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DETERMINATION OF DILTIAZEM HCI LEVELS IN TABLETS ULTRAVIOLET SPECTROPHOTOMETRY

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ABSTRACT
Derivative belongs to the calcium antagonists used to treat hypertension, angina pectoris, and arrhythmias. This research aims to apply the spectrophotometric method and determine the levels of diltiazem in generic tablet preparations and trade names on the market. The method used is ultraviolet spectrophotometry in 0.1 N HCI solvent at a wavelength of 236 nm. This method has several advantages. Among others, it can be used to analyze a substance in small quantities. The process is fast and relatively cheaper than the High-Performance Liquid Chromatography (HPLC) method. And the results of determining the levels of tablets found in the market obtained levels for generic diltiazem tablets (Kimia Farma) 107.69 ± 0.31%, generic diltiazem tablets (Indofarma) 96.97 ± 0.26%, tablets trade name Farmabes® (Fahrenheit) 92.20 ± 0.86%., Herbesser®(Tanabe)gg 06 $, 0.33% and Dilmen® (Sanbe) 100.96± 0.52%. According to the fourth edition of the 1995 Indonesian Pharmacopoeia, all prescribed tablets met the content requirements, namely not less than 90.0% and not more than 110.0% of the amount stated on the label.

Keywords : diltiazem, generic, trade name, assay, ultraviolet spectrophotometry.

INTRODUCTION

According to RI law NO. 36 of 2009, determining the levels of efficacious substances from drug preparations
is one of the requirements that must be carried out to ensure the quality of the drug. Medicinal preparations of good quality will provide the expected therapeutic effect. One of the parameters of that quality is the level of the active substance that must meet the level requirements listed in the Indonesian Pharmacopoeia or other standard books.

Hypertension is a significant health problem to date that can lead to complications in various other organs, thus requiring severe treatment. This hypertension treatment can be in the form of antihypertensive drugs. One of them is a calcium antagonist with an excellent antihypertensive effect in mild or moderate hypertension (Nafrialdi, 2007). Diltiazem HCI is a drug that belongs to the calcium antagonist group, known as a benzothiazepine derivative which has strong vasodilating properties and is a primary drug for angina, hypertension and is also used as an antiarrhythmic drug (Tjay and Rahardja, 2007).

Since 1989, the government has issued a generic drug policy to get quality, safe and

effective drugs at affordable prices. Unfortunately, many people still consider generic drugs as second-class drugs and tend to doubt their quality because the prices are much lower than trade name drugs. The monograph of Diltiazem HCl in the Indonesian Pharmacopoeia Edition IV (1995) and USP 30 (2007) was found in the form of raw materials and tablet preparations by assaying by High-Performance Liquid Chromatography (HPLC). This method requires expensive tools and costs and a relatively longer analysis time compared to the spectrophotometric method.

Judging from the molecular structure of diltiazem HCl having chromophore and autochrome groups, it is possible that Ultra Violet Spectrophotometry can determine the levels in the tablet preparation. According to Moffat (2004), diltiazem HCl in acidic solution has a maximum absorption at 236 nm and in alkaline solution at a wavelength of 237 nm. Diltiazem HCl in 0.1 N HCl solution has a maximum absorption at a wavelength of 236 nm (A_1^1 = 533) and in 0.1 N NaOH at a wavelength of 237 nm (A_1^1 = 555) Dibbern (2002),

Based on p. In order to determine the quality of the generic diltiazem HCl tablets and the trade names available in the market, it is necessary to carry out a test of determination of assay, which is one of the parameters of the tablet quality test. The method used is ultraviolet spectrophotometry because this method has the advantage that it is cheaper, the process is fast and straightforward.

MATERIALS AND METHODS

This research was carried out at the Pharmacy Physicochemical Analysis Chemistry Laboratory, Faculty of Pharmacy, Tjut Nyak Dhien University, Medan from July to September 2010, which used in this study an ultraviolet/visible spectrophotometer (Shimadzu 1700), analytical balance (Sartorius), and glass instruments. . The materials used in the study were HCl(P) 37% (E. Merck). distilled water (PT Rudang), diltiazem HC1 BPFI (Badan POM RI), generic diltiazem HCl tablets (Indofarma and Kimia Farma), trade name tablets, Farmabes® (Fahrenheit), Herbesser® (Tanabe), and Dilmenz (Sanbe).

Samples were taken from 2 Pharmaceutical Industries, which manufactures generic diltiazem HCl tablets and 3 from Indust' Pharmaceuticals which manufactures tablets under the trade name.

Statistical Data Analysis

Levels can be calculated using the regression line equation, and to determine whether the data is accepted or rejected, the following formula is used:

$$t_{count} = \frac{XX}{SD/\sqrt{n}}$$

On the basis of data rejection, if t_{count} t_{table}

To find the actual level with a confidence level of 99 % with degrees of freedom dk = n-1, the formula is used:

$$\mu = X \pm t(1\text{-}1/2\alpha)dk \times \frac{SD}{\sqrt{n}}$$

Information:

μ	= confidence interval
x	= sample mean rate
X	= sample rate
t	= price t the table corresponds to dk= n-1
α	= confidence level
dk	= degrees of freedom
SD	=Standard Deviation (standard deviation)
n	= number of repetitions

RESULTS AND DISCUSSION

The determination of the wavelength is carried out at the concentration that gives absorption with the smallest photometric error of ± 0.434. To obtain this concentration, it can be calculated from the specific absorptivity value of diltiazem HCl (A_1^1= 533) in 0.1 N HCl solvent at a wavelength of 236 nm. From the calculation results obtained a concentration of 8.0 g/ml (calculations can be seen in appendix 1 page 8), and the maximum wavelength of diltiazem HCl at 236.40 nm with an absorption of 0.4227. The maximum wavelength obtained meets the conditions determined by the Indonesian Pharmacopoeia Edition IV, which is ± 2 nm from the wavelength determined in the literature, which is 236 nm (Moffat, 2004, Dibbern, 2004). Determination of the linearity of the diltiazem HCl

BPFI calibration curve in 0.1 N HCl solvent was determined in the concentration range of 4.0 g/ml – 11.0 g/ml at a maximum wavelength of 236.40 nm. The regression equation Y = 0.052918 X + 0.002686 is obtained.

The results of determining the levels of diltiazem HCl in tablet preparations can be seen in the table below.

Table 1. Average Level and Range of Diltiazem HCl Levels from Tablets

No.	Name **Preparation**	**Average**	**Actual Concentration** %
1	Generic Diltiazem HCl (Indo Farma)	9929	99.48 ± 0.49
2	Generic Diltiazem HCl (Kimi Farma)	97.50	97.50 ± 0.56
3	Dilmen® (Sanbe)	99.06	99.06 ± 1.34
4	Herbesser® (Tanabe)	100.94	100.94 ± 1.27
5	Farmabes® (Fahrenheit)	100, 96	100.96 ± 0.52

From the above data, it is obtained that the diltiazem HCl level in tablet preparations with trade names and generics circulating in the market that meets the requirements of the levels stated in the Indonesian Pharmacopoeia IV edition of 1995 is not less than 90.0% and not more than 110.0% of the amount stated on the label.

CONCLUSION

From the results of the study, it was shown that all tablets analyzed, both generic and trade names, met the tablet content requirements according to the Indonesian Pharmacopoeia IV edition of 1995, namely not less than 90.0% and not more than 110.0% of the amount stated on the label. Ultraviolet spectrophotometry method can be used to determine the concentration of diltiazem HCl in tablet preparations using 0.1 N HCl solvent.

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