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Development and Validation of Omeprazole Analysis Methods in Capsules with Absorbance Methods and Areas under Curves Methods with UV-Vis Spectrophotometry

Harrizul Rivai[1*], Rizqa Hasanah[2], Zikra Azizah[2]

[1]Faculty of Pharmacy, Andalas University, Limau Manih Campus, Padang 25163, Indonesia
E-mail address: harrizul@phar.unand.ac.id and harrizul@yahoo.co.id
[2]School of Pharmaceutical Science, Jl. Tamansiswa No. 9, Padang 25138, Indonesia
E-mail address: rizqahasanah30@gmail.com

Abstract

Two simple spectrophotometric methods have been developed to analyse omeprazole in the capsule. This method uses sodium hydroxide 0.1 N as a solvent. The absorbance method was performed at a wavelength of 304.80 nm and the under-curve area method was performed at wavelengths between 281.60 nm-333.60 nm. The linearity of both methods was obtained at a concentration range of 10 µg / mL - 18 µg / mL. The absorbance method shows the correlation coefficient of 0.9998 and the area-under-curve method shows the correlation coefficient of 0.997. The percentage of generic omeprazole capsules with absorbance method was 105.48% and with the method of area under the curve was 102.87%. The percentage of omeprazole capsules of the trademark obtained by absorbance method was 104.02% and by the method of area under the curve was 103.62%. Percentage of both samples meets the requirements of Pharmacopoeia Indonesia edition V that is 90% -110%. The average per cent of recovery obtained from both samples with the absorbance method and the area under the curve satisfy the requirements of the validation parameter, i.e., 80% -120%. The relative standard deviation for both methods is <2%. Statistical analysis showed that between the absorbance method and the area under the curve did not differ significantly (sig. 2-tailed> 0.05).

Keywords: methods of absorbance, methods of area under the curve, omeprazole, UV-Vis spectrophotometry

1. Introduction

Omeprazole is a substituted benzimidazole group that inhibits the production of stomach acid by the binding of H^+, K^+, and ATPase which are essential for acid secretion by parietal cells. In addition, when omeprazole is added, the protons will bind the proton pump irreversibly. Therefore, omeprazole inhibits the secretion of basal gastric acid and inhibits secretion very effectively (Radde & Macleod, 1999).

Omeprazole has molecular formula $C_{17}H_{19}N_3O_3S$ and molecular weight 345.42 g/mol. Chemically, omeprazole is 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2 pyridinyl) methyl] sulfinyl] benzimidazole as presented in Figure 1. The chemical properties for omeprazole are white to almost white powder, melt at 150 to 160 ºC with decomposition, soluble in dichloromethane, rather soluble in methanol and in ethanol; very difficult to dissolve in water (Kementerian Kesehatan, 2014).

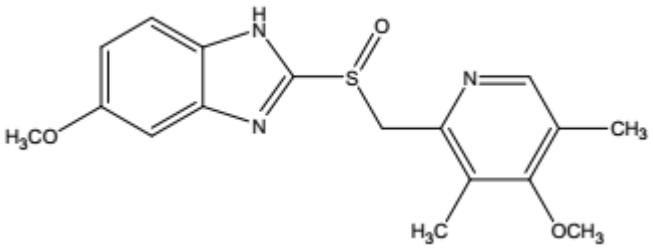

Figure 1: Chemical structure of omeprazole

Determination of omeprazole levels can be performed with high performance liquid chromatography (HPLC), high performance thin layer chromatography (HPTLC), polarography and spectrophotometry (Ozaltin & Kocer, 1997; Bhuva & Patel, 2012; Karljikovic-Rajic *et al*., 2003). Several other methods have also been used for the determination of omeprazole levels as pharmaceutical raw materials, including: direct method, using flow injection system, photo degradation method, complex formation, trophotometric method, polarography, differential and voltammetry (Salama *et al*., 2003). The determination of omeprazole levels in pharmaceutical preparations has been carried out by various methods such as capillary electrophoresis, TLC and HPTLC (Wahbi *et al*., 2002).

Various methods of omeprazole analysis that have been done generally take a long time, involving expensive instrumentation and the use of organic solvents are excessive and toxic. As an alternative to existing methods, it is necessary to develop and validate the omeprazole analysis method and determine the levels of omeprazole in pharmaceutical preparations using the relatively cheap, simple and simple method of UV-Vis spectrophotometry. This method is expected to be useful as quality control and quality assurance of pharmaceutical preparations (Bhandage *et al*., 2009).

Among the various methods used in the determination of drug levels, UV-Vis spectrophotometry is still very popular. In our previous research we have developed several analytical methods using the absorption method and the area measurement method under the curve with ultraviolet-visible spectrophotometry (Rivai *et al*., 2017a; Rivai *at al*., 2017b; Rivai *et al*., 2017c; Chandra *et al*., 2017; Chandra *et al*., 2016; Asra *et al*., 2016). In this research, the best solvent search for omeprazole analysis was done, and then developed method for determination of omeprazole concentration by UV-Vis spectrophotometry. The method developed is the method of absorbance and method of area under the curve.

2. Materials and Methods

2.1 Tools and materials

The instruments used were UV-Vis spectrophotometry set (Shimadzu 1800), Analytical scales (Precisa), sonicator (Branson), funnel, measuring cup (Iwaki), measuring pipette (Iwaki), dropper pipette, spatula, measuring flask (Iwaki) , filter paper (Whatman No. 41), mortars, stamfer and glass tools that support the research. Materials used in this study were omeprazole pellets (Hetero Corporate), omeprazole trademark (PT Ifars), generic omeprazole (PT Novell), potassium dihydrogen phosphate (Merck), potassium biphthalate (Merck), distilled water, hydrochloric acid (Merck)), sodium hydroxide (Merck).

2.2 Preparation of reagent solution

2.2.1 Phosphate buffer solution pH 7.2

50 mL of 0.2 M dihydrogenphosphate potassium solution was mixed with 34.7 mL of 0.2 N sodium hydroxide solutions in a measuring flask, then diluted with distilled water up to 200 mL (Kementerian Kesehatan, 2014).

2.2.2 Phthalate buffer solution pH 3.0
50 mL of 0.2 M potassium biphthalate solution was mixed with 22.3 mL 0.2N hydrochloric acid in a measuring flask and diluted with distilled water up to 200 mL (Kementerian Kesehatan, 2014).

2.2.3 Preparation of 0.1 N hydrochloric acid solutions
Dilute 85 ml of concentrated hydrochloric acid with distilled water up to 1000 mL. Pipette 100 mL of this solution, put in 1000 mL measuring flask, and add carbon dioxide-free distilled water to the limit mark (Kementerian Kesehatan, 2014).

2.2.4 Preparation of 0.1 N sodium hydroxide solutions
Thoroughly weighed 2 grams of sodium hydroxide were then fed into a 500 mL measuring flask and then added and treated with distilled water up to 500 mL, then the mixture filtered with Whatman No 41 filter paper (Kementerian Kesehatan, 2014).

2.3 Preparation of omeprazole stock solution 1000 µg / mL

2.3.1 Stock solution in phosphate buffer solvent pH 7.2
Standardized omeprazole solution of 1000 µg / mL was prepared by weighing 100 mg of pure omeprazole using an analytical scale, fed into a 100 mL measuring flask, then partially added phosphate buffer pH 7.2 shaken until dissolved, then supplied with phosphate buffer pH 7, 2 to the limit mark (Kumaraswamy *et al.*, 2010).

2.3.2 Stock solution in phthalate buffer solvent pH 3.0
The standard solution of omeprazole at 1000 µg / mL was prepared by weighing 100 mg of pure omeprazole using an analytical scale, fed into a 100 mL measuring flask, then partially added a phthalate buffer of pH 3.0 shaken until dissolved, then supplied with phthalate buffer pH 3.0 to boundary mark (Kumaraswamy *et al*., 2010).

2.3.3 Stock solution in a 0.1 N hydrochloric acid solvent
The standard solution of omeprazole at 1000 µg / mL was prepared by weighing 100 mg of pure omeprazole using an analytical scale, put into a 100 mL measuring flask, then partially added 0.1 N HCl, shaken, then supplied with 0.1 N HCl until boundary mark (Kumaraswamy *et al*., 2010).

2.3.4 Stock solution in 0.1 N sodium hydroxide solvent
The standard solution of omeprazole at 1000 µg / mL was prepared by carefully weighing 100 mg of pure omeprazole using an analytical scale, fed into a 100 mL measuring flask, then partially added 0.1 N NaOH, shaken until dissolved, then supplied with 0.1 N NaOH N to the limit (Kumaraswamy *et al*., 2010).

2.4 Determination of maximum absorption wavelength omeprazole
Each 1000 µg / mL omeprazole parent solution prepared with four various solvents (phosphate buffer pH 7.2, phthalate buffer pH 3.0, 0.1 N NaOH, and 0.1 N HCl) was diluted to a solution concentration of 100 µg / mL by measuring with a pipette of 1 mL of the solution, feed into a 10 mL measuring flask and dilute it with each solvent until the boundary marks, then homogenize. Then each solution of omeprazole 100 µg / mL with a variety of solvents, pipetted with 1 mL measuring pipette into a 10 mL measuring flask and then sufficient with each solvent to the limit, shake homogeneously to obtain a concentration of 10 µg / mL. Measure the absorbance in the wavelength range 200-400 nm with the UV-Vis spectrophotometer to obtain the maximum wavelength omeprazole (Kumaraswamy *et al*., 2010).

2.5 Preparation of the calibration curve of omeprazole
Five series of omeprazole solutions were prepared with concentrations of 10 µg / mL, 12 µg / mL, 14 µg / mL, 16 µg / mL, 18 µg / mL used for the manufacture of calibration curves. The standard solution of omeprazole

1000 µg / mL was piped in 1 mL to prepare the standard solution of omeprazole with a concentration of 100 µg / mL, after which the standard omeprazole solution of 100 µg / mL pipetted as much as 1 mL, 1.2 mL, 1.4 mL, 1, 6 mL, and 1.8 mL, put each into a 10 mL measuring flask, diluted with 0.1 N NaOH and suffice up to the boundary mark. Measure the absorbance and area under the curve with UV-Vis spectrophotometry at a wavelength of 304.80 nm. Then find the linear regression equation of the omeprazole (Kumaraswamy et al., 2010).

2.6 Determination of omeprazole levels in capsules

The sample solution was prepared by taking each of the 20 generic omeprazole capsules and the tradable omeprazole, then each of them was crushed until smooth and weighed a total weight of 20 capsules. The weight of 20 capsules for generic omeprazole is 5.3089 g and the omeprazole trademark is 4.7281 g. Then the sample was weighed equivalent to 100 mg of omeprazole, for generic omeprazole the weight weighed was 1.327 g and for omeprazole trademark was 1.1820 g. Both samples were dissolved in 0.1 N NaOH in a 100 mL measuring flask, then added solvent to the limit, sonication for about 15 minutes, and the solution was filtered using Whatmann no 41 paper.

This sample solution was piped in 1 mL and put into a 10 mL measuring flask, diluted with 0.1 N NaOH to the limit mark, homogeneous shake. After that, the solution was re-piped 1 mL, put into a 10 mL measuring flask, 0.1 N NaOH added to the limit mark and shake homogeneously to obtain a concentration of 10 µg / mL. Measure the absorbance and area under the curve at a wavelength of 304.80 nm with UV-Vis spectrophotometry. Determine the sample content based on the obtained linear omeprazole linear regression equation (Kumaraswamy *et al*., 2010).

2.7 Validation of analytical methods

2.7.1 Test linearity

From the measurement data calibration curve, then analysed with linear regression so that obtained correlation coefficient (r) which shows the linearity. The good linearity value is $0.995 \leq r \leq 1$ (Harmita, 2012).

2.7.2 Limit detection and limit quantization tests

The detection limit (LOD) and the quantification limit (LOQ) determined the regression of the standard curve obtained. The value of LOD = 3.3 (S_{yx}/S) and LOQ = 10 (S_{yx}/S). S_{yx} is the standard deviation of response determined based on residual deviation standard (residual standard deviation). S is the value of the slope of the line or linear regression y = a + bx (Harmita, 2012).

2.7.3 Test accuracy

The preparation of the sample solution for accuracy was made by weighing a sample equivalent to 100 mg of pure powder, put into a 100 mL measuring flask, then weighing 80%, 100% and 120% pure omeprazole powder of the sample mean weight, inserted into a measuring flask and dissolved with 0.1 N NaOH to the limit marker, sonication for approximately 15 minutes, and the solution was filtered using Whatmann no 41 paper. From this solution, 5.5 mL, 5 mL and 4.5 mL of solution taken, then put into a 10 mL measuring flask, diluted with 0.1 N NaOH to the limit mark, shake until homogeneous. Thereafter, re-pelleted as much as 1 mL into a 10 mL measuring flask is sufficient with a 0.1 N NaOH solvent to a limit marker and a homogeneous shake. Thereafter, the solution was pierced 1 mL, put into a 10 mL measuring flask, 0.1 N NaOH solvent added to the limit mark and shake until homogeneous. Measure the absorbance and area under the curve at a wavelength of 304.80 nm with UV-Vis spectrophotometry (Harmita, 2012).

2.7.4 Precision test

The precision test is performed at the repeatability level by measuring the standard omeprazole solution with repeatability 3 times each. Precision testing was performed by measuring standard omeprazole solution concentrations at 14 µg / mL, 16 µg / mL and 18 µg / mL. Measurements of omeprazole levels were performed at 3 different times of the day (intraday) with repetitions of each 3 times as well as measurement of standard

omeprazole solutions of the same concentration. The omeprazole concentration was performed on 3 consecutive days (interday) with repetition of each 3 times (Harmita, 2012).

2.8 Data analysis

2.8.1 Determination of omeprazole levels
Omeprazole levels in the capsule were determined based on the linear regression equation y = a + bx.

$$a = \frac{\sum y - b\sum x}{n}$$

$$b = \frac{n\sum xy - \sum x.\sum y}{n\sum x^2 - (\sum x)^2}$$

Information:
y = absorbance / area under the curve
x = concentration (µg / mL)
a = intercept / intersection on the Y axis
b = slope

2.8.2 Linearity
Linearity is determined by the value of the correlation coefficient (r) of the regression equation y = a + bx.

$$r = \frac{\sum x_i y_i - \sum x_i \sum y_i / n}{\sqrt{\sum (x_i - \bar{x})^2 \sum (y_i - \bar{y})^2}}$$

This regression equation can be used if the correlation factor is $0.995 \leq r \leq 1$ (Rohman, 2007).

2.8.3 Limit of detection (LOD) and limit of quantitation (LOQ)
Limit of detection and limit of quantification can be determined by:

$$LOD = \frac{3.3\ Sy/x}{b}$$

$$LOQ = \frac{10\ Sy/x}{b}$$

2.8.4 Accuracy
Accuracy is measured as the number of recovered analytes.
Per cent recovery = (CF-CA) / (C * A) x 100
Information:
CF = total concentration of the sample obtained from the measurement
CA = actual sample concentration
C * A = concentration of analyte added
The validation method is eligible if the per cent of return is 80% - 120% (Rohman, 2007).

2.8.5 Precision
Precision is expressed by a percentage of relative standard deviation (RSD) or per cent coefficient of variation. Per cent of RSD is said to meet the validation method if the RSD value is between 1-2% (Rohman, 2007).

2.8.6 Statistical analysis of research data
Statistical analyses were performed on sample levels, recovery, interday and intraday precision of both methods on each sample. In this research, two paired samples were t-tested using SPSS 20 (Jones, 2010).

3. Results and Discussion

3.1 Best solvent

Figure 2 shows an omeprazole absorption spectrum of 10 µg / mL in a 0.1 N NaOH solvent with a maximum wavelength of 304.80 nm and an absorbance of 0.341.

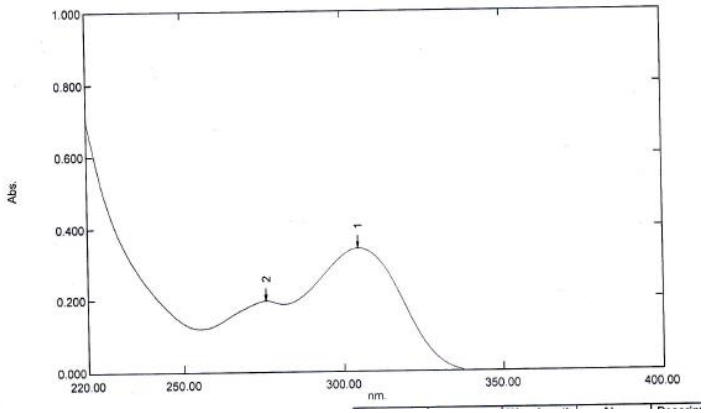

Figure 2: The omeprazole absorption spectrum of 10 µg / mL in a 0.1 N NaOH solvent

Figure 3 shows the omeprazole absorption spectra of 10 µg / mL in a 0.1 N HCl solvent with a maximum wavelength of 275.60 nm and an absorbance of 0.148.

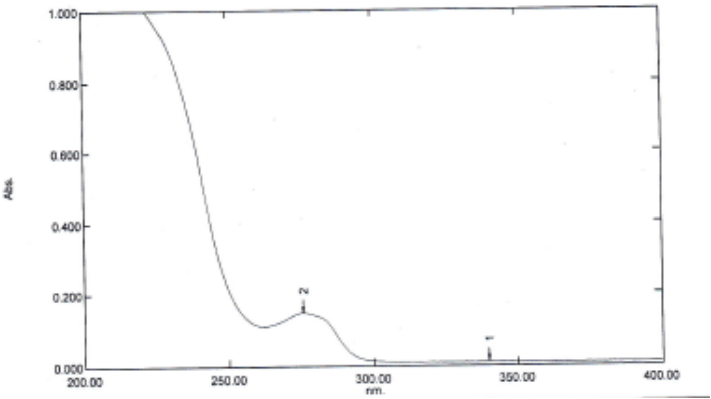

Figure 3: Omeprazole absorption spectra of 10 µg / mL concentration in 0.1 N HCl solvent

Figure 4 shows the omeprazole absorption spectra of 10 µg / mL in phosphate buffer pH 7.2 with a maximum wavelength of 229.40 nm and an absorbance of 0.148.

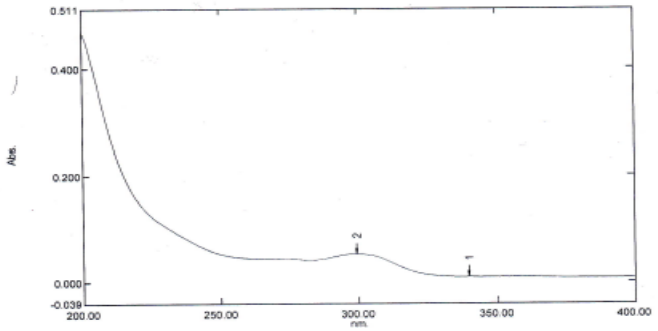

Figure 4: The omeprazole absorption spectra of 10 µg / mL in phosphate buffer pH 7.2.

Figure 5 shows an omeprazole absorption spectrum of 10 µg / mL in a phthalate buffer of pH 3.0 with a maximum wavelength of 215.00 nm and an absorbance of -2.989.

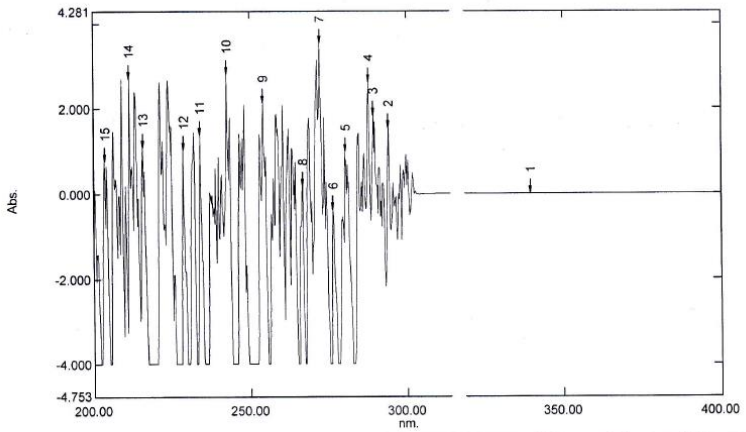

Figure 5: The omeprazole absorption spectra of 10 µg / mL in phthalate buffer pH 3.0.

The best solvent determination used for omeprazole analysis was used four types of solvents, among which 0.1 N NaOH, 0.1 N HCl, phosphate buffer pH 7.2 and phthalate buffer pH 3.0. The best solvents of some solvents are seen from several criteria, including the results of the maximum wavelength omeprazole in the solvent that approaches the maximum wavelength of omeprazole in the literature, the absorbance value that enters the range (0.2-0.8), the shape of the spectrum that resembles bells, solvents are not toxic, solvents can dissolve substances completely and environmentally friendly solvents. The best solvent determination result showed that the best solvent of omeprazole for analysis in this study was 0.1 N NaOH.

3.2 Calibration curves

Figure 6 shows an omeprazole calibration curve in a 0.1 N NaOH solvent at a wavelength of 304.80 nm with an absorbance method. This calibration curve was made with concentration of 10 µg / mL, 12 µg / mL, 14 µg / mL, 16 µg / mL and 18 µg / mL and obtained by linear regression equation y = 0,05060 x - 0,18272.

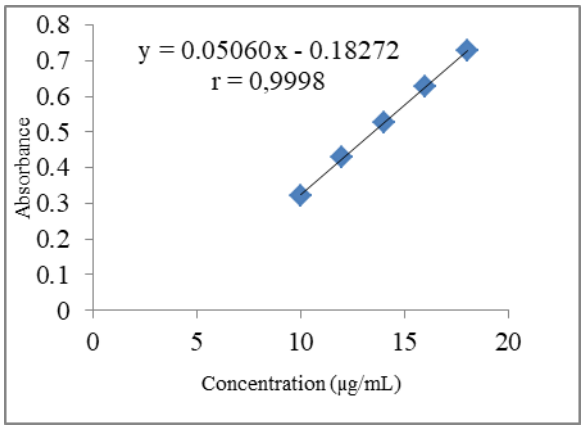

Figure 6: Omeprazole calibration curve in 0.1 N NaOH solvent at wavelength 304.80 nm with absorbance method

The calibration curve of omeprazole solution in a 0.1 N NaOH solvent was prepared in five series of concentrations. The concentrations made were 10 µg / mL, 12 µg / mL, 14 µg / mL, 16 µg / mL and 18 µg / mL. In the absorbance measurement of each solution obtained values of 0.321, 0.428, 0.527, 0.626, and 0.727, so obtained linear regression equation for the absorbance of y = 0.05060 x - 0.18272. On the measurement of area under the curve obtained the area of each solution of 5.479, 7,215, 8,842, 10,195, and 12,082, so obtained linear regression equation for the area under the curve that is y = 0.809 x - 2.567.
Figure 7 shows the omeprazole calibration curve in a 0.1 N NaOH solvent at a wavelength of 304.80 nm with a method of area under the curve. This calibration curve was made with concentration of 10 µg / mL, 12 µg / mL, 14 µg / mL, 16 µg / mL and 18 µg / mL and linear regression equation was y = 0,809 x - 2,567.

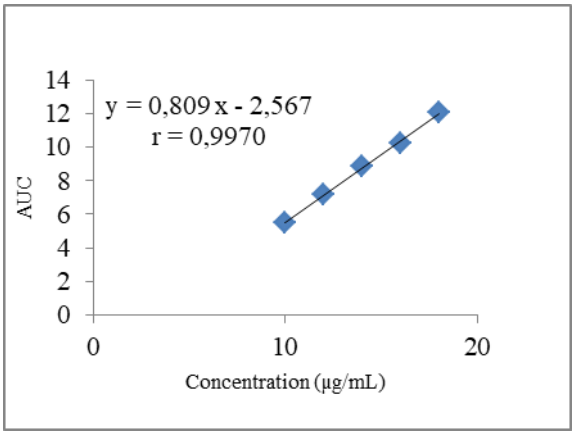

Figure 7: Omeprazole calibration curve in 0.1 N NaOH solvent at wavelength 304.80 nm by method of area under the curve

3.3 Omeprazole levels in capsules

In the determination of generic omeprazole level in capsule with absorbance method obtained level of 105,48% ± 0,007%, whereas with method of area under the curve obtained level of 102,87% ± 0,012%. In the determination of omeprazole value of trade name in capsule with absorbance method obtained omeprazole level of 104.03% ± 0.005%, whereas with the method of area under the curve obtained omeprazole level of 103.62% ± 0.027%.

In Table 1, the result of determination of generic omeprazole content with absorbance method showed an average level of 105.48% with SD value of 0.007%.

Table 1: Determination of generic omeprazole levels by absorbance method

No	Absorbance	Levels obtained (µg/mL)	Levels obtained (%)
1.	0.352	10.568	105.67
2.	0.354	10.607	106.07
3.	0.347	10.469	104.69
Average			105.48
SD			0.007

In Table 2, the result of determination of generic omeprazole content with the method of area under the curve obtained an average level of 102.87% with an SD value of 0.012%.

Table 2: Determination of generic omeprazole levels by area under the curve method

No	AUC	Levels obtained (µg/mL)	Levels obtained (%)
1.	5.787	10.326	103.26
2.	5.829	10.378	103.78
3.	5.650	10.157	101.57
Average			102.87
SD			0.012

Table 3 shows the results of the determination of omeprazole level of trademark with absorbance method of 104.02% with an SD value of 0.005%.

Table 3: Determination of omeprazole levels of the trademark by the absorbance method

No	Absorbance	Levels obtained (µg/mL)	Levels obtained (%)
1.	0.341	10.350	103.50
2.	0.345	10.429	104.29
3.	0.345	10.429	104.29
Average			104.02
SD			0.005

Table 4 shows the results of the determination of the omeprazole content of the trademark with the method of area under the curve obtained an average level of 103.62% with an SD value of 0.0027%.

Table 4: Determination of the trademark omeprazole content by the method of the area under the curve

No	AUC	Levels obtained (µg/mL)	Levels obtained (%)
1	5.566	10.053	100.53
2	5.935	10.509	105.09
3	5.947	10.524	105.24
Average			103.62
SD			0.0027

3.4 Methods validity

3.4.1 Linearity

Linearity is determined by processing the relationship data between concentration (x) with absorbance (y) and concentration (x) with the area under the curve (y) obtained from the calibration curve using linear regression equation, to obtain correlation coefficient value. The result of linearity measurement omeprazole with absorbance method obtained r value = 0.9998, whereas with method area under the curve obtained r value = 0.9970. The correlation coefficient obtained from these two calibration curves shows a linear result, because it meets the acceptance criterion that is the correlation coefficient value of $0.995 \leq r \leq 1$.

3.4.2 Limit of detection and limit of quantification

Detection limit values and quantification limit values of omeprazole obtained by absorbance method were 0.436323 µg / mL and 1.322192 µg / mL, while the detection limit values and quantization limit values of omeprazole obtained by the method of area under the curve were 1.110547 µg / mL and 3.365285 µg / mL.

3.4.3 Accuracy

The accuracy of this method is measured as the number of recovered analyte. The recovery was measured by addition of 80%, 100% and 120% omeprazole standard solutions in the sample. The results of generic omeprazole measurements with absorbance method showed 99.44%, 97.20%, and 100,87%, respectively. The average yield is 99.17% ± 0.01848%. The results of generic omeprazole recovery measurements with the method of area under the curve showed 100.18%, 100.62%, and 103.28%, respectively. The average recovery is 101.70% ± 0.01405%. The results of measurements of recovered omeprazole from trademark with absorbance method showed 98.45%, 98.32% and 101.68%, respectively. The average recovery was 99.48% ± 0.0190%. The results of the measurement of trademark omeprazole recovered by area-wide method under the curve showed 99.82%, 99.12%, and 101.98%, respectively. The average recovery is 100.30% ± 0.0149%.

3.4.4 Precision

The result of measurement of generic omeprazole intraday precision value with absorbance method showed RSD at 14 µg / mL concentration of 0.33%, 0.53% and 0.53%, respectively; at concentrations of 16 µg / mL of 0.47%, 1.03% and 1.00%, respectively; at a concentration of 18 µg / mL of 0.89%, 0.17% and 0.13%, respectively. The results of the measurement of the interday precision values by the area-wide method under the curve showed RSD at a concentration of 14 µg / mL of 1.37%, 0.55% and 0.49%, respectively; at concentrations of 16 µg / mL of 0.43%, 0.05% and 0.12%, respectively; at concentrations of 18 µg / mL of 0.19%, 0.04% and 0.08%, respectively. The result of measurement of intraday precision omeprazole value of trademark with absorbance method showed RSD at 14 µg / mL concentration of 0.24%, 0.96% and 0.24%, respectively; at concentrations of 16 µg / mL of 0.21%, 0.07% and 0.12%, respectively; at a concentration of 18 µg / mL of 0.23%, 0.06% and 0.33%, respectively. The results of the measurement of intraday precision values of omeprazole trademarks by the wide area method under the curve showed RSD at a concentration of 14 µg / mL of 0.27%, 0.75% and 0.27%, respectively; at a concentration of 16 µg / mL of 0.22%, 0.02% and 0.02%, respectively; at a concentration of 18 µg / mL of 0.02%, 0.04% and 0.05%, respectively.

The results of the measurement of generic omeprazole inter-day precision values with absorbance method showed RSD at 14 µg / mL concentration of 0.96%, 0.62% and 1.05%, respectively; at a concentration of 16 µg / mL of 0.97%, 0.12% and 0.19%, respectively; at a concentration of 18 µg / mL of 0.34%, 0.54% and 0.16%, respectively. The results of the measurement of generic omeprazole inter-day precision values with the area-wide method under the curve showed RSD at 14 µg / mL concentrations of 0.85%, 0.76% and 1.13%, respectively; at a concentration of 16 µg / mL of 1.09%, 0.09% and 0.10%, respectively; at a concentration of 18 µg / mL of 0.38%, 0.26% and 0.17%, respectively. The results of the measurement of the inter-day precision values of the trademark omeprazole by the absorbance method showed RSD at 14 µg / mL concentrations of 0.60%, 0.24% and 1.04%, respectively; at a concentration of 16 µg / mL of 0.95%, 0.07% and 0.13%, respectively; at a concentration of 18 µg / mL of 0.66%, 0.13% and 0.23%, respectively. The results of the inter-day precision measurements of the trademark omeprazole with the area-wide method under the curve showed RSD at a concentration of 14 µg / mL of 0.95%, 0.37% and 0.97%, respectively; at concentrations of 16 µg / mL of 0.89%, 0.05% and 0.07%, respectively; at a concentration of 18 µg / mL of 0.52%, 0.09% and 0.22%, respectively.

4. Conclusion

The best solvent used for omeprazole analysis by absorbance method and the area under the curve by UV-Vis spectrophotometry is 0.1 N NaOH. The absorbance method and the area under the curve indicate that both methods are valid methods for omeprazole analysis. According to Pharmacopoeia Indonesia edition V 2014 the capsule level of delayed omeprazole is listed is not less than 90% and not more than 110%. Generic omeprazole levels and omeprazole levels of the trademark obtained with both of these methods qualify as those listed in Pharmacopoeia Indonesia Edition V 2014. Thus the absorbance method and the area under the curve by UV-Vis spectrophotometry can be used for the determination of omeprazole levels in the formulation capsule.

Conflict of Interests

The authors declare that no conflict of interest is associated with this work.

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