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Formulation stability analysis aloe vera leaf extract gel and shell collagen

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***Abstract*---**Toga plant that has the potential as a medicinal ingredient is aloe vera leaf. Aloe vera leaves have benefits in moisturizing the skin because of the vitamin E content. Aloe vera is often used to moisturize hair and skin. Collagen is the result of extraction from shells which serves to give elasticity to the skin. Aloe vera is often used to moisturize hair and skin. Therefore, aloe vera leaf flesh and clam shell collagen when combined will produce a moisturizer that can increase skin elasticity. Experimental research the post test only controlled group design with ANOVA method. The purpose of this study was to obtain the desired conditions in the shortest possible time aloe vera gel and clam shell collagen by storing the preparation at a temperature of 27oC and 40oC. Phytochemical test on aloe vera leaf extract showed the presence of flavonoid compounds, saponins. Aloe vera leaf gel preparations contain saponins and flavonoids. These compounds are antioxidant compounds that can support in increasing skin elasticity along with clam shell collagen. In the stability test of aloe vera leaf and shell collagen with polyvinyl alcohol base at a temperature of 270C and unstable at a temperature of 400C on homogeneity, elasticity, pH, and organoleptic stability tests, dispersion tests and dry time. The preparations of aloe vera leaf gel and shell collagen at a temperature of 270C and 400C in the organoleptic test, homogeneity, elasticity, pH were the most stable at a concentration of 10% at a temperature of 27oC.

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Keywords---aloe vera leaf, extract gel, shell collagen, content of flavonoid, saponin compounds, storage stability.

Introduction

Aloe vera leaf is a toga plant that is owned by almost every family. The content of aloe vera leaves is a saponin compound, the content of aloe vera saponins can soften, moisturize and add to the smoothness of the skin (1). Aloe vera also contains lignin compounds that are able to hold skin moisture so that the skin does not easily become dry, wrinkled, or scaly (2). Likewise with clam shell collagen whose function is to support the working mechanism of aloe vera in increasing skin elasticity (3). The stability of aloe vera gel is the ability of a drug product in the form of a gel to survive within the specified limits applied throughout the period of storage and use to ensure the identity, strength, quality and purity of the aloe vera gel product. The stability of an aloe vera leaf gel and shell collagen is a factor that must be considered in making a pharmaceutical preparation. The physical quality of the gel preparation is influenced by the composition of the polyvinyl alcohol (PVA) base. The range of concentrations of polyvinyl alcohol is 5-10% (4).

Testing the stability of aloe vera leaf gel and shell collagen in a short time can be obtained by conducting an accelerated stability test. Tests on aloe vera gel and clam shell collagen were carried out to obtain the desired conditions in the shortest possible time by storing the preparations in conditions designed to accelerate the changes that normally occur under normal conditions at 27oC and 40oC. Aloe vera leaves during harvest season in Bungangin, Kendal and collagen prepared from clam shells from Bandengan, Kendal are abundant and largely untapped. Based on the above background, the authors are interested in conducting research by testing the stability of aloe vera leaf extract gel and shell collagen in moisturizing the skin.

Method

Ingredient

The ingredients used were aloe vera leaf, polyvinyl alcohol, propylene glycol, methyl paraben, propyl paraben, ethanol 96%, distilled water, caisin, silica gel, Lieberman-Buchard reagent, Dragendorf reagent, Meyer reagent, Wagner reagent, and filter paper. , phytochemical test materials.

Tool

The tools used are hot plates, glassware, thermometers, mortars and stampers, pipettes, analytical scales, pH meters, spatulas, ovens, porcelain dishes, petri dishes, test tubes, funnels, dropper drops, drip plates, pots.

Research Stages

This research was conducted at the Pharmacy Technology Laboratory of STIKES Kendal. The study was initiated by extracting aloe vera leaves with ethanol as a solvent and extracting clam shell collagen. The extract was then tested for phytochemicals.

Sample Preparation

Aloe vera leaves used are leaves from Bugangin Kendal. Aloe vera leaves are peeled, washed, drained, and cut into pieces and soaked to remove the mucus. The aloe vera leaf flesh was mashed using a crusher with a size of 40 mesh to obtain a homogeneous aloe vera leaf flesh (5). Meanwhile, the extracted collagen from the shells of the shells was extracted to produce chitin which was extracted again to obtain collagen (6).

Preparation of Aloe Vera Leaf Extract

A total of 75 grams of aloe vera leaf flesh was macerated using 96% ethanol as solvent. Extraction was carried out until the color of the solution was colorless. The aloe vera leaf meat marinade was filtered using filter paper and the filtrate was stored. The filtrate obtained was combined and then concentrated using a rotary evaporator to obtain 96% ethanol extract (5). Meanwhile, Haril collagen was extracted from chitin shells (7).

Phytochemical Test
Saponin Test

A total of 500 mg of aloe vera leaf flesh was added to 10 mL of hot water and boiled for 5 minutes and then filtered. A total of 10 mL of aloe vera leaf flesh fitrat was shaken in a closed test tube for 10 seconds and then left for 10 minutes. The presence of saponins was indicated by the formation of stable foam in the mixture of aloe vera leaf flesh (8).

Flavonoid Test

A total of 500 mg of aloe vera leaf flesh was added to 10 mL of hot water and then boiled for 5 minutes and filtered. A total of 5 mL of the filtrate from aloe vera leaf flesh was added with 0.5 grams of Mg powder, 1 mL of concentrated HCl, and 1 mL of amyl alcohol then shaken vigorously. A positive test is indicated by the appearance of a red, yellow or orange color on the amyl alcohol layer in the mixture with the aloe vera leaf flesh (9).

Making Aloe Vera Leaf Gel

Gel formula
R/ Aloe vera leaf extract 10%
10% clam shell collagen
PVA (5%; 7.5%; 10%)
Propylene Glycol 10%

Methyl Paraben 0.05%
Ethanol 96% 15%
Aquadest ad 20 g

Gel making

Making aloe vera leaf gel begins with smoothing polyvinyl alcohol then developed using distilled water heated at 900C in a hot mortar. The mixture with aloe vera leaf flesh is stirred until it expands completely and a homogeneous PVA gel base is formed. After the PVA expands completely, propylene glycol is put in pot 1 and then stirred until homogeneous. In another container, the thick extract of aloe vera leaf flesh is dissolved first with some aquadest. Then mixed in pot 1 until homogeneous. In another separate pot, methyl paraben was first dissolved in 96% ethanol, then put in pot 1 and stirred until homogeneous. Aquadest is put into a 1 to 10 gram pot and stirred again until homogeneous along with the aloe vera leaf flesh (4) and (10).

Results and Discussion

Extraction

The results of aloe vera leaf extraction are carried out to separate the components of the active compound from a material using a solvent. The extraction method of aloe vera leaf flesh used to extract samples is maceration. This method is a simple method that can be used to extract samples of aloe vera leaves that are neither heat-resistant nor heat-resistant, so as to avoid damage to the components of the non-heat-resistant compounds. The choice of solvent in the extraction of aloe vera leaves also needs to be considered to obtain certain desired chemicals (11). Maceration extraction in this study using aloe vera leaf samples was carried out using 96% ethanol as solvent. The maceration process of aloe vera leaves is assisted by stirring, which is intended to increase the possibility of a collision process between the material and the solvent so that the active compound can be dissolved quickly into the solvent. The maceration process of aloe vera leaves was carried out for 1 x 24 hours by repeating until the filtrate was colorless (12). It aims to increase the chemical compounds from aloe vera leaves dissolved in the solvent. The resulting aloe vera leaf filtrate was then concentrated using a rotary evaporator to obtain a concentrated extract. The results of the filtrate are then made preparations with various concentrations. The range of use of aloe vera flour in cosmetic products is around 0.025 – 0.1% while aloe vera gel can reach 5 – 20% (13). So in this study using a concentration of 10%. The yield of each extract is presented in Table 2. Table 2 shows that the yield of aloe vera leaf extract with 96% ethanol as solvent and 9.820%. The 96% ethanol filtrate produced is a clear liquid. These results are because according to (13), that aloe vera contains 95% water and the remaining 5% is in the form of active ingredients including essential oils, amino acids, minerals, vitamins, enzymes, and glycoproteins. So it is only natural that a relatively small yield is obtained.

Phytochemical Test

The phytochemical test of aloe vera leaves aims to test the presence of a class of secondary metabolite compounds such as saponins, flavonoids. The positive test results for alkaloids in aloe vera leaves were indicated by the formation of colored precipitates of white, brown, and red orange respectively against Meyer, Wagner, and Dragendorf reagents. The formation of a red, yellow, or orange color on the amyl alcohol layer is the basis for determining the presence of flavonoids in aloe vera leaves. Saponins can form a stable foam for 10 minutes when the aloe vera leaf sample is shaken. Differences in the content of secondary metabolites in aloe vera plants often occur due to environmental influences or different phytochemical determination methods. The yield of aloe vera leaf extract and shell collagen and Phytochemical test results are presented in Table 1 and Table 2.

Table 1
The yield of aloe vera leaf extract and shell collagen

Sample	Solvent	Initial sample weight (g)	Initial sample weight (g)	Yield (%)
Aloe vera leaf extract	Etanol 96%	100	9,820	9,820
Collagen		1000	140,32	14,3

Table 2
Phytochemical test results of aloe vera leaf extract

Simplicia	Simplicia	Ethanol Extract 96%
Flavonoid	-	-
Saponins	+	+

Description: (-) not detected; (+) detected

Based on the qualitative test, in this aloe vera leaf, saponin compounds were detected. This is in accordance with the research that aloe vera leaf extract contains the active substances Saponins, Sterols, Acemannan (14).

Test Results of Aloe Vera Leaf Extract Gel and oyster shell collagen
Organoleptic test

The organoleptic test of aloe vera gel and shell collagen was carried out by visual observation including color, odor and consistency of the preparation. The organoleptic results showed that the 5 formulas for 1 month at a temperature of 270C were light translucent, smelled of ethanol and had a thick consistency. In formula 1 to formula 5 weeks 1-2 at a temperature of 400C, it is light in color, smells of ethanol and has a thick consistency. At week 3 it showed a clear clear

color, smelled of ethanol, slightly watery and week 4 showed a clear brownish color. At the 4th week, it undergoes oxidation with a change in color to brown. This is due to unstable oxidation by changes in pH, temperature, light, oxygen and other factors such as enzymes and metals. It is known that betacyanin is stable at pH 4-6, while the pH of the preparation is close to pH 8 (15). In addition, betacyanin will change color to yellow-brown at alkaline pH (16).

Homogeneity Test

The results of the homogeneity test of the three aloe vera leaf extract gel formulas showed that during the 1st week to the 4th week the formula remained homogeneous with no coarse grains on the glass object. At the concentration of polyvinyl alcohol (PVA) gel, namely F1 5%, F2 7.5% and F3 10% homogeneity of each gel was homogeneous.

Aloe Vera Leaf Extract Gel and oyster shell collagen pH Test

The initial pH value of each formula until after testing both at room temperature and high temperature was slightly outside the skin pH range of 4.5 - 7 but the pH of the three formulations did not exceed neutral pH so it was not alkaline. . The pH test is shown in Table 3.

Table 3
Test Results Aloe Vera Leaf Extract Gel and oyster shell collagen pH at a temperature of 27oC and 40oC

Temperature	Old (Week-)	pH F1	pH F2	pH F3
27°C	1	5,00	5,00	5,00
	2	5,60	5,60	5,60
	3	5,50	5,50	5,50
	4	5,60	5,60	5,60
40°C	1	6,70	6,70	6,70
	2	6,60	6,60	6,60
	3	6,50	6,50	6,50
	4	6,40	6,40	6,40

Table 4 shows that none of the three formulations exceeds neutral pH so they are not alkaline. At a temperature of 27oC the pH is less than 6. While at 40oC the pH of the gel is above 6. This is in accordance with the theory that it is known that betacyanin in aloe vera leaves is stable at pH 4-6, while the pH of the preparation is close to pH 8 (15). In addition, betacyanin will change color to yellow-brown at alkaline pH (16). So it can be concluded that the pH is stable at 27oC storage temperature.

Elasticity Test

The formulation with the lowest elasticity was F1 with 5% PVA concentration and the most elastic was found in F3 with 10% PVA concentration, with no tearing

when peeled off the skin surface. The results of the elasticity test show that the higher the concentration of PVA used, the stronger the elasticity (17)(18). The elasticity could be due to the presence of a compound containing mannose-6-phosphate which can increase the synthesis of collagen (19) and (20). In addition, shell collagen also has an effect on increasing skin elasticity (7).

Spreadability Test

The results of the dispersion test at 27oC and 40oC are shown in Table 5.

Table 5
Spreadability Test Results Aloe Vera Leaf Extract Gel and oyster shell collagen at a temperature of 27oC and 40oC

Temperature	Load (grams)	Spreadability F1	Spreadability F2	Spreadability F3
27°C	100	5,2	5,4	5,5
	100	5,6	5,7	5,8
	100	5,7	5,8	5,8
	100	6,1	6,2	6,2
40°C	100	5,6	5,6	5,6
	100	6,6	6,6	6,6
	100	7,0	7,0	7,0
	100	6,8	6,9	6,9

Table 5 shows that at 27oC the gel spreadability. The results of the dispersion test showed that the higher the concentration of PVA used, the better the dispersion with the difference in dispersion. But with the temperature difference between 270C and 400C, it can be said that at 400C the gel is unstable. This is because at that temperature the gel becomes dilute and changes color to brown (16).

Stable Time Test after applied to skin

The results of the stable time test at 27oC and 40oC are shown in Table 6.

Table 6
Test Results Stable time of Aloe Vera Leaf Extract Gel and oyster shell collagen after being applied to the skin at a temperature of 27oC and 40oC

Temperature	Old (Week-)	Steady Time F1(seconds)	Steady Time F2 (seconds)	Steady Time F3 (seconds)
27°C	1	26	26	26
	2	26	26	26
	3	27	27	25
	4	27	27	2
40°C	1	34	34	34
	2	36	36	36
	3	37	37	37

4	38	38	38

Table 6 shows that in storage for 1 month, aloe vera gel at F3 with a concentration of 10% PVA gel became more stable in viscosity and the color remained clear at 27oC compared to F1 PVA 5% and F2 7.5% at the same temperature. Meanwhile, with the increase in temperature to 40oC, the gel becomes more dilute and the color changes to brown both at small concentrations at F1 and high at F3. The results of the stable time test showed that the higher the concentration of PVA used, the faster the drying time. Therefore, aloe vera leaf gel should be stored at temperatures below 27oC.

The stability of an aloe vera leaf gel and shell collagen is a factor that must be considered in making a pharmaceutical preparation. This is because a preparation is usually produced in large quantities and takes a long time to get to the hands of consumers who need it. Drugs that are stored for a long time can decompose and result in a reduced dose received by the patient. Sometimes the decomposition products of these substances are toxic so that they can endanger the patient's life. Factors that can affect the stability of a substance include heat, light, humidity, oxygen, pH, microorganisms, and additives used in the formulation of the drug. In the past, to evaluate the stability of a pharmaceutical preparation, observations were made on the conditions under which the drug was stored, for example at room temperature. It turns out that this method takes a long time. Now to speed up the analysis, an "accelerated stability test" can be carried out, namely by observing changes in concentration at high temperatures.

Conclusion

Aloe vera leaf gel preparations and shell collagen contain saponins and flavonoids. In the stability test with polyvinyl alcohol base at a temperature of 270C and unstable at 400C in the homogeneity, elasticity, pH test, and unstable on organoleptic, dispersion test and dry time. The preparation of aloe vera leaf gel at a temperature of 270C and 400C in the organoleptic test, homogeneity, elasticity, pH were the most stable at a concentration of 10% at a temperature of 27oC.

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