono Shastho Pharmaceuticals Ltd., Dhaka-1344 Bangladesh. None of samples were bought and analyzed which date of expiry had already been passed and all of these samples were stored under appropriate condition.

General appearance: The general appearance of a tablet, its visual identity and overall "elegance", is essential for consumer acceptance, for control of lot-to-lot uniformity and general tablet-to-tablet uniformity and for monitoring trouble-free manufacturing. The control of the general appearance of a tablet involves the measurement of a number of attributes such as a tablet's size, shape, color, presence or absence of an odor, taste, surface texture, physical flaws and consistency and legibility of any identifying markings (Mullaicharam *et al*., 2012; Makooi-Morehead *et al*., 2003).

Diameter size and thickness: The diameter size and shape of tablets depends on the die and punches selected for making the tablets. The tablets are prepared in various sizes and shapes but generally they are circular with either flat or biconvex faces. Thickness of tablets can vary without any change in its weight. This is generally due to the difference of density of granules, pressure applied for compression and the speed of compression (Leon. Lachman: Industrial Pharmacy). The thickness of a tablet can be determined with the help of slide calipers. The thickness variation limits allowed are ±5% of the size of the tablet. The variation in thickness leads to counting and packing problems.

Weight variation test: The difference of weight in tablets can lead to variations in doses. Therefore all the tablets of a batch must conform to this test. The test was carried out according to USP monograph. Twenty tablets were taken randomly and the individual weight of each tablet was taken and also average weight of the tablet was calculated. The weight of each individual tablet was then compared with the average weight calculated and ensured that not more than one tablet fell outside the range. The limit depends on average weight of the tablets and in terms of USP specification as follows:

Average weight of tablets (mg)	Maximum percentage difference allowed
130 or less	±10%
130-324	±7.5%
More than 324	±5%

Maximum and minimum percentage deviation of individual weight was calculated according to the following equation:

Table 1: Table shows the ten tested of ranitidine HCl tablets with their Pharmaceutical Brand name, Companies name, Mfg. lic. No, batch No., Manufacturing date and Expiry date

Code No.	Brand name	Name of the company	Mfg. Lic. No.	Batch No.	Mfg. Date	Exp. Date
Rt1	Xantid	ACI limited	51 and 213	NM45	February 2012	February 2015
Rt2	Norma-H	Renata limited	45 and197	02612009	February 2012	February 2014
Rt3	Asinar	Aventis limited	39 and 176			
Rt4	Peptil-H	SK-F Bangladesh limited	385 and 130	3008	January 2012	July 2014
Rt5	Neotack	Square pharmaceuticals limited	235 and 460	21008	January 2012	December 2014
Rt6	Rinitid	Opsonin pharma limited	12 and 80	TBB112	February 2012	February 2014
Rt7	Neoceptin	Beximco pharmaceuticals limited	379 and 119	05925	January 2012	January 2015
Rt8	Inseac	The IBN SINA pharmaceutical industry limited	150 and 405	995	January 2012	January 2015
Rt9	Ulcar	Drug international limited	127 and 389	0112	January 2012	January 2015
Rt10	Ranidin	ACME laboratories limited	250 and 115	T1122164	January 2012	January 2015

Table 2: Table showing diameter and thickness of the selected brands of ranitidine HCL tablets (150 mg U.S.P)

Brand name by code	Total No. of Tablets	Average diameter of tablets (mm)	Average thickness of tablets
Rt1	20	9.98	4.26
Rt2	20	9.17	4.23
Rt3	20	9.59	4.2
Rt4	20	9.99	3.71
Rt5	20	9.11	3.66
Rt6	20	9.12	3.43
Rt7	20	11.14	3.86
Rt8	20	10.12	5.56
Rt9	20	10.56	4.39
Rt10	20	9.25	4.2

$$PD\ (\%) = \frac{\text{Maximum wt.} - \text{Average wt.}}{\text{Average wt.}} x100$$

$$ND\ (\%) = \frac{\text{Minimum wt.} - \text{Average wt.}}{\text{Average wt.}} x100$$

Where:
PD : Positive deviation
ND : Negative deviation

Hardness test: The hardness of the tablets was measured using a hardness tester (Toyama Sangyo Co., Osaka, Japan). The tablet to be tested was held between a fixed and moving jaw while reading of the indicator was adjusted to zero position. The force applied to the edge of the tablet was gradually increased by moving the screw knob forward until the tablet breaks (Ashok., Introduction to Pharmaceutics-1). The reading was noted from the scale which indicates the pressure required in kg to break the tablet. The hardness required 4 kg of pressure is considered as the suitable tablets for handling which is again conformed by friability test. Too much hardness is also not desirable as the tablet may fail in dissolution study (Ahmed *et al*., 2003; Alagusundaram *et al*., 2009). For the hardness test 10 tablets were used and the results were averaged.

Determination of average hardness:

$$\text{Average hardness} = \frac{\text{Total hardness of tablet}}{\text{No. of tablet}}$$

Friability test: The instrument used for this test is known 'Friability Test Apparatus' or 'Friabilator'. It consists of a plastic chamber which is divided into two parts. Twenty tablets were taken randomly and Twenty tablets were placed into a drum (USP24 and JP14, Toyama Sangyo Co., Ltd., Osaka, Japan) and the drum was rotated at 25 rpm for 4 min following USP 24. During each revolution the tablets fall from a distance of six inches to undergo shock. After 100 revolutions the tablets are re-weighted to calculate the weight loss. The acceptable limits of weight loss should not be more than 0.8%. Percentage determination of Friability = (Initial Tab. wt.-Final tab. wt./Initial Tab. wt. x100)

Disintegration test: The USP disintegration apparatus was used for this test is known as disintegration test apparatus. Disintegration is evaluated to ensure that the tablets disintegrate and the drug substance becomes fully available for dissolution and absorption from the gastrointestinal tract (Banker and Anderson, 2009). Disintegration time was measured for 6 tablets by inserting disks using 900ml purified water at 37±2°C in Disintegration Apparatus. The tube was allowed to move up and down at a constant rate i.e., 30 times per minute through a distance of 75 mm (Cappola, 2001).

$$\text{Average time} = \frac{\text{Total time of disintegration}}{\text{No. of tablet}}$$

Procedure for dissolution test: Dissolution test was adopted from USP 31 (2008). The apparatus for dissolution test consists of a cylindrical stainless steel basket which is attached to the end of the stirred shaft, 1000ml vessel made of glass or other inert, transparent material fitted with a cover, a variable speed motor driven stirrer which can rotate at a speed of 25-150 revolutions per minute and a suitable thermostatically controlled water bath to maintain the temperature of the dissolution medium at a temperature of 37±0.5°C. For performing the test 900ml of dissolution medium (0.1N HCl) was filled in the glass vessel submerged in the water bath to maintain at 37°C (Borst *et al*., 1997; Abad-Santos, 1996). The tablet to be tested was introduced in the basket and fitted in position. For std. claimed amount of Ranitidine hydrochloride powder was introduced in the basket and fitted in position. The motor is started with 50 rounds per minute. The samples were withdrawn at 5 min. intervals and replaced immediately by a 0.1N HCl solution in order to maintain a constant volume in the vessel (Yu *et al*., 2002; Dave *et al*., 2004). The samples were collected and 10 times dilution of each were made and measured the absorbance at 313 nm wavelength. Not less than 80% of the labeled amount of ranitidine has to be dissolved in 45 min.

Assay

Test sample preparation: At least 20 tablets of each brand were weighed and triturated to make powder.0.0118 g Ranitidine Hydrochloride Reference Standard was taken in a 100ml Volumetric Flask (VF) containing about 50ml of water. Then the flask was shaken gently to get the substance dissolved and diluted to the mark with distilled water. Pipetted out 10ml of this solution into another 100ml V.F. and diluted to the mark with distilled water. Then the absorbance was taken at 313 nm (in 1cm cell) by using UV spectrophotometer (USP 23, 1995).

Reference sample preparation: Weighted out 0.025 g powdered granules of Ranitidine tablet in a 100ml V.F. containing about 50ml of water. Then the flask was shaken gently to get the substance dissolved and diluted to the mark with distilled water. Pipetted out 10ml of this solution into another 100ml V.F. and diluted to the mark with distilled water. Then the absorbance was taken at 313 nm (in 1cm cell).

Blank: Distill water.

$$RH\ (\%) = \frac{\text{Wt. of Std. x abs. of sample x Potency of std}}{\text{Wt. of sample x abs. of std}}$$

$$\text{Stated amount} = \frac{\text{Ranitidine (\%) x Average wt. of tablet}}{100}$$

$$\text{Stated amount (\%)} = \frac{\text{Stated amount of tablet}}{\text{Wt. of sample}} \times 100$$

Where:
RH : Ranitidine hydrochloride

RESULTS AND DISCUSSION

Weight variation test: The percentages of positive and negative deviations of weight variation test results are in the Table 3. The quality (Q) evaluation on each of the individual generics was done based on their (+) and (-) deviation values. It was found that the Rt1 sample had 0% of weight deviation it was the best sample in terms of weight and content uniformities among the all selected brands. On the other hand, Rt4 was found as the second best sample which had an actual percentage of weight deviation value of 0.07 only. Rest of the brands comply USP weight variation test. However, the brands Rt8, Rt5 and Rt6 had expressed positive (+) weight deviation of values above 1 and below 2 respectively. Therefore, from the overall study on weight variation it can be concluded that the selected brands of Ranitidine Tablets available in Bangladesh are within the limits of USP specifications.

Hardness test: Hardness of 4 kg is considered suitable for handling the tablets. Hardness of 6 kg or more will produce tablets of highly compact nature (USP 24-NF 19, 2000). Hardness of tablets should be within the USP limit because it can cause disturbances in dissolution, disintegration and absorption of drug. Tablets with hardness range below the limit may not withstand the handling during packing and shipment throughout their shelf-life. Six (Rt_6>Rt_8>Rt_1>Rt_3>Rt_9>Rt_2) out of the ten selected generics of Ranitidine hydrochloride tablets (150 mg U.S.P) were found highly compact in nature. The brand 'Rt_6' has shown the highest average hardness value (11.5 kg) among the ten brands based on USP specifications for quality of tablets. The current study showed that Rt10, Rt4 and Rt5 have proved almost similar results of hardness in kg which are below 6 kg (the maximum of the limit). Secondly, the brands which had got the average hardness values nearer to maximum were Rt2, Rt9 Rt6. The hardness variations values are shows bellow by the Table 4.

Friability test: The friability test for ten selected brands of ranitidine hydrochloride tablets has proved that Rt1, Rt, Rt8, Rt4 and Rt9 have shown a weight loss of less than 0.3%. The rest of the brands have got a weight loss of more than 0.3% and below 0.45%. The friability test results given in Table 5. Therefore, it could be concluded that all the selected brands of Ranitidine HCl tablets were found within the USP limit for friability test which is not more than 0.1%.

Disintegration test: Generally the disintegration time for uncoated tablets is not more than 15 min and for coated tablets maximum disintegration time is 30 min according to USP specification. Ranitidine tablets are film coated. The disintegration time of the selected generics was measured and the observed results are shown in Table 6. It was seen from result (Table 7) that none of the marketed Ranitidine HCl sample exceeded the specification, therefore it can be said that the entire marketed sample complied with the specification for tablet disintegration time.

Dissolution test: Since USP ranitidine tablets require at least 80% drug dissolution after 45 min, all dissolution profiles were evaluated for T80 and A45. The Table 7

Table 3: Table showing the weight variation with standard deviations of selected brands of ranitidine hydrochloride 150mg (USP)

Brand name by code	Total wt. of tab. Tablets (mg)	Av. wt. of tab. (mg)	Max. wt. of tab. (mg)	Min. wt. of tab. (mg)	Positive deviation (%)	Negative deviation (%)	Q. evaluation
Rt1	63300	316.5	325	308	2.69	-2.69	0.00
Rt2	61940	309.7	315	300	1.71	-3.13	-1.42
Rt3	68080	340.4	347	335	1.94	-1.59	0.35
Rt4	61080	305.4	310	301	1.51	-1.44	0.07
Rt5	50720	253.6	260	251	2.52	-1.03	1.49
Rt6	49700	248.5	258	243	3.82	-2.21	1.61
Rt7	49440	347.2	354	342	1.96	-1.50	0.46
Rt8	54720	273.6	285	265	4.16	-3.14	0.46
Rt9	68180	340.9	348	335	2.08	-1.73	0.35
Rt10	51620	258.1	261	253	1.12	-1.98	-0.86

Table 4: Table showing the hardness of ten selected brands of Ranitidine hydrochloride based on USP limit

Brand name by code	Average Hardness of Tab. (kg)	Nature of compact
Rt1	10.9	Highly compact
Rt2	6.4	Highly compact
Rt3	7.6	Highly compact
Rt4	5.3	suitable
Rt5	5.5	suitable
Rt6	11.5	Highly compact
Rt7	9.8	Highly compact
Rt8	11.1	Highly compact
Rt9	6.6	Highly compact
Rt10	5.3	suitable

Table 5: Table showing friability test for ten selected brands of Ranitidine hydrochloride tablets (150 mg U.S.P)

Brand name by code	Initial wt. of Tablet (mg)	Final wt. of Tablet (mg)	Loss of Tab. Wt. (mg) = Initial tablet weight-Final tablet weight	Wt. loss (%)
Rt1	6344	6330	14	0.22
Rt2	6214	6194	20	0.32
Rt3	6832	6808	24	0.35
Rt4	6124	6108	16	0.26
Rt5	5094	5072	22	0.43
Rt6	4982	4970	12	0.24
Rt7	4960	4944	16	0.32
Rt8	5486	5472	14	0.25
Rt9	6838	6818	20	0.29
Rt10	5184	5162	22	0.42

Table 6: Table showing the disintegration time of six ranitidine hydrochloride tablets from each selected individual brand at a time

Brand	Disintegration time of individual tablet (min)						TTD	ATD	
by code	T_1	T_2	T_3	T_4	T_5	T_6	(min)	(min)	Limit
Rt1	9.35	10.5	9.50	10.5	9.42	9.46	58.73	9.78	Pass
Rt2	10.15	10.35	10.30	9.55	9.35	9.58	59.28	9.88	Pass
Rt3	12.22	11.45	12.25	11.10	10.55	10.55	68.12	11.35	Pass
Rt4	11.34	12.2	11.45	10.23	10.35	11.10	66.67	11.11	Pass
Rt5	10.20	10.42	10.31	10.25	10.12	10.30	61.6	10.26	Pass
Rt6	7.49	7.56	7.57	7.35	8.10	7.55	37.52	6.25	Pass
Rt7	10.30	10.56	10.45	10.10	10.35	10.25	62.01	10.33	Pass
Rt8	14.12	14.11	14.12	13.56	13.45	13.40	82.76	13.79	Pass
Rt9	10.30	10.42	10.56	10.35	10.25	10.35	62.23	10.37	Pass
Rt10	7.44	7.52	6.58	7.56	6.10	7.45	42.65	7.10	Pass

TTD: Total time of disintegration, ATD: Average time of disintegration

Table 7: Standard (Ranitidine) Showing the time and absorbance of std.

Sample code	Time (min.)	After 10 times dilution (ABS.)
R-1	5	0.856
R-2	10	0.888
R-3	15	0.867
R-4	20	0.892
R-5	25	0.919
R-6	30	0.918
R-7	35	0.849
R-8	40	0.840
R-9	45	0.846
R-10	50	0.832

shows that the samples with maximum absorbance (λmax) comparable to the standard are Rt_4 to Rt_{10} which have a minimum value of 0.809 and a maximum 0.91. The samples with the minimum absorbance (λmin) relative to standard are Rt_6 to Rt_{10} which have a minimum value of 0.62 and of maximum 0.775. The samples with average absorbance (λav) values belonged to Rt_6 to Rt_{10} which are 80% of the standard. Among all the tested samples, Rt_8, Rt_9 and Rt_{10} showed the best results. Rt_1 to Rt_5 showed no results at or above 60% compared to the standard for the three parameters. Dissolution test results show that all our samples met the USP requirements and released 80% of their drug content in less than 45 mins (with one borderline value for Rt7) and that the amount of drug released in 45 mins varied between 77.5% for Rt10 to 86.4% for Rt1 (Table 9).

Potency test: The potency of the 10 brands of Ranitidine HCl tablets was determined. The obtained results are shown in Table 9. Ranitidine tablets must contain an amount of Ranitidine hydrochloride ($C_{13}H_{22}N_4O_3S$). HCl

Table 8: The table shows dissolution test for ten randomly selected Brands at equal time interval of (5min) for 1 hour with UV absorbance

Tested samples	Time in minute											
	5	10	15	20	25	30	35	40	45	50	55	60
Rt_1	0.319	0.677	0.724	0.892	0.911	0.909	0.888	0.886	0.864	0.874	0.804	0.803
Rt_2	0.191	0.257	0.386	0.487	0.586	0.633	0.840	0.832	0.821	0.821	0.826	0.795
Rt_3	0.191	0.366	0.532	0.627	0.780	0.870	0.892	0.822	0.778	0.789	0.806	0.780
Rt_4	0.263	0.366	0.479	0.722	0.801	0.821	0.821	0.892	0.826	0.788	0.775	0.731
Rt_5	0.181	0.334	0.607	0.786	0.852	0.851	0.872	0.831	0.783	0.786	0.775	0.765
Rt_6	0.276	0.364	0.464	0.479	0.541	0.621	0.630	0.720	0.819	0.807	0.792	0.788
Rt_7	0.284	0.407	0.516	0.665	0.781	0.862	0.836	0.808	0.785	0.796	0.851	0.805
Rt_8	0.155	0.375	0.459	0.579	0.721	0.739	0.780	0.896	0.859	0.829	0.818	0.809
Rt_9	0.342	0.546	0.655	0.742	0.809	0.909	0.889	0.865	0.836	0.789	0.780	0.755
Rt_{10}	0.316	0.692	0.752	0.808	0.830	0.849	0.823	0.780	0.775	0.757	0.744	0.752
Standard	0.856	0.888	0.867	0.892	0.919	0.918	0.849	0.840	0.846	0.832	0.826	0.795

Table 9: Table shows the percentage of drug released vs. time in different brands of ranitidine HCl tablets

Code no.	Time for 80% drug released (min)	Drug released in 45 minutes (%)
Rt1	20	86.4
Rt2	35	82.1
Rt3	30	77.8
Rt4	25	82.6
Rt5	25	78.3
Rt6	45	81.9
Rt7	30	78.5
Rt8	40	85.9
Rt9	25	83.6
Rt10	20	77.5
Standrad	5	84.6

Dissolution test results show that all our samples met the USP requirements and released 80% of their drug content in less than 45 mins (with one borderline value for Rt7) and that the amount of drug released in 45 mins varied between 77.5% for Rt10 to 86.4% for Rt1

Table 10: Potency determination of 10 brands of Ranitidine HCl tablets according to USP

Brand name	Abs. of std.	Abs. of sample	Potency of std.	Average wt. of tab. (mg)	Amount of drug present (mg)	Assay (%)	Limit
Xantid	0.5295	0.531	98.95	316	148.01	98.67	Yes
Norma-H	0.5295	0.522	98.95	313	150.36	100.24	Yes
Asinar	0.5295	0.5304	98.95	335	15068	100.45	Yes
Peptil	0.5295	0.537	98.95	300	154.4	102.96	Yes
Neotack	0.5295	0.519	98.95	252	145.66	97.11	Yes
Ranitid	0.5295	0.520	98.95	244	147.25	98.17	Yes
Neoceptin	0.5295	0.539	98.95	350	148.6	99.1	Yes
Inseac	0.5295	0.521	98.95	275	143.6	95.7	Yes
Ulcar	0.5295	0.532	98.95	341	148.16	98.77	Yes
Ranidin	0.5295	0.514	98.95	255	144.51	96.34	Yes

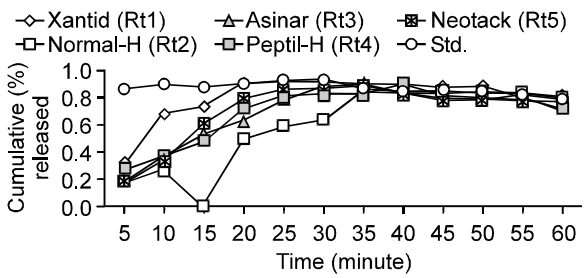

Fig. 1: Cumulative percentage of drug released vs. time in minutes of different brands of ranitidine HCl tablets

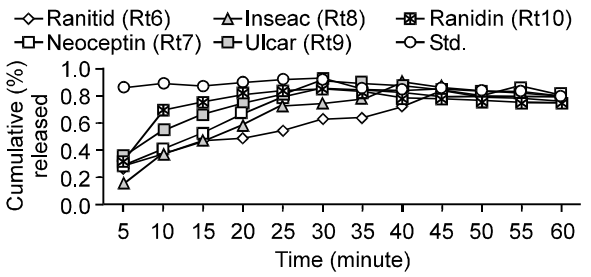

Fig. 2: Cumulative percentage of drug released vs. time in minutes of different brands of ranitidine HCl tablets

equivalent to not less than 90.0 percentage and not more than 110.0 percent of the labeled amount of Ranitidine (USP 23, 1995). From the result (Table 10), it was evident that 3 out of 10 brands of Ranitidine HCL

tablets (Rt1, Rt3 and Rt2) meet the specification of potency more than 100% and another 4 showed their a potency above 98% and rest of them also exceeded the specification of potency over 95%. From these results, it can be concluded that all the selected Ranitidine generics exhibited excellent potency according to USP specifications for potency test.

Conclusion: These results are the outcome of a random analysis of samples available in the market of Bangladesh. To maintain the quality of this pharmaceutical product, pharmaceutical companies should adhere to the USP requirements. In this country more than 50 Ranitidine HCl generics are being produced. However, testing samples from all these brands was beyond the scope of this study. The respective authority should strictly supervise the pharmaceutical products frequently with respect to standard quality procedures in order to supply quality generic products and safe guard the public health.

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