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Effect of Emulsifier Concentration on the Physical Stability of Kepundung Leaf Ethanol Extract Cream (*Baccaurea racemosa)*

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ABSTRACT

This study aimed to formulate and evaluate the physical quality of a cream containing an ethanol extract of kepundung leaves (*Baccaurea racemosa*) using varying concentrations of stearic acid and triethanolamine (TEA) as emulsifiers. The ethanol extract of kepundung leaves was obtained through maceration using 96% ethanol, yielding 12.35%, and was found to contain secondary metabolites, including flavonoids, alkaloids, tannins, saponins, and steroids/triterpenoids, based on phytochemical screening. The cream formulations were prepared using the hot emulsification method in three different formula variations, followed by evaluation of physical quality parameters, including organoleptic properties, homogeneity, pH, spreadability, and adhesiveness during a 14-day storage period at 25°C as a preliminary short-term stability screening. The results showed that all formulations produced homogeneous creams and maintained acceptable physical characteristics throughout the storage period. Variations in emulsifier concentration influenced the characteristics of the formulations, where increasing concentrations of stearic acid and TEA tended to enhance adhesiveness whilst reducing spreadability. The pH values of all formulations remained within the acceptable range for topical preparations, namely pH 5–8, while spreadability and adhesiveness were maintained within the acceptable ranges of 5–7 cm and 2-300 second, respectively. Overall, each formulation exhibited distinct characteristics; however, all fulfilled the evaluated physical quality requirements. Among the formulations evaluated, F2 provided the most balanced combination of spreadability, adhesiveness, and pH characteristics. Therefore, the formulation of kepundung leaf ethanol extract cream has potential as a basis for the further development of topical dosage forms. Nevertheless, additional long-term and accelerated stability studies are required to confirm the long-term stability of the formulations.

Keywords:
Baccaurea racemosa; Cream; Emulsifier; Stearic acid; Triethanolamine; Physical stability

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1. Introduction

Kepundung (*Baccaurea racemosa*) is a plant that is now becoming increasingly rare due to the low economic value of its fruit, meaning it is seldom cultivated. Nevertheless, this plant contains several secondary metabolites with potential for development as medicinal compounds. Extracts of kepundung leaves, prepared using ethanol as a solvent, contain polyphenols, terpenoids, flavonoids and tannins that contribute to strong antioxidant activity, about 9-10 ppm [1], [2].

The direct use of ethanol extract of kepundung leaves is considered impractical and has limitations in topical application; therefore, it needs to be formulated into a more stable and user-friendly topical preparation. Cream is an ideal form of topical preparation as it is easy to apply, provides comfort to the skin, enhances skin hydration, and increases the contact time of the active ingredient with the skin's surface. Oil in water (O/W) type creams are frequently chosen as they provide a cooling sensation on the skin and are suitable for formulations containing active ingredients with limited water solubility [3], [4]. The development of natural-based creams also presents a promising alternative as they utilise plant-derived ingredients and are relatively safe for topical use [5], [6].

The success of a cream formulation is greatly influenced by the choice and concentration of the emulsifier in the formulation. The combination of stearic acid and triethanolamine (TEA) is one of the emulsifier systems commonly used in O/W-type cream formulations, as it is capable of forming a stable emulsion through the in situ formation of triethanolamine stearate [7], [8] . In addition to acting as an emulsifier, stearic acid also serves to improve the consistency of the formulation, whilst TEA can influence the pH of the system [4], [9] .

It is known that the concentrations of stearic acid and TEA in creams can influence various physical quality parameters such as spreadability, adhesion, and pH, which play a role in determining the comfort of use and stability of the formulation [7], [8], [10] . However, studies specifically examining the relationship between variations in emulsifier concentration in formulations of kepundung leaf extract cream and physical quality parameters such as adhesion, spreadability, and pH remain limited. The novelty of this study lies in the systematic evaluation of stearic acid (8–12%) and TEA (2–4%) combinations under the same storage conditions to assess their effects on the physical stability of kepundung leaf extract cream. Understanding the relationship between emulsifier composition and the physical characteristics of the formulation is essential for producing a stable cream formulation that is acceptable for use. Therefore, this study aims to investigate the effect of varying concentrations of stearic acid and TEA in an ethanol leaf extract cream formulation of *Baccaurea racemosa* on physical characteristics and short-term stability.

2. Method

This study is a laboratory experimental study focusing on the formulation and evaluation of the physical quality of a cream preparation containing kepundung leaf extract, using varying concentrations of stearic acid and TEA emulsifiers.

Extraction of Kepundung Leaves

The dried kepundung leaves were extracted using a maceration method modified from Telaumbanua et al. [11]. The dried leaves were macerated in 96% ethanol at a ratio of 1:5 (w/v) at room temperature for 3 days with periodic stirring. The macerate was then filtered to separate the filtrate from the residue. The residue was subsequently re-macerated twice using fresh solvent at the same ratio for an additional 2 days. All collected filtrates were combined and concentrated using a rotary evaporator at 40°C under 75 mbar pressure. The concentrated extract was stored in a glass vial wrapped in aluminum foil at 4°C until further formulation.

Phytochemical Screening of Kepundung Leaf Extract

Phytochemical screening of the ethanol extract of kepundung leaves was carried out qualitatively to detect the presence of flavonoids, tannins, saponins, alkaloids, and steroids/triterpenoids. Flavonoids were identified using the Shinoda method with magnesium powder and concentrated HCl. Tannins were identified using a gelatin solution. Saponins were examined via a foam test by shaking the extract solution in water. Alkaloids were identified using Dragendorff's reagent. Meanwhile, steroids/triterpenoids were examined using the Liebermann–Burchard reaction after the extract was dissolved in chloroform [12] .

Formulation of a Cream From Kepundung Leaf Extract

The formulation of kepundung leaf ethanol extract cream was optimized by varying the concentrations of the emulsifiers, namely stearic acid (8%, 10%, and 12%) and triethanolamine (TEA) (2%, 3%, and 4%). Variations in stearic acid and TEA concentrations were combined in pairs within each formula to produce different emulsifier systems. The composition and concentration of each ingredient are presented in **Table 1**.

Table 1. Variations in the formula for kepundung leaf ethanol extract cream

Ingredients	Ingredient composition (%)		
	F1	F2	F3
Ethanol extract of kepundung leaves	1.5	1.5	1.5
Stearic acid	8	10	12
TEA	2	3	4
Cetyl alcohol	2	2	2
Olive oil	5	5	5
Glycerine	10	10	10
Propylene glycol	15	15	15
BHT	0.1	0.1	0.1
Methylparaben	0.2	0.2	0.2
Propylparaben	0.2	0.2	0.2
Distilled water q.s.	100	100	100

The cream formulations were prepared using the hot emulsification method. The oil phase, consisting of olive oil, stearic acid, cetyl alcohol, butylated hydroxytoluene (BHT), and propylparaben, was melted in a water bath at 70°C. The aqueous phase, consisting of glycerin, TEA, methylparaben, distilled water, and a portion of propylene glycol, was heated separately to 70°C. The ethanol extract of kepundung leaves was dispersed separately in the remaining propylene glycol. After both phases reached 70°C, the aqueous phase was gradually poured into the oil phase. The mixture was then homogenized by homogenizer at 1000 rpm for 10 min until a homogeneous cream base was formed. Subsequently, the extract dispersion was added gradually to the cream base and homogenized.

Stability Test

Stability testing was carried out on all three formulations at 25°C for 14 days, with testing points on days 0, 1, 3, 7, 10 and 14. Stability testing was carried out over 14 days as a preliminary stability study to evaluate short-term physical changes in the cream formulation, which is commonly used in the initial formulation screening stage prior to long-term stability testing. Each test was performed in triplicate. Physical quality evaluation included organoleptic testing, homogeneity, pH, adhesion, and spreadability.

Organoleptic Test

The organoleptic test was carried out by observing the shape, colour, odour and homogeneity using the five senses. The homogeneity of the preparation was assessed by placing 0.1 g of cream between two glass slides. The preparation was deemed homogeneous if its texture appeared uniform, showed no particle aggregation, felt smooth to the touch, and contained no coarse particles [13] .

pH Test

The pH of the cream formulation was tested using a pH meter. One gram of cream was dissolved in 10 mL of distilled water and then homogenised. The pH meter electrode was then immersed in the cream solution, and the pH value displayed on the instrument's screen was recorded [14] .

Adhesion Test

A total of 0.1 g of the cream preparation is placed on the surface of a glass slide and covered with another glass slide. A weight of 0.5 kg is then applied for 5 minutes. Next, one end of the glass slide is clamped with an 80 g weight to pull the lower part of the slide. The adhesion of the preparation is indicated by the time taken for the two glass slides to separate [15] .

Spreadability Test

A total of 0.5 g of the cream formulation was placed in the centre of the spreadability tester and covered with a glass plate. Loads of 50 g, 100 g, and 150 g were sequentially applied at 1-minute intervals. The spreadability value reported in this study was the final spread diameter measured under the maximum applied load of 150 g [14].

Statistical Analysis

The analysis was carried out using statistical software. Data from physical quality evaluations, including pH, spreadability, and adhesion, were expressed as mean ± standard deviation from three replicates. Statistical analysis was performed using repeated measures two-way ANOVA to evaluate differences among formulations during the 14-day storage period. Post hoc multiple comparison tests were conducted when significant differences were observed ($p < 0.05$). All statistical analyses were performed using IBM SPSS Statistics software version 32 at a 95% confidence level.

3. Results and Discussion

Extraction and Phytochemical Screening

The powdered crude material of kepundung leaves was macerated with 96% ethanol, yielding an extract with a yield of 12.35%. The results of the phytochemical screening are presented in **Table 2**, which shows that the kepundung leaf extract contains flavonoids, alkaloids, tannins, saponins, and steroids/triterpenoids.

Table 2. Results of phytochemical screening of the kepundung leaf ethanol extract

Secondary metabolites	Reagent	Result
Flavonoids	Mg + HCl	+
Alkaloid	Dragendorff	+
Tannin	Gelatin	+
Saponin	Water	+
Steroids/Triterpenoids	Liebermann-Burchard	+

Organoleptic and Homogeneity Tests

Based on the results of the organoleptic test, it was found that the cream formulation possesses a distinctive aroma derived from the extracts in the formulation. The formulation has a semi-solid consistency in line with its intended purpose and exhibits a brownish-green colour, as shown in **Figure 1**. Observations also revealed that all three cream formulations have a homogeneous texture, characterised by the absence of coarse particles or lumps in the formulation. Differences in the concentrations of TEA and stearic acid in each formulation did not result in any differences in organoleptic characteristics. Observations over a 14-day storage period showed that there were no changes in the organoleptic parameters; thus, the odour, form, colour, and homogeneity of the cream preparations remained the same as in the initial observations. Furthermore, the creams did not undergo oxidation, as indicated by the absence of a rancid odour in the preparations [16] .

Figure 1. Representative appearance of kepundung leaf ethanol-extract creams (F1–F3) showing homogeneous texture and no visible phase separation during 14-day storage at 25°C

pH Test

The results of pH measurements of the kepundung leaf ethanol extract cream formulations during the 14-day storage period are presented in **Table 3**. Although statistically significant changes in pH were observed over time, the magnitude of these changes was small, and all formulations remained within the acceptable pH range for topical preparations throughout storage. F1 consistently showed the lowest pH values, followed by F2, whereas F3 exhibited the highest pH values. Overall, the pH values ranged from 6.58–6.66 for F1, 7.27–7.37 for F2, and 7.85–7.94 for F3. These values remained within the acceptable pH range for topical preparations (5–8), indicating that all formulations met the pH requirements for topical application [3],[17].

Statistical analysis using repeated measures two-way ANOVA (**Table 6**) demonstrated significant effects of both storage time ($F = 11.755$, $p < 0.001$) and formulation ($F = 7758.018$, $p < 0.001$) on pH values. In contrast, the interaction between storage time and formulation was not significant ($F = 0.494$, $p = 0.880$). These findings indicate that although slight changes in pH occurred during storage, the pattern of pH change was comparable among all formulations. Post hoc Tukey analysis (**Table 7**) further confirmed significant differences between all formulation pairs ($p < 0.05$), indicating that variations in emulsifier concentration significantly influenced the pH characteristics of the cream.

The higher pH values observed in F2 and F3 may be attributed to the increased concentration of TEA, which is alkaline and can increase the pH of the formulation system [3], [4]. Conversely, stearic acid contributes to the acidic component of the formulation and interacts with TEA to form triethanolamine stearate in situ, which functions as an emulsifier in the O/W emulsion system [10], [15]. The balance between these two components plays an important role in determining the final pH of the formulation, whereby a higher concentration of TEA relative to stearic acid tends to result in a higher pH value.

Table 3. Results of pH stability testing of kepundung leaf ethanol extract cream

Day	pH value (mean ± SD, n=3)		
	F1	F2	F3
0	6.59 ± 0.03	7.27 ± 0.03	7.85 ± 0.03
1	6.58 ± 0.02	7.27 ± 0.01	7.86 ± 0.03
3	6.60 ± 0.04	7.31 ± 0.03	7.86 ± 0.04
7	6.62 ± 0.02	7.35 ± 0.03	7.89 ± 0.03
10	6.62 ± 0.04	7.35 ± 0.04	7.91 ± 0.04
14	6.66 ± 0.03	7.37 ± 0.04	7.94 ± 0.04

The relatively small magnitude of pH variation observed during storage, despite being statistically significant, suggests that the formulations maintained acceptable pH characteristics throughout the 14-day preliminary short-term stability screening. Furthermore, the absence of a significant interaction between storage time and formulation indicates that the different emulsifier concentrations did not substantially alter the overall pattern of pH change during storage.

Spreadability Test

Spreadability is an important parameter in topical preparations because it influences the ease of application and the ability of the formulation to distribute evenly over the skin surface. The results of the spreadability test during the 14-day storage period are presented in **Table 4**. Differences in spreadability values were observed among formulations, and a gradual increase in spreadability was noted during storage. F1 exhibited the highest spreadability, followed by F2, whereas F3 showed the lowest spreadability. The spreadability values ranged from 6.5–6.8 cm for F1, 6.1–6.5 cm for F2, and 5.4–5.8 cm for F3. These values remained within the acceptable range for cream formulations (approximately 5–7 cm), indicating that all formulations possessed satisfactory spreading properties for topical application [7],[8],[17].

The results of repeated measures two-way ANOVA (**Table 6**) showed that storage time ($F = 40.230$, $p < 0.001$), formulation ($F = 609.215$, $p < 0.001$), and the interaction between storage time and formulation ($F = 3.724$, $p = 0.002$) had significant effects on spreadability. These findings indicate that spreadability changed during storage and that the pattern of change differed among formulations. Post hoc Tukey analysis (**Table 7**) further demonstrated significant differences between all formulation pairs ($p < 0.05$), confirming that variations in stearic acid and TEA concentrations significantly affected the spreadability characteristics of the cream.

The higher spreadability observed in F1 may be associated with a lower internal structural resistance of the formulation, whereas the lower spreadability observed in F3 may be related to the higher concentration of stearic acid. Stearic acid is known to function not only as a component of the emulsifier system but also as a consistency-enhancing agent in cream formulations. Consequently, increasing its concentration may contribute to a thicker cream structure and reduced spreadability. However, viscosity was not directly measured in the present study; therefore, any relationship between spreadability and viscosity remains speculative and requires further confirmation through rheological evaluation.

Table 4. Results of the spreadability stability test for kepundung leaf ethanol extract cream

Day	Spread value (cm) (mean ± SD, n=3)		
	F1	F2	F3
0	6.5 ± 0.07	6.1 ± 0.07	5.4 ± 0.08
1	6.5 ± 0.03	6.2 ± 0.03	5.4 ± 0.01
3	6.6 ± 0.07	6.2 ± 0.06	5.4 ± 0.04
7	6.7 ± 0.06	6.2 ± 0.02	5.5 ± 0.03
10	6.7 ± 0.08	6.4 ± 0.07	5.6 ± 0.08
14	6.8 ± 0.08	6.5 ± 0.09	5.8 ± 0.09

The spreadability of a cream is also influenced by the structure of the emulsion system formed during formulation. In this study, the cream was designed as an O/W emulsion based on the predominance of the aqueous phase and the use of stearic acid–TEA as the emulsifier system. The interaction between these components may contribute to the formation of a more structured emulsion network, which can influence the mobility of the dispersed and continuous phases and subsequently affect spreadability [3], [10].

Although statistically significant changes in spreadability were observed during storage, the magnitude of these changes remained relatively small and all formulations continued to meet the acceptable spreadability criteria throughout the 14-day storage period. Furthermore, the significant interaction between storage time and formulation indicates that the extent of spreadability change differed among formulations. Nevertheless, all formulations maintained acceptable spreading characteristics during the preliminary short-term stability screening.

Adhesion Test

Adhesion is an important parameter in the evaluation of topical preparations because it reflects the ability of a formulation to remain in contact with the skin surface for a certain period of time. A longer adhesion time may increase the residence time of the active ingredient on the skin and potentially enhance its effectiveness [3], [10]. The adhesion test results during the 14-day storage period are presented in **Table 5**. Differences in adhesion values were observed among the formulations, with a general tendency for adhesion to increase during storage. F3 consistently exhibited the highest adhesion, followed by F2, whereas F1 showed the lowest adhesion at all observation points. Overall, adhesion values ranged from 2.4–2.6 seconds for F1, 2.6–3.0 seconds for F2, and 3.3–3.8 seconds for F3. All formulations met the acceptable adhesion criteria for cream preparations, which generally range from 2–300 seconds [8],[15], indicating satisfactory adhesive properties throughout the storage period.

The results of repeated measures two-way ANOVA (**Table 6**) demonstrated significant effects of storage time ($F = 45.844$, $p < 0.001$), formulation ($F = 940.925$, $p < 0.001$), and the interaction between storage time and formulation ($F = 3.850$, $p = 0.002$) on adhesion values. These findings indicate that adhesion changed significantly during storage and that the pattern of change differed among formulations. Post hoc Tukey analysis (**Table 7**) further confirmed significant differences between all formulation pairs ($p < 0.05$), demonstrating that variations in stearic acid and TEA concentrations significantly influenced the adhesive characteristics of the cream.

Table 5. Results of the adhesion stability test for kepundung leaf ethanol extract cream

Day	Adhesion strength (seconds) (mean ± SD, n=3)		
	F1	F2	F3
0	2.4 ± 0.08	2.7 ± 0.07	3.3 ± 0.07
1	2.4 ± 0.02	2.6 ± 0.03	3.3 ± 0.03
3	2.4 ± 0.06	2.7 ± 0.02	3.3 ± 0.08
7	2.4 ± 0.04	2.8 ± 0.04	3.4 ± 0.06
10	2.6 ± 0.04	2.8 ± 0.06	3.5 ± 0.09
14	2.6 ± 0.05	3.0 ± 0.08	3.8 ± 0.09

The higher adhesion observed in F2 and F3 may be associated with the increased concentration of stearic acid in these formulations. Stearic acid is known to contribute to the consistency and structural characteristics of cream systems, which may promote stronger interactions between the formulation and the contact surface. Consequently, formulations containing higher concentrations of stearic acid tended to exhibit longer adhesion times. However, viscosity was not directly measured in this study; therefore, any relationship between adhesion and viscosity can only be suggested and should be confirmed through future rheological studies.

Furthermore, the higher adhesion observed in F3 corresponded to its lower spreadability compared with the other formulations. This observation is consistent with previous reports indicating that formulation characteristics affecting adhesion and spreadability are often interrelated [8], [10], [15]. Together with the spreadability results, these findings suggest that increasing stearic acid and TEA concentrations influenced the physical consistency of the cream, resulting in stronger adhesion but lower spreading ability. However, because viscosity measurements were not performed, the mechanism underlying this relationship could not be directly confirmed in the present study.

Table 6. Summary of repeated measures two-way ANOVA results

Parameter	Effect	F value	P value
pH	Time	11,755	<0,001
	Formula	7758,018	<0,001
	Time x Formula	0,494	0,880
Spreadability	Time	40,230	<0,001
	Formula	609,215	<0,001
	Time x Formula	3,724	0,002
Adhesion	Time	45,844	<0,001
	Formula	940,925	<0,001
	Time x Formula	3,850	0,002

Although statistically significant changes in adhesion were observed during storage, the magnitude of these changes remained within the acceptable adhesion range for all formulations throughout the 14-day storage period. Furthermore, the significant interaction between storage time and formulation indicates that the extent of adhesion change differed among formulations. Nevertheless, all formulations maintained satisfactory adhesive properties during the preliminary short-term stability screening.

Overall, the results demonstrated that variations in stearic acid and TEA concentrations significantly influenced the physical characteristics of the cream formulations. Increasing the concentrations of these components tended to decrease spreadability while increasing adhesion, whereas all formulations maintained pH values within the acceptable range for topical preparations. These findings suggest that the emulsifier system exerted a greater influence on the mechanical characteristics of the cream than on its pH suitability. Among the formulations evaluated, F2 exhibited the most balanced combination of spreadability, adhesion, and pH characteristics. However, no formal optimization procedure was performed in this study; therefore, this interpretation should be regarded as descriptive rather than indicative of an objectively optimal formulation.

Table 7. Post hoc tukey multiple comparison among formulations

Parameter	Comparison	Mean Difference	p value
pH	F1 vs F2	-0,7083	<0,001
	F1 vs F3	-1,2733	<0,001
	F2 vs F3	-0,5650	<0,001
Spreadability	F1 vs F2	0,3300	<0,001
	F1 vs F3	1,0800	<0,001
	F2 vs F3	0,7500	<0,001
Adhesion	F1 vs F2	-0,3000	<0,001
	F1 vs F3	-0,9667	<0,001
	F2 vs F3	-0,6667	<0,001

This study has several limitations. First, viscosity was not directly measured; therefore, any discussion regarding the possible relationship between viscosity, spreadability, and adhesion should be interpreted with caution. Second, the emulsion type was inferred from the formulation composition and emulsifier system but was not experimentally confirmed. In addition, the stability evaluation was limited to a 14-day storage period at 25°C and should therefore be regarded as a preliminary short-term stability screening rather than evidence of long-term stability. Further studies involving rheological evaluation, experimental determination of emulsion type, and accelerated and long-term stability testing are required to provide a more comprehensive assessment of the formulation characteristics and stability.

4. Conclusion

An ethanol extract of *Baccaurea racemosa* leaves, obtained by maceration with a yield of 12.35% and containing various secondary metabolites, was successfully formulated into a cream preparation with acceptable physical characteristics. Variations in the concentrations of stearic acid and TEA significantly influenced the physical properties of the cream, with increasing concentrations tending to increase adhesion and reduce spreadability. All formulations maintained acceptable organoleptic characteristics, homogeneity, pH, spreadability, and adhesion throughout the storage period evaluated. Each formulation exhibited distinct physical characteristics, with F2 providing the most balanced combination of pH, spreadability, and adhesion among the formulations tested. However, no formal optimization procedure was performed. Therefore, the formulated *Baccaurea racemosa* leaf ethanol extract cream may serve as a basis for the further development of topical preparations. The results of this study indicate that the formulations maintained acceptable physical characteristics throughout the 14-day storage period at 25°C. However, this evaluation should be regarded as a preliminary short-term stability screening rather than confirmation of long-term stability. Further studies involving rheological evaluation, extended storage periods, and accelerated stability testing are required to confirm the long-term stability and performance of the formulations.

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Conflict of Interest:
All authors confirm that there are no actual or potential conflicts of interest associated with this research.

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