ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

Formulation And Evaluation Of Herbal Cold Cream Using Lycopene Extract.

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ABSTRACT

This study aimed to formulate and evaluate an herbal cold cream incorporating lycopene extract. Six formulations were developed using a base of beeswax, liquid paraffin, Cetyl alcohol, borax, methyl paraben, and perfume, with water as the vehicle. The formulation process demonstrated consistent and reproducible results, yielding a cream with favourable organoleptic properties, including acceptable colour, odour, texture, and appearance, ensuring consumer appeal. The cream exhibited good homogeneity and was easily washable, with pH values compatible with the skin's natural balance, minimizing irritation risks. Viscosity tests confirmed optimal thickness and spreadability for smooth application. F2 Formulation Undergone Safety assessments revealed that no adverse skin reactions, while antibacterial tests indicated efficacy against *Escherichia coli* and *Staphylococcus aureus*, suggesting potential antimicrobial benefits. Stability tests showed the cream maintained its pH and spreadability under various temperature conditions, indicating good shelf life. Overall, the herbal cold cream proved to be a stable, effective, and user-friendly product, suitable for both cosmetic and therapeutic applications. Future research should include long-term stability and in-vivo studies to further validate its effectiveness and safety.

Keywords: Herbal cold cream, Lycopene Extract, Homogeneity, Antibacterial Activity

https://doi.org/10.33887/rjpbcs/2024.15.6.16

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ISSN: 0975-8585

INTRODUCTION

Skin is the outer covering of the body. In human, it is the largest organ of the integumentary system. The skin is making up 12-15% of body weight and with a surface area of 1-2m^2. The skin has up to seven layers of ectodermal tissue and guards the underline muscles, bones, ligaments and internal organs. Human skin is similar to that of most other mammals. Skin is composed of three layers such as Epidermis, Dermis, Hypodermis or Subcutis. Skin is very effective as a selective penetration barrier [1].

Herbal cosmetics are the preparation, which represents cosmetics associated with active bioactive ingredients or pharmaceuticals. The use of phytochemicals from a variety of botanicals has dual functions, they serve as cosmetics for the care of body and its parts and the botanical ingredients present influence biological function of skin and provide nutrients necessary for the healthy skin or hair. Herbal cosmetics, here in after referred as products, are formulated, using varies permissible cosmetic ingredients to form the base in which one or more herbal ingredients are used to provide defined cosmetic benefits only, shall be called as "herbal cosmetics" [2].

The main principle of cold cream involves slow evaporation of water phase which leads to cooling sensation. On storage, phase inversion occurs and water-in-oil emulsion cream is formed and this is often known as cold cream. On application, due to evaporation of water, cold sensation is observed; hence, it is called cold cream. Oily film remaining on the skin gives emollient action and protection the skin [3].

Characteristics of Cold Cream [4]

A good cleansing cream or cold cream should have the following characteristics

- As a cosmetic it should be stable and have a good appearance.
- It should melt or soften on application to the skin.
- It should spread easily without too much drag. During application, it should not feel greasy or oily.
- After evaporation of any water, the cream residue should not become viscous.
- Its physical action on the skin and pore opening should be that of flushing rather than absorption.
- A light emollient film should remain on the skin after use of the cream.
- Consistency should be optimum.
- Should not be sticky.
- Must be non-irritant and non-inflammatory.
- Should give cooling effect.

MATERIALS AND METHODS

Preparation Of Herbal Cold Cream

Table 1: Formulation Table of Herbal Cold Cream

INGREDIENTS	F1	F2	F3	F4	F5	F6
Lycopene(mg)	25	50	75	100	125	150
Bees wax(gm)	8	8	8	8	8	8
Liquid paraffin(ml)	25	25	25	25	25	25
Cetyl alcohol(gm)	0.52	0.52	0.52	0.52	0.52	0.52
Borax (gm)	0.2	0.2	0.2	0.2	0.2	0.2
Methyl paraben(gm)	0.1	0.1	0.1	0.1	0.1	0.1
Water(ml)	15	15	15	15	15	15
Perfume(ml), Qs to 50gm.	Qs	Qs	Qs	Qs	Qs	Qs

Formulation of Herbal Cold Cream involves three steps

Step one preparation of aqueous phase

- In a 50 ml of beaker 16.6ml of water, 0.2g of Borax and 0.1 ml of methyl paraben is added and heated up to 75^0C by using water bath.

Step two preparation of oil phase

- Simultaneously, 8 gm of bees wax, 25 ml of liquid paraffin and 0.52 gm of Cetyl alcohol are added in porcelain china dish separately and melted up to 75^0C by using water bath.

Step three mixing of both the phases

- To an oil phase, aqueous phase is added drop wise with constant stirring until it comes to 45 to 75^0C. Then, to this mixture the Herbal Drug and perfume are added with constant stirring [5].

Characterization of Herbal Cold Cream

Percentage yield [6]

The prepared herbal cold cream of all batches were accurately weighed. The measured weight of prepared herbal cold cream was divided by total amount of all the excipients and drug used in the preparation of the herbal cold cream gives the total percentage of herbal cold creams. It was calculated by the following equation.

$$\text{Percentage yield} = \frac{\text{Actual weight of the product}}{\text{Total weight of the excipients and drug}} \times 100$$

Evaluation of Herbal Cold Cream

Organoleptic Evaluation [7]

- The organoleptic properties like color, odor, physical state, appearance and roughness of the prepared herbal cold cream was evaluated.

Washability [7]

- The cream was applied on the hand and observed under the running water.

pH [7]

- The pH meter was calibrated with the help of 6.8 standard buffer solution. Weigh 0.5g of prepared cream and dissolve it in 50ml of distilled water and its pH was measured with the help of digital pH meter.

Viscosity [8]

- Viscosity of the herbal cream was determined with the help of Brookfield viscometer at 100 and 60 rpm with a spindle number 64.

$$cP = TK \times SMC \times \frac{10000}{RPM}$$

Where,

cP = Viscosity
TK = Torque %
SMC = Spindle multiplier constant

Irritancy test [9]

- Mark an area (1sq.cm) on the left-hand dorsal surface. The cream was applied to the specified area and time was noted. Irritancy, erythema, edema was checked if any for regular intervals up to 24 hours and reported.

Homogeneity [9]

- The formulations were tested for the homogeneity by visual appearance and by touch.

Spreadability test [10]

- The herbal cream sample was applied between the two glass slides and was compressed between the two glass slides to uniform thickness by placing 100g of weight for 5minutes then weight was added to the weighing pan. The time in which the upper glass slide moved over the lower slide was taken as a measure of spread ability.

$$\text{Spreadability} = \frac{M \times L}{T}$$

Where,
M = weight tied to upper slide
L = length moved on the glass slide
T = time taken to separate the slide

Antibacterial activity [11]

Antibacterial studies for prepared gel containing Clarithromycin loaded Solid Lipid Nanoparticles. 42,86.87 In-vitro antibacterial activity was evaluated by agar well diffusion method. The gel containing Clarithromycin loaded Solid Lipid Nanoparticles were taken for the study. 60 ml of nutrient agar media was prepared and sterilized at 15 lb pressure for 20 min in an autoclave. Under aseptic condition, 20 ml of nutrient agar media was transferred into sterile Petri plates. After solidification, bacterial suspensions including gram-positive Staphylococcus aureus and gram-negative Pseudomonas aeruginosa were spread on the media with the help of a swab. Subsequently, following the aseptic condition 5mm diameter wells were punched. Finally, 50µg/ml and 100µg/mL of the solution at different concentration were prepared from formulations, Formulated Cream was used as positive control and DMSO was used as a negative control were added to wells and plates were incubated for 48 hours at 37°C. Then, the zone of inhibition around the wells after incubation was measured.

Stability test [12]

The stability of the creams was checked by measuring both pH and homogeneity of the prepared creams at three different temperature conditions i.e., placing creams in an oven, refrigerator and at room temperature for 1 week. The temperature was 40°C in an oven, below 10°C in the refrigerator and at ambient conditions/Room temperature. The stability study was carried out by comparing values at time 0 and after a 1-week interval.

RESULTS AND DISCUSSION

Formulation of Herbal cold cream

Lycopene possesses a various pharmacological activities like anti-inflammatory activity, antibacterial activity, antifungal activity, antiviral activity, antitumor activity, immunomodulatory activity and antioxidant activity. These are selected as a model drug to formulate an Herbal cold cream for topical delivery. Bases such as Beeswax, Borax, Liquid paraffin, Cetyl alcohol and Methyl paraben were used to formulate the Herbal cold cream. Bees wax is used as an emulsifying agent, stabilizer and also it gives thickness to the cream.

Borax is used as an Emulsifier and it provide whiteness. Liquid paraffin is used as a lubricating agent. Cetyl alcohol is used as an emollient, which help to reduce rough and dry skin. Methyl paraben is

used as a preservative to prevent the microbial growth. Herbal cold cream was prepared by taking required quantity of waxy material and mineral oil in a porcelain china dish and heated on a water bath up to 75 ℃to obtain a molten mask. (Phase-A or oily phase). In another beaker, take borax and water and heated up to 75℃ (Phase-B or aqueous phase). Mix both the solutions by adding one phase into another phase with continuous stirring till a cream like consistency formed.

Figure 1: Formulated Herbal Cold Cream

Figure 2: Formulation batches F1, F2, F3, F4, F5 & F6 of the formulated cold cream

Characterization of herbal cold cream

Percentage yield

Percentage yield of different formulation F1 to F6 were shown in Table 1. The percentage of practical yield slightly increases with increase in the concentration of drug respectively.

Table 2: Percentage yield of Lycopene loaded herbal cold cream

Formulation code	Theoretical yield (gm)	Practical yield (gm)	Percentage yield (%)
F1	50	45.4	92.8
F2	50	48.24	96.88
F3	50	45.2	90.4
F4	50	47.34	94.68
F5	50	48.5	97
F6	50	48.56	97.12

ISSN: 0975-8585

Evaluation of Herbal Cold Cream

Determination of pH

The pH of all Six formulations was performed by pH meter and it shown in the pH range of 5.2 to 5.9 as shown in Table 4**.** The formulations F1, F2, F3 and F5. shows highest pH compare to their other formulations. Change in drug concentration may leads to changes in the pH of preparations.

The pH of different formulations from F1 to F6 was shown in Table 5. The pH varies from one formulation to another according to their bases ratio with drug.

Table 3: Study of pH for different formulation.

Formulation	pH
F1	5.85
F2	5.05
F3	5.50
F4	4.60
F5	4.72
F6	4.96

Organoleptic evaluation

The colour, odour, texture and state of all different formulations were shown in Table No 3

Table 4: a) Colour, odour, texture and state of lycopene formulation F1 to F3.

SI No	Parameter	F1	F2	F3
1	Colour	Light pink	Faint pink	Faint pink
2	Odour	Pleasant	Pleasant	Pleasant
3	Texture	Smooth	Smooth	Smooth
4	State	Semisolid	Semisolid	Semisolid

Table 4: b) Colour, odour, texture and state of lycopene formulation F4 to F6

SI No	Parameter	F4	F5	F6
1	Colour	Faint Pink	Faint Pink	Faint Pink
2	Odour	Pleasant	Pleasant	Pleasant
3	Texture	Smooth	Smooth	Smooth
4	State	Semisolid	Semisolid	Semisolid

Homogeneity

The formulations were tested for the homogeneity by visual appearance and by touch.

Irritancy test

Mark an area (1cm^2) on the left-hand dorsal surface. Then the cream was applied and the time was noted. Then it was checked for irritancy, erythema and edema if any for an interval up to 24 hrs and reported. According to the result, all the formulations i.e. F1 to F6 showed no sign of irritancy, erythema and enema.

ISSN: 0975-8585

Figure 3: Application of Cream for Checking irritancy

Washability studies

Washability test was carried out by applying a small amount of cream on the hand and then washing it with tap water. According to the result, all the formulations i.e. F1 to F6 are easily washable as shown in Figure

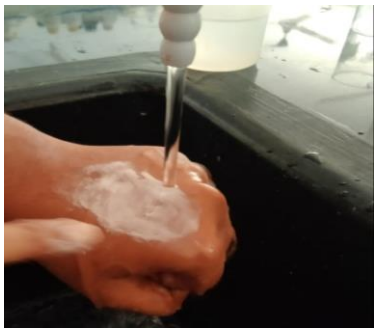

Figure 4: Washability test

Viscosity studies

The Viscosity was determined by Brook-field viscometer using spindle no.64 as shown in Table no 4. The viscosity of F2 formulation was in the range of 499990 to 30000cps, which indicates that the cream is easily spreadable by small amount of shear.

Table 5: Study of Viscosity of different formulation.

Formulations	Spindle No	RPM	Run Time	Torque (%)	Viscosity (cps)
F2	Spindle No.64	60	30 Sec	17.4	41345
		100	30 Sec	21.7	40381

Spreadability test:

The spreadability of all formulations were carried out and that is shown in Table 4 and Figure.

Figure 5: Spreadability Test

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Table 6: Study of spreadability for different formulations.

SI.no	Formulations	Time (Sec)	Spreadability (g * cm/sec)
1	F1	21.4	17.34
2	F2	21.78	16.62
3	F3	22.53	15.70
4	F4	23.43	15.098
5	F5	24.53	14.42
6	F6	25.10	14.09

Antibacterial Activity

Antibacterial studies were done by agar well diffusion method using bacterial suspensions including gram-positive bacteria *Staphylococcus aureus* and gram-negative *bacteria Pseudomonas aeruginosa*. The zone of inhibition around the wells after incubation was measured.

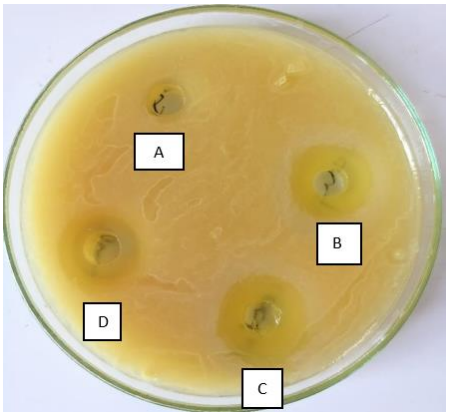

Figure 6: Zone of inhibition (mm) for *S. aureus* in plate

Table 7: Zone of inhibition (mm) around wells containing different formulations and control groups for *S. aureus.*

Formulation code	Zone of inhibition (mm)
Placebo	-
F1	7
F2	9
F3	11

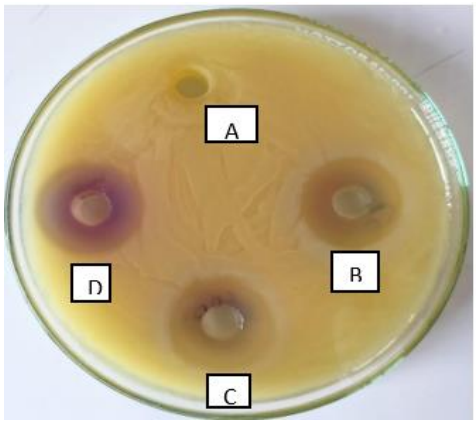

Figure 7: Zone of inhibition (mm) for *P. aeruginosa* in plate

Table 8: Zone of inhibition (mm) around wells containing different formulations and control groups for *P. aeruginosa.*

Formulation code	Zone of inhibition (mm)
Placebo	-
F1	8
F2	19
F3	12

Stability Studies

The stability was checked by two parameters pH and homogeneity by measuring it at time 0 and after the one-week interval at three different temperature ranges i.e. 40°C in an oven, below 10°C in the refrigerator and at room temperature. All the formulations passed the test of homogeneity at the selected temperature ranges over one week. However, there was a slight variation in the pH (Fig. 5).

Table 9: Evaluation Herbal Cold Cream formulation F2 after stability studiesunder three different conditions.

SL NO	Evaluation Parameters	Before stability testing	After stabilitytesting		
			10^0C	25^0C	40^0C
1.	pH	5.05	4.95	4.98	5.09
2.	Homogeneity	Appearance & touch	No change	No change	No change

CONCLUSION

The Herbal Cold Cream containing Lycopene extract was successfully formulated using beeswax, liquid paraffin, Cetyl alcohol, borax, methyl paraben, and perfume, with water as the vehicle. The formulation process yielded consistent results across all batches, demonstrating efficiency and reproducibility. Organoleptic evaluation showed that the cream had an acceptable color, odor, texture, and appearance, making it appealing for consumer use. The cream also exhibited good homogeneity, ensuring even distribution of ingredients throughout the formulation.

In terms of functionality, the cream was easily washable, enhancing user convenience. Its pH values were within the range suitable for topical use, ensuring compatibility with the skin's natural pH and reducing the risk of irritation. The spreadability of the cream was also favorable, allowing for easy application without feeling greasy or requiring excessive effort.

Based on above evaluation parameters Formulation F2 considered as optimized formulation. F2 formulation was undergone Viscosity and Anti-bacterial activity. The viscosity measurements confirmed that the cream had an ideal consistency, balancing thickness and spreadability, which are important for smooth application. The irritancy test revealed no signs of adverse skin reactions like erythema or edema, confirming the safety of the cream for topical application. Additionally, the cream exhibited antibacterial activity against *Pseudomonas aeruginosa* (Gram-negative) and *Staphylococcus aureus* (Gram-positive), suggesting potential antimicrobial benefits that could help prevent minor skin infections.

Finally, the stability test showed that the cream maintained its pH and spreadability under different temperature conditions, including oven, refrigerator, and room temperature, indicating good shelf life and durability. Overall, the herbal cold cream is a stable, effective, and user-friendly product with antimicrobial properties, making it suitable for both cosmetic and therapeutic applications.

In future, they may further be subjected for long term stability studies and *in-vivo* studies using human voluntaries.

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