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Research Paper

Formulation and Evaluation of a Sesame Oil-Based Foot Crack Cream for Wound Healing

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ABSTRACT

The field of wound management keeps advancing, yet finding an optimal dressing material or topical agent is still a difficult task, especially as drug-resistant microorganisms become more common and fewer new antibiotics are being developed. This gap has brought renewed attention to traditional and complementary methods of treating wounds. In this work, an oil-in-water type skin cream was developed with sesame oil as the main active component, along with stearic acid, liquid paraffin, beeswax, stearyl alcohol, Tween-80, methyl paraben, sorbitol solution, and potassium hydroxide, intended for possible application in wound repair and cracked-heel care. Three batches (F1 through F3) were prepared using different excipient proportions and assessed for their appearance, heat stability, pH, and ability to spread. Each batch appeared semi-solid with a distinct smell; F1 and F2 had a pale yellow tint whereas F3 was white in colour. When subjected to accelerated heat-stability trials, F1 and F2 exhibited minor separation of oil, while F3 stayed stable without any phase separation. Measured pH values fell between 5.94 and 6.02, near the natural pH of the skin surface. As excipient levels rose, spreadability also improved, moving from 13.7 g·cm/s for F1 up to 14.2 g·cm/s for F3. Under ICH-recommended stability conditions (40 ± 2 °C / 75 ± 5% RH), the formulations retained their physical integrity across a three-month period. Based on these observations, a stable and skin-friendly sesame oil-based cream appears achievable as a topical barrier product, though its actual wound-healing performance still needs to be confirmed through in vivo studies.

INTRODUCTION

Creams belong to the semi-solid category of dosage forms and are applied externally to the

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skin, or occasionally to mucosal surfaces such as the eye, nose, vagina, or rectum, serving therapeutic, protective, or cosmetic functions. Their mode of action is local, since they enable drugs to penetrate into the skin or mucosal tissue beneath, with the skin itself functioning as the target site [1,2]. Structurally, creams are emulsions combining oil and water in semi-solid form, and fall into two broad categories: oil-in-water (O/W) systems, where small oil droplets are suspended within a continuous water phase, and water-in-oil (W/O) systems, where water droplets are dispersed throughout a continuous oil phase. O/W-type creams tend to be preferred cosmetically because they feel less oily and rinse off more easily, while W/O-type creams, although somewhat harder to apply, are better suited to delivering hydrophobic drugs and forming a more occlusive, moisture-retentive layer that limits water loss through the skin [2].

Wound healing refers to the biological process through which skin and other tissues re-establish cellular and structural continuity following damage caused by physical, chemical, thermal, microbial, or immune-related injury. This process involves a coordinated series of cellular and biochemical steps aimed at restoring both structure and function. In clinical practice, wounds may fail to heal, heal too slowly, or heal excessively, and the overall goal of wound-care management is to reduce healing time or limit any adverse outcomes associated with these patterns [3]. Growing resistance among pathogenic organisms to multiple drugs, combined with a slowdown in the discovery of new antibiotic agents, has rekindled both clinical and public interest in alternative and traditional wound-care strategies. Organisations such as the World Health Organization, along with various national health bodies, have encouraged the use of traditional medicine as an affordable and accessible option, particularly within developing nations [3,4].

Being the largest organ within the integumentary system, the skin shields the body from pathogens and unwanted water loss while also contributing to temperature regulation, sensory perception, vitamin D production, and social/aesthetic expression [4,5]. Plant-derived oils have a long history of use within traditional healing systems — texts such as the Rigveda and Yajurveda, along with the Ayurvedic, Unani, and Homeopathic traditions, all reference herbal methods of skin care — and merging this accumulated knowledge with contemporary formulation science provides an opportunity to design topical products that are safe, effective, and broadly accepted [3]. Within Ayurveda, sesame oil (referred to as Tila taila) is regarded as the foundational base for most topical preparations. It is a rich source of the antioxidant compound sesamol as well as essential fatty acids, and has been credited with antioxidant, anti-inflammatory, moisturising, and wound-healing effects, in addition to its conventional use in managing cracked heels [3,6].

While numerous cream-based formulations have been investigated for their wound-healing potential, the extent of tissue regeneration they achieve is often reported as modest, which continues to drive further formulation research in this field [3]. Accordingly, the present study set out to develop and characterise a sesame oil-based skin cream as a potential barrier and wound-care formulation.

1.1 Aim and Objective

This study aimed to develop and characterise a herbal skin cream incorporating sesame oil, intended for possible use in wound care and the treatment of cracked heels. The prepared cream was assessed for its physical characteristics, pH, viscosity, spreadability, and stability, with excipient proportions adjusted across batches to determine which combination yielded the most

favourable spreadability, viscosity, and overall stability.

2. MATERIALS AND METHODS

2.1 Materials

Sesame oil used in this study was purchased from a retail pharmacy in Solapur. The remaining excipients — stearic acid, liquid paraffin, beeswax, stearyl alcohol, methyl paraben, potassium hydroxide, Tween-80, and sorbitol solution — were sourced from the Pharmaceutics laboratory at D.S.T.S. Mandal's College of Pharmacy, Solapur (Table 1).

Table 1. Materials used and their sources

Sr. No.	Material	Source
1	Sesame oil	Pharmacy retail shop, Solapur
2	Stearic acid	Pharmaceutics laboratory, COP Solapur
3	Liquid paraffin	Pharmaceutics laboratory, COP Solapur
4	Bees wax	Pharmaceutics laboratory, COP Solapur
5	Stearyl alcohol	Pharmaceutics laboratory, COP Solapur
6	Methyl paraben	Pharmaceutics laboratory, COP Solapur
7	Potassium hydroxide	Pharmaceutics laboratory, COP Solapur
8	Tween-80	Pharmaceutics laboratory, COP Solapur
9	Sorbitol solution	Pharmaceutics laboratory, COP Solapur

2.2 Excipient Profile

Sesame oil was chosen as the main active ingredient owing to its antioxidant content (sesamol), anti-inflammatory action, moisturising ability, and traditional reputation for supporting wound healing and repairing cracked heels. Within the oil phase, stearic acid, beeswax, and stearyl alcohol functioned as emulsifying and consistency-building agents, while liquid paraffin provided emollient and occlusive barrier properties. Tween-80 acted as the surfactant/emulsifying component, methyl paraben served as an antifungal preservative, and sorbitol solution was included as a humectant. Potassium hydroxide was used to adjust alkalinity and pH, saponifying the fatty-acid fraction and helping stabilise the resulting emulsion. Table 2 lists the physicochemical characteristics of these key excipients.

Table 2. Physicochemical properties of the excipients used

Excipient	Form	Colour/Odour	Melting point	Boiling point
Stearic acid	White solid	Pungent, oily odour	69.3 °C	361 °C
Liquid paraffin	Liquid	Colourless, odourless	Undetermined	>300 °C
Bees wax	Solid	Yellow to dark brown, characteristic odour	62–64 °C	—
Stearyl alcohol	Waxy flakes	Unctuous white, faint odour	59.5 °C	366 °C
Tween-80	Liquid	Umber, characteristic odour	— (flash pt. 148 °C)	100 °C
Methyl paraben	Crystal	Colourless, odourless	125–128 °C	270–280 °C
Sorbitol solution	Dry powder/liquid	White crystalline, odourless	111 °C	295 °C
Potassium hydroxide	Solid pellets	White/colourless, odourless	380 °C	1324 °C

Stearic acid density: 0.9408 g/cm³ (20 °C).

2.3 Formulation of the Cream

Two phases were prepared independently: an oil phase containing sesame oil, liquid paraffin, beeswax, stearyl alcohol, Tween-80, and stearic acid; and an aqueous phase consisting of methyl paraben, sorbitol solution, and potassium hydroxide dissolved in deionised water. Both phases were heated to 75 °C using a water bath. The aqueous phase was then introduced into the oil phase in a slow, dropwise manner under continuous homogenisation at 2000 rpm for 15 minutes. Homogeniser speed was subsequently lowered to 1000 rpm for 5 additional minutes, and finally to 500 rpm for another 5 minutes, yielding the completed sesame oil cream. Excipient concentrations were varied across the three batches (F1–F3) as shown in Table 3.

Table 3. Composition of the formulated creams (% w/w)

Sr. No.	Ingredient	F1 (%)	F2 (%)	F3 (%)
1	Sesame oil	2.5	2.5	3
2	Liquid paraffin	2.5	2.5	5
3	Stearic acid	1.5	1.5	3
4	Bees wax	2.5	2.5	5
5	Stearyl alcohol	5	5	10
6	Tween-80	4	4	8
7	Methyl paraben	0.6	0.6	0.12
8	Sorbitol solution	3	3	6
9	Potassium hydroxide	2.5	2.5	5
10	Deionised water	16.5	16.5	33

2.4 Evaluation of the Formulated Cream

2.4.1 Physical evaluation: Each formulation was examined visually to record its appearance, colour, and odour characteristics.

2.4.2 pH: The pH meter was first calibrated against standard buffer solutions of pH 4, 7, and 9, after which the electrode was immersed directly into each sample. Readings were taken at room temperature after allowing 10 minutes for equilibration.

2.4.3 Viscosity: A Brookfield Viscometer (model DV-I Prime, USA) was used to determine viscosity at rotational speeds of 0.3, 0.6, and 1.5 rpm. The dial reading obtained at each speed was multiplied by the appropriate conversion factor from the Brookfield catalogue to calculate the final viscosity value.

2.4.4 Spreadability: An identical volume of each sample was sandwiched between two glass slides of equal thickness. A 70 g weight was placed on top of the upper slide, and the time required for the slides to separate was noted. Spreadability (S) was then calculated using the formula $S = M \cdot L / T$, where M denotes the weight attached to the upper slide, L represents the slide length, and T is the separation time.

2.4.5 Stability: Stability testing followed ICH accelerated-condition guidelines. Sealed containers of each formulation were placed in a humidity-controlled chamber set to 40 ± 2 °C and 75 ± 5% RH for a period of three months; thermal stability at ambient room temperature (65 ± 5% RH) was also evaluated separately. At the end of this period, all samples were re-examined for physical appearance, pH, and viscosity.

3. RESULTS AND DISCUSSION

3.1 Physical properties

All three batches presented as semi-solid preparations with a distinctive odour. F1 and F2 exhibited a light-yellow colouration, whereas F3, formulated with higher excipient levels, appeared white (Table 4).

Table 4. Physical properties of the formulated creams

Sr. No.	Property	F1	F2	F3
1	Appearance	Semi-solid	Semi-solid	Semi-solid
2	Odour	Characteristic	Characteristic	Characteristic
3	Colour	Light yellow	Light yellow	White

3.2 Thermal stability

During accelerated thermal-stability evaluation at room temperature (65 ± 5% RH), minor oil separation was observed in F1 and F2, whereas F3 showed no phase separation and remained stable throughout (Table 5). This outcome suggests that the increased excipient concentration in F3 helped enhance the stability of its emulsion.

Table 5. Thermal stability of the formulated creams

Formula 1	Formula 2	Formula 3
Slight oily separation	Slight oily separation	Stable, no separation

3.3 pH

Measured pH values across the formulations fell within the 5.94–6.02 range (Table 6), a level close to the skin's natural pH and indicative of favourable skin compatibility.

Table 6. pH of the formulated creams

Formula 1	Formula 2	Formula 3
5.97	5.94	6.02

3.4 Spreadability

A modest rise in spreadability accompanied increasing excipient concentration, progressing from 13.7 g·cm/s in F1 to 14.0 g·cm/s in F2 and 14.2 g·cm/s in F3 (Table 7). These values confirm that each formulation had sufficient spreadability for topical use.

Table 7. Spreadability of the formulated creams

Formula 1	Formula 2	Formula 3
13.7	14.0	14.2

3.5 Viscosity and overall stability

Rather than being measured as an independent baseline parameter, viscosity was recorded as part of the accelerated ICH stability protocol described in Section 2.4.5. Throughout the three-month stability period (40 ± 2 °C / 75 ± 5% RH), no

meaningful changes were observed in appearance, consistency, viscosity, or pH, pointing to acceptable physicochemical and rheological stability under the tested storage conditions.

Overall, all three formulations displayed satisfactory spreadability, stable pH and consistency across the study duration, with F3 showing no signs of phase separation. Having been prepared with comparatively higher concentrations of oil-phase and structure-forming excipients, F3 emerged as the most physically stable of the three batches, combining an absence of phase separation on thermal testing with the highest recorded spreadability and pH values.

CONCLUSION

An oil-in-water cream formulated with sesame oil as its primary active constituent was successfully developed, meeting the pharmaceutical standards expected of a topical preparation. All batches displayed good spreadability, with F3 in particular maintaining consistent texture and showing no signs of phase separation throughout the testing period. None of the monitored stability parameters — appearance, consistency, viscosity, or pH — changed significantly over the course of the study, and pH values close to 6 confirmed compatibility with the skin's natural secretions. The formulations also remained stable under ICH accelerated conditions (40 ± 2 °C / 75 ± 5% RH) across a three-month period. Collectively, these findings support the feasibility of developing a sesame oil-based cream suitable for use as a topical skin barrier. Confirming the in vivo wound-healing efficacy of this formulation remains an important task for future investigation, as it has not yet been experimentally assessed.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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