OPTIMIZATION, STABILITY, AND IRRITATION TEST OF HALAL NON-AROMATIC STICK DEODORANT

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Abstrak

High temperatures in Mecca cause pilgrims to sweat excessively, leading to body odor. Deodorant sticks are a practical solution that leaves no wet residue and can be developed as a fragrance-free halal cosmetic product suitable for pilgrims who avoid scented formulations during worship. This study aims to optimize the formulation, evaluate physical stability, and assess primary irritation in a halal, unscented stick deodorant based on sunflower seed oil. Formulation optimization was performed using the Simplex Lattice Design method with beeswax, stearic acid, and triethanolamine as the main components. The formulations were evaluated through accelerated testing, room-temperature testing, and irritation testing using albino rabbits. Evaluation parameters included organoleptic properties, homogeneity, adhesion, spreadability, and pH. Data were analyzed using the Paired t-Test in the Statistical Package for the Social Sciences and the Bonferroni Post Hoc test in Analysis of Variance. The optimal formulation contained 19.80% beeswax, 20% stearic acid, and 0.2% triethanolamine, with a desirability value of 0.926. This formulation demonstrated stable pH, adhesion, spreadability, and homogeneity. The stability test met the required parameters, with significant differences in adhesion and pH values ($p = 0.008$ and 0.005). The primary irritation test met the parameters with a very mild category that did not cause primary irritation. In conclusion, the optimal halal, fragrance-free sunflower seed oil-based deodorant stick exhibits good physical stability and very mild irritation, making it suitable as a halal cosmetic formulation for Hajj pilgrims.

***Kata Kunci**: Deodorant stick, Sunflower seed Oil, Simplex Lattice design, Stability test, Irritation test*

Introduction

Summer is in full swing in the Holy Land of Makkah where extreme temperatures are expected to rise to 55°C. Hot temperatures will cause the body to regulate sweat production, one of which is by the apocrine glands. The resulting sweat production will cause problems, one of which is body odor (Baker, 2019). In some people who perform the pilgrimage in the holy land, unpleasant body odour is a serious problem because it causes a lack of confidence in the surrounding people. Bad odour is caused by the process of decomposing bacteria. The kinds of bacteria that cause body odour are *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Staphylococcus epidermidis* (Wilyanti *et al*, 2021). One way in alternative solution to body odour problems is using deodorant preparations.

Deodorants have a mechanism of action in eliminating body odour by acting as an antibacterial, which stops bacterial flora from growing on the skin (Gasparri, 2017). Natural ingredients that empirically have antibacterial content are sunflower seeds (*Helianthus annuus* L.). In line with the research (Aboki *et al*, 2012) sunflower seed oil as an antibacterial with a concentration of 6% b/v can inhibit the growth zone of *Staphylococcus aureus* bacteria by 8 mm and *Pseudomonas auregenosa* by 8 mm which can cause body odour. However, the manufacture of deodorant preparations from sunflower seed oil as an antibacterial has never been done so it is formulated in the form of stick deodorants. Deodorant sticks have the advantage of having a drier consistency compared to other forms of deodorant. This will make it comfortable when used without leaving a wet or sticky sensation on the skin (Saefafuna *et al,* 2019). Therefore, stick deodorants can be used by people who perform the Hajj pilgrimage before entering the ihram, with its dry consistency it will not leave a wet and sticky sensation that can get on their ihram clothes to keep them holy and clean.

Preparations of formula with the best combination is needed, one of which uses the Simplex Lattice Design (SLD) optimization method which aims to find the best formula when compared to the previous trial-and-error method Simplex Lattice Design (SLD) can save time, costs, and energy (Patel *et al,* 2021). Sunflower seed oil stick deodorant preparation is not enough to be judged by the optimum formula obtained. However, a good topical preparation must have physical stability and safety values that meet the evaluation indicators.

According to (Depkes RI, 2014) a pharmaceutical preparation must have characteristics that do not change with the conditions since it was originally produced. Meanwhile, to determine the safety value of a topical product, based on (BPOM RI, 2022) concerning guidelines for preclinical toxicity tests in vivo, states that to ensure the quality and safety of the use of a pharmaceutical preparation in humans, preclinical toxicity tests must be carried out in vivo to determine the side effects of using a substance that can pose a health risk to humans. Based on the explanation above, a study was conducted to optimize the formula, stability test, and irritation test of sunflower seed oil stick deodorant preparation for pilgrims.

Materials and Methode

Materials

The materials used in this study were sunflower seed oil *(Helianthus annuus* L.) (CV. Happy Green), cera alba (Bratachem), stearic acid (Bratachem), triethanolamine (Bratachem), propylene glycol (Bratachem), propylparaben (Bratachem), butylated hydroxytoluene (Bratachem), virgin coconut oil (Bratachem), and albino rabbits (Research animal breeder, Batu, East Java).

Instruments

The instruments used include an oven (Memmert UN30), water bath (Memmert WNB29L4), refrigerator (Samsung), design expert software version 13, and universal pH paper (one med).

Formula Optimization Using Design Expert Version 13

One of the methods of design experts is simplex lattice design (SLD). The Simplex Lattice Design (SLD) method is an optimization method for determining the optimum formula from several ingredient mixture (Hidayat *et al*, 2020). Formula optimization is carried out by varying the X variable which is an independent variable, namely Cera alba (X1), stearic acid (X2), and triethanolamine (X3) while the Y variable is the characteristic test response, namely the pH test response (Y1), melting point test (Y2), spreadability test (Y3), adhesion test (Y4). In this method, data on the upper and lower limit ranges are entered in accordance with the acceptance criteria. Then the software will provide recommendations for the initial run formula. The three ingredients that will be varied will produce 16 run formulas. From the 16 formulas, the optimum formula will be selected, which is seen from the desirability value (favorability score) which is close to 1.

Validation and Verification

Sunflower seed oil stick deodorant preparation was validated with 3 times replication to ensure the preparation was in accordance with the optimum formula results. Verification is done by comparing the prediction results with the results. Verification can be seen from the 95% Prediction interval (PI) range value or the range value consisting of the upper limit and lower limit values. Then to find out the significance, experiments were carried out using the parametric t-test if the data were normally distributed and the non-parametric Wilcoxon test if the data were not normally distributed. Normality testing is carried out for each preparation evaluation result. The software used for the verification process is Statistical Package for the Social Sciences (SPSS) software (Mariyam *et al*, 2024).

Preparation Procedure

Weighed all the ingredients needed in the formulation then melted stearic acid with cera alba over bunsen until dissolved, then added virgin coconut oil (VCO) and butylated hydroxytoluene (BHT) stirred until homogeneous. Sunflower seed oil was added and stirred until homogeneous. Propylene glycol, triethanolamine, and propylparaben were added and stirred until homogeneous. Then poured into the mold until it solidifies and stored at 25ºC (Ningrum *et al*, 2019).

Accelerated stability test method

The cycling test method of the accelerated physical stability test was carried out for 6 cycles with a cycle time of 48 hours. The preparation was placed at ±40°C for 24 hours and then transferred to a refrigerator at ±4°C for 24 hours. Storage time in both temperatures is called one cycle. Then the physical properties of the stick deodorant preparation were observed for 6 cycles (Rahmayanti *et al*, 2023).

Room Temperature Stability Test Method

The room temperature physical stability test using the room temperature method was carried out for 28 days on stick deodorant preparations with storage at room temperature, namely 30 ° C ± 2 ° C in the same packaging and physical stability observations were made every week (Suryani *et al*, 2017).

Evaluation of Physical Characteristics

Organoleptic test

The organoleptic test of the preparation is a test parameter that is carried out by observing the five senses the shape, colour, and smell of the preparation (Alyidrus *et al,* 2014).

Homogeneity test

Homogeneity testing is carried out by visually observing the distribution of particles in the preparation using the sense of sight (Amalina *et al,* 2024).The homogeneity test is observed by applying the preparation to a glass object. Then observe the glass object to see whether there were coarse particles or not (Alyidrus *et al,* 2014).

pH Test

The pH test was carried out using a universal pH by taking a preparation of 0.5 grams and then dissolving it in 10 ml and dipping a universal pH indicator. Then observe the colour change that occurs on the universal indicator and compare the colour with the standard colour.

Melting Point Test

Melting point testing of deodorant sticks was taken half lengthwise in each formula with the same weight, then put into a beaker glass and then heated on a heater, the temperature was slowly increased from 50ºC and observed when the deodorant could melt (Mawazi *et al,* 2022).

Spreadability Test

The spreadability test was carried out by placing 0.5 grams of the preparation at the center of a circular glass plate, covered with another glass plate, and loaded with a 100-gram weight for 5 minutes. The diameter of the spread preparation was then measured using a caliper (Indriatmoko *et al*, 2021). This test was conducted to evaluate the ability of the deodorant stick to spread evenly on the skin surface. An appropriate spreadability value indicates that the preparation can be applied easily and uniformly without excessive pressure during use.

Adhesion Test

Adhesion testing was carried out by placing the preparation between two glass plates with a load of 1 gram applied for 5 minutes, followed by measuring the separation time using a stopwatch (Andriani *et al*, 2019).. This test was conducted to evaluate the ability of the deodorant stick to adhere to the skin surface.

Primary Irritative Test

A primary irritative test was conducted on three albino rabbits consisting of one male and two females. The test was carried out by taking 0.5 grams of the preparation and applying the topical preparation on a predetermined box. Then the area was bandaged with non-irritant gauze and plaster. The score results will be calculated using the irritation index formula.

$$Primary\ Irritation\ Index = \frac{A - B}{C}$$

Description :

A : Sum of erythema and oedema scores of all sample observation points

B : Sum of erythema and oedema scores across control observation points

C : Total of animals

Table I. Respond Category

Respond Category	Average Value
Negligible	0,0 – 0,4
Slight	0,5 – 1,9
Moderate	2,0 – 4,9
Severe	5,0 – 8,0

Data Analysis

The results of the study on stick deodorant formulations yielded both qualitative and quantitative data. Qualitative data included the results of organoleptic, homogeneity, and irritation tests, which were analyzed by comparison with relevant literature. Quantitative data included the results of pH, spreadability, adhesion, melting point, and melting time tests, which were analyzed using the Simplex Lattice Design (SLD) method and statistically evaluated using the Statistical Package for the Social Sciences (SPSS). In the accelerated stability test, pH, spreadability, and adhesion data were analyzed using a Paired T-Test. Meanwhile, in the long-term stability test, pH data were analyzed using the Kruskal–Wallis Test, while spreadability and adhesion data were analyzed using Analysis of Variance (ANOVA) followed by the Bonferroni Post Hoc Test.

Result and Discussion

Formula Rationalization Result

Formula rationalization was conducted to ensure that each component in the deodorant stick formulation contributed appropriately to the desired physical properties and product stability. Sunflower seed oil was used as the active ingredient due to its antibacterial activity, while cera

alba and stearic acid functioned as stiffening agents to maintain the solid consistency of the preparation.The results of formula rationalization are presented in Table II.

Table II. Deodorant Stick Formula

Raw Material	Function
Sunflower Seed Oil	Active ingredients
Cera Alba	Stiffening agent
Stearic Acid	Stiffening agent
Triethanolamine	Alkalizing agent
Propylene Glycol	Humectant
Butylated Hydroxytoluene	Antioxidant
Propylparaben	Preservative
Virgin Coconut Oil	Solvent

Formula Optimization Results

Formula optimization was performed to determine the optimum combination of formulation components that could produce desirable physical characteristics of the deodorant stick preparation. The optimization results are presented in Table III. The components selected for optimization were cera alba (X1), stearic acid (X2), and triethanolamine (X3) because these ingredients significantly influence the consistency, stability, pH, adhesion, and spreadability of the preparation.

Cera alba was optimized within a concentration range of 5–20%, stearic acid within 1–20%, and triethanolamine within 0.2–1%. These concentration ranges were determined based on preliminary studies and literature references to obtain a stable and acceptable stick deodorant formulation. The total concentration of the three optimized components used in the formulation was 40%.

Table III. Design Expert Formula Design Results

Run	X1 (%)	X2 (%)	X3 (%)	Y1 pH	Y2 Melting point (°C)	Y3 Adhesion (sec)	Y4 Spreadability (cm)
1.	20	19	0.7	6	56.5	163	3.50
2.	20	19	0.5	5	55.0	170	3.50
3.	20	19	1.0	7	54.3	140	3.50
4.	19	19	0.5	4	55.0	170	4.00
5.	19	19	0.2	5	57.0	180	3.75
6.	19	19	0.4	5	55.0	176	3.85
7.	19	19	0.7	6	56.5	167	3.57
8.	19	19	0.5	5	54.3	170	3.97
9.	19	19	1.0	7	54.3	140	3.62
10.	20	19	0.5	5	55.0	170	3.50
11.	19	19	0.9	7	54.3	147	3.55
12.	19	19	1.0	7	54.3	140	3.89
13.	19	19	0.9	7	54.3	172	3.82
14.	19	19	0.5	5	55.0	170	3.97

15.	19	20	1.0	7	54.3	140	3.50
16.	19	19	0.2	4	57.0	180	3.75

Optimum Formula Result

The optimum formula was determined based on the optimization results of the three formulation components, namely cera alba, stearic acid, and triethanolamine. The optimization process aimed to obtain a formulation with the most desirable physical characteristics, including acceptable pH, melting point, spreadability, and adhesion values. The optimum formula obtained from the Design Expert analysis is presented in Table IV.

Table IV. Optimum Formula Results

Material Component (X)			Predicted Value of Response Variable (Y)				
Cera Alba (%)	**Stearic Acid (%)**	**TEA (%)**	**pH**	**Melting Point**	**Spreadability**	**Adhesion**	***Desirability***
19.800	20.000	0.200	4.382	56.595	3.833	185.479	0.926 **Suggested**
20.000	19.797	0.203	4.764	57.000	3.523	185.302	0.925
19.902	19.887	0.211	4.598	57.000	3.678	184.950	0.923
19.455	20.000	0.545	4.614	54.300	3.978	169.237	0.843

The optimum formula results obtained from the analysis of each response showed a significant model. The optimum formula was determined based on the desirability value, which is used to evaluate how well the formulation fulfills the predetermined optimization criteria. In the Design Expert software, the desirability value ranges from 0 to 1, where values closer to 1 indicate a more optimal formulation with better overall responses [20].

The formulation containing 19.80% cera alba, 20% stearic acid, and 0.2% triethanolamine showed the highest desirability value of 0.926, indicating that the formulation successfully achieved the desired balance among pH, melting point, spreadability, and adhesion responses. The high desirability value may be attributed to the balanced interaction between cera alba and stearic acid as stiffening agents, which contributed to the solid consistency and adhesion properties of the preparation. Meanwhile, the low concentration of triethanolamine helped maintain the pH within the acceptable range for topical preparations.

In addition, the combination of these components produced a preparation with stable physical characteristics and acceptable application properties. Therefore, the formulation was considered optimal and suitable for further stability and irritation testing.

The optimization results based on the desirability value are also presented in the contour plot (Figure 1), which illustrates the interaction among the three formulation components. The graph demonstrates that different combinations of cera alba, stearic acid, and triethanolamine produced varying desirability values. Blue-colored areas represent lower desirability values, indicating less optimal formulations, whereas red-colored areas indicate higher desirability values and more optimal formulation regions.

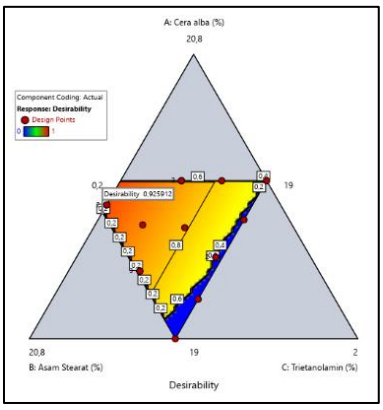

Figure 1. Contour plot graph of desirability value of optimum formula

Validation and Verification Optimum Formula

Validation is making preparations based on the optimum formula for three replications. Verification is a step taken to prove that the optimum point solution offered by the design expert software version 13 meets the requirements of the research conducted (Ni'maturohmah, 2019).

Table V. T-Test Results Comparison of Prediction with Experiment

Parameter	Prediction	Experiment Result (X ± SD)	*P-value*	*Significance*
pH	4.38	4±0.00	0.199	Not significantly different
Melting point	56.59	57±0.00	0.250	Not significantly different
Spreadability	3.83	3.73±0.04	0.083	Not significantly different
Adhesion	185.47	174.66±9.45	0.083	Not significantly different

Description : $\bar{x}$: average; SD: Standard Deviation; n: 3

Based on the comparison between the predicted and experimental results, all evaluated parameters showed no statistically significant differences, as indicated by p-values greater than 0.05. These results demonstrate that the experimental responses were consistent with the predicted values generated by the Design Expert software. This indicates that the optimization model was accurate and reliable in predicting the physical characteristics of the deodorant stick formulation

In addition, the small differences between predicted and experimental values suggest that the selected combination of cera alba, stearic acid, and triethanolamine produced stable and reproducible formulation characteristics. Therefore, the optimum formula was considered valid for further stability and irritation testing[14].

Stability Test Result

The accelerated stability test was conducted to evaluate the physical stability of the deodorant stick preparation, and the results are presented in Table VI.

Table VI. Accelerated Test Method Results

Evaluation	Cycle 0		Cycle 6	
	Base	Optimum Formula ($\bar{x}$±SD)	Base	Optimum Formula ($\bar{x}$±SD)
Organoleptic	White, solid, waxy color	Yellowish white, solid, waxy scent	White, solid, waxy scent	Yellowish white, solid, waxy scent
Homogeneity	Homogeneous	Homogeneous	Homogeneous	Homogeneous
Spreadability (cm)	4.30	3.60 ± 0.32	4.30	3.80 ± 0.10
Adhesion (sec)	180.90	176.86 ± 6.14	98.70	107.06 ± 6.54
pH	4.00	4.00 ± 0.00	5.00	4.00 ± 0.00

Description : $\bar{x}$: average; SD: Standard Deviation; n: 3

Based on Table VI and Figure 2, the organoleptic properties of the preparation did not show significant differences between cycle 0 and cycle 6. The preparation maintained its color, odor, and consistency throughout the accelerated stability test. This result indicates that the formulation remained physically stable during storage under varying temperature conditions.

A preparation is considered homogeneous if no coarse or gritty particles are observed [15]. Based on the observations, the deodorant stick preparation remained homogeneous throughout the testing period, with no visible phase separation or particle formation. This stability may be attributed to the compatibility of formulation components, particularly cera alba and stearic acid, which helped maintain the structural integrity of the preparation.

Figure 2. Room temperature stability test results

The pH test results of the stick deodorant preparation met the acceptable range requirements for topical preparations and showed no statistically significant difference between cycle 0 and cycle 6, with a p-value of 1.00. According to SNI 16-4951-1998, the acceptable pH range for topical preparations is 3.0–7.5. The stable pH value indicates that the formulation components remained chemically stable during the accelerated stability test. In addition, the low

concentration of triethanolamine and the presence of stearic acid may have contributed to maintaining the pH balance of the preparation throughout storage.

The spreadability test results also met the required range of 3–5 cm for solid stick preparations and showed no statistically significant difference between cycle 0 and cycle 6, with a p-value of 0.62 (Pawestri *et al,* 2023). The stable spreadability value may be influenced by the balanced proportion of cera alba and stearic acid, which maintained the semisolid consistency while still allowing the preparation to spread evenly on the skin surface.

In the adhesion test, the preparation fulfilled the required adhesion criteria of more than 4 seconds (Ramadhani, 2017), although a statistically significant difference was observed between cycle 0 and cycle 6, with a p-value of 0.008. Despite this difference, the adhesion value remained within the acceptable range for stick preparations. The significant change may be caused by repeated temperature changes during the accelerated stability test, which could affect the chemical structure of cera alba and stearic acid as stiffening agents. These changes may reduce viscosity, thereby influencing the adhesion value of the preparation (Ramadhani, 2017).

Optimum Formula Room Temperature Test Result

The room temperature stability test was conducted to evaluate the stability of the optimum formula during storage at room temperature, and the results are presented in Table VII.

Table VII. Room Temperature Test Method Results

Week	Formula	Evaluation				
		Organoleptic	Homogenity	Spreadability (cm)	Adhe-sion (sec)	pH
Week 1	Base	White, solid, waxy scent	Homogeneous	5.70	120.90	4.00
	Optimum Formula ($\bar{x}$±SD)	Yellowish white, solid, waxy scent	Homogeneous	3.67 ± 0.32	101.34 ± 44.07	4.00 ± 0.00
Week 2	Base	White, little mushy, waxy scent	Homogeneous	4.50	45.40	5.00
	Optimum Formula ($\bar{x}$±SD)	Yellowish white, solid, waxy scent	Homogeneous	3.83 ± 0.25	55.70 ± 5.45	5.00 ± 0.00
Week 3	Base	White, slightly mushy solid, waxy scent	Homogeneous	4.50	118.67	5.00
	Optimum Formula ($\bar{x}$±SD)	Yellowish white, solid, waxy scent	Homogeneous	3.67 ± 0.11	63.67 ± 2.60	5.00 ± 0.00
Week 4	Base	White, slightly mushy solid, waxy scent	Homogeneous	4.0	9.19	5.00
	Optimum Formula ($\bar{x}$±SD)	Yellowish white, solid, waxy scent	Homogeneous	3.76 ± 0.30	41.86 ± 3.32	6.00 ± 0.00

Description : $\bar{x}$: average; SD: Standard Deviation; n: 3

Based on Table VI, the organoleptic test results did not differ between weeks. The preparation is said to be homogeneous if there are no coarse or gritty grains in it [5]. Based on observations for 28 days every week, the results of the preparation are homogeneous and do not change between weeks. The pH test results obtained by stick deodorant preparations meet the range requirements but have statistically significant differences with a p-value of 0.005 each week. The requirements for good topical preparations are within the range of 3.0 - 7.5 in accordance with SNI 16-4951-1998. The significant difference is influenced by long storage at room temperature and humidity around storage, which can affect the stability conditions of stearic acid which then results in the degradation of stearic acid. The impact of this degradation will reduce the stability of stearic acid in maintaining acid pH. The presence of too little acid in the preparation is unable to neutralize the pH of the presence of triethanolamine so it makes the pH value of the preparation rise again. Based on the observation of the spreadability of the stick deodorant preparation, the results showed that the value met the range requirements and did not have a statistically significant difference with a p-value of 1.00 between weeks. Stick deodorant preparations are solid preparations that have a spreadability requirement of 3 - 5 cm [22]. Based on the observations, the adhesion value of the preparation meets the range of requirements and does not have a statistically significant difference with a p-value of 0.053 in each week. The requirements for the adhesion of a good stick preparation, which has an adhesion of more than 4 seconds (Maesaroh *et al,* 2020).

Optimum Formula Irritative Test Results

The primary irritation test has received ethical approval by the ethics commission with ethics certificate number No.58/02/EC/KEPK-FKIK/10/2024, which was then carried out in 2 stages, namely the preliminary test was carried out using one male rabbit. Based on the table preliminary test result, primary irritation index value of 0 which is included in the very mild category.

Table VIII. Preliminary Test Results

Times	Formula	Eritema Score	Oedema Score
3rd minutes	Base	-	-
	Optimum Formula	-	-
	($\bar{x}$±SD)		
1st hour	Base	-	-
	Optimum Formula	-	-
	($\bar{x}$±SD)		
4th hours	Base	-	-
	Optimum Formula	-	-
	($\bar{x}$±SD)		

Description : $\bar{x}$: average; SD: Standard Deviation; n : 3; (-) : no symptoms; (+) : symptoms

Then the confirmation test was continued by adding two rabbits and showed that there were no signs of erythema and oedema in both rabbits. Based on the table bellow, the results of primary irritation index value is 0 was obtained, which is included in the very mild category.

Table XI. Confirmation Test Results

Times (hour)	Formula	Eritema Score	Oedema Score
1	Base	-	-
	Optimum Formula	-	-
	($\bar{x}$±SD)		
24	Base	-	-
	Optimum Formula	-	-
	($\bar{x}$±SD)		
48	Base	-	-

	Optimum Formula ($\bar{x}$±SD)	-	-
72	Base	-	-
	Optimum Formula ($\bar{x}$±SD	-	-

Description : $\bar{x}$: average; SD : Standard Deviation; n : 3; (-) : no symptoms; (+) : symptoms

Harmonized research related to the primary irritative test, shows that topical preparations are said not to have the potential to cause irritating effects if after treatment they do not cause erythema and oedema spots on the skin of test animals.

Conclusion

1. The optimum composition for sunflower seed oil stick deodorant preparation with cera alba 19.80%, stearic acid 20%, and triethanolamine 0.2% with a desirability value of 0.926.
2. Comparison of the predicted optimum formula with experimental results has a p-value > 0.05, proving that there is no difference, so it is valid and reliable.
3. Sunflower seed oil stick deodorant preparations meet all the physical parameters of good preparation on organoleptic indicators, homogeneity, spreadability, stickiness, and pH in two methods, namely accelerated test and room temperature test.
4. The preparation meets the requirements of the primary irritation test which is classified in the very mild category

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