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DETERMINATION OF RANITIDINE HYDROCHLORIDE IN FIVE MARKETED TABLET PREPARATION

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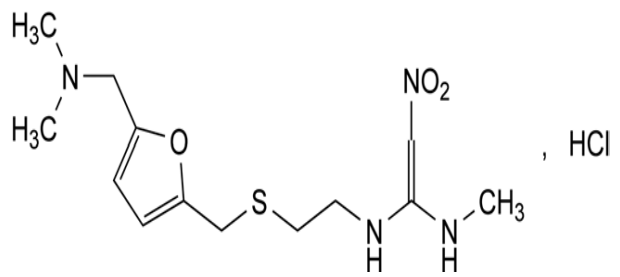
ABSTRACT

This study was aimed to evaluate the pharmaceutical quality of ranitidine hydrochloride in five randomly selected samples registered on the market of Bosnia and Herzegovina. This samples were assayed spectrophotometrically and their various physical parameters such as appaearance, weight variation and uniformity of dosage units. Acceptance criteria were set according to European Pharmacopoeia and British Pharmacopoeia (95 – 105% of claimed potency).

KEYWORDS: Ranitidine Hydrochloride, Spectrophotometric Assay, Physical Parameters.

INTRODUCTION

Ranitidine belongs to a group of drugs called H_2 receptor blockers. This group of drugs reduces the secretion of stomach acid required in the digestive process, but if excreted excessively it can cause a number of unpleasant gastrointestinal disorders. Ranitidine is a competitive reversible antagonist of the histamine H_2 receptor in the parenteral cells of the gastric mucosa. With this competitive blockade of histamine H_2 receptors, ranitidine inhibits basal and stimulating secretion of gastric acid. Reducing the total volume of gastric juice causes a proportional decrease in secretion of pepsin. Thus, ranitidine has a complex effect on upper GIT disorders caused by or accompanied by hypersecretion of gastric acid. Today, ranitidine has been successfully used in the trio terrain in patients with duodenal and ventricular ulcer caused by gram negative bacteria, Helicobacter pylori.[1]



Ranitidin hydrochloride, chemically, *E*)-1-*N*'-[2-[[5-[(dimethylamino)methyl]furan-2-yl]methylsulfanyl]ethyl]-1-*N*-methyl-2-nitroethene-1,1-diamine; hydrochloride. It is white or pale yellow, crystalline powder, hygroscopic., freely soluble in water, sparingly soluble or slightly soluble in anhydrous ethanol, very slightly soluble in methylene chloride. It shows polymorphism.[2]

MATERIAL AND METHODS

Ranitidine hydrochloride was from USP standard. Water was from Millipore system. As analytical equipment were used UV Spectrophotometer Shimadzu, Digital weighing balance Mettler Toledo and Ultra sonicator Sonis. To determine appearance, uniformity of mass, uniformity of dosage units and assay content of Ranitidine hydrochloride in conventional tablet available in Bosnian market, randomly select products and labeled as sample 1 to sample 5. Sample from 1 was 75 mg strength, sample 4 was 300 mg strength and samples from 2, 3 and 5 were 150 strength.

Physical Parameters

Appearance. Samples of 20 tablets from each batch were randomly selected and their properties analyzed such as color, shape, shape of the surface, the presence of the described grooves and monograms all on based on visual observation.

Uniformity of mass. Uniformity of mass was tested according to European Pharmacopoeia. Individually point to twenty randomly selected dosage forms, or if each one is one the preparation separately packaged takes up the contents of 20 packs, and calculates the average mass. Only two average masses may deviate more than the permissible percentage deviation, according to European Pharmacopoeia, and no average mass may deviate by more than twice values of permitted percentage of deviation.[3]

Uniformity of dosage units. The test for mass variation is applicable for film-coated tablets, containing 25 mg or more of an active substance comprising 25 per cent or more, by mass, of the dosage unit and calculate the acceptance value according European Pharmacopoeia 2.9.40.[4]

Selection of Analytical Wavelenth for Assay Determination

From the standard stock solution, a mixture of dilutions ranging between 7-11µl were prepared and scanned within the wavelength range of 500-400nm on spectrum mode, using water as blank. Ranitidine hydrochloride shows λ_{maax} at 313nm.

RESULTS AND CONCLUSION

Appearance

From these visual observations, we can say that all samples are of adequate appearance, without any flaws and damage (Figure 1). Detailed observations of the appearance of the tested samples are in Table 1.

Figure 1: Appearance of Tested Samples.

Table 1: Detailed Observations of The Appearance.

Parameter	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Shape and colour	Triangular, pink	Round, white	Round, pink	Round, white	Round, yellow
Surfaces	Biconvex, flat surfaces	Biconvex, flat surfaces	Biconvex, flat surfaces	Biconvex, flat surfaces	Biconvex, flat surfaces
Engraving	/	/	/	/	/
Damage	/	/	/	/	/

Uniformity of mass

From the below results, all the tested samples satisfy the criteria defined by the European Pharmacopoeia Requirement 2.9.5.

Table 2: Uniformity of Mass for Sample 1.

	mass (mg)	%	Deviation (%)
1.	153.65	96.81	3.19
2.	157.82	99.43	0.57
3.	159.16	100.28	-0.28
4.	164.66	103.74	-3.74
5.	157.93	99.50	0.50
6.	153.76	96.88	3.13
7.	157.99	99.54	0.46
8.	159.15	100.27	-0.27
9.	158.04	99.57	0.43
10.	164.67	103.75	-3.75
11.	157.95	99.51	0.49
12.	153.68	96.82	3.18
13.	164.66	103.74	-3.74
14.	158.02	99.56	0.44
15.	159.22	100.32	-0.32
16.	153.77	96.88	3.12
17.	159.23	100.32	-0.32
18.	158.23	99.69	0.31
19.	164.75	103.80	-3.80
20.	158.01	99.55	0.45
PMT	158.72		

Table 3: Uniformity of Mass for Sample 2.

	Mass (mg)	%	Deviation (%)
1.	275.29	101.75	-1.75
2.	273.50	101.09	-1.09
3.	267.11	98.72	1.28
4.	267.76	98.97	1.03
5.	268.80	99.35	0.65
6.	273.53	101.10	-1.10
7.	268.84	99.36	0.64
8.	267.10	98.72	1.28
9.	267.81	98.98	1.02
10.	275.44	101.80	-1.80
11.	275.47	101.81	-1.81
12.	268.88	99.38	0.62
13.	267.83	98.99	1.01
14.	267.15	98.74	1.26
15.	273.52	101.09	-1.09
16.	267.84	98.99	1.01
17.	273.58	101.12	-1.12
18.	268.95	99.40	0.60
19.	267.20	98.76	1.24
20.	275.50	101.83	-1.83
PMT	270.56		

Table 4. Uniformity of Mass for Sample 3.

	mass (mg)	%	Deviation (%)
1.	265.03	99.41	0.59
2.	268.04	100.54	-0.54
3.	269.22	100.98	-0.98
4.	265.29	99.50	0.50
5.	264.65	99.26	0.74
6.	265.20	99.47	0.53
7.	265.55	99.60	0.40
8.	269.41	101.05	-1.05
9.	268.34	100.65	-0.65
10.	264.90	99.36	0.64
11.	265.16	99.46	0.54
12.	264.80	99.32	0.68
13.	265.57	99.61	0.39
14.	269.30	101.01	-1.01
15.	268.33	100.65	-0.65
16.	265.53	99.59	0.41
17.	264.88	99.35	0.65
18.	268.32	100.64	-0.64
19.	265.27	99.50	0.50
20.	269.40	101.05	-1.05
PMT	266.61		

Table 5. Uniformity of mass for Sample 4.

	mass (mg)	%	Deviation (%)
1.	649.34	102.26	-2.26
2.	636.41	100.22	-0.22
3.	623.78	98.23	1.77
4.	633.33	99.73	0.27
5.	631.94	99.51	0.49
6.	649.44	102.27	-2.27
7.	633.30	99.73	0.27
8.	636.41	100.22	-0.22
9.	623.74	98.22	1.78
10.	632.00	99.52	0.48
11.	649.46	102.27	-2.27
12.	633.47	99.76	0.24
13.	632.11	99.54	0.46
14.	636.49	100.23	-0.23
15.	623.78	98.23	1.77
16.	623.82	98.24	1.76
17.	649.50	102.28	-2.28
18.	636.52	100.24	-0.24
19.	632.12	99.54	0.46
20.	633.45	99.75	0.25
PMT	635.02		

Table 6: Uniformity of mass for Sample 5.

	mass (mg)	%	Deviation (%)
1.	304.00	99.88	0.12
2.	308.72	101.43	-1.43
3.	302.41	99.36	0.64
4.	300.46	98.72	1.28
5.	306.03	100.55	-0.55
6.	304.00	99.88	0.12
7.	306.02	100.55	-0.55
8.	302.48	99.38	0.62
9.	308.74	101.44	-1.44
10.	300.53	98.74	1.26
11.	300.51	98.74	1.26
12.	308.75	101.44	-1.44
13.	306.06	100.56	-0.56
14.	302.42	99.36	0.64
15.	304.05	99.90	0.10
16.	304.02	99.89	0.11
17.	306.10	100.57	-0.57
18.	302.47	99.38	0.62
19.	300.55	98.75	1.25
20.	308.81	101.46	-1.46
PMT	304.36		

Uniformity of Dosage Units

From the below results, all tested samples meet the criteria defined by the European Pharmacopoeia 2.9.40. Acceptable values of parameter L are less than 15.

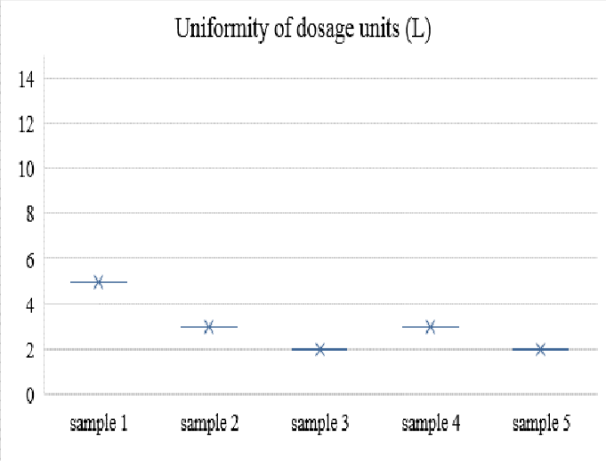


Figure 2: Uniformity of dosage units for tested samples.

Spectrophotometric Assay Determination

Appropriate aliqouts were pipette out from the standard stock solution into 10 ml volumetric flasks. Verification of method was tested in the range from 7 to 11 µg/ml, with linear relationship r=0.998 (Figure 3). From the below results, we see that all samples meet the quality requirements of the ICH 3AQ11a guidelines, Specifications and Control Tests on Finished Products, as well as BP requirements 95.0% -105.0%.[5]

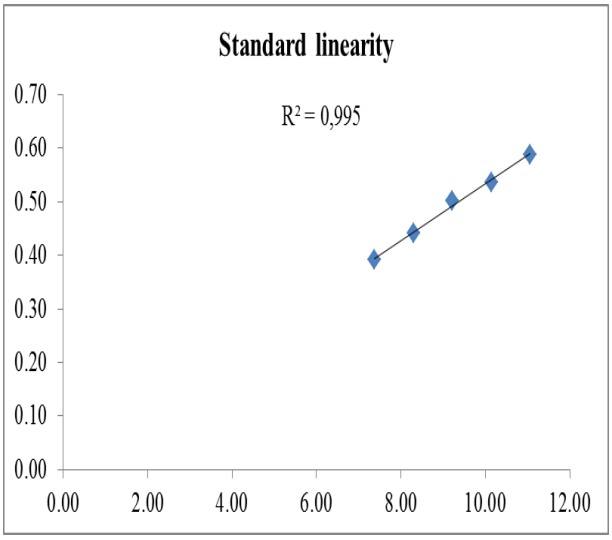


Figure 3: Standard calibration curve.

Table 7. Linearity data of Ranitidine hydrochloride.

Standard Solutions	Concentration (µg/ml)	Absorbance
1	7	0.3927
2	8	0.4414
3	9	0.5011
4	10	0.5356
5	11	0.5885

Table 8. Data Regarding Tested Samples.

	Apsorbanca	µg/ml	%	mg
Sample 1	0.5337	10.01	98.75	74.06
Sample 2	0.5306	9.95	98.17	147.26
Sample 3	0.5482	10.29	101.46	304.39
Sample 4	0.5535	10.39	102.46	153.68
Sample 5	0.5398	10.13	99.89	149.84

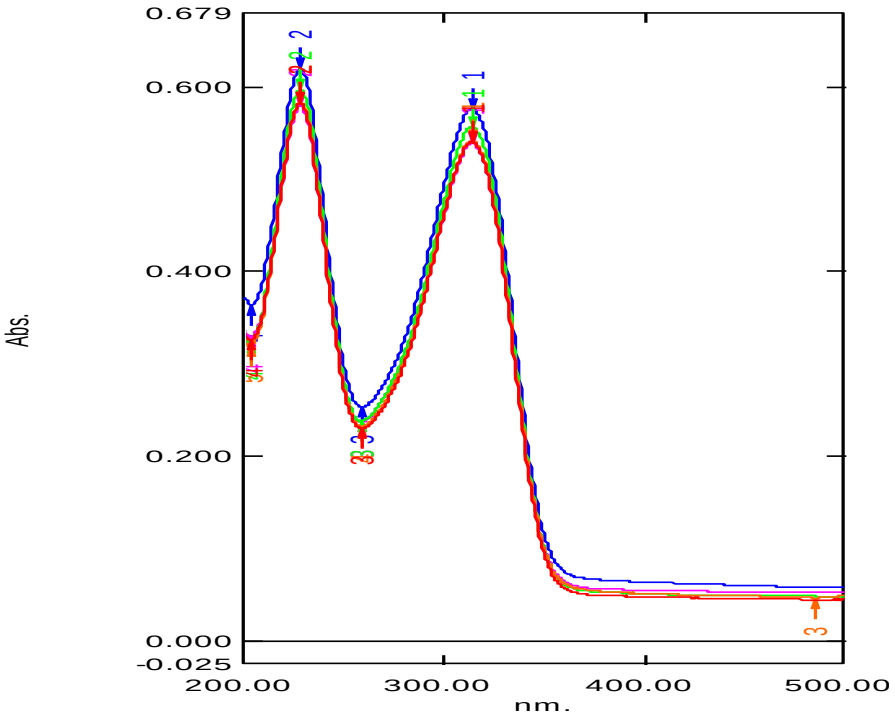


Figure 4: Wavelength of Ranitidine Hydrochloride Standard and Sample Solutions.

CONCLUSION

For Ranitidine hydrochloride tablets, official pharmacopoieses provide monographs that make it easy to set up specification requirements. The aim of this study was to demonstrated quality of Ranitidine hydrochloride tablets on Bosnian market. After the experimental work and the processing of results we can conclude all tested samples of Ranitidine hydrochloride tablets correspond to the appearance, uniformity of mass and uniformity of dosage units In the present investigation, a simple, sensitive spectrophotometric method was used for assay determination of Ranitidine hydrochloride tablets. This method can be used for the routine quantitative determination of Ranitidine hydrochloride in tablets.

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