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Optimization of stearic acid and triethanolamine in the cream formulation of ethyl acetate fraction of clove leaves (*Syzygium aromaticum* l.)

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ABSTRACT

The ethyl acetate portion of clove leaves is a potential ingredient for topical applications. However, achieving the ideal stability and physical characteristics remains a significant challenge. This study's goal was to use simplex lattice design to calculate the ratio of stearic acid to triethanolamine in a cream formulation that contained the ethyl acetate fraction of clove leaves. Triethanolamine was then adjusted from 2 to 4% and stearic acid from 14 to 16%. The parameters that were put to the test were adhesiveness, spreadability, pH, and viscosity. In contrast to lower viscosity (7,117–9,137 cPs) and adhesiveness (1.13–1.90 s), the results showed that an increase in triethanolamine concentration resulted in greater pH (7.43–8.46) and spreadability (4.70–6.68 cm). Higher stearic acid concentrations, on the other hand, increased viscosity and adhesiveness while decreasing pH and spreadability ($p<0.05$), however, all parameters remained within acceptable limits. These findings indicate that although the optimized formulation exhibits good physical characteristics, further formulation improvements are required to enhance long-term storage stability.

1. INTRODUCTION

The active chemicals found in clove leaves (*Syzygium aromaticum* L.) give them a variety of therapeutic benefits. Bioactive substances found in clove leaves, including flavonoids, alkaloids, saponins, glycosides, and tannin, are also thought to act as antibacterial agents that promote burn healing

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(Sukirawati & Muzdalifah, 2020). Flavonoids found in clove leaves can stop germs from developing by damaging their cell membranes and reducing inflammation (Ugha et al., 2019). These compounds tend to dissolve better in semi-polar solvents such as ethyl acetate, so extraction with this solvent produces a higher concentration of flavonoids (Fitriyanti et al., 2020). A study by Ramadhani et al. (2020) stated that the 10% ethyl acetate fraction of clove leaves has an antibacterial effect on *Staphylococcus aureus* and *Escherichia coli* with an inhibition zone of approximately 17 mm. These findings confirm the enormous potential of clove leaves as an active ingredient for the development of pharmaceutical products, particularly antibacterial and anti-inflammatory drugs (Ramadhani et al., 2020). Previous studies on *Syzygium aromaticum* leaves have predominantly focused on phytochemical profiling and the evaluation of biological activities such as antioxidant, antimicrobial, and anti-inflammatory effects. However, most investigations were limited to crude extracts or essential oils, with minimal emphasis on standardized topical dosage form development. Although several topical preparations containing clove extracts have been reported, formulation strategies were generally empirical and lacked systematic optimization of critical excipient ratios.

Topical administration of drugs has various benefits, including local effects on targeted tissues and increased patient comfort. This method also eliminates the risk of side effects, such as gastrointestinal irritation, which often occurs with oral administration (Haque & Sugihartini, 2015). Creams are semi-solid emulsion topical preparations made from active ingredients that have been dissolved or distributed in a suitable base. No research has been done on inhibitors such stearic acid and triethanolamine (TEA) that were optimized in an in-situ type emulsifying system using cream formulations that contain the ethyl acetate portion of clove leaves. Since soap production affects pH, viscosity, spreadability, adhesiveness, and physical stability, the stearic acid-triethanolamine system is essential to comixing and establishing the emulsifying stability of the O/W cream. Prior formulations, however, typically employed fixed concentrations without quantifying changes in the features (stability parameters) brought about by variations in their proportions.

Moreover, while the ethyl acetate fraction is known to contain semi-polar bioactive compounds such as flavonoids and phenolic constituents with promising dermatological potential, its incorporation into a systematically optimized cream base has not been adequately investigated. There is limited evidence regarding how excipient ratio variations affect the stability and performance of formulations containing this specific fraction.

Therefore, this study addresses these gaps by applying a systematic optimization approach to determine the optimal ratio of stearic acid and TEA in the cream formulation of the ethyl acetate fraction of clove leaves. A quality cream must be stable during storage, have a soft consistency, and be easy to use. To achieve stability, emulsifier components such as TEA and stearic acid are required. TEA functions as an emulsifier and alkalization agent, while stearic acid plays a role in improving the consistency of the cream (Sari et al., 2021). Emulsifiers reduce the surface tension of water and oil to produce a stable emulsion. When stearic acid and TEA interact, they form stearic acid-TEA salt, which acts as an emulsifier for M/A type creams, helping to encapsulate oil droplets in the aqueous phase and improve emulsion stability (Mansauda et al., 2022). The concentration of stearic acid in cream formulations generally ranges from 1 to 20%, while TEA ranges from 2 to 4% (Rowe et al., 2017). According to research by Opod et al. (2024), the optimal combination of 16% stearic acid and 2% TEA

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produce a cream with good physical stability. This research not only advances formulation science through rational excipient optimization but also contributes to the development of more stable, reproducible, and pharmaceutically acceptable topical herbal products. The novelty of this work lies in integrating fraction-based phytochemical development with structured formulation optimization to achieve improved physical characteristics and stability outcomes. However, studies that specifically optimize the combination of stearic acid and TEA in cream formulations containing the ethyl acetate fraction of clove leaves using a systematic experimental design approach, such as Simplex Lattice Design (SLD), are still limited.

Optimizing the concentration of TEA and stearic acid is necessary to guarantee that the cream formulation has the best possible physical properties. SLD is a mixture design approach that is particularly suitable for optimizing formulations in which the total proportion of components is fixed, such as emulsifier systems in cream formulations. This method allows systematic evaluation of the individual and combined effects of formulation components, enabling the identification of an optimal ratio with a limited number of experimental runs. SLD was selected in this study to efficiently optimize the ratio of stearic acid and TEA and to determine their influence on the physical characteristics of the cream formulation. A desirability value near 1 is used in SLD analysis to determine the optimal formula (Purwanto et al., 2024). Therefore, this study aimed to optimize the concentrations of stearic acid and TEA in a cream formulation containing the ethyl acetate fraction of clove leaves using the SLD method to obtain optimal physical characteristics, including pH, viscosity, spreadability, and adhesiveness.

2. METHODOLOGY

2.1 Materials

The main materials used include clove leaves (*Syzygium aromaticum* L.). Clove leaf samples were obtained from the Bergas area, Semarang Regency, Central Java, Indonesia. Botanical identification of the clove leaves was conducted at the School of Pharmaceutical Sciences, Semarang Pharmacy Foundation (STIFAR), based on macroscopic and organoleptic characteristics, and the plant material was confirmed as *Syzygium aromaticum* L. The authenticated leaves were subsequently cleaned, oven-dried, and ground into powder prior to extraction, 96% ethanol, ethyl acetate, phytochemical reagents, GF254 TLC plates, cetyl alcohol, stearic acid, triethanolamine, glycerin, methyl paraben, propyl paraben, and distilled water. The equipment used includes laboratory glassware (Pyrex), digital scales (Ohaus), rotary evaporators (DLAB RE 100-pro), water baths (WB100-8F), brookfield viscometers (WVS-2M), pH meters (Milwaukee), spreadability testers, adhesiveness testers, moisture balances (Ohause), Design Expert version 13 and IBM SPSS Statistics 23 software.

2.2 Extraction

The extraction of clove leaves (*Syzygium aromaticum* L.) using the maceration method. The dried clove leaf powder was macerated with 96% ethanol at a plant-to-solvent ratio of 1:5 (w/v) for 72 hours, with occasional stirring every 8 hours. The extraction was performed in triplicate. The combined filtrates were concentrated using a rotary evaporator at 50°C. Subsequently, the extract underwent standardization, which

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encompassed specific parameters such as organoleptic properties, ethanol and water-soluble extractive values, phytochemical screening, and thin-layer chromatography profiling.

2.3 Thin layer chromatography (TLC) identification

TLC analysis was carried out as part of extract standardization. Silica gel GF254 plates were used as the stationary phase. The ethanol extract and ethyl acetate fraction of clove leaves, along with quercetin as a reference standard, were spotted onto the plates. The plates were developed in a closed chamber using n-butanol: glacial acetic acid: water (4:1:5, v/v/v) as the mobile phase for flavonoid separation. After development, the plates were dried and observed under ultraviolet (UV) light at a wavelength of 254 nm. Flavonoid compounds were identified by comparing the Rf values and spot characteristics of the samples with those of the quercetin standard. As well as nonspecific parameters, including moisture content, total ash, acid-insoluble ash, and loss on drying.

2.4 Fractionation

The next step is to fractionate the extract using the liquid-liquid extraction method with ethyl acetate solvent to obtain a semi-polar fraction rich in flavonoids. Liquid–liquid fractionation was carried out using ethyl acetate in a separatory funnel with a solvent ratio of 1:1 (v/v). The fractionation process was repeated three times to ensure optimal separation. The ethyl acetate fraction obtained was then used as the active ingredient in the cream formulation.

2.5 Formula optimization

Formula optimization was carried out using the Simplex Lattice Design (SLD) approach with Design Expert software version 13, by varying the concentrations of two main components, namely stearic acid (14–16%) and triethanolamine (2–4%).

2.6 Cream preparation process

The eight formulas produced in the design were then processed into cream preparations by combining two phases, namely the oil phase consisting of stearic acid, cetyl alcohol, and propyl paraben, and the water phase containing methyl paraben, glycerin, and triethanolamine. The oil phase was heated to 70–80°C before being mixed with the liquid phase to produce a homogeneous emulsion system. The concentration of the ethyl acetate fraction of clove leaves used in all cream formulations was 10% w/w. This concentration was kept constant across all formulations to ensure that the observed differences in physical characteristics were solely influenced by variations in stearic acid and triethanolamine concentrations. The ethyl acetate fraction of clove leaves was then gradually added to the cream base while stirring continuously until a stable preparation was formed.

2.7 The physical characteristics of the cream

The physical characteristics of the cream containing the ethyl acetate fraction of clove leaf ethanol extract were evaluated to assess the effect of the combination of stearic acid and triethanolamine. The tests included organoleptic properties, homogeneity, spreadability, adhesiveness, pH, viscosity, and stability.

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i. Organoleptic test: Organoleptic evaluation was conducted by visual observation to assess color, odor, and consistency.

ii. Homogeneity test: Homogeneity was examined by spreading a small amount of cream on a glass slide to ensure the absence of coarse particles or phase separation.

iii. Spreadability test: Spreadability was determined by placing 0.5 g of cream on an extensometer and measuring the diameter after one minute, followed by the gradual application of loads of 50 g up to 150 g at one-minute intervals.

iv. Adhesiveness test: Adhesiveness was evaluated by placing 0.5 g of cream between two glass slides under a 50 g load for one minute, and the time required for the slides to separate was recorded.

v. pH test: The pH of the cream was measured using a calibrated digital pH meter by immersing the electrode into the sample until a stable reading was obtained.

vi. Viscosity test: Viscosity was measured using a brookfield viscometer equipped with spindle number 4 at a rotational speed of 60 rpm. All measurements were performed in triplicate to ensure accuracy and reproducibility of the results.

vii. Stability test: To assess product stability, an accelerated stability test was conducted for 30 days at a temperature of 40°C and a relative humidity of 75%, with evaluation of the same physical parameters on day 0 and day 30.

2.8 Statistical analysis

The evaluation data were analyzed using analysis of variance (ANOVA) and model goodness-of-fit tests to ensure model suitability in the SLD design. Normality testing was performed using the Shapiro–Wilk test. Comparisons between model predictions and actual values of the optimum formula were analyzed using a one-sample t-test, while parameter changes during storage were analyzed using a paired t-test or Wilcoxon test according to the data distribution. The optimum formula was determined based on the highest desirability value produced by the prediction model. All experiments and measurements were performed in triplicate (n = 3).

3. RESULTS

Table 1. Composition of clove leaf fraction cream formula based on SLD method results

Ingredients	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)	F6 (%)	F7 (%)	F8 (%)
Ethyl acetate fraction of clove leaves	10	10	10	10	10	10	10	10
Triethanolamine	4	2	3.5	2.5	3	4	2	3
Stearic acid	14	16	14.5	15.5	15	14	16	15
Cetyl alcohol	4	4	4	4	4	4	4	4
Glycerin	15	15	15	15	15	15	15	15
Methly paraben	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Propyl paraben	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
Aquadest	Ad 100	Ad 100	Ad 100	Ad 100	Ad 100	Ad 100	Ad 100	Ad 100

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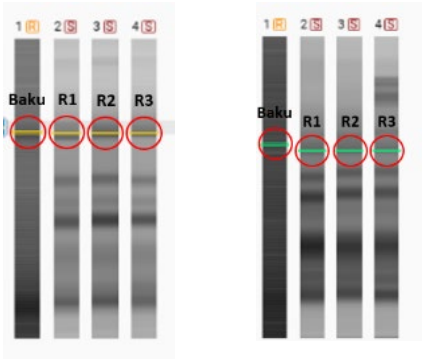
Table 2. Specific and non-specific parameter results of ethanol extract of clove leaves

Parameter Type	Test Parameter	Result
Specific	Organoleptic	
	Color	Dark brown
	Odor	Distinctive clove aroma
	Shape	Thick extract
	Phytochemical screening	
	Alkaloids	+ (Positive)
	Flavonoids	+ (Positive)
	Saponins	+ (Positive)
	Tannins	+ (Positive)
	Steroids	- (Negative)
	Triterpenoids	+ (Positive)
	Terpenoids	+ (Positive)
	Water-soluble compound content Ethanol-soluble compound content	32.3 ± 0.17 % 55.5 ± 7.47 %
Non-specific	Moisture content	1.70 ± 0.05 %
	Ash content	1.73 ± 0.42 %
	Acid-insoluble ash content	0.10 ± 0,00 %
	Drying loss	6.10 ± 0.46%



(a) (b)

Fig. 1. TLC results. Description: (a) Results of TLC test of ethanol extract of clove leaves at a wavelength of 254 nm, (b) Results of TLC test of ethyl acetate fraction of clove leaves at a wavelength of 254 nm

Table 3. Results of physical characteristic tests of cream in formula optimization using the SLD method

Response	F1	F2	F3	F4	F5	F6	F7	F8
Spreadability (cm)	6.675±0.08	4.972±0.23	5.125±0.08	4.704±0.23	5.302±0.17	6.155±0.07	4.824±0.08	5.102±0.08
Adhesion (seconds)	1.230±0.18	1.900±0.03	1.460±0.07	1.610±0.05	1.705±0.16	1.130±0.04	1.780±0.02	1.660±0.22
pH	8.460±0.03	7.430±0.01	8.150±0.02	7.650±0.05	7.940±0.02	8.180±0.00	7.460±0.01	7.980±0.02
Viscosity (cPs)	7,460±196.98	9,137±800.90	8,407±365.01	8,980±878.46	8,963±814.51	7,117±438.22	9,053±120.97	8,030±377.23

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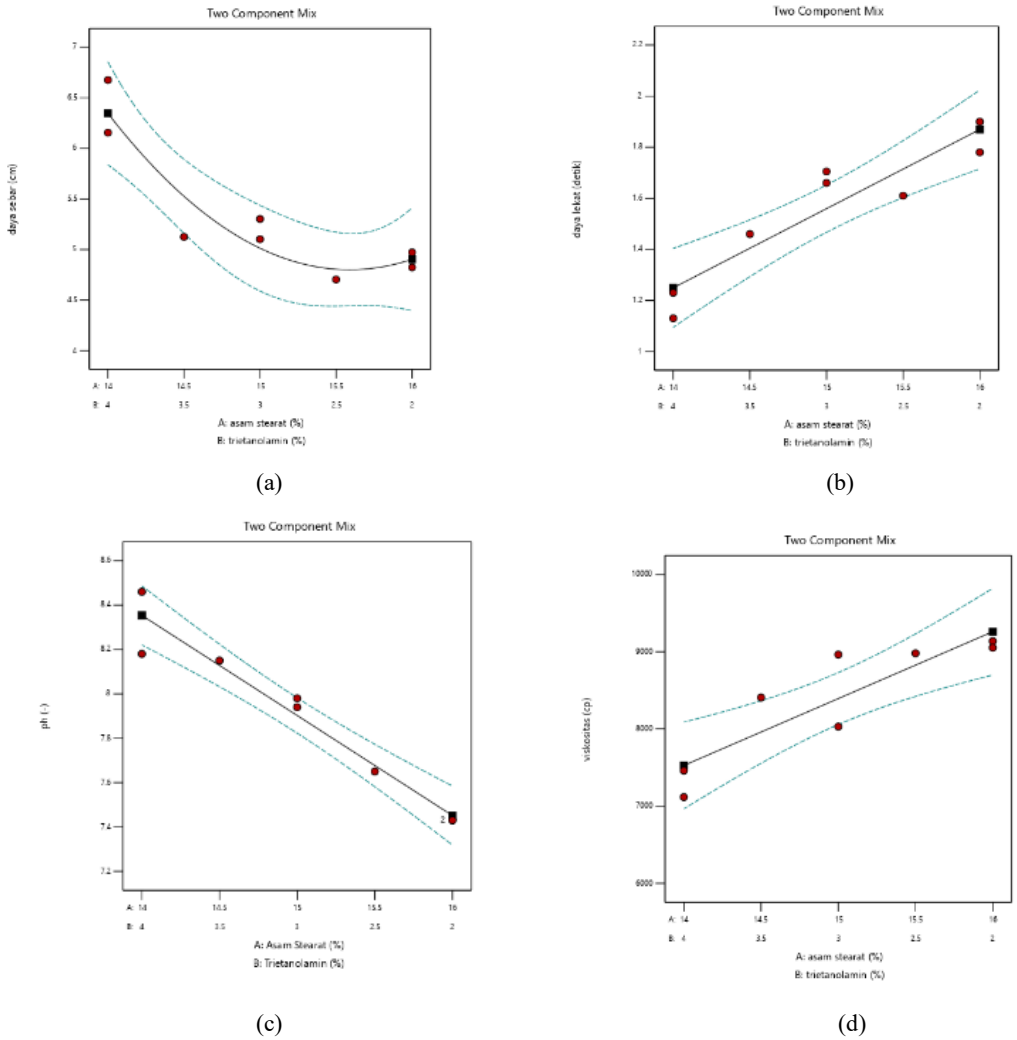

Fig. 2. SLD response model graphs results

Table 4. SLD equation ethyl acetate fraction clove leaf cream

	Equation	Model linier mixture	Lack of Fit	Adeq precision
Spreadability	Y=4.90 (A) + 6.35 (B) – 2.45 (AB)	0.0055	0.2500	8.6924
Adhesion	Y=1.87 (A) + 1.25 (B)	0.0009	0.1341	11.5738
pH	Y=7.46 (A) + 8.35 (B)	<0.0001	0.8619	19.4167
Viscosity	Y=9,259.93 (A) + 7,526.82 (B)	0.0033	0.5594	8.8999

Description: response (Y), stearic acid component (A), triethanolamine component (B), stearic acid–triethanolamine component (AB).

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Table 5. Physical characteristics of the optimal formula

Test Parameters	Results	SLD Predicted Value	Requirements
Organoleptic	A thick consistency, dark brown with a slightly greenish hue, and possessing the characteristic aroma of clove leaves		
Homogeneity	Homogen		
Spreadability (cm)	4.98 ± 0.02	5.00	5-7
Adhesion (seconds)	1.56 ± 0.01	1.565	>1
pH	7.85 ± 0.05	7.898	4.5-8
Viscosity (cPs)	8,316.67 ± 223.99	8,409.53	2,000-50,000

4. DISCUSSION

4.1 Extraction and fractionation

The maceration method was selected for the extraction process because the target compounds, flavonoids, are thermosensitive and become unstable when exposed to heat; therefore, an extraction technique conducted at room temperature is required (Sa'adah & Nurhasnawati, 2017). Ethanol was chosen as the solvent due to its safety, selectivity, and neutral characteristics. It is miscible with water in various proportions and can evaporate at low temperatures, making it suitable for extracting heat-sensitive constituents. Additionally, ethanol at concentrations ≥20% effectively prevents microbial and fungal contamination in the extract (Nor et al., 2018). The yield of the ethanolic extract of clove leaves was 24.28%. Standardization of the extract was performed to ensure the quality of the material used. Table 4 illustrates the results of the specific and non-specific parameters of the clove leaf ethanol extract of cloves leaves. Fractionation is a process that separates and groups chemical compounds in an extract based on their polarity (Taupik et al., 2022). The advantage of using fractions is that they are purer and easier to handle, thereby requiring smaller doses. Cloves contain flavonoid compounds that are highly soluble or extractable in semi-polar solvents such as ethyl acetate (Fitriyanti et al., 2020). Ethyl acetate was selected as the solvent because it is volatile and non-toxic (Agustina et al., 2018). The yield of the ethyl acetate fraction of clove leaves was 74.48%, characterized by a thick consistency, a blackish-brown color, and a distinctive clove aroma.

4.2 TLC identification

Based on the results of TLC analysis in Fig. 1, both ethanol extract and ethyl acetate fraction obtained from clove leaves were identified as containing flavonoid compounds. This identification was evident from the appearance of brownish-yellow spots when the samples were observed under UV light at a wavelength of 254 nm. In the ethanol extract test, the spots showed an average Rf value of 0.703. The quercetin standard produced an Rf of 0.708. The ethyl acetate fraction also showed flavonoid compounds with an average sample Rf value of 0.634, while the quercetin standard produced an Rf of 0.657. The comparative Rf value of quercetin as a reference has a range of 0.69–0.81 (Amalia et al., 2023). According to the Kementerian Kesehatan R.I. (2017), the Rf value range for flavonoid compounds is 0.29–0.76. The antibacterial effectiveness of these compounds comes from their phenolic group, which efficiently kills bacteria by coagulating proteins, inactivating enzymes, and damaging cell wall integrity. Cloves have anti-inflammatory activity due to the content of several compounds, including flavonoids, phenolic compounds,

and essential oils. These compounds contribute to reducing inflammation and improving health (Anggitasari et al., 2023).

4.3 Formula optimization

Optimization was performed using Design Expert software version 13 using the SLD method, which has the potential to produce more optimal, efficient, and higher-quality dosage forms. From the optimization results, eight formulas were obtained with a comparison of the variation in stearic acid and TEA concentrations used as independent variables and physical characteristics of the preparation, including spreadability, adhesiveness, pH, and viscosity, as dependent variables used to determine the optimal formula. After obtaining the eight formulas, the preparation of the ethyl acetate fraction of clove leaf cream was carried out, and the physical characteristics of the preparation were tested. Table 3 illustrates the results of the physical characteristics test of the cream in formula optimization using the SLD method. The organoleptic evaluation of the ethyl acetate fraction cream derived from clove leaves indicated a thick texture, a dark greenish-brown color, and a characteristic clove aroma. Homogeneity testing demonstrated that all formulations exhibited an even distribution of particles with no presence of coarse particles, confirming that the preparations were homogeneous. According to Arifin (2025), homogeneity testing is essential to ensure that all components in the formulation are uniformly dispersed and free from particle aggregation. This uniformity supports the optimal achievement of the intended therapeutic effect upon application (Arifin, 2025).

Table 4 illustrates the data analysis performed using Design Expert software version 13, which generated a linear mixture model that was statistically significant for all evaluated parameters ($p<0.05$). In contrast, the lack-of-fit test produced non-significant results ($p<0.05$), confirming the validity of the model. Fig. 2 illustrates the response surface plots generated by the simplex lattice design, showing the interaction effects of stearic acid and triethanolamine on the physical characteristics of the cream. The contour patterns indicate that triethanolamine predominantly influences pH and spreadability, whereas stearic acid plays a major role in increasing viscosity and adhesiveness. The interaction region between both components demonstrates that an appropriate balance between stearic acid and triethanolamine is required to obtain a cream with optimal physical properties. Excessive stearic acid results in a highly viscous formulation with limited spreadability, while higher levels of triethanolamine produce a less viscous cream with improved spreadability but reduced adhesiveness.

The spreadability evaluation, which assesses the cream's ability to disperse across the skin surface, yielded notable findings. As illustrated in Fig. 2, increasing the concentration of stearic acid tended to decrease spreadability, whereas higher levels of triethanolamine enhanced it (Witanti & Endriyatno, 2024). According to the SLD-derived equation, triethanolamine (coefficient 6.35) exerts a greater influence on spreadability compared with stearic acid (coefficient 4.90), with an interaction coefficient of –2.54. A higher proportion of triethanolamine improves the cream's spreadability, thereby expanding the contact area between the active compound and the skin (Trisnawita et al., 2022). Conversely, increasing stearic acid results in a cream with greater thickness. This finding demonstrates an inverse relationship between spreadability and viscosity; as spreadability increases, the viscosity of the cream decreases.

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The objective of the adhesion test is to evaluate the cream's ability to remain attached to the skin. This parameter is crucial because prolonged adherence allows for more effective absorption of the active compounds, thereby enhancing therapeutic outcomes (Nuraini et al., 2023). Based on the SLD analysis equation, stearic acid (1.87) exhibits a stronger positive influence on adhesion compared to triethanolamine (1.25). The interaction between these two components also contributes positively to the adhesion response, as reflected by the positive interaction coefficient. According to the results presented in Fig. 2, the adhesive strength of the cream increases as the concentration of stearic acid rises, but decreases with higher levels of triethanolamine. The acidity or alkalinity of the cream is evaluated by measuring its pH to ensure that the formulation aligns with the skin's natural pH range of 4.5–8, thereby ensuring safety and user comfort. A pH below this range may lead to skin irritation, whereas an excessively high or alkaline pH can cause skin dryness (Nuraini et al., 2023). According to the SLD analysis equation, triethanolamine (8.35) has a stronger influence on increasing the pH compared with stearic acid (7.46). Higher concentrations of triethanolamine raise the cream's alkalinity, while elevated levels of stearic acid lower the pH, making the formulation more acidic. Viscosity testing is carried out to determine the thickness of the cream and to ensure that it can be applied easily. An ideal formulation should exhibit a balanced viscosity, not excessively thick nor overly fluid (Tungadi & Pakaya, 2023). According to the SLD analysis equation, stearic acid (9,259.93) exerted a stronger influence on viscosity compared to triethanolamine (7,526.82). As shown in Fig. 2, although the interaction between stearic acid and triethanolamine contributed positively to the viscosity response, the main effect of triethanolamine was to reduce the viscosity of the cream. Increasing the amount of triethanolamine decreased the viscosity of the cream, while higher concentrations of stearic acid led to an increase in viscosity due to the formation of a denser internal structure. These findings confirm that triethanolamine acts to reduce viscosity within the studied concentration range. Studies by Chomariyah et al. (2019) and Dina et al. (2017) reported that creams with lower viscosity exhibited greater flowability, making them easier to apply and distribute evenly on the skin (Chomariyah et al., 2019; Dina et al., 2017).

Using Design Expert software version 13, an analysis was performed to optimize the cream formulation containing the ethyl acetate fraction of the ethanolic extract of clove leaves. The optimization focused on four key physical parameters: spreadability (5–7 cm), adhesion (1–1.9 seconds), pH (4.5–8), and viscosity (2,000–50,000 cPs). These criteria were selected based on standard quality requirements for creams to ensure both effectiveness and user comfort. The analysis identified one optimal formulation with a desirability value of 0.628, approaching the ideal value of 1. The optimal composition consisted of 15.019% stearic acid and 2.981% triethanolamine. Verification of the formula was conducted by reproducing the composition generated by the Design Expert software in triplicate to enhance the validity and accuracy of the results. The obtained data were subsequently compared with the predicted values of the Simplex Lattice Design optimal formulation.

4.4 Physical characteristics

The physical characteristics of the cream were analyzed using a one-sample t-test after confirming that the data met the assumptions of normality and homogeneity. The normality assessment was conducted using the Shapiro–Wilk test, which is recommended for sample sizes fewer than 50. The results indicated that all data fulfilled the normality requirements ($p > 0,05$), demonstrating that the dataset was normally distributed. Based on the one-sample t-test, no significant differences were observed between the experimental measurements and the predicted values of the optimal formula generated through the Simplex Lattice

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Design method. This conclusion is supported by p-values greater than 0.05 for all evaluated parameters, namely: spreadability ($p = 0.235$), adhesion ($p = 0.449$), pH ($p = 0.235$), and viscosity ($p = 0.547$). The 30-day stability testing of the cream included evaluations of organoleptic properties, homogeneity, spreadability, adhesiveness, pH, and viscosity. The results showed no changes in organoleptic properties or homogeneity. The Wilcoxon test applied to spreadability indicated no significant difference ($p = 0.109$). However, the paired t-test revealed significant changes in adhesiveness ($p = 0.011$), pH ($p = 0.003$), and viscosity ($p = 0.024$). Although an increase in spreadability and decreases in the other parameters were observed, all changes remained within acceptable limits. Therefore, the formulation cannot be classified as physically unstable; rather, it demonstrates limited physical stability, indicating that further formulation optimization is required to improve long-term storage stability.

5. CONCLUSION

Optimization of stearic acid and triethanolamine in the cream formulation containing the ethyl acetate fraction of clove leaves resulted in an optimal formula consisting of 15.019% stearic acid and 2.981% triethanolamine, with a desirability value of 0.628. The physical characteristics of the optimized formulation showed no significant differences between the predicted values and the experimental results. The 30-day accelerated stability test indicated statistically significant changes in adhesiveness, pH, and viscosity, while spreadability remained stable; however, all parameters were still within acceptable limits, indicating limited physical stability. Future studies are recommended to improve long-term stability by optimizing the concentration of stabilizing agents, evaluating alternative emulsifier systems, and conducting extended stability testing under real-time storage conditions. Additionally, further investigations on microbiological stability and in vivo or clinical performance are suggested to support the potential topical application of this formulation.

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CONFLICT OF INTEREST STATEMENT

The authors declared that they have no conflicts of interest to disclose.

AUTHORS' CONTRIBUTIONS

Destiana Putri Ariyani: Conceptualization, investigation, data collection, writing-original draft. **Ranatri Puruhita:** Coresponden, data collection, data analysis, writing–review & edit. **Tunik Saptawati:** Data collection, data analysis, writing–review & edit. **Firstca Aulia Rachma:** Data collection, data analysis, writing–review & edit. **Danik Sulistyoningsih:** Data collection, data analysis, writing–review & edit.

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