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Physical Stability Test of Ethanol Extract Cream of Kepok Banana Leaves (*Musa paradisiaca L.*)

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Abstract. Kepok banana leaves (*Musa paradisiaca L.*) contain of active compounds such as tannins, flavonoids and polyphenols has known for wound healing activity in rats. Cream are drug dosage forms which are widely used because comfortable and relatively stable. The aim of this study is to evaluate the physical stability of ethanol extract cream of *Musa paradisiaca L.* leaves. Cream preparations were made by varying stearic acid concentration, F1 (10%); F2 (15%) and F3 (20%). Physical stability tests carried out on days of 1 and 21 at a low temperature of (4±2^{0}C), room temperature (25±2^{0}C), and high temperature (40±2^{0}C) included organoleptic, spreadability, pH, viscosity, cycling tests, and centrifuges. The research results show that all the formulas showed stable physical characteristics of cream and the best cream preparations is showed on formula F2.

Keywords: cream, banana leaves, wound, physical stability

1 Introduction

Banana (*Musa paradisiaca L.*) leaves has been known to possess wound healing activity [1, 2]. Aqueous extract of banana leaves has been reported for the activity of wound healing with various mechanisms, such as antioxidant and antimicrobial activity [3, 4]. The effect may be due to the presence of active compounds, such as alkaloids, flavonoids, steroids, glycosides and saponins [5].

Creams are included in semi-solid pharmaceutical, emulsion forms, containing one or more ingridients dissolved or dispersed in suitable basic ingredients . Creams are preferred because easy to apply to the skin for a long time, and easily cleaned with water [4, 6] . Stearic acid is a cream base that is often used in cream formulas that function as emulsifying agents. Formulation of cream with the use of stearic acid emulsifier can affect the texture, viscosity, and pH of the preparation [7]. Viscosity is critical to the long term stability of the cream [8].

The aim of this study was to evaluate the effect of creams formulation on the physical stability at a certain period of time at a storage temperature of 4±2^{0}C, 25±2^{0}C, and 40±2^{0}C [8–11]. Formulation of cream used various stearic acid consentration as as emulsifying agents.

2 Methodology

The main ingredients used in the study were kepok banana leaves (*Musa paradisiaca L*); stearic acid, paraffin liquidum, triethanolamine, adeps lanae, nipagin, nipasol, aquadest. All other ingredients were of analytical grade.

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2.1 Formulation of Ethanol Extract Cream of *Musa paradisiaca L.* Leaves

Table 1. Formulation of Ethanol Extract Cream of *Musa paradisiaca L.* Leaves

Ingredient	F1 (g)	F2 (g)	F3 (g)
Extract	10	10	10
Stearic Acid	10	15	20
Parafin liquidum	25	25	25
Triethanolamin	1.5	1.5	1.5
Adeps lanae	3	3	3
Nipagin	0.1	0.1	0.1
Nipasol	0.05	0.05	0.05
Aquadest	ad 100	ad 100	ad 100

2.2 Procedure Of Cream Preparation

The oil phase (paraffin liquidum, stearic acid, adeps lanae) was heated on a waterbath at a temperature of 70^0C until melted. The water phase (nipagin, nipasol, TEA and aquadest) was heated on a waterbath at a temperature of 70^0C until melted. The oil phase was transferred to the mortar and a water phase was added (mixing was undertaken at a temperature of 60^0C - 70^0C, mixing until it was cold and a homogeneous cream mass was formed. Adding the extract to the mortar. Then, adding the cream base to 100 grams, then mixed until homogeneous [6].

2.3 Physical Stability Test of Cream Formula for Ethanol Extract of *Musa paradisiaca L.* Leaves

Physical stability test of the ethanol extract cream formula of Musa pradisiaca L. leaves was carried out by storing cream preparations for 28 days at various storage temperatures 4^0C; 25^0C; and 40^0C. Tests and observations of cream stability were carried out on days of 1 and 28 [12, 13].

2.4 Organoleptic

Observing the color, smell, texture, and homogeneity.

2.5 pH

The pH of the various cream formulations was determined by using digital pH meter.

2.6 Spreadability

A total of 0.5 grams of sample was placed in the middle of a scaled glass and covered again with glass or other loads up to a weight of 150 grams. After placing a waiting load 1 minute then observed the diameter of the distribution and the area was calculated.

2.7 Viscosity test

Cream samples were put into a 100 mL beaker. Viscosity measurement was by using Rion viscometer test equipment.

2.8 Cycling *test*

The samples were stored at 4 ± 2^0C for 24 hours and then transferred to an oven at 40 ± 2^0C for 24 hours. The time during storage of 2 temperatures was considered as one cycle. Stability tests were carried out as many as 6 cycles, then observed whether there was phase separation and crystal formation.

2.9 Centrifugal test

Cream samples of 10 grams were put in a centrifugation tube and then put into a centrifugator at a speed of 3750 rpm for 5 hours. Samples were then observed for the presence or absence of separation phase.

3 Result and Discussion

Cream formulation of ethanol extract of *Musa paradisiaca L.* leaves 10% was made by various of stearic acid concentration of 10%; 15%; and 20%. Stearic acid was a fat phase cream base that was often used as an emulsifying agent in the concentration range of 1 - 20% [7].

Preparation stability of ethanol extract cram of *Musa paradisiaca L.* leaves 10% was done by physical observation of cream on days of 1 and 28 at a storage temperature of 4 ± 2^0C (cold); 25 ± 2^0C (storage); and 40 ± 2^0C (heat). Cream stability was observed with organoleptic test, pH, dispersing power, viscosity, centrifugal test and cycling test.

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3.1 Organoleptic observation

Organoleptic testing was signified to see the physical appearance of a preparation which includes form, color and smell. According to the results of organoleptic observations on ethanol extract cream formulation of *Musa paradisiaca L*. leaves 10% at the storage of the three different temperatures (4±2^{0}C, 25±2^{0}C, 40±2^{0}C) are stated organoleptically stable, does not experience significant changes. The four creams remain stable in four weeks, equally thick green, typical of leaves, and homogeneous. This shows that the oil phase in the cream does not experience oxidation which is characterized by the absence of a rancid odor.

Table 2. Organoleptic observation results of ethanol extract cream of *Musa paradisiaca L*. leaves

Formulation	Days to-	Organoleptic observation			
		Colour	Smell	Texture	Homogeneity
F1	1	Thick green	Typical of leaves	Soft, rather liquid	Homogeneous
	28 (4±2^{0}C)	Thick green	Typical of leaves	Soft, rather liquid	Homogeneous
	28 (25±2^{0}C)	Thick green	Typical of leaves	Soft, rather liquid	Homogeneous
	28 (40±2^{0}C)	Thick green	Typical of leaves	Soft, rather liquid	Homogeneous
F2	1	Thick green	Typical of leaves	Soft, semi-solid	Homogeneous
	28 (4±2^{0}C)	Thick green	Typical of leaves	Soft, semi-solid	Homogeneous
	28 (25±2^{0}C)	Thick green	Typical of leaves	Soft, semi-solid	Homogeneous
	28 (40±2^{0}C)	Thick green	Typical of leaves	Soft, semi-solid	Homogeneous
F3	1	Thick green	Typical of leaves	Soft, solid	Homogeneous
	28 (4±2^{0}C)	Thick green	Typical of leaves	Soft, solid	Homogeneous
	28 (25±2^{0}C)	Thick green	Typical of leaves	Soft, solid	Homogeneous
	28 (40±2^{0}C)	Thick green	Typical of leaves	Soft, solid	Homogeneous

3.2 pH Test

One way to find out the safety of cream preparations that do not irritate the skin is by pH test. pH values which is too acidic can cause itching, redness, and scaly skin.

Table 3. pH Test Result of Ethanol Extract Cream of *Musa paradisiaca L*. Leaves

Formulation	Days to-1	Days to-28 (4±2^{0}C)	Days to-28 (25±2^{0}C)	Days to-28 (40±2^{0}C)
F1	5.50	5.52	5.49	5.48
F2	5.43	5.44	5.43	5.42
F3	5.19	5.13	5.16	5.04

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pH test results show that increasing the use of stearic acid can reduce the pH value because of its acidic group. However, pH range that is obtained during 21 days of storage at a temperature of 4±2^{0}C; 25±2^{0}C and 40±2^{0}C still enter the skin pH range that is required to be safe in the skin, which is 4.5 to 6.5, although the test results show a decrease and increase in pH. Changes in the pH value can be caused by an increase in the reaction rate to double every temperature increase of 10^{0}C. The F2 formula has a relatively stable pH value with insignificant increase or decrease compared to the F1 and F3 formulas.

3.3 Spreadability test

Spreadability tests are carried out to describe the spread and distribution of cream when applied to the skin.

Table 4. Dispersing power test of ethanol extract cream of *Musa paradisiaca L*. leaves

Formulation	Days to-1	Days to-28 (4±2^{0}C)	Days to-28 (25±2^{0}C)	Days to-28 (40±2^{0}C)
F1	6.6	6.5	6.7	6.9
F2	6.5	6.4	6.6	6.8
F3	6.2	6.2	6.3	7.1

Consistency of semi-solid preparations that are comfortable to use ranges from the range of spreadability of 5-7 cm. The results of spreadability show that the cream of ethanol extract of *Musa paradisiaca L*. leaves 10% has a fairly good distribution with a range of 6.2 - 7.1 cm. The F2 formula has a relatively stable spreadability and is better than the F1 and F3 formulas.

3.4 Viscosity test

Viscosity and flow characteristics are a statement of resistance of a liquid to flow, the higher of the viscosity then the greater the resistance.

Table 5. Viscosity test result of ethanol extract of *Musa paradisiaca L*. leaves

Formulation	Days to-1	Days to-28 (4±2^{0}C)	Days to-28 (25±2^{0}C)	Days to-28 (40±2^{0}C)
F1	1100 cp	1180 cp	1080 cp	1040 cp
F2	1400 cp	1470 cp	1380 cp	1350 cp
F3	2400 cp	2480 cp	2360 cp	2380 cp

Viscosity value of ethanol extract cream of *Musa paradisiaca L*. leaves 10% at room temperature storage (25± 2^{0}C) is relatively more stable, compares to storage at low temperatures (4±2^{0}C) and height (40±2^{0}C). The F2 formula has a relatively stable viscosity value with no significant increase or decrease compared to the F1 and F3 formulas. At low temperature storage shows an increase in viscosity, whereas in high temperature storage tends to decrease viscosity. The viscosity of the emulsion will decrease if the temperature is raised, and will increase when the temperature is low. This is because the heat gained will increase the distance between atoms, thus the force between atoms will decrease, the distance becomes tenuous resulting in decreased viscosity of the cream[1].

3.5 Cycling test

Cycling test is an indicator of emulsion stability which is seen from the presence or absence of crystallization and phase separation [1].

Table 6. Cycling test result on leaves extract of *Musa paradisiaca L*.

Formulation	Cycles to-0		Cycles to-6	
	Crystallization	Separation of phase	Crystallization	Separation of phase
F1	Not occur	Not occur	Not occur	Not occur
F2	Not occur	Not occur	Not occur	Not occur
F3	Not occur	Not occur	Not occur	Not occur

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Cycling test results on Table 6 show that all cream formulas of ethanol extract of *Musa paradisiaca L.* leaves 10% have a good emulsion system, where the cream does not experience crystallization and does not experience phase separation. The emulsifying film in the cream formula can work again under a pressure which is induced by ice before coalescence occurs.

3.6 Centrifugal test

Centrifugal test observation is one indicator of the physical stability of the cream which is affected by the force of gravity. Cream samples that were centrifuged at a speed of 3750 rpm for 5 hours are equivalent to the effect of gravity for one year [8,9].

Table 7. Centrifugal test result of *Musa paradisiaca L.* leaves extract

Formulation	Result
F1	Stable: no separation of phase
F2	Stable: no separation of phase
F3	Stable: no separation of phase

Test results of cycling test on Table 7 show that the cream formula of ethanol extract of *Musa paradisiaca L.* leaves 10% has good cream stability, where the cream does not experience phase separation.

Conclusion

Based on the resuts of this study it appears stable cream of extract Banana leaves formulation. Based on spreadability and viscosity, the best formulation shown on F2 used stearic acid 15%.

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