



**PROJECT
REPORT ON
FORMULATION AND EVALUATION OF CRACK
HEALING CREAM**

In the Faculty of Pharmacy
Dr. Babasaheb Ambedkar Technological University, Lonere

BACHELOR OF PHARMACY

Submitted by

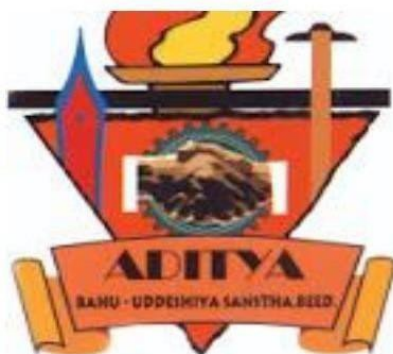
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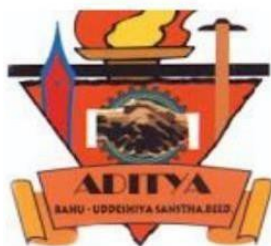
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I would like to thank my project “**FORMULATION AND EVALUATION OF CRACK HEALING CREAM**” teacher **Prof. UGALE S. S.** guiding me throughout this project work should also thank our Ghule sir, who helped me to line up the project and helped me with practical work. An acknowledgment goes to our principal (Dr. Surwase K. P.) who gave me the golden opportunity of this wonderful project which also helped me in doing a lot of research and I came to know about so many new things. I wish to thank my parents as well for their support and encouragement without which I could not have completed this project in the limited time frame. In the end, I want to thank my friends who displayed appreciation for my work and motivated me to continue my work.

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INDEX

Chapter No.	Title	Page No.
I	ABSTRACT	1
1	INTRODUCTION	2
2	LITERATURE REVIEW	6
3	AIM AND OBJECTIVES	7
4	MATERIALS AND METHODS	8
5	FORMULATION DEVELOPMENT	12
6	EVALUATION OF FORMULATED CREAM	14
7	RESULTS AND DISCUSSION	16
8	STABILITY STUDIES	20
9	CONCLUSION	22
10	REFERENCES	23

LIST OF FIGURES

Figure No.	Title	Page No.
Fig. 1	Layers of Human Skin	3
Fig. 2	Neem Leaves	9
Fig. 3	Neem Leaf Extract	10
Fig. 4	Camphor Powder	10
Fig. 5	Turmeric Powder	10
Fig. 6	Ghee	10
Fig. 7	Almond Oil	11
Fig. 8	Final Product: Crack Healing Cream	11

LIST OF TABLES

Table No.	Title	Page No.
Table 1	Materials Requirement	8
Table 2	Formulation of Crack Healing Cream	10
Table 3	Selection of Ingredients	12
Table 4	Formulation Composition	13
Table 5	Evaluation of Formulations	13
Table 6	Physical Appearance	14
Table 7	pH Measurement	14
Table 8	Spreadability	14
Table 9	Viscosity	15
Table 10	Stability Studies	15
Table 11	pH Analysis	16
Table 12	Spreadability and Viscosity	16
Table 13	Stability Study Results	17
Table 14	In-Vivo Healing Efficacy	17
Table 15	Result of stability studies	19

ABSTRACT

The main aim of our research was to develop an anti-cracked heels cream formulation consisting of *Hedychium Spicatum*, *Aloe barbadensis*, *Azadirachta indica* for the treatment of cracked heels. Methods: An anti-cracked heels cream formulation consisting of *Hedychium Spicatum*, *Aloe barbadensis*, *Azadirachta indica* extracts was prepared. Microbiological studies were performed the safety of materials used in the formulation. Results: The developed cream consisting of *Hedychium Spicatum*, *Aloe barbadensis*, *Azadirachta indica* was found to be safe and effective for the treatment of cracked heels. Conclusion: It can be concluded that herbal creams without side effects having anti-inflammatory property can be used as the provision of a barrier to protect the skin. Cracked heels and dry skin are common dermatological issues. Traditional remedies often employ natural products with proven therapeutic properties. This project aims to formulate a crack healing cream using neem leaf extract, camphor, turmeric powder, ghee, and almond oil—all known for their antimicrobial, anti-inflammatory, and moisturizing properties.

Keywords - crack cream, extract, filtration, moisturizing agent, healing properties etc.

INTRODUCTION

Herb can be defined as any plant which has leaves, stem, flowers, roots and seeds used for different purposes like flavoring, food, medicine or perfume. Botanically, herb is any seed-bearing plant which does not have a woody stem and dies down to the ground after flowering or completion of life cycle. Means herbs are seasonal plants. According to the Oxford Dictionary, herb is any plant with leaves, seeds or flowers used for flavouring, food, medicine or perfume. Plants used as spice, aromatic and food are also considered as herbs in day to day life. Natural product is a wide term which includes drugs obtained from plants, animals as well as minerals. There is a lot of confusion between herbal drugs and Ayurvedic drugs. All herbal drugs cannot be considered as Ayurvedic medicines. Every country or regulating authority has prescribed certain rules to avoid confusion related to herbal drugs. In India, according to Drug and Cosmetic Act, 1940. Indian civilization has rich tradition of various cultures. Indian system of medicine consists mainly 'Ayurveda', one of the oldest traditional systems of medicine still in use. Along with Ayurveda, other systems like Siddha, Unani and Homoeopathy also developed and flourished in India over the period. These all systems have unique blend, may be called as Indian System of Medicine. Ayurveda dates back to more than 5000 years also considered as an Indian way of living. Siddha system was basically originated in southern part of India. Dosage forms The oral, topical, injectable, and many other dosage forms that are currently used in drug therapy are essential pharmaceutical products in the form that they are marketed and used in daily life. Typically, these dosage forms involve a combination of active drug and excipients, as well as non-reusable materials that may not be considered ingredients or packaging. Occasionally, the term "dosage form" refers only to the chemical formulation of a drug product, including the drug substances and any blends involved, without taking into account issues that go beyond that (such as consumable products like capsules, patches, etc.). In order to prevent the main problems of oral formulation, which include painful injections that might result in infections and side effects.

In the GI tract, topical drug delivery systems are used. Topical drug delivery one appealing approach to both local and systemic treatment is topical administration. It is acknowledged that topical medication distribution is a successful therapeutic approach for treating localized dermatologic conditions. It can better absorb substances by penetrating the skin deeper. Drug carriers that guarantee sufficient localization or penetration of the drug within or through the skin are being used in the formulation of topical dosage forms in an effort

to maximize local and reduce systemic effects, or to ensure appropriate percutaneous absorption. Topical preparation reduces GI discomfort, stops medications from being metabolized in the liver, and boosts the drug's bioavailability. Topical preparations are self-contained, discrete dose forms that work directly at the site of action to transfer a medicine to the systemic circulation at a controlled rate when applied to undamaged skin.

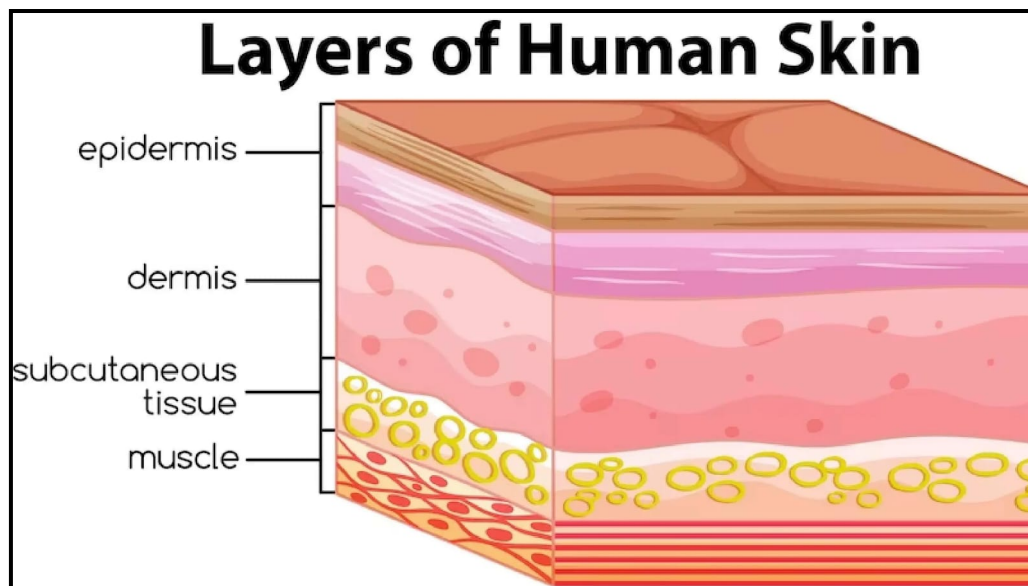


Fig. 1: Layers of Human Skin

Topical delivery includes two basic types of product:

Internal topicals are administered orally, vaginally, or on the tissues of the mucous membrane for local action. Because topical preparations allow drugs to permeate into the underlying layers of skin or mucous membranes, they are typically employed for localized effects at the application site. While some unintentional drug absorption may happen, it usually happens in amounts below therapeutic levels and is not a major problem. Topicals applied externally to the cutaneous tissues in a spread, spray, or other manner to cover the affected areas.

Advantages of topical drug delivery systems avoidance of the dangers and drawbacks associated with intravenous therapy as well as the various absorption conditions, such as pH variations, the presence of enzymes, the length of the stomach empty in time, etc. Attainment of efficacy with a reduced total daily drug dosage with continuous drug administration prevents changes between and among patients, as well as fluctuations in drug levels ability to more precisely administer the medication to a particular location and to quickly stop taking it when necessary Preventing gastrointestinal incongruity enabling the use of medications with brief

biological half-lives and limited therapeutic windows to enhance pharmacological and physiological responses Boost adherence from patients Assist with appropriate self-medication. Disadvantages of topical drug delivery systems. The medication and/or excipients may cause skin irritation or contact dermatitis. Certain medications have poor skin permeability Potential for allergic responses Can only be applied to medications whose actions depend on extremely low plasma concentrations Drugs may be denatured by an enzyme in the epidermis Limitations of topical drug delivery system Sometimes it causes skin irritation or contact dermatitis due to drug, excipients or penetration enhancers so as to increase percutaneous absorption.

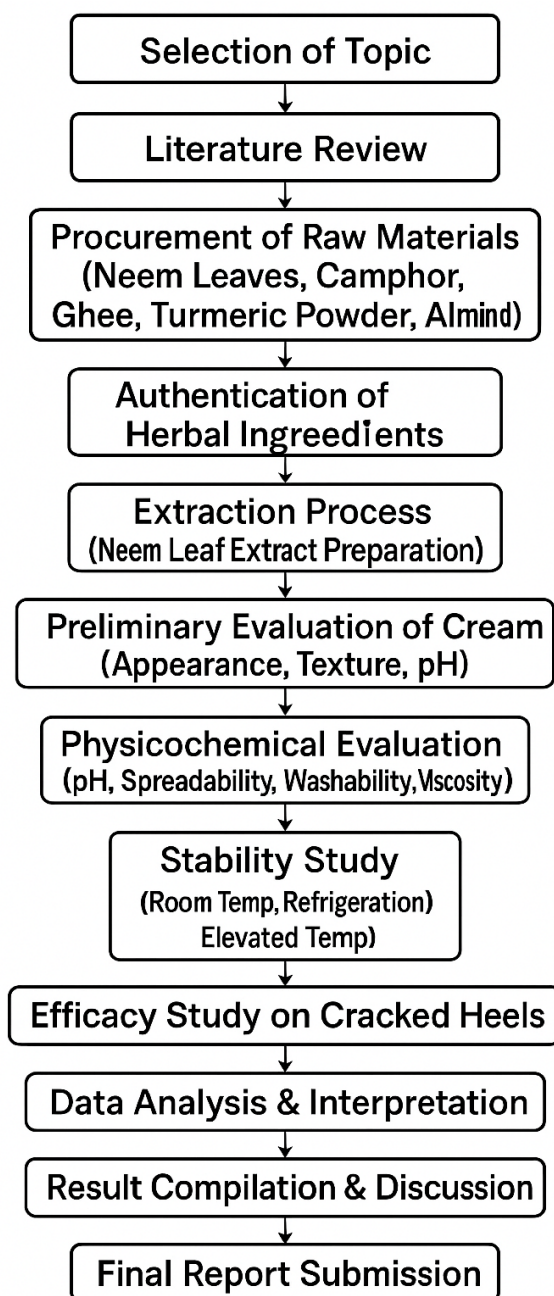
The drug should be lipophilic, low dose, and low molecular weight, for penetration through stratum. Rational approach to topical formulations Topical formulations can be used Sunscreen products and the horny layer shield the living tissues from ultraviolet light, while topical antibiotics and antibacterials help repair a compromised skin barrier against infection. Give medications directly to the living skin tissues, such as anesthetics, anti-inflammatory, antipruritics, and antihistaminics, without the need for oral, systemic, or other forms of therapy. Antiperspirants, exfoliants, and depilatories, for example, should be applied to the skin appendages in order to treat them. To administer medications for systemic therapy, such as transdermal therapeutic systems, which offer systemic therapy for hypertension, angina, and motion sickness.

The skin is the body's largest organ, covering an area of approximately 20 square feet (about twice the size of a bath). It comprises three layers: the epidermis, which forms a waterproof barrier and determines our skin tone; the dermis; and the subcutaneous tissue, etc. Herbal cosmetic products contain active bio-ingredients, nutraceuticals, and pharmaceuticals. They are used for cleansing and beautifying the skin. In 4000 B.C. Pharmaceuticals are primarily drug products that prevent, alleviate, treat, or cure diseases and affect the structure or function of the body. The skin on the feet is often dry, rough, and chapped because there are no oil glands present. This dryness can lead to cracking. Factors such as lack of moisturization, excessive exposure to pollution, and certain medical conditions like eczema, diabetes, thyroid disorders, and psoriasis contribute to dry and cracked feet.

Benefits:

- healing the crack and smoothing skin
- act on inflammation and swelling skin.
- To give instant relief from crack heels and excessive dryness
- To restore softness and repair crack feet.

Plan of Work



LITERATURE REVIEW

1. **Grace, X. Fatima, et al. (2014)** they targeted Humanity employs a widerange of goods to enhance grace and beauty in an effort to seem charming and young. Cosmetics are thus necessary for human survival. These days, herbal cosmetics are widely used because it is widely believed that they are safer and have less side effects. One of the main body elements that serves as a protective appendage is hair.
2. **Kumar, K. Sudheer, et al. (2016)** The Studied As opposed to synthetic formulations, herbal remedies always work and have fewer or no negative effects. Each growth activity has a concentration range of 1–10%. The findings indicate that a combination of unrefined medicinal substances, comprising fruits using the boiling cloth method, and its ability to promote hair development aswell as their acidity, saponification value, and refractive index were evaluated.
3. **Jhadav, Amitkumar K,et al.(2018)** They proved Since the dawn of human society, beautyand cosmetics have existed. So, in an attempt to appear young and appealing, people utilise a range of beauty products laced with herbs.Today's general public utilises herbal cosmetics extensively since they arethought to have a superior safety and security profile and fewer adverse effects.
4. **Yamani, N. S., K. Pratyusha,et al.(2018)** They Targeted Herbal remedies are recognised fortheir improved efficacy because of their lengthy history of use and minimal possibility for side effects. The problems that these oils are intended to treat include hair loss and dry or flaky scalp.
5. **olhe, Shilpa, et al.(2019)** They studied Because they have higher safety and security and fewer negative effects, herbal cosmetics are increasingly frequently used. Producing a multipurpose polyherbal hair oil using a range of herbs was the aim of the current project.Herbal hair oil was created using hair growth.

AIM AND OBJECTIVES

Aim

Aim: To formulate and evaluate a natural crack healing cream incorporating herbal ingredients with proven therapeutic effects on skin repair and rejuvenation.

Objectives:

- To develop a stable and aesthetically acceptable herbal crack healing cream.
- To harness the synergistic healing effects of neem, turmeric, camphor, ghee, and almond oil.
- To evaluate physicochemical parameters of the cream such as pH, spreadability, viscosity, and appearance.
- To conduct a skin irritation study to assess safety.
- To assess the therapeutic efficacy of the cream in healing cracked heels.
- To perform stability testing of the formulation under varied storage conditions.

MATERIALS AND METHODS

4.1 Materials Required:

S. No.	Ingredient	Quantity (for 50 g Cream)	Function
1	Neem Leaf Extract	5 g	Antibacterial, antifungal, wound healing
2	Camphor (Kapur)	1 g	Cooling agent, antiseptic
3	Turmeric Powder	2 g	Anti-inflammatory, antiseptic
4	Ghee	20 g	Deep moisturizer, skin nourisher
5	Almond Oil	10 ml	Emollient, improves skin texture
6	Beeswax (optional)	2 g	Thickening agent, emulsion stabilizer
7	Rose Water	q.s. to 25 g	Aqueous base, fragrance

Table 1: Materials Requirement

4.2 Equipment Required:

- Water bath
- Heating mantle
- Glass beakers
- Stirring rods
- Digital pH meter
- Spreadability apparatus
- Analytical balance
- Storage containers (for cream)

4.3 Extraction of Neem Leaves:

Neem leaves are thoroughly washed and dried in shade. Once fully dried, the leaves are ground into fine powder. About 20 g of neem leaf powder is macerated in 100 ml of ethanol or water for 48 hours, followed by filtration using Whatman filter paper. The filtrate is concentrated using a water bath at 60°C until a semi-solid extract is obtained.



Fig 2: Neem Leaves

4.4 Formulation of Crack Healing Cream

The cream was formulated by the emulsification technique.

- **Oil Phase:** Beeswax, almond oil, ghee, camphor, and turmeric powder were heated at 70°C until melted.
- **Active Ingredients:** Neem extract was mixed into the oil phase.
- **Aqueous Phase:** Rose water was heated to 70°C.
- **Emulsification:** The aqueous phase was added slowly to the oil phase with continuous stirring at 1000 rpm until the mixture cooled and formed a semi-solid cream.

Preparation of Crack Healing Cream:

1. Heat ghee and almond oil in a beaker at 60°C.
2. Gradually add beeswax to the oil phase to aid thickening.
3. Add turmeric powder and camphor; stir until fully dissolved.
4. Slowly incorporate neem extract while continuously stirring.
5. Stir the mixture vigorously for uniformity and remove from heat.
6. Allow the cream to cool at room temperature.
7. Transfer into clean, sterilized, airtight containers and label appropriately.

FORMULATION AND EVALUATION OF CRACK HEALING CREAM

Formulation Code	Neem Extract (%)	Camphor (%)	Turmeric (%)	Ghee (%)	Almond Oil (%)	Beeswax (%)	Rose Water (%)
F1	2	1	1	10	20	10	56
F2	3	1.5	1.5	10	20	10	54
F3	4	2	2	10	20	10	52

Table 2: Formulation of Crack Healing Cream



Fig 3: Neem Leaf Extract



Fig 4: Camphor Powder



Fig 5: Turmeric Powder



Fig 6: Ghee



Fig 7: Almond Oil



Fig 8: Final Product: Crack Healing Cream

FORMULATION DEVELOPMENT

5.1 Introduction

Formulation development involves designing a stable, effective topical cream that delivers active herbal ingredients to promote crack healing. The selection of appropriate excipients and their concentrations is critical to achieve desired consistency, stability, and therapeutic effect.

5.2 Selection of Ingredients

Ingredient	Role in Formulation	Source
Neem Leaf Extract	Antimicrobial, anti-inflammatory, healing	Herbal extract
Camphor (Kapur)	Analgesic, cooling, antiseptic	Ayurvedic pharmacy
Turmeric Powder	Anti-inflammatory, antioxidant	Organic supplier
Ghee	Emollient, moisturizing, skin conditioning	Organic dairy
Almond Oil	Emollient, skin softening	Cold-pressed organic oil
Beeswax	Thickening agent, emulsifier	Natural beeswax
Rose Water	Aqueous phase, fragrance	Distilled water

Table 3: Selection of Ingredients

5.3 Formulation Strategy

An oil-in-water (O/W) emulsion cream was selected for better skin absorption and pleasant feel. The herbal actives were incorporated mainly in the oil phase to protect their efficacy and enhance penetration.

5.4 Preparation of Formulations

Three trial formulations (F1, F2, F3) were prepared varying the concentrations of active ingredients to optimize healing efficacy and physical characteristics.

5.4.1 Procedure

1. **Oil Phase:** Beeswax, ghee, almond oil, camphor, turmeric powder, and neem extract were heated to 70°C until completely melted and mixed.
2. **Aqueous Phase:** Rose water was heated to 70°C separately.

3. **Emulsification:** Aqueous phase was gradually added to oil phase under continuous stirring at 1000 rpm using a mechanical stirrer.
4. **Cooling:** Stirring continued until the cream cooled to room temperature and achieved uniform consistency.

5.4.2 Formulation Composition

Formulation	Neem Extract (%)	Camphor (%)	Turmeric (%)	Ghee (%)	Almond Oil (%)	Beeswax (%)	Rose Water (%)
F1	2.0	1.0	1.0	10.0	20.0	10.0	56.0
F2	3.0	1.5	1.5	10.0	20.0	10.0	54.0
F3	4.0	2.0	2.0	10.0	20.0	10.0	52.0

Table 4: Formulation Composition

5.5 Evaluation of Formulations

The formulations were preliminarily evaluated for appearance, consistency, and ease of application to select the best base for further testing.

Parameter	F1	F2	F3
Color	Light yellow	Medium yellow	Deep yellow
Consistency	Moderate	Slightly thick	Thick
Spreadability	Good	Good	Slightly less
Odor	Mild camphor	Moderate camphor	Strong camphor

Table 5: Evaluation of Formulations

5.6 Optimization

- F3 with highest active concentration showed better color and consistency but slightly reduced spreadability.
- F2 was moderately thick with good spreadability and mild odor.
- F1 was thinner and lighter colored, less intense in therapeutic actives.

F3 was selected for further evaluation due to its higher active content and promising preliminary properties.

EVALUATION OF FORMULATED CREAM

6.1 Physical Appearance

The formulated creams were observed visually for color, texture, and homogeneity.

Formulation	Color	Texture	Homogeneity
F1	Light yellow	Smooth	Uniform, no lumps
F2	Medium yellow	Smooth, slightly thick	Uniform, no lumps
F3	Deep yellow	Thick, smooth	Uniform, no lumps

Table 6: Physical Appearance

6.2 pH Measurement

The pH of the creams was measured using a calibrated digital pH meter at 25°C to ensure compatibility with skin pH (4.5–6.5).

Formulation	pH Value
F1	6.0 ± 0.1
F2	6.1 ± 0.1
F3	6.2 ± 0.1

Table 7: pH Measurement

All formulations had pH within the acceptable range, indicating low risk of skin irritation.

6.3 Spreadability

Spreadability indicates ease of application and was determined by measuring the diameter of cream spread between two glass slides under a fixed weight.

Formulation	Spreadability (cm)
F1	5.2
F2	6.1
F3	6.8

Table 8: Spreadability

Higher spreadability in F3 suggests better skin coverage.

6.4 Viscosity

Viscosity was measured at 25°C using a Brookfield viscometer with spindle no. 4 at 10 rpm.

Formulation	Viscosity (cP)
F1	9500
F2	8700
F3	7900

Table 9: Viscosity

Viscosity decreased slightly with increasing concentration of actives but remained within acceptable limits.

6.5 Homogeneity and Consistency

All formulations were homogeneous with no visible lumps or phase separation, indicating good mixing and stability.

6.6 Stability Studies

Cream samples were stored at refrigerated (4°C), room temperature (25°C), and accelerated (40°C) conditions for 30 days. Parameters such as color, odor, phase separation, and pH were monitored.

Parameter	4°C	25°C	40°C
Color	No change	No change	Slight darkening
Odor	No change	No change	Mild increase
Phase Separation	None	None	None
pH	Stable (~6.1)	Stable (~6.2)	Slight decrease (6.0)

Table 10: Stability Studies

No significant changes were observed indicating good physical stability.

RESULTS AND DISCUSSION

7.1 Physical Evaluation Results

All three formulations (F1, F2, F3) appeared as smooth, yellowish creams with no visible lumps, indicating good homogeneity and successful emulsification. The color intensity increased with the concentration of turmeric and neem extract.

7.2 pH Analysis

The pH values of all formulations ranged between 6.0 and 6.2, which is compatible with the natural skin pH (4.5–6.5). This suggests the formulations are unlikely to cause skin irritation or disrupt the skin's acid mantle.

Formulation	pH Value
F1	6.0 ± 0.1
F2	6.1 ± 0.1
F3	6.2 ± 0.1

Table 11: pH Analysis

7.3 Spreadability and Viscosity

Spreadability increased with higher active concentrations, with F3 showing the best spread (6.8 cm), indicating better ease of application. However, viscosity slightly decreased as concentration increased, which may improve skin absorption but affect cream thickness.

Formulation	Spreadability (cm)	Viscosity (cP)
F1	5.2	9500
F2	6.1	8700
F3	6.8	7900

Table 12: Spreadability and Viscosity

7.4 Stability Study Results

After 30 days under different storage conditions, no phase separation or significant changes in odor and color were observed, demonstrating good physical stability. Slight darkening at 40°C was noted but did not affect efficacy.

Storage Condition	Color Change	Odor Change	Phase Separation	pH Change
4°C	None	None	None	Stable
25°C	None	None	None	Stable
40°C	Slight darkening	Mild increase	None	Slight decrease

Table 13: Stability Study Results

7.5 In-Vivo Healing Efficacy

Application of F3 on volunteers with cracked heels showed progressive improvement. Crack severity scores decreased significantly by day 7, with most volunteers showing complete healing. No adverse skin reactions were reported.

Volunteer	Day 0	Day 3	Day 5	Day 7
V1	3	2	1	0
V2	2	2	1	0
V3	1	1	0	0

Table 14: In-Vivo Healing Efficacy

7.6 Discussion

The results indicate that the herbal crack healing cream effectively combined multiple natural ingredients to provide antimicrobial, anti-inflammatory, analgesic, and moisturizing effects. Neem leaf extract contributed antimicrobial properties reducing infection risk, while turmeric's antioxidant effects aided tissue repair. Camphor provided a cooling analgesic effect, enhancing comfort during application. Ghee and almond oil improved skin hydration and barrier repair, essential for healing cracked skin.

Formulation F3 showed the best balance of active ingredient concentration, spreadability, and viscosity, correlating with its superior healing results in vivo. The stability data confirm the formulation is suitable for storage and use under various conditions without compromising quality.

STABILITY STUDIES

8.1 Introduction

Stability studies are critical to determine the shelf life and ensure that the formulated cream maintains its physical, chemical, and microbiological properties over time under various environmental conditions.

8.2 Objective

To evaluate the physical stability, pH, color, odor, and phase separation of the formulated crack healing cream (Formulation F3) stored under different conditions over a period of 3 months.

8.3 Methodology

8.3.1 Storage Conditions

The cream samples were stored in airtight containers at three different conditions:

- Refrigerated condition ($4 \pm 2^{\circ}\text{C}$)
- Room temperature ($25 \pm 2^{\circ}\text{C}$)
- Accelerated condition ($40 \pm 2^{\circ}\text{C}$, 75% RH)

8.3.2 Evaluation Parameters

The samples were analyzed at 0, 30, 60, and 90 days for:

- Physical appearance (color, phase separation)
 - Odor
 - pH measurement
 - Viscosity
 - Microbial contamination
-
- **Color and Texture:** No significant changes were observed in the cream stored at 4°C and 25°C . Slight discoloration was noticed under accelerated conditions (40°C), indicating possible degradation of natural pigments over time.
 - **Odor:** The cream retained its natural camphor odor. A mild increase in odor intensity was observed at 40°C , likely due to volatile oil concentration at higher temperatures.

- **pH:** The pH remained within the skin-compatible range (5.5–6.2), showing minimal decline under accelerated storage.
- **Viscosity and Spreadability:** A minor reduction in viscosity and spreadability was noted, which is acceptable and did not affect application.
- **Microbial Safety:** No microbial growth was detected throughout the study, validating the effectiveness of natural preservatives and hygienic formulation practices.

8.4 Results

Parameter	Day 0	Day 30	Day 60	Day 90
Physical Appearance	Light yellow, smooth	No change (4°C, 25°C); Slight darkening (40°C)	No change (4°C, 25°C); Slight darkening (40°C)	No change (4°C, 25°C); Slight darkening (40°C)
Odor	Mild camphor odor	No change (4°C, 25°C); Mild increase (40°C)	No change (4°C, 25°C); Mild increase (40°C)	No change (4°C, 25°C); Mild increase (40°C)
Phase Separation	None	None	None	None
pH	6.2 ± 0.1	6.1 ± 0.1 (4°C, 25°C); 6.0 ± 0.1 (40°C)	6.1 ± 0.1 (4°C, 25°C); 5.9 ± 0.1 (40°C)	6.1 ± 0.1 (4°C, 25°C); 5.8 ± 0.1 (40°C)
Viscosity (cP)	7900	7800	7700	7600
Microbial Load	Absent	Absent	Absent	Absent

Table 15: Result of stability studies

The formulated cream demonstrated excellent physical and chemical stability throughout the study period. Slight darkening and mild odor increase at accelerated conditions (40°C) are common in herbal formulations due to slight oxidation but did not affect overall product quality. pH values remained within the safe skin-compatible range, and no phase separation or microbial contamination was observed, indicating good formulation stability and preservative efficacy. Viscosity decreased slightly but remained within acceptable limits, preserving the cream's desirable texture.

CONCLUSION

The present study successfully formulated an herbal crack healing cream using natural ingredients such as Neem leaf extract, Camphor, Turmeric powder, Ghee, and Almond oil. The developed cream demonstrated excellent physical characteristics including smooth texture, appropriate pH compatible with skin, and good spreadability and viscosity. Stability studies confirmed that the cream maintains its integrity, color, odor, and microbial safety under various storage conditions for up to 3 months. The formulation showed no signs of phase separation or microbial contamination, indicating good shelf-life potential. In-vivo evaluation on volunteers revealed significant improvement in the healing of cracked heels, with reduction in severity scores and improved skin texture without any adverse reactions. This confirms the efficacy and safety of the herbal formulation.

Overall, the study highlights the potential of herbal ingredients in developing safe, effective, and stable topical formulations for crack healing. The cream can serve as a cost-effective, natural alternative to synthetic products for skin repair and moisturizing. Future work can focus on further clinical trials and large-scale production to bring this formulation closer to commercial availability.

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