analysis BKO

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The International Allied Health Student Conference (IAHSC) 2022
2nd Edition

"Health Innovation for Strengthening Global Health"

Indonesia, 14-15 September 2022

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ANALYSIS OF DRUG CHEMICALS (BKO) DICLOFENAC SODIUM IN RHEUMATIC HERBAL PRODUCTS CIRCULATED IN BEKASI CITY USING UV-VISIBLE SPECTROPHOTOMETRY METHOD

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Abstract

Introduction: Rheumatic herbal products are an alternative treatment to relieve rheumatic pain. It is not uncommon to find rheumatic herbal products containing drug chemicals (BKO) to provide a better therapeutic effect. Based on PERMENKES No. 7 of 2012, states that herbal medicine is prohibited from containing BKO. This study aims to analyze the content of BKO diclofenac sodium in five rheumatic herbal products circulated in Bekasi City.

Method: The type of study is non-experimental descriptive with non-probability purposive sampling method. The study was carried out qualitatively with organoleptic and color tests with $KMnO_4$ and quantitatively with UV-Visible spectrophotometry.

Results: The results of the qualitative analysis showed that five samples of herbal medicine were identified as positive because they reacted with $KMnO_4$. The maximum wavelength of diclofenac sodium was found at 292 nm. The linear equation is $y = 0.0981x - 0.6501$ with a value of $r^2 = 0.9986$. The analysis results of BKO diclofenac sodium in rheumatic herbal products were found to be 152,176 mg; 144,183 mg; 128,582 mg; 170,963 mg; and 146,656 mg.

Conclusion: Based on these results, it is concluded that the content of BKO in rheumatic herbal products is contrary to PERMENKES No. 7 of 2012, which states that herbal medicine is prohibited from containing BKO.

Keywords: *BKO, diclofenac sodium, drug chemical, rheumatic herbal products, UV-Visible Spectrophotometry*

INTRODUCTION

Indonesia has long been able to create treatment methods based on natural ingredients that have been known empirically. This treatment method is called traditional medicine which is still trusted and used by the community (Pertiwi and Suariyani 2020). The use of traditional medicine in society is inseparable from the role of parents in preserving the nation's culture (Andriati and Wahjudi 2016). People tend to prefer traditional medicine because apprehensive of synthetic drugs' side effects and think traditional medicine is better (Ege 2021). The use of traditional medicine is considered by the community to have a quick effect on disease at affordable prices, although this can happen the other way around (Sidoretno and Oktaviani 2018).

The level of public awareness to make more use of natural ingredients as treatment has made the traditional medicine industry in Indonesia grow rapidly. The development of traditional medicine needs to be supported by various scientific studies as standardization that can be adapted to the applicable health care system (Hanum et al. 2017). On the other hand, this triggers the production of traditional medicines that do not meet CPOTB (Indonesia's Drug GMP) regulations (Pertiwi and Suariyani 2020). This has also led to the distribution of illegal traditional medicines by adding drug chemicals (BKO) to the products. The distribution of illegal traditional medicines containing BKO is certainly disturbing to the public because it can have harmful effects on health, such as side effects, contraindications, overdose, and even death (Hanum et al. 2017).

In October 2021, the Food and Drug Supervisory Agency of the Republic of Indonesia (BPOM) issued a public warning No. HM. 01.1.2.10.21.18 in the form of findings the traditional medicinal products and health supplements containing drug chemicals including diclofenac sodium, ephedrine HCl, sildenafil citrate, paracetamol, dexamethasone, and phenylbutazone. The product findings then will be followed up administratively, in the form of revocation of distribution permits, product withdrawals from the market, and product destruction. The discovery of many herbal products containing drug chemicals on the market has encouraged researchers to identify drug chemicals in traditional medicinal products in various regions of Indonesia.

A study on the analysis of drug chemicals in traditional medicinal products conducted by Tahir et al. (2018) in Makassar City, found that 3 out of 7 brands of herbal medicine contained diclofenac sodium. A subsequent study in Mataram City by Rosyada et al. (2019), also found that 3 out of 10 herbal medicine brands contained diclofenac sodium with the highest amount of 135,1982 mg. Similarly, a study on the

variant of rheumatic herbal medicine conducted by Dewi et al. (2019) in Subang City, found that 3 out of 10 herbal medicine brands contained diclofenac sodium with the highest amount of 16,11 mg.

With BPOM regulation and supervision of traditional medicinal products added with drug chemicals that do not cover the entire territory of Indonesia and there was research evidence that traditional medicinal products added with drug chemicals are still found, the researchers wanted to analyze the medicinal chemical diclofenac sodium in rheumatic herbal medicine products circulated in Bekasi City, Indonesia. This study was conducted using the UV-Visible spectrophotometric method for analysis of BKO diclofenac sodium.

METHOD

Design of Study

The design of this study is descriptive non-experimental.

Location and Time of Study

This study was conducted at STIKes Mitra Keluarga Chemical Laboratory, Bekasi City, West Java, Indonesia from February to March 2022.

Population and Sample

Samples were taken by non-probability purposive sampling technique. The study population consisted of all traditional drug stores selling rheumatic herbal products in the Bekasi City area. The sample is based on the calculation of the SLOVIN formula and applies the following criteria: products with indications of rheumatic herbal products, products in powder form, with no expiration date, and products that are of interest to the public. The number of samples determined was 5 (five) brands of rheumatic herbal products labeled with brands A, B, C, D, and E.

Instruments and materials

The instruments used were glassware (*Iwaki, Pyrex*), Analytical Balance (*Ohaus*), UV-VIS Spectrophotometer (*Thermo Scientific Genesys 10S UV-Vis v4.006*), and Micropipette (Socorex).
The materials used were 5 (five) brands of rheumatic herbal products, diclofenac sodium standard (Aarti), Methanol p.a. (Merck), and KMnO4 (Merck).

Qualitative Analysis

Organoleptic Test

The organoleptic test was carried out by observing samples of rheumatic herbal products in terms of shape, color, smell, and taste with the human senses without the help of any instruments (Ningrum, Wirasti, and Sugeng 2018).

Preparation of 1% $KMnO_4$ reagent

100 mg of $KMnO_4$ dissolved in 100 mL of distilled water, stir until dissolved. Heat at 70°C for 15 minutes. The solution was allowed to stand and then filtered. Store the solution in a tightly closed bottle and lined with aluminum foil (Maulida, Hakim, and Mohtar 2020).

Color Test with 1% $KMnO_4$

50 mg of samples were dissolved in methanol p.a. 1 mL, stir until dissolved and filtered. Prepare a positive control solution and a negative control solution. Positive control solution was 50 mg of diclofenac sodium standard dissolved in methanol p.a. 1 mL. The negative control solution was methanol p.a. 1 mL. The entire solution was reacted with ± 2-3 drops of 1% $KMnO_4$ reagent until it turned brown. The color change indicates that the solution has a double-bond compound (Dewi, Hendrayanti, and Nurhayati 2019).

Analysis Method Verification

Preparation of Diclofenac Sodium Standard Solution

50 mg of diclofenac sodium standard was dissolved in 50 mL methanol p.a., stir until dissolved (main standard solution 1000 ppm). The main solution was then diluted to 100 ppm by taking 1 mL of the solution and diluted with methanol p.a. 10 mL (standard solution 100 ppm) (Rosyada, Muliasari, and Yuanita 2019).

Maximum Wavelength Measurement of Diclofenac Sodium

Standard solution of 100 ppm was taken as much as 10 ppm and 20 ppm, then measured with UV-Vis spectrophotometry in the range of 200 – 400 nm. The result of the wavelength spectrum with the highest absorbance is defined as the maximum wavelength (Rosyada et al. 2019).

Linearity

Standard solutions of 100 ppm were made into series solutions in concentrations of 10, 11, 12, 13, 14, and 15 ppm. The blank solution (methanol p.a.) was prepared. Measure the absorbance of the entire solution with
UV-Vis spectrophotometry at a predetermined maximum wavelength. The absorbance obtained then plotted on the linear equation of concentration to absorbance. The test was replicated three times (Rosyada et al. 2019).

Accuracy

The accuracy test was carried out by the addition method. The accuracy test was carried out in the range of 80-120% with a sample and standard ratio of 70: 30. Measure the absorbance of the solution with a UV-Vis spectrophotometer and replicated it three times. Accuracy is expressed in the percentage of recovery (% recovery). The accuracy value is acceptable in the range of 80-110% (Riyanto 2016).

Precision

The standard solution of 100 ppm was taken at 10 ppm, 11 ppm, and 12 ppm, then the concentration of the solution was measured using a UV-Vis spectrophotometer and replicated three times. Precision is expressed in %RSD value. The precision value is acceptable if the %RSD value is ≤ 2% (Riyanto 2016).

Quantitative Analysis

Preparation of Rheumatic Herbal Products Sample Solution

Samples of brands A, B, C, D, and E were 50 mg each and dissolved in methanol p.a. as much as 50 mL. Stir until dissolved and filtered (main sample solution 1000 ppm). Then the solution was diluted to 100 ppm (sample solution 100 ppm) (Rosyada et al. 2019).

Determination of the Amount of Diclofenac Sodium in the Sample

The sample solution of 100 ppm was measured for absorbance at the maximum wavelength that had been determined by UV-Visible spectrophotometry. The test was replicated three times. The amount of diclofenac sodium was determined by the following formula:

$$\text{Amount in the packaging (mg)} = \text{Amount in sample (mg)} \times \frac{Weight\ of\ packaging\ (mg)}{Weight\ of\ sample\ (mg)}$$

Data analysis

Data analysis was carried out based on the test results obtained in the form of maximum wavelength and the ratio of concentration to absorbance. From the graph, the statistical data will be processed descriptively.

RESULTS

Preliminary Analysis of Sample Packaging

Samples of rheumatic herbal products that have been labeled will be observed on the product tag on the packaging. The results of the analysis are shown in Table 1.

Table 1. Result of Preliminary Analysis of Sample Packaging

Product Tag	Sample

	A	B	C	D	E
Product name	+	+	+	+	+
Name and address of the manufacturer	+	+	+	+	+
Batch Number	-	-	-	-	-
Registration Number	+	+	-	+	+
Expired Date	-	-	-	-	-
Indication	+	+	+	+	+
Herbal product logo	+	+	-	+	+
Herbal product label	-	+	-	+	+

Qualitative Analysis

Organoleptic Test

An organoleptic test was carried out on each sample by observing the sample in terms of shape, color, smell, and taste. The organoleptic test results are listed in Table 2. and Figure 1.

Table 2. Result of Organoleptic Test

Sample Code	Organoleptic Test			
	Form	Odor	Flavor	Color
A	Powder	Typical herb odor	Bitter	Yellowish dark green
B	Powder	Typical herb odor	Bitter	Dark yellow
C	Powder	Typical herb odor	Bitter	White, with other colors like black, brown, and orange
D	Powder	Typical herb odor	Bitter	Light yellow
E	Powder	Typical herb odor	Bitter	White, with other colors like black, brown, and orange

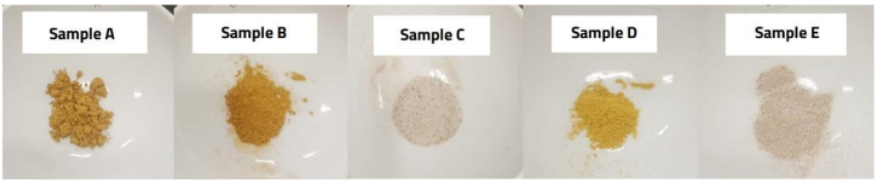

Figure 1. Result of Organoleptic Test

Color test with $KMnO_4$

The color test was carried out to determine the presence of a redox reaction in the diclofenac sodium double bond in each sample by reacting the sample solution of rheumatic herbal medicine with $KMnO_4$. A positive result is indicated by a change in the color of the solution to a brown color. The color test results are listed in Table 3. and Figure 2.

Table 3. Result of Color Test

Sample Code	Result of Color Test		Conclusion
	Before Test	After Test	
A	Dark yellow	Light brown	+
B	Light yellow	Light brown	+
C	Clear	Light brown	+
D	Light yellow	Light brown	+
E	Clear	Light brown	+
Control (+)	Clear	Dark brown	+
Control (-)	Clear	Purple	-

Conclusion :

+ : Contain double-bond groups

- : Does not contain double-bond groups

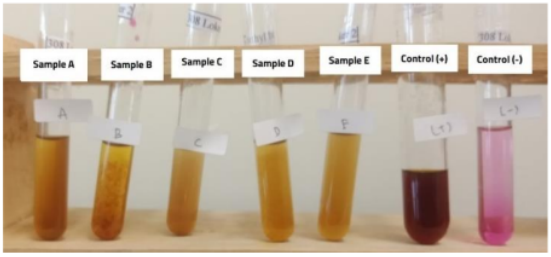

Figure 2. Result of Color Test

Analysis Method Verification

Determination of the Maximum Wavelength of Diclofenac Sodium

Determination of diclofenac sodium levels using the stand of diclofenac sodium with concentrations of 10 ppm and 20 ppm. The maximum wavelength was found at 292 nm. The determination of the maximum wavelength is shown in Figure 2.

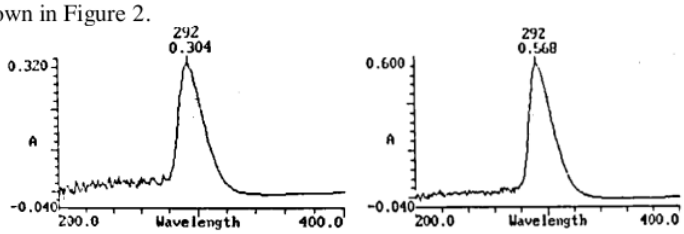

Figure 2. Maximum wavelength diclofenac sodium at 10 dan 20 ppm

Linearity

The linearity test was carried out by measuring the absorbance of diclofenac sodium standard solution series with concentrations of 10, 11, 12, 13, 14, and 15 ppm at a maximum wavelength of 292 nm. The absorbance value against the concentration was plotted on a linear regression equation which then obtained the following results: y = 0.0981x - 0.6501 with r2 value = 0.9986. The standard curve of diclofenac sodium is shown in Figure 3.

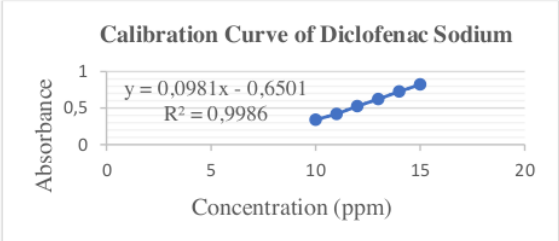

Figure 3. Calibration Curve of Diclofenac Sodium

Precision

The precision test was carried out by measuring the absorbance of the standard solution of diclofenac sodium at concentrations of 10, 11, and 12 ppm with three replications. The results of the precision test showed that the %RSD at each concentration was 0.24%; 1.02%; and 0.70%. The test results have met the precision requirements, namely %RSD 2%. The precision test results are shown in Table 4.

Table 4. Precision Test

Conc. (ppm)	Abs	Measured Conc. (ppm)	Avg. Conc. (ppm)	SD	RSD (%)
10	0,402	10,725	10,749	0,026	0,24%
	0,404	10,745			
	0,407	10,776			

11	0,453	11,245	11,306	0,115	1,02%
	0,452	11,234			
	0,472	11,438			
12	0,590	12,641	12,563	0,088	0,70%
	0,573	12,468			
	0,584	12,580			

Accuracy

The accuracy test was carried out by measuring the absorbance of the standard solution to which the sample solution had been added with a ratio of 70: 30. The accuracy test was carried out in the range of 80%, 100%, and 120% with three replications. The results of the test show that each range has met the accuracy requirements, 80 – 110%. The results of the accuracy test are shown in Table 5.

Table 5. Accuracy Test

Range	Abs	Sample Conc. (ppm)	Standard Conc. (ppm)	% Recovery	Avg. Recovery (%)
80%	0,297	6,72	2,88	101,89%	101,89%
	0,288	6,72	2,88	98,70%	
	0,306	6,72	2,88	105,08%	
100%	0,537	8,40	3,60	102,80%	101,10%
	0,525	8,40	3,60	99,41%	
	0,531	8,40	3,60	101,10%	
120%	0,773	10,08	4,32	102,47%	101,92%
	0,764	10,08	4,32	100,34%	
	0,775	10,08	4,32	102,94%	
Entire Avg conc. (%)					101,64%

Quantitative Analysis

Determination of the Amount of Diclofenac Sodium in Sample

Determination of the amount of diclofenac sodium in the sample was carried out by measuring the absorbance of the 100 ppm sample solution. The absorbance was plotted on a linear regression equation so that the diclofenac sodium content in the sample was obtained. The results of diclofenac sodium levels (ppm) were converted into the form of amounts (mg). The results of the precision test are shown in Table 6.

Table 6. Determination of the Amount of Diclofenac Sodium in Sample

Sample Code	Abs	Amount in Sample (mg)	Amount in the packaging (mg)	Avg amount (mg)	Conclusion
A	0,291	0,959	151,373	152,176	N
	0,289	0,957	152,253		
	0,293	0,961	152,901		
B	0,360	1,030	144,153	144,183	N
	0,380	1,050	144,408		
	0,377	1,047	143,987		
C	0,314	0,933	129,816	128,582	N
	0,299	0,986	136,380		
	0,256	0,868	119,549		
D	0,291	0,983	175,495	170,963	N
	0,289	0,967	173,108		
	0,293	0,924	164,285		
E	0,278	0,946	130,622	146,656	N
	0,268	0,936	128,960		
	0,624	1,299	180,386		
Entire Average amount (mg)				148,512	N

Conclusion :

N = Not in accordance with CPOTB regulations.

DISCUSSION

Preliminary Analysis of Sample Packaging

A total of five samples were pre-analyzed on the sample packaging. In addition to looking directly at the packaging, this analysis is carried out by checking the product on the official BPOM RI website, namely www.cekbpom.pom.id with product name, registration number, and packaging categories. Based on Table 1. it was found that all samples did not meet the requirements set for traditional medicinal products that could be circulated in Indonesia. Incompatibility of tag on sample packaging with applicable regulations is found in batch number, registration number, expiration date, herbal medicine logo and label.

In Table 1. it is known that all samples do not include batch numbers, while registration numbers are listed in all samples except sample C. The results of checking on the BPOM website also note that samples A, B, D, and E cannot be found in various categories so it can be concluded that the registration number listed on the packaging is fake. This is not by the provisions of PERMENKES No. 7 of 2012, which states that traditional medicinal products must have a distribution permit number. This is also in line with PerKBPOM RI No. HK.00.05.41.1384 of 2005, which regulates the criteria and procedures for registering traditional medicines to be able to register traditional medicinal products at BPOM, various documents must be included, including claims for indications, the dosage of use, and batch number. If viewed from the results of the analysis obtained, it can be concluded that all samples are not officially registered with BPOM.

The batch number is a marker of the number of products made in one cycle so that they have uniform characteristics and quality, while the registration number is a form of approval that the product can be circulated in Indonesia. If these two things are not listed on the packaging, it can be concluded that the sample product cannot be circulated in Indonesia and may be subject to sanctions. The expiration date of traditional medicinal products is also regulated in PerKBPOM RI No. HK. 03.1.23.06.10.5166 of 2010, with a definition in the form of a description of the time limit for traditional medicines that are suitable for consumption. Article 6 states that traditional medicines must include an expiration date on the label. In Table 1. it is found that all samples include expiration dates so they do not meet the applicable provisions.

The traditional medicine logo has been established in BPOM RI Decree No. 00.05.4.2411 of 2004 which regulates the grouping of traditional medicines so the shape of the logo and label attached to the packaging of traditional medicine is very important to explain the type of traditional medicine of a product. In Table 1. it is found that samples B, D, and E have the appropriate herbal medicine logos, sample A includes the herbal medicine logo but does not include the herbal medicine label, while sample C does not include either the herbal medicine logo or label.

The results of the initial identification on the packaging showed that the samples did not meet the applicable provisions. It can be concluded that the samples are products that should not be circulated in Indonesia. However, this is accompanied by the fact that these herbal products are products that are of interest to the public, requiring more attention to herbal products circulated in the community. BPOM RI as a regulator needs to supervise the circulation of these products.

Organoleptic Test

The organoleptic test was not only intended to determine the characteristics of the sample but also aimed to determine the similarity of the description of the sample with BKO diclofenac sodium. In Table 2. it is stated that all samples have the same shape, smell, and taste, namely in the form of a powder with a characteristic odor of herbal medicine and a bitter astringent taste. The five samples have different colors because the types of plants made for herbal products are also different. Herbal medicine can be made from various plant parts such as roots, leaves, stems, fruits, rhizomes, or other parts that give a certain color to the product. Samples C and E have a striking color difference because there are some parts of the powder that are not homogeneous in the form of a mixture of white, black, orange, and brown powders. According to the Indonesian Pharmacopoeia edition VI (2020) of the BKO diclofenac sodium, it is a white to almost white crystal powder (Depkes RI 2020). With the discovery of white powder in samples C and E, it can be indicated that both contain BKO diclofenac sodium.

Color Test

The color test is intended to determine the ratio of the reactions formed in the samples of herbal medicine and BKO diclofenac sodium when reacted with $KMnO_4$. In this color test, all samples were tested with positive and negative controls. The positive control was a standard solution of diclofenac sodium in methanol while the negative control only contained solvent. Diclofenac sodium has an alkene group in its chemical structure and will react with KMnO4. The reaction mechanism between diclofenac sodium and $KMnO_4$ is as follows:

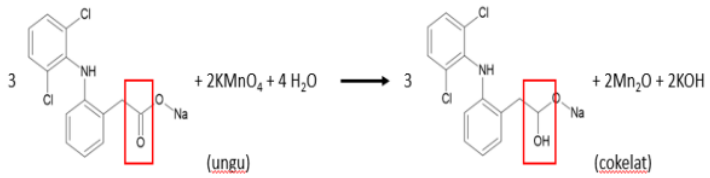

Figure 4. Reaction Mechanism of KMnO4 with alkene group on diclofenac sodium

In Table 3. It is known that all study samples and positive controls reacted with $KMnO_4$ and produced a brown color change. These results concluded that all samples of herbal medicine had a double bond group which was oxidized by $KMnO_4$. However, this color change also does not mean that the sample contains BKO diclofenac sodium because the alkene group is found in secondary metabolites of medicinal plants such as alkaloids, tannins, flavonoids, saponins, steroids, and so on. Therefore, the results of this color test will be continued to the next analysis, namely quantitative analysis using UV-Visible spectrophotometry to confirm the presence of BKO diclofenac sodium.

Analysis Method Verification

Determination of the Maximum Wavelength of Diclofenac Sodium

Determination of the maximum wavelength aims to determine the maximum sensitivity of diclofenac sodium in the UV-Visible wavelength range. Determination of the maximum wavelength requires a standard solution of diclofenac sodium 10 ppm and 20 ppm in methanol p.a. solvent. Both solutions were measured in the wavelength range of 200-400 nm. The results of the measurement of the maximum wavelength of diclofenac sodium at 292 nm at 10 ppm with an absorbance value of 0.304 and 20 ppm with an absorbance value of 0.568. At a wavelength of 292 nm, an absorption peak was formed which indicated that the compound detected by the spectrophotometer was diclofenac sodium. This wavelength was selected as the maximum wavelength of diclofenac sodium and used for subsequent analysis.

Linearity

Linearity is one of the parameters of the method verification test that was carried out to determine the ability of the spectrophotometric method to detect the concentration of diclofenac sodium in the sample. Linearity is expressed in the correlation coefficient (r) of the linear regression curve y = a + bx with an ideal value of a = 0 and r = +1 or -1 (Riyanto 2016). The linearity test was carried out by measuring the absorbance of the standard diclofenac sodium solution at various concentrations of 10 ppm, 11 ppm, 12 ppm, 13 ppm, 14 ppm, and 15 ppm and replicated three times to obtain consistent absorbance results. In Figure 3. It is shown that the calibration curve formed from the variation in concentration gives an absorbance response according to Lambert's Beer's law, which is in the range of 0.2 - 0.8. The calibration curve for each replication gives the coefficient of determination (r^2) values, respectively, as follows: 0.9941; 0.9986; 0.9944. The calibration curve is declared to meet the linearity criteria because it has a value of R2 0.99. With the fulfillment of the linearity criteria, the UV-Visible spectrophotometric method can be used as a method for the analysis of BKO diclofenac sodium in rheumatic herbal products. Based on these results, replication 2 gave a better r^2 value with the equation y = 0.0981x - 0.6501 so the linear equation in replication 2 was chosen as the basis for measurement in the next analysis.

Precision

Precision is a parameter of the method verification test or the accuracy carried out to determine the

suitability of repeated measurements on the same sample, in this case, the measurement of diclofenac sodium levels (Riyanto 2016). Precision is calculated based on the standard deviation or relative standard deviation (coefficient of variation) of the sample measurement results. Precision is applied according to the ICH procedure, which is a minimum of nine measurements (three concentrations with three replications) or a minimum of six measurements at one concentration (ICH 2005). The generally accepted precision criterion is 2%. The precision test was applied to three different concentrations of 10 ppm, 11 ppm, and 12 ppm and replicated three times. The results of the precision test at these concentrations showed the %RSD values successively as follows: 0.24%; 1.02%; and 0.70%. The %RSD value is declared to have entered the required precision criteria, namely 2%. With these precision results, it can be stated that the UV-Visible spectrophotometric method provides good precision and the method can be used for subsequent analysis.

Accuracy

Accuracy as a verification test parameter is intended to determine the degree of accuracy of the measurement results with the actual levels. The accuracy test is expressed in % recovery (% recovery). The accuracy test was applied based on the ICH procedure, namely the measurement of a minimum of three concentrations with three repetitions (replication). The accuracy test in this study used the addition method, in which a sample of herbal medicine was added with a standard amount of diclofenac sodium and the absorbance was measured, then the recovery rate was calculated using a predetermined regression equation. In addition method, the accuracy test is measured in the concentration range of 80%, 100%, and 120%. The comparison between the sample used and the standard added was 70: 30. The accuracy results in the range of 80%, 100%, and 120% respectively were 101.89%; 101.10%; and 101.92%. The average overall recovery is 101.64%. Acceptable accuracy criteria for an analyte concentration of 10 ppm are in the range of 80-110% (Riyanto 2016). Based on these results, it can be stated that the UV-Visible spectrophotometric method used in this study has an acceptable level of accuracy.

Quantitative Analysis

The amount of Diclofenac Sodium in the sample was determined based on a predetermined linear regression equation. The results of the calculation have known levels of diclofenac sodium (ppm) which is then converted into the form of amounts (mg). In Table 6. it is stated that samples A, B, C, D, and E were positive for diclofenac sodium in the range of 120 mg – 175 mg per package. The average amount of BKO obtained was 148,512 mg. The amount of BKO obtained has exceeded the maximum dose of diclofenac sodium per day, which is 150 mg. The tag of how to use the herbal medicine packaging varies between 2-3 times of consumption per day. Of course, this result is worrying because it can pose a health hazard such as overdose. All of the following analysis results are declared not to meet the requirements of PERMENKES No. 7 of 2012 that herbal medicine may not contain medicinal chemicals or psychotropic drugs and narcotics or other substances that are considered to be harmful to health. This is also in line with PerBPOM No. 32 of 2019, which establishes that traditional medicine manufacturers must ensure the safety and quality of traditional medicines. If this is not complied with, administrative sanctions can be imposed as established in PerKBPOM RI No. 5 of 2016 such as written warnings, product withdrawals from circulation, and production cessation.

CONCLUSION

Based on the results of the study, the analysis of BKO diclofenac sodium in rheumatic herbal medicine products has been carried out qualitatively with organoleptic tests and color tests and quantitatively with UV-Visible spectrophotometric methods. The results of the study concluded that samples A, B, C, D, and E of rheumatic herbs circulating in Bekasi City were positive for BKO diclofenac sodium.

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