HYDROGEN
JURNAL KEPENDIDIKAN KIMIA
https://e-journal.undikma.ac.id/index.php/hydrogen/index

April 2024. 12(2)
e-ISSN: 2656-3061
p-ISSN: 2338-6487
pp. 226-231

Analysis Of Ranitidine Hydrochloride Content In Drug X Samples Using A UV-Visible Spectrophotometry

Lilis Rosmainar & Manuel Yanwerico*
Department of Chemistry, Faculty of Mathematics and Natural Sciences, University of Palangka Raya, Kampus UPR Tunjung Nyaho, Jl. Yos Sudarso, Palangka Raya, Kalimantan Tengah, Indonesia 73111
* Corresponding Author e-mail: manuel.y.werico@gmail.com

Article History
Received: 13-03-2024
Revised: 08-04-2024
Published: 30-04-2024

Keywords: dissolution, ranitidine hydrochloride, UV-Vis spectrophotometry

Abstract
The development and progress of modern society cannot be separated from the availability of health medicines. Conventional medicinal products such as capsules and tablets are formulated to release active compounds immediately after consumption. Tablets are solid drug dosage forms consisting of one or more medicinal ingredients. One type of solid drug dosage form is ranitidine hydrochloride. Ranitidine hydrochloride belongs to a class of antagonist drugs that attack histamine H receptors$_2$ selectively and reversibly by reducing the process of secretion by gastric acid which is widely used for the treatment of stomach ulcers, intestinal ulcers (duodenum ulcers), Zollinger-Ellison syndrome, *Gastro Esophageal Reflux Disease* (GERD) and esophageal erosion. Determination of ranitidine hydrochloride levels was carried out using an ultraviolet spectrophotometer validation method with maximum absorption at a wavelength of ±314 nm. In UV spectrophotometer analysis, peaks were detected at wave number 313.80 nm with absorbance values of 0.425, 0.416, 0.421, 0.424, 0.413, and 0.418. The concentration results obtained for each sample were sample I 119.22%, sample II 116.70%, sample III 118.10%, sample IV 118.94%, sample V 115.85%, and sample VI 117.26% which fulfilled the requirements.

How to Cite: Rosmainar, L., & Yanwerico, M. (2024). Analysis of Ranitidine Hydrochloride Content In Drug X Samples Using A UV-Visible Spectrophotometry. Hydrogen: Jurnal Kependidikan Kimia, 12(2), 226-231. doi:https://doi.org/10.33394/hjkk.v12i2.11059

https://doi.org/10.33394/hjkk.v12i2.11059

INTRODUCTION

The development and progress of modern society cannot be separated from the availability of health medicines. A large number of finished drugs with the same active substance circulating in the community requires scientific proof of the quality of generic and branded generic drugs (Kusuma & Apriliani, 2018). Drugs are substances that are obtained chemically, from animals or vegetables with the effect of curing, alleviating, or preventing the following diseases with their symptoms at certain doses (Ismail & Kanitha, 2020). Conventional drug products such as capsules and tablets are formulated to release active compounds immediately after being consumed orally so that the process of systemic absorption of drugs takes place quickly and completely (Pradana et al., 2015). Tablets are solid drug dosage forms consisting of one or more medicinal ingredients. Tablets differ in size, shape, weight, hardness, or thickness (Ismail & Kanitha, 2020). One type of solid drug dosage form is ranitidine hydrochloride.

Ranitidine hydrochloride was first patented by Allen and Hanburys in 1977 and marketed in 1981 under the trade name Zantac (*N*-[2[[[5-[(dimethylamino)methyl]furan-2-y1]methyl]thio]ethyl]-*N*-methyl-2-nitroethane-1,1-diamine hydrochloride (Abbas & Rasheed, 2018). Ranitidine is a furan compound whose inhibitory power against acid secretion is stronger than cimetidine, but milder than proton pump inhibitors (omeprazole, lansoprazole).

Ranitidine drug preparations can be found in various forms such as tablets, injection solutions, and oral liquids (Chandra et al., 2018).

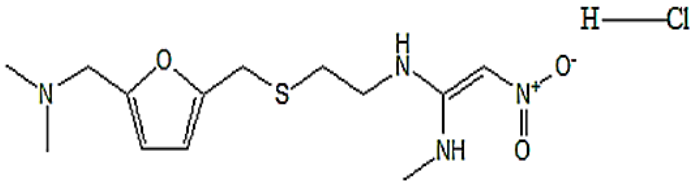


Figure 1. Ranitidine Hydrochloride Chemical Structure (Abbas & Rasheed, 2018)

Ranitidine hydrochloride belongs to a class of antagonist drugs that attack histamine H receptors$_2$ selectively and reversibly by reducing the process of secretion by gastric acid which is also widely used for the treatment of stomach ulcers, intestinal ulcers (*duodenum ulcers*), Zollinger-Ellison syndrome *Gastro Esophageal Reflux Disease* (GERD) and esophageal erosion (Pradana et al., 2015). The recommended oral dose of ranitidine hydrochloride is 150 mg (2 times a day) or 300 mg (1 time a day). Giving a dose of 150 mg ranitidine hydrochloride can inhibit gastric acid secretion if the dose is increased it will cause fluctuations in plasma. Ranitidine hydrochloride has a very short half-life of 2.5-3 hours which is adsorbed in the early part of the small intestine with an absolute bioavailability of 50% (Wahyuni et al., 2018).

The bioavailability of solid drug preparations is determined based on two important parameters, namely the destruction of the drug (solubility) and the absorption of the active drug substance (permeability) (Cascone, 2017). Therefore, in-vitro dissolution testing plays an important role in the creation of new formulations and the development of more efficient drug dosage forms. Dissolution testing is carried out to understand the kinetics of the release of active drug ingredients into liquid media (under standard conditions of temperature, agitation, flow rate, volume, and composition of the media) in solid or semisolid dosage forms. The dissolution method should be based on the physical and chemical properties of the drug. Some of the physical and chemical properties of drug substances are (a) solubility in water and other suitable solvents, (b) ionization constant, (c) dissolution stability, (d) particle size/surface area, (e) crystal form, (f) ionic effect, (g) ionic strength, (h) buffering effect, (i) octanol/water partition coefficient, and (j) effect of temperature on solubility (Gray & Rosanske, 2020).

Figure 2. Dissolution Instrument

The introduction should contain (in order) the general background, a review of the previous literature (state of the *art*) as the basis for the statement of the scientific novelty of the article, the statement of scientific novelty, and the problem of research or hypothesis. At the end of the introduction should be written the purpose of the review of the article. In the format of scientific

articles, there is no literature review as in the research report, but it is manifested in the form of a review the previous literature (*state of the art*) to show the scientific novelty of the article.

In addition to determining the level of bioavailability of a drug through the dissolution method, the determination of ranitidine hydrochloride levels in tablet formulations can be carried out using the ultraviolet spectrophotometer validation method with maximum absorption at a wavelength of 313.5 nm (Chandra et al., 2018).

METHOD

The materials used in this research were Aquades, Reference Standard For Ranitidine Hydrochloride BPFI, Brand X Ranitidine Hydrochloride Drug Samples, Glassware, Pipettes, Instrument UV-Vis Spectrophotometer (Shimadzu UV-1900), and Dissolution.

Determination of ranitidine hydrochloride levels was carried out by taking 6 samples of brand x ranitidine hydrochloride drugs which were put into the vessel. The dissolution medium used was 900 mL of distilled water. The dissolution test used ranitidine hydrochloride tablets using a type 2 dissolution apparatus (*paddle method*) at 50 rpm for 45 minutes.

The dissolution media solution was taken and the sample and standard levels were measured using a UV spectrophotometer at a maximum wavelength of ±314 nm. The absorbance value obtained is used to calculate the ranitidine hydrochloride level in drug sample x through the following equation:

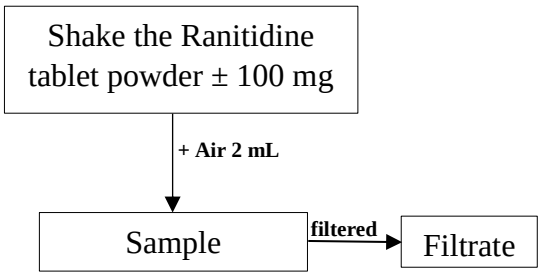
$$\text{Correction rate} = \frac{100-\text{Moisture Content}}{100} \times \text{Raw grade} \quad \ldots\ldots\ldots\ldots \text{ f1)}$$

$$\text{Multiplication factor (Fk)} = V \times \frac{Fu \times Bb \times Kb}{Fb \times Ab \times Ke} \times 100\% \quad \ldots\ldots\ldots\ldots \text{ f2)}$$

$$\text{Solutes (Dx)} = Fk \times Au \quad \ldots\ldots\ldots\ldots\ldots\ldots \text{ f3)}$$

Notes that V: Volume (mL); Fu: Dilution Factor; Bb: Standard Weight; Kb: Purity/Correction Level (%); Fb: Standard Dilution Factor; Ab: Standard Absorbance; Ke : Etiquette Level (mg); and Au : Absorbance Test

a) Identification



b) Disolution

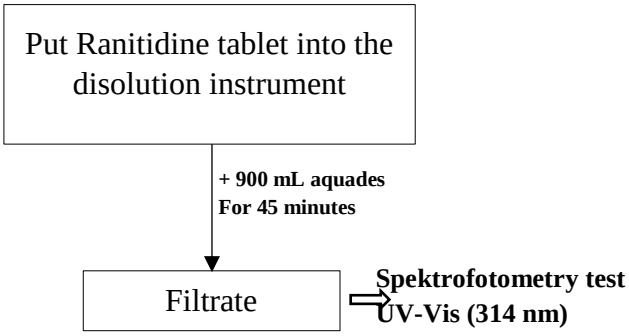


Figure 3. Flowchart for determining Ranitidine Hidrocloride levels

RESULTS AND DISCUSSION

The dissolution test was carried out for 45 minutes provided that it must dissolve not less than 80% of the amount stated on the label. 6 samples of ranitidine hydrochloride brand X were tested for dissolution using dissolution media in the form of distilled water which is classified as an environmentally friendly solvent. The sample was checked for absorbance using a UV spectrophotometer at a maximum wavelength of ±314 nm.

In the UV spectrophotometer analysis of ranitidine hydrochloride brand X, the peak was detected at a wave number of 313.80 nm with an absorbance value of 0.425 (Figure 3). This analysis was carried out using standard reference ranitidine hydrochloride at a wavenumber of 313.80 nm with an absorbance value of 0.362 (Figure 4).

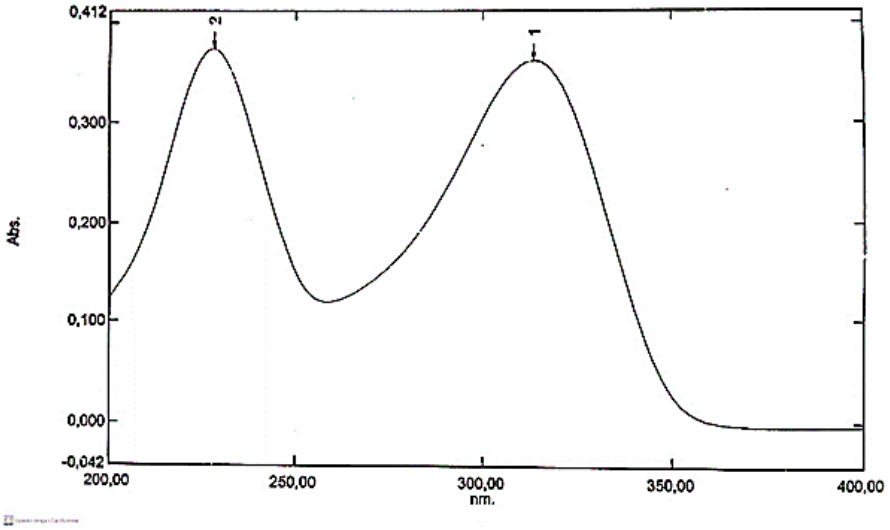


Figure 4. Results of Ranitidine Hydrochloride Standard UV Spectrophotometer Analysis

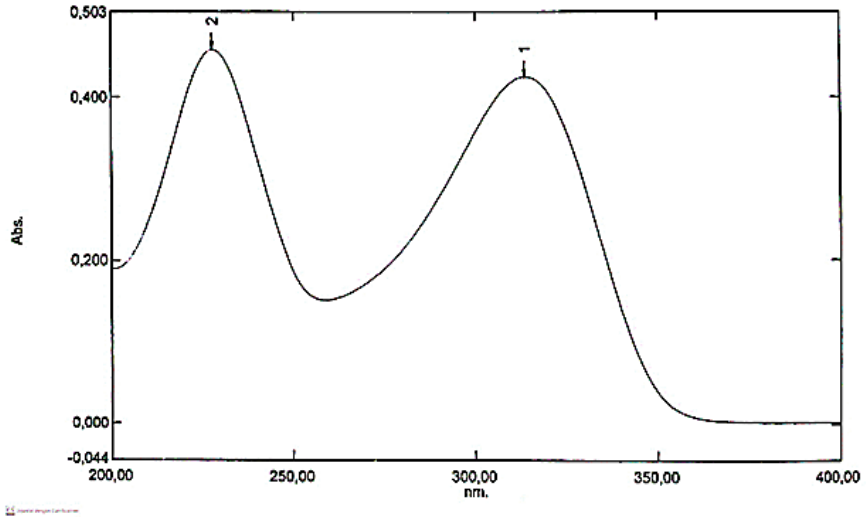


Figure 5. Result of UV Spectrophotometer Analysis of Drug Samples X

Measuring the levels of ranitidine hydrochloride in brand x solid drug preparations was carried out by calculating the levels using the absorbance values that had been obtained. The absorbance value obtained is used to calculate the levels of dissolved active substances in drug samples. Based on the absorbance obtained, concentration levels were calculated using formula 1), 2), and 3). The results showed in table 2.

Table 1. Absorbance Value of Ranitidine Hydrochloride in Drug Samples X

Substance	Absorbance
1	0.425
2	0.416
3	0.421
4	0.424
5	0.413
6	0.418

Table 2. Calculation Results of Ranitidine Hydrochloride Levels in Drug Samples X

Substance	Weight (mg)	Absorbance	FP	Purity (%)	Etiquette Level (mg)	Volume (mL)	Levels (%)
1	5.321	0.425	20	99.41	150	900	119.22
2		0.416	20	99.41	150	900	116.70
3		0.421	20	99.41	150	900	118.10
4		0.424	20	99.41	150	900	118.94
5		0.413	20	99.41	150	900	115.85
6		0.418	20	99.41	150	900	117.26

Table 2 shows that the Ranitidine Hidrocloride level in sample 1 have a higher concentration (119.22%) and sample 5 has the lowest (115.85%). But, all of the sample drug already meets the requirements according to the standard, namely $Q_{30} \geq 80\%$.

CONCLUSION

Testing samples of ranitidine hydrochloride brand x using a UV spectrophotometer with a wave number of 313.80 nm, showed the absorbance values of each sample were 0.425, 0.416, 0.421, 0.424, 0.413, and 0.418.

Testing samples of ranitidine hydrochloride drug brand X showed the levels in each sample, namely sample I 119.22%, sample II 116.70%, sample III 118.10%, sample IV 118.94%, sample V 115.85%, and sample VI 117.26% which fulfilled the requirements.

RECOMMENDATIONS

There are no potential problems reported by the author.

ACKNOWLEDGEMENTS

The author thanks to Palangka Raya University for helping and guiding in the process of analyzing ranitidine hydrochloride drug samples.

BIBLIOGRAPHY

Abbas, M. A., & Rasheed, A. S. (2018). Retention Characteristic Of Ranitidine Hydrochloride On New Polymer-Based In Zwitter Ion Chromatography-Hydrophilic Interaction Chromatography Stationary Phases. *Journal of the Chemical Society of Pakistan*, *40*(1).

Cascone, S. (2017). Modeling and Comparison Of Release Profiles: Effect Of The Dissolution

Method. *European Journal of Pharmaceutical Sciences*, *106*, 352–361.

Chandra, B., Rivai, H., & Marianis. (2018). Pengembangan Dan Validasi Metode Analisis Ranitidin Hidroklorida Tablet Dengan Metode Absorbansi Dan Luas Daerah Di Bawah Kurva Secara Spektrofotometri Ultraviolet. *Jurnal Farmasi Higea*, *8*(2).

Gray, V. A., & Rosanske, T. W. (2020). *Dissolution*.

Ismail, F., & Kanitha, D. (2020). Identifikasi Dan Penetapan Kadar Pentoxyfillin Dalam Sediaan Tablet Secara Spektrofotometri Fourier Transform Infrared (FT-IR) Dan Spektrofotometri Uv-Visibel. *Jurnal Farmagazine*, *7*(2).

Kusuma, D., & Apriliani, E. D. (2018). Evaluasi Fisik Tablet Parasetamol Generik dan Tablet Parasetamol Bermerk Dagang. *Jurnal Kefarmasian Akfarindo*, *3*(1), 1–7.

Pradana, A. T., Parfati, N., & Shira, S. A. (2015). Formulasi Floating Tablet Menggunakan Variasi Konsentrasi HPMCK100M Terhadap Kemampuan Mengapung dan Profil Disolusi Tablet Ranitidine HCl. *Jurnal Sains & Teknologi*, *9*(1).

Wahyuni, Y. S., Lely, N., & Oktariani, S. (2018). Formulasi Tablet Sistem Floating Ranitidin HCl Menggunakan Polimer Kombinasi HPMC dan Pektin. *Jurnal Ilmiah Bakti Farmasi*, *3*(2), 35–44.