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Formulation and Evaluation of All Purpose Cream Using Box Behnken Design

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A B S T R A C T

The versatility of the all-purpose cream allows it to address a broad range of skin issues, making it appropriate for everyday usage. The moisturizing, soothing, and protecting properties of steric acid, liquid paraffin, and bee wax are blended into the cream's formulation. Phase inversion temperature approach was utilised to develop the cream. The potential applications of the all-purpose cream in promoting overall skin health and well-being. Consistency, elegance, and a smooth feel were observed. Using Box-Behnken Design and three independent and dependent factors, the cream was optimised by DoE. By using DoE to optimise the cream, 12 runs were produced. The formulation undergoes rigorous testing to ensure safety, efficacy, and compatibility with diverse skin types. Evaluation such as pH, viscosity, spreadability, irritancy test was carried out. The pH, viscosity, spreadability, and washability of the developed cream were found to be 6.3, 2567 cps, 8.9 cm and 9 sec, respectively. It can be used in foot, hand cracks, and to maintain the skin healthy. Based on the results, we can suggest that the formulations were stable and can be safely used on the skin. Stability testing for prepared formulation was performed by stirring it at constant temperature condition for time period 24th for 20 days and a shows very slight changes.

Keywords: All-purpose cream, Box-Behnken Design, DoE, pH, Viscosity

1. Introduction

Cosmetic is a Greek term that implies adornment (the adding of anything decorative to a person or object). It can be defined as a substance that comes into contact with numerous areas of the human body such as skin, hair, nails, lips, teeth, and mucous membranes, among others. Cosmetic ingredients assist to improve or change the appearance of the body and also disguise the scent of the body. It preserves and maintains the skin's condition. Cosmetics are exterior preparations that are applied to the body's external parts.

Cosmetics are now regarded as necessary components of daily living. They not only lure people to it, but they also have psychological effects on them. It has grown in popularity over the previous three to four decades, and its use has surged tremendously in both males and girls. Hair colours, powders, and lotions are the most popular cosmetics. (Sharma et al., n.d.)

Cosmetics have been used since the Vedic and Puranic periods to enhance or protect the attractiveness of the human body. Earlier human races of the tribal era adorned their bodies with animal parts, vegetable leaves, flowers, colour stones, shells, and so forth. Herbal cosmetic compositions abound in the ancient ayurveda literature. Nowadays, cosmetics are regarded as one of life's necessities. Make-up is a subset of cosmetics that primarily refers to coloured products used to alter the user's look. Skin-care creams, lotions, powders, perfumes, lipsticks, fingernail polishes, eye and facial makeup, permanent waves, hair colours, deodorants, baby goods, bath oils, bubble baths, and a variety of other products are all examples of cosmetics. They are widely used, particularly by women in Western countries. These are over-the-counter (OTC) and, in some cases, non-prescription (NPM) medications.(Nema et al., n.d.)

1.1 Creams

Creams are the semisolid dosage forms that are intended for topical application to the skin, placement on the surface of the eye, or usage nasally, vaginally, or rectally for medicinal, protective, or cosmetic activity. These preparations are utilised for localised effects caused by medication penetration into the underlying layer of skin or mucous membrane at the place of application. These items are intended to deliver drugs into the skin in order to treat dermal ailments, with the skin serving as the target organ. Creams are oil-and-water emulsions that are semi-solid. They are classified into two types: oil-in-water (O/W) creams, which are made up of small droplets of oil spread in a continuous phase, and water-in-oil (W/O) creams, which are made up of small droplets of water dispersed in an oily phase. (Manavalan,M-Pharm, n.d.)

1.2 Classification of Cream on the Basis of Function

- Cleansing and cold cream.
- Foundation and vanishing cream.
- Night and massage cream.
- Head and body cream.
- All purpose and general cream.

All-purpose cream act as nourishing night creams when applied exclusively, they function as hand cream when applied sparingly, thus they are called as All-purpose cream. It is used by sports men or skilling or outdoor activities.

"All-purpose cream" often refers to a multi-functional beauty product designed to give a number of advantages for the skin and, in some cases, other sections of the body in the context of cosmetics and skincare. These creams are designed to address a variety of skincare conditions and may have numerous functions. The ingredients and features of such creams can differ between brands and product lines. (Prakash Reddy et al., 2018)

1.3 Benefits of All-purpose cream

All-purpose creams, also referred to as multipurpose or universal creams, have several benefits that make them consumer-friendly and adaptable. The following are some main benefits of all-purpose creams:

- All-purpose creams are designed to serve multiple functions, reducing the need for consumers to purchase and use multiple specialized products.
- It may be less expensive to use one all-purpose cream rather than several specialty ones.
- People with busy lifestyles can save time by streamlining their skincare routine with an all-purpose cream.
- The various skincare requirements that are met by all-purpose creams include hydration, nourishment, and the addition of additional advantageous components.
- Having an all-purpose cream that can be used for many purposes can be beneficial for people who travel frequently or are always on the go.
- Many all-purpose creams are formulated with ingredients that provide hydration and nourishment to the skin.(Mali & V, 2013)

1.4 Drawbacks of All-purpose cream

- These creams might not be specialised to treat particular skin conditions because they are meant for everyday usage.
- Certain all-purpose creams could be thicker or greasier than others, making them unsuitable for people with oily or acne-prone skin.
- Treatments specific to conditions like psoriasis, eczema, or extreme dryness may be necessary; an all-purpose cream may not be sufficient for these conditions.
- Certain components found in all-purpose creams, like thick emollients or occlusive agents, may clog pores.(Patil et al., 2022)

2. Materials and methods

2.1 Materials

All of the items utilised in this study were obtained in India. Steric acid, bee wax, liquid paraffin, lanolin, triethanolamine, sorbitol, EDTA, methyl paraben, propylene glycol, propyl paraben, tween 80, and perfume were taken from your college laboratories at the Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research, Porur, Chennai.

2.2 Method

The formulation can be prepared by adding two phases which are mentioned as following.

Phase 1:

Two China dishes were used; determined amounts of oil phase components such as steric acid, liquified paraffin, beewax, and lanolin were added to one dish, i.e., Part A.

Phase 2:

Then, in another dish, estimated amounts of aqueous phase components such as tween 80 triethylamine, sorbitol, and EDTA were applied. Methyl paraben and propyl paraben were dissolved in propylene glycol and added to the aqueous phase, i.e., Part B.

Both phases were heated separately over a water bath until the temperature reached 70°C. Once the temperature reached 70°C, the oil phase was introduced to the aqueous phase and thoroughly mixed. It was then cooled to room temperature and blended simultaneously. Finally, the perfume oil was dissolved in the alcohol and added. The manufactured cream was then placed in a collapsible tube and labelled.(Aswal et al., n.d.)

2.3 Optimization of cream

The cream was optimized by DoE using Box-Behnken (Anbarasan & Niranjanasree, 2023) Design by taking three independent variables steric acid (A), bee wax (B), and liquid paraffin (C) as factors and three dependent variables pH (R1), spreadability (R2), and viscosity (R3) as a response.

Table 1 - Optimization of cream.

Std	Run	Factor 1 A: Steric Acid	Factor 2 B: Bee Wax	Factor 3 C: Liquid Paraffin	Response 1 pH	Response 2 Spreadability	Response 3 Viscosity
		g	g	ml		cm	cps
12	F1	7	1.5	13	6.1	9	2670
2	F2	8	0.5	12	5.8	9.2	2639
3	F3	6	1.5	12	6.3	8.6	2235
8	F4	8	1	13	5.9	8.6	2790
6	F5	8	0.5	11	5.9	8.5	2570
11	**F6**	**7**	**1**	**12**	**6.3**	**8.9**	**2567**
7	F7	6	1	13	6.4	8.6	2368
10	F8	7	1.5	11	6.2	8.4	2510
9	F9	7	0.5	11	6	8.3	2459
4	F10	8	1.5	12	6.5	9.1	2839
5	F11	6	1	11	5.7	8.2	2205
1	F12	6	0.5	13	5.9	8.5	2540

It was found that **F6** was the most optimal value for cream preparation after optimizing it for about 12 runs.

Table 2 - Variables Used in the Design.

Independent Variables	Dependent Variables
Steric acid	pH
Bee wax	Spreadability
Liquid paraffin	Viscosity

Table 3 - Formulation Chart.

Effect of independent variable on pH

S. No	Ingredients	Inference	Optimized formulation -Quantity (mg/ml)
1	Steric Acid	Thickening agent	7g
2	Bee Wax	Smoothing agent	1g
3	Liquid Paraffin	Emollient	12ml
4	Lanolin	Moisturizing agent	1.5g
5	Triethanolamine	Emulsifying agent	1ml
6	Sorbitol	Moisturizing agent	1ml
7	EDTA	Chelator	1ml
8	Methyl Paraben	Preservative	0.02g
9	Propylene Glycol		2ml
10	Propyl Paraben	Preservative	0.01g
11	Tween 80	Moisturizing agent	1ml
12	Water	Base	25ml
13	Perfume	Flavouring agent	Q. S

ANOVA for Reduced Cubic model

Response 1: pH

Table 4 – Effect of independent variable on pH.

Source	Sum of Squares	df	Mean Square	F-value	p-value	
Model	0.5978	3	0.1993	13.40	0.0017	**Significant**
B-Bee Wax	0.0147	1	0.0147	0.9921	0.3484	
AC	0.2498	1	0.2498	16.80	0.0034	
A^2B	0.1365	1	0.1365	9.18	0.0163	
Residual	0.1189	8	0.0149			
Cor Total	0.7167	11				

Factor coding is **Coded**.

Sum of squares is **Type III - Partial**

The **Model F-value** of 13.40 implies the model is significant. There is only a 0.17% chance that an F-value this large could occur due to noise.

P-values less than 0.0500 indicate model terms are significant. In this case AC, A^2B are significant model terms. Values greater than 0.1000 indicate the model terms are not significant. If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model.

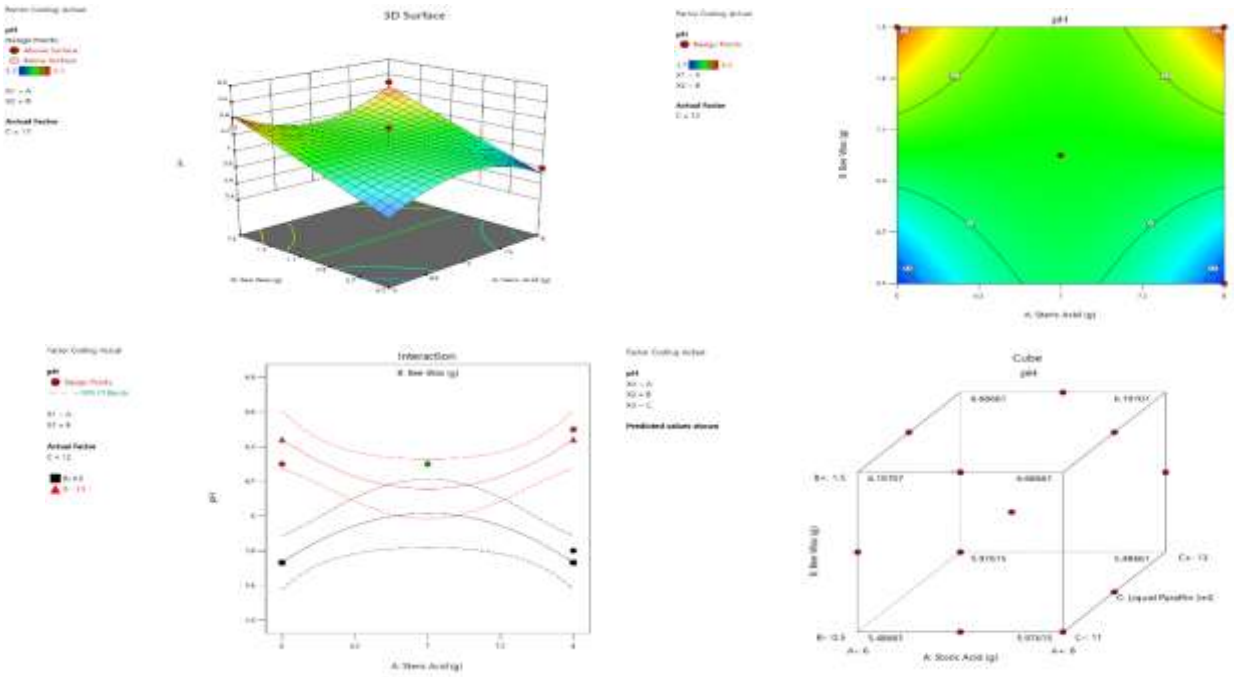

Fig. 1 - (a) 3D Surface; (b) Contour; (c) Interaction; (d) Cube.

Effect of independent variable on Spreadability

ANOVA for Reduced Linear model

Response 2: Spreadability

Table 5 - Effect of independent variable on Spreadability.

Source	Sum of Squares	df	Mean Square	F-value	p-value	
Model	0.5622	2	0.2811	4.46	0.0450	**Significant**
A-Steric Acid	0.3510	1	0.3510	5.57	0.0426	
C-Liquid Paraffin	0.2810	1	0.2810	4.46	0.0639	
Residual	0.5669	9	0.0630			
Cor Total	1.13	11				

Factor coding is **Coded**.

Sum of squares is **Type III - Partial**

The **Model F-value** of 4.46 implies the model is significant. There is only a 4.50% chance that an F-value this large could occur due to noise.

P-values less than 0.0500 indicate model terms are significant. In this case A is a significant model term. Values greater than 0.1000 indicate the model terms are not significant. If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model.

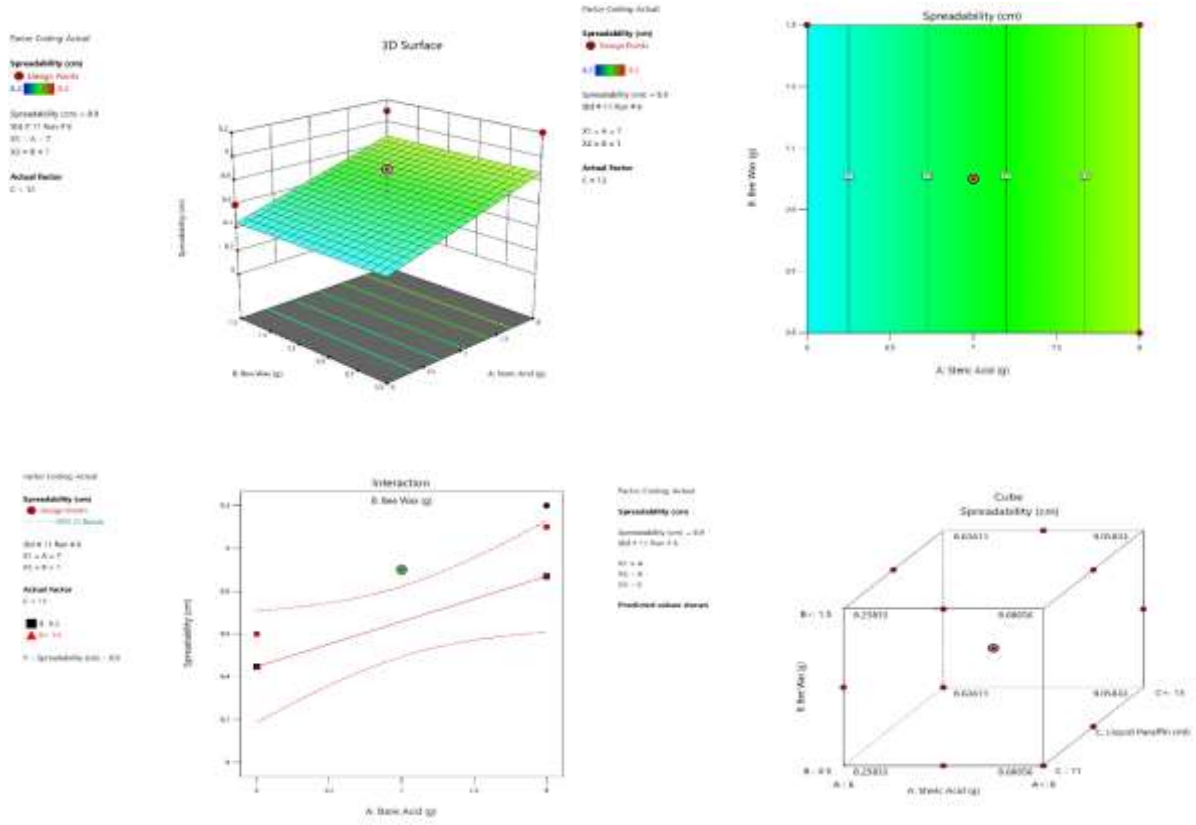

Fig. 2 - (a) 3D Surface; (b) Contour; (c) Interaction; (d) Cube.

5. Effect of independent variable on Viscosity

ANOVA for Reduced Quadratic model

Response 3: Viscosity

Table 6 - Effect of independent variable on Viscosity.

Source	Sum of Squares	df	Mean Square	F-value	p-value	
Model	4.190E+05	5	83806.14	176.44	< 0.0001	**Significant**
A-Steric Acid	3.134E+05	1	3.134E+05	659.70	< 0.0001	
C-Liquid Paraffin	51332.43	1	51332.43	108.07	< 0.0001	
AB	42390.36	1	42390.36	89.24	< 0.0001	
A^2	4780.92	1	4780.92	10.07	0.0193	
B^2	3632.28	1	3632.28	7.65	0.0326	
Residual	2849.95	6	474.99			
Cor Total	4.219E+05	11				

Factor coding is **Coded**.

Sum of squares is **Type III - Partial**

The **Model F-value** of 176.44 implies the model is significant. There is only a 0.01% chance that an F-value this large could occur due to noise.

P-values less than 0.0500 indicate model terms are significant. In this case A, C, AB, A^2, B^2 are significant model terms. Values greater than 0.1000 indicate the model terms are not significant. If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model.

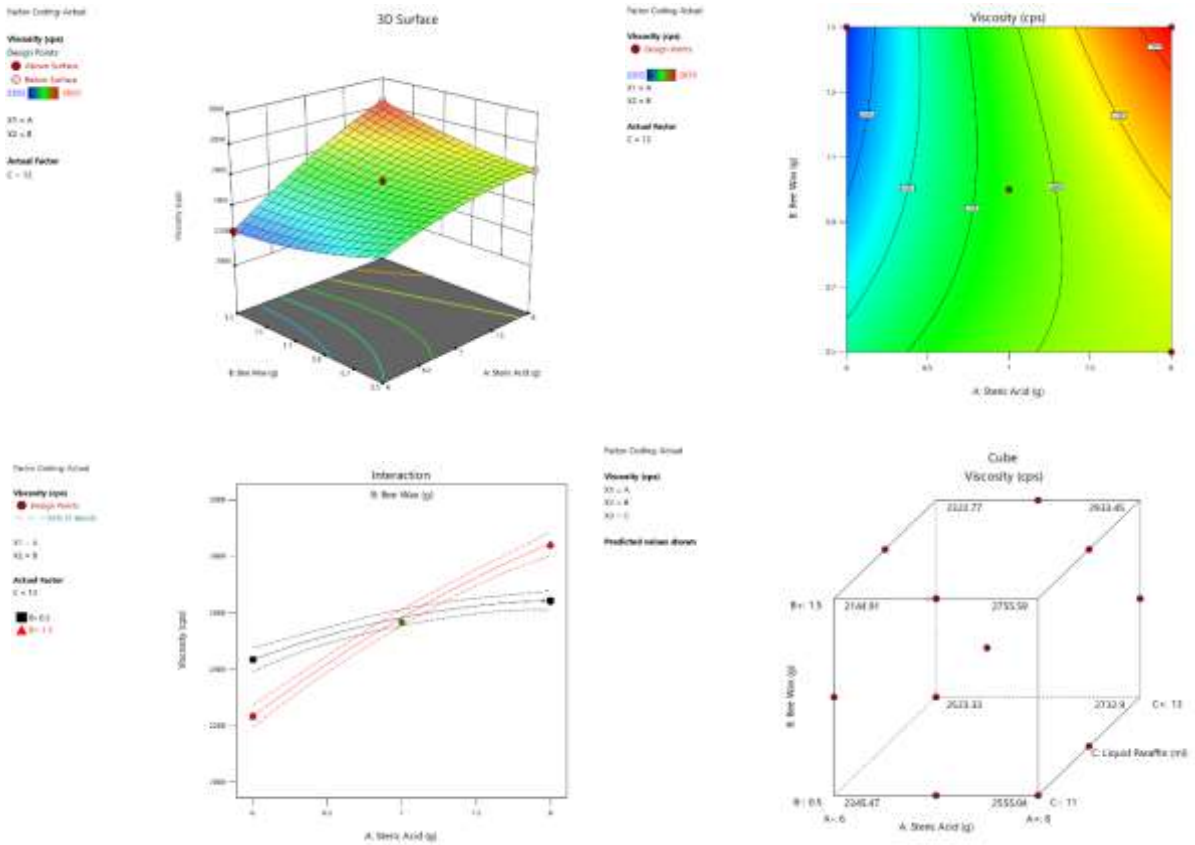

Fig. 2 - (a) 3D Surface; (b) Contour; (c) Interaction; (d) Cube.

Evaluation tests of Cream

- **Physical evaluation:**

This is mostly used to assess the colour, odour, texture, and stability of cream. (Kumar et al., 2022)

- **Spreadability:**

The spreadability was expressed in terms of the time it took two slides to slip off from the cream, which was placed in between the slides, under specific strain. The shorter the time required to separate the two slides, the greater the spreadability. Two standard-sized sets of glass slides were taken. The cream formulation was then placed on a suitable sized slide. Then another slide was placed on top of the formulation. The cream between the two slides was then squeezed uniformly to form a thin layer by placing a weight or a certain load on the upper slide. The weight was then removed, and any extra formulation sticking to the slides was scraped off. The force of the weight linked to the upper slide allowed it to glide off effortlessly. The time it took the upper slide to slip off was recorded. (Navindgikar et al., 2020)

- **pH**

Dissolve 0.5g of cream in 50ml of purified water. Then, using a digital pH metre, check the pH.(Davkhar et al., n.d.)

- **Irritancy**

A small amount of the item to be tested was placed on a piece of fabric or a funnel and applied to a sensitive area of the skin, such as the region behind the ears. The cosmetics to be tested were applied to a 1 sq.m. area of skin. There were also control patches used. After 24 hours, the patch site was inspected.(Ghutke et al., 2021)

- **Viscosity**

The viscosity was determined using the Brookfield Viscometer II + model and spindle no S - 64 at 20 rpm and 25 °C. The results were recorded once the viscometer displayed a consistent number.(Saptarini & Hadisoebroto, 2020)

- **Homogeneity**

The homogeneity of the formulations was evaluated visually and by touch.(Dhyani et al., 2019)

- **Type of smear**

The type of film or smear created on the skin after applying the cream was examined.(Dhyani et al., 2019)

- **Washability**

The composition was applied to the skin, and the ease of washing with water was evaluated.(FVanarase & Tambe, n.d.)

- **Phase separation**

The prepared cream is maintained in a firmly covered container at room temperature away from sunshine for 24 hours and the phase is observed. (Davkhar et al., n.d.)

- **Test for microbial growth**

The creams were inoculated on agar media plates using the streak plate method, and a control was created by eliminating the cream. The plates were placed in the incubator and incubated at 37 C for 24 hours. After the incubation period, the plates were removed and compared to the control to determine microbial growth.(Mali & V, 2013)

- **Dye test emulsion type**

The scarlet red dye is combined with the cream. A drop of the cream was placed on a microscopic slide, which was then sealed with a cover slip and viewed under a microscope. If the dispersion globules are red and the ground is colourless, the cream is O/W type. In W/O type cream, the dispersion globules appear colourless in the red ground.(Dhyani et al., 2019)

- **After Feel**

The residue that remained after a certain quantity of cream was applied was measured.(Sekar et al., 2017)

- **Accelerated stability testing**

The two most stable generated formulations were subjected to accelerated stability testing at room temperature following a seven-day study period. The formulations were kept both at room and elevated temperature and observed on 0th, 5th, 10th, 15th and 20th day for the different parameters.(Mundada et al., n.d.)

- **Moisture absorption studies**

A watch glass with about 50mg of cream was consumed. A beaker was filled to the brim with water, placed in an adsorbent-free desiccator, and left to become saturated. A cream-colored watch glass was added to the desiccator. It was kept for a full day.(Dhase et al., 2014)

Results and Discussion

- **Physical properties**

Colour, odour, and texture were used to evaluate the physical attributes and all prepared cream.

Table 7 – Physical properties of cream

Parameters	**Characteristics**
Colour	Pale Yellow
Odour	Characteristic odour
Texture	Smooth

- **Spreadability:**

The spreadability of the formulations was measured after one minute by measuring the spreading diameter of 1 g of material between two horizontal glass plates (10 cm 20 cm). The upper plate's typical weight was 25 g.

Table 8 – Spreadability of cream

Formulation	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**	**F11**	**F12**
Spreadability (cm)	9	9.2	8.6	8.6	8.5	**8.9**	8.6	8.4	8.3	9.1	8.2	8.5

- **pH**

The pH of produced creams was found to be approximately 6, making them appropriate for topical use. Because the pH of skin ranges from 4.5 to 6.5.

Table 9 – pH of cream

Formulation	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**	**F11**	**F12**
pH	6.1	5.8	6.3	5.9	5.9	**6.3**	6.4	6.2	6	6.5	5.7	5.9

- **Irritancy**

During irritancy tests, the formulations exhibit no redness, oedema, inflammation, or irritation.

- **Viscosity**

The viscosity was determined at 20 rpm and 25 °C using the Brookfield Viscometer II + model and spindle no S - 64. Cream had a viscosity range of 2000 to 3000 cp. This means that the cream was non greasy.

Table 10 – Viscosity of cream

Formulation	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**	**F11**	**F12**
Viscosity (cps)	2670	2639	2235	2790	2570	**2567**	2368	2510	2459	2839	2205	2540

- **Homogeneity**

During the four weeks of observation, there was no clog in the cream. These results showed that the base cream was homogeneous as a result of the earlier grinding of the foundation materials.

- **Type of smear**

The type of smear produced on the skin after using the cream was non-greasy.

- **Washability**

Small amount of cream was applied by hand and rinsed under running tap water.

Table 11 – Washability of cream

Formulation	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**	**F11**	**F12**
Washability (sec)	10	10	7	11	9	9	8	9	8	12	7	9

- **Phase separation**

The prepared cream was kept intact in a closed container at 25-100 °C, away from light. For 30 days, phase separation was closely monitored every 24 hours. Then it was found that prepared cream has no phase separation.

- **Test for microbial growth**

After a 24-hour incubation period at 37°C, there were no indicators of microbial development.

- **Dye test emulsion type**

The manufactured creams were an O/W type emulsion, it was easily washable with plain water, resulting in improved customer compliance.

- **After Feel**

After application, all formulation has a cooling sensation and high extrubility.

- **Accelerated stability testing**

The properties of the produced formulations F6 and F10 shows very slight changes.

Table 12 – Stability test of cream

Days	Temp	Formulation	pH	Colour	Viscosity	Type of Emulsion	Type of Smear	Irritancy
0	40 ºC ±1 ºC	F6	6.3	Pale Yellow	2567	O/W	Non-greasy	No Irritation
		F10	6.5	Pale Yellow	2839	O/W	Non-greasy	No Irritation
5	40 ºC ±1 ºC	F6	6.3	Pale Yellow	2567	O/W	Non-greasy	No Irritation
		F10	6.5	Pale Yellow	2839	O/W	Non-greasy	No Irritation
10	40 ºC ±1 ºC	F6	6.3	Pale Yellow	2567	O/W	Non-greasy	No Irritation
		F10	6.5	Pale Yellow	2845	O/W	Non-greasy	No Irritation
15	40 ºC ±1 ºC	F6	6.3	Pale Yellow	2567	O/W	Non-greasy	No Irritation
		F10	6.6	Pale Yellow	2850	O/W	Non-greasy	No Irritation
20	40 ºC ±1 ºC	F6	6.4	Pale Yellow	2573	O/W	Non-greasy	No Irritation
		F10	6.7	Pale Yellow	2852	O/W	Non-greasy	No Irritation

- **Moisture absorption studies**

The moisture absorption was measured after a day, and it shows no moisture absorption.

Conclusion

All of the creams met the criteria, however the formula with F6 that was non-irritating was the most preferred. Since the cream was prepared by using simple ingredients and simple methods so the cream is also economical. We conclude that all of these formulations are stable and appropriate for use on skin based on the results. Different cream experiments' outcomes showed that the formulation may be applied topically to shield skin from harm.

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