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FORMULATION AND EVALUATION OF TOPICAL TRISHIELD CREAM WITH TRIPLE ACTION PROPERTIES (ANTI- INFLAMMATORY, ANTISEPTIC AND ANTIMICROBIAL)

Ms. Vishakha Ramkrushna Nagare*¹, Ms. Pratiksha Sunil Marathe², Rutuja Sunil Yeole³, Mansi Vijay Shirude⁴, Dr. Avinash B. Darekar⁵

1,3,4,5 Department of Pharmaceutics "Krantiveer Vasantrao Narayanrao Naik Shikshan Prasarak Sanstha's Institute of Pharmaceutical Education and Research", Nashik – 422002, Maharashtra, India.

²Department of Pharmacognosy "Krantiveer Vasantrao Narayanrao Naik Shikshan Prasarak Sanstha's Institute of Pharmaceutical Education and Research", Nashik – 422002, Maharashtra, India.



*Corresponding Author: Ms. Vishakha Ramkrushna Nagare

Department of Pharmaceutics "Krantiveer Vasantrao Narayanrao Naik Shikshan Prasarak Sanstha's Institute of Pharmaceutical Education and Research", Nashik – 422002, Maharashtra, India.

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ABSTRACT

This study presents the formulation and evaluation of Trisheild Cream, a topical preparation designed to provide triple action properties: anti-inflammatory, antiseptic, and antimicrobial effects. This study presents the topical formulation infused with natural essential oils known for their anti- inflammatory, antiseptic, and antimicrobial properties. The formulation incorporates Eucalyptus oil, Clove oil, Tea tree oil, Lemongrass oil, Sandalwood oil & Vit.E capsule, each contributing unique therapeutic benefits. The formulation was developed as an oil-in-water emulsion to ensure optimal skin absorption and stability. Comprehensive evaluation included assessments of physicochemical parameters such as pH, viscosity, spreadability, and homogeneity. The cream exhibited a semi-solid, homogeneous texture, a neutral pH suitable for skin application, and effective spreadability. The results suggest that Trisheild Cream is an effective and well-tolerated topical treatment for a range of inflammatory and infectious skin conditions, offering a convenient and comprehensive therapeutic option.

KEYWORDS: Topical application, Trisheild Cream, anti-inflammatory, antiseptic, antimicrobial.

INTRODUCTION

In recent years, there has been a growing demand for topical formulations that effectively address multiple skin concerns, including inflammation, infection, and discomfort. This formulation combines the synergistic benefits of natural essential oils and established medicinal compounds to create a powerful solution.

Together, these ingredients create a versatile formulation that not only promotes faster healing but also provides a protective barrier against pathogens. This formulation is designed for individuals seeking an effective and holistic approach to managing minor skin irritations, muscle soreness, and joint discomfort. By blending nature and science, this cream aims to support overall skin health and wellbeing.

SKIN ANATOMY

Understanding the anatomy of the skin is essential when considering how creams and other topical products interact with the skin. The skin is the body's largest organ and serves as a barrier, protecting the body from external elements, regulating temperature, and providing sensory information. Here's a detailed breakdown of the skin's structure and how it relates to the efficacy of creams:

1. The Layers of the Skin

The skin is composed of three main layers: the epidermis, dermis, and hypodermis (also known as subcutaneous tissue). These layers have different functions and interact with creams in distinct ways.

A. Epidermis (Outer Layer)

- Structure: The epidermis is the outermost layer of the skin, typically about 0.1 mm thick. It is primarily made up of keratinocytes (cells that produce keratin, a tough protein), melanocytes (cells that produce melanin, the pigment responsible for skin color), and Langerhans cells (involved in immune response).
- Functions: It acts as a protective barrier, preventing harmful microorganisms and chemicals from entering the body, and also helps in waterproofing the skin. The top layer of the epidermis, the stratum corneum, is made up of dead, flattened skin cells filled with keratin and serves as the skin's outer defense.
- How Creams Interact: Creams often target the

epidermis, especially the stratum corneum. Active ingredients such as moisturizers (e.g., glycerin, hyaluronic acid) and exfoliants (e.g., alpha hydroxy acids, retinoids) are absorbed into the epidermis to hydrate, nourish, or renew the skin

B. Dermis (Middle Layer)

- > Structure: The dermis is located beneath the epidermis and is much thicker. It contains blood vessels, nerve endings, hair follicles, sebaceous (oil) glands, sweat glands, and connective tissue.
- Functions: The dermis supports the epidermis and is responsible for supplying nutrients to the skin, regulating temperature (through sweat and blood flow), and providing structural support. The dermis is also home to collagen and elastin fibers, which give the skin its strength and elasticity.
- ➤ How Creams Interact: While most creams primarily affect the epidermis, some active ingredients (such as peptides, growth factors, and certain lipophilic

substances) can penetrate deeper into the dermis. For example, ingredients like retinoids and certain antiaging compounds may target the dermis to stimulate collagen production or improve skin firmness.

C. Hypodermis (Subcutaneous Tissue)

- Structure: The hypodermis is the innermost layer of skin, consisting mostly of fat cells (adipocytes) and connective tissue. It serves to insulate the body, absorb shock, and anchor the skin to underlying muscles and bones.
- Functions: The hypodermis helps cushion the body and regulate temperature by storing fat.
- ➤ How Creams Interact: Topical creams rarely penetrate this deep unless they contain specialized delivery systems. However, creams can still help with skin hydration and texture by improving the overall health of the epidermis and dermis.

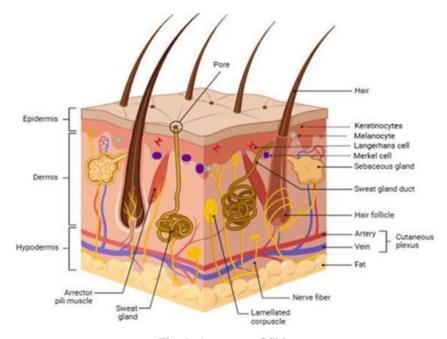


Fig. 1: Anatomy of Skin.

2. Skin Barrier Function

The skin's barrier function is crucial for maintaining homeostasis and protecting the body. The barrier function is primarily provided by the stratum corneum and its components:

- Lipids: The skin barrier is made up of lipids (ceramides, fatty acids, cholesterol) that form a "brick and mortar" structure with skin cells acting as "bricks."
- ➤ Hydration: Healthy skin barrier function requires proper hydration. When the barrier is damaged (due to dryness, environmental factors, or irritants), the skin becomes more susceptible to irritation, infection, and aging.
- How Creams Interact: Moisturizers are designed to replenish the skin's lipid barrier and prevent water

loss. They often contain humectants (e.g., glycerin, hyaluronic acid), emollients (e.g., shea butter, squalane), and occlusives (e.g., petrolatum, dimethicone) to restore hydration and fortify the skin's natural barrier.

3. Skin's pH and Topical Formulations

The skin's surface has a naturally acidic pH, typically ranging from 4.5 to 5.5. This acid mantle helps to maintain the skin's protective barrier by preventing the growth of harmful bacteria and fungi.

➤ How Creams Interact: It's important for creams and lotions to be formulated with a pH that matches the skin's natural acidity. Products that are too alkaline can disrupt the acid mantle, leading to dryness and irritation.

4. Absorption and Permeation

Creams and lotions contain active ingredients designed to treat or improve specific skin concerns (e.g., acne, wrinkles, pigmentation). The absorption and penetration of these ingredients depend on several factors:

- Molecular Size: Smaller molecules are more likely to penetrate the skin barrier. For example, hyaluronic acid and retinol are small enough to penetrate the epidermis effectively.
- Solubility: Lipophilic (oil soluble) ingredients are more likely to penetrate the lipidrich layers of the skin. Hydrophilic (water soluble) ingredients, on the other hand, tend to stay in the outer layers.
- Delivery Systems: Some formulations use advanced delivery technologies like liposomes, nanosomes, or microemulsions to help active ingredients penetrate deeper into the skin.

5. Key Ingredients in Skin Creams and Their Functions

- Moisturizers: Hydrate the skin and support the skin barrier.
- Humectants: Draw water into the skin (e.g., glycerin, hyaluronic acid, propylene glycol).
- Emollients: Soften and smooth the skin by filling in gaps between skin cells (e.g., squalane, shea butter, ceramides).
- Occlusives: Create a barrier to prevent moisture loss (e.g., petroleum jelly, dimethicone).
- Exfoliants: Remove dead skin cells to promote cell turnover.

Alpha hydroxy acids (AHAs): Water soluble acids that help exfoliate the outer layer of the skin (e.g., glycolic acid, lactic acid).

Beta hydroxy acids (BHAs): Oil soluble acids that penetrate pores and exfoliate inside them (e.g., salicylic acid).

- ➤ Physical exfoliants: Fine particles or beads (e.g., microbeads, sugar) used for scrubbing.
- ➤ Antiaging ingredients: Improve the appearance of fine lines and wrinkles by stimulating collagen production and improving skin texture.
- ➤ Retinoids (retinol, tretinoin): Promote cell turnover and collagen synthesis.
- ➤ Peptides: Short chains of amino acids that stimulate collagen production.
- Vitamin C: Antioxidant that helps brighten skin and stimulate collagen synthesis.
- Sunscreens: Protect the skin from UV radiation and prevent photoaging.

Physical (mineral) sunscreens: Contain zinc oxide or titanium dioxide to physically block UV rays.

Chemical sunscreens: Contain ingredients like avobenzone or octinoxate that absorb UV radiation and convert it to heat.

6. Skin Conditions and Treatment Considerations

Certain skin conditions affect how creams interact with the skin:

- Sensitive Skin: Products for sensitive skin should avoid fragrances, alcohol, and harsh exfoliants, which can irritate the skin.
- Dry Skin: Dry skin benefits from richer formulations containing occlusives and emollients to restore moisture and reinforce the skin barrier.
- Acne: Acne treatments often contain ingredients like salicylic acid, benzoyl peroxide, or retinoids, which can reduce inflammation and help clear blocked pores.
- ➤ Hyperpigmentation: Ingredients like vitamin C, niacinamide, and hydroquinone are used to treat discoloration and even out skin tone.

TRISHIELD CREAM

1. Active Ingredients

Trishield Cream typically combines three active ingredients designed to address a variety of skin conditions. Based on the name "Trishield," it is likely that the cream contains a combination of the following types of ingredients:

- Hydrocortisone (Corticosteroid): A mild antiinflammatory agent that helps reduce redness, itching, and swelling in various inflammatory skin conditions such as eczema, dermatitis, and allergic reactions.
- Antibiotics: Commonly used antibiotics in combination creams for dermatological purposes include neomycin or bacitracin, which help to treat or prevent bacterial infections on the skin.
- Antifungal Agents: It may also include an antifungal component like clotrimazole or miconazole, which are used to treat superficial fungal infections like athlete's foot, ringworm, and candidiasis.

2. Classification of Trishield Cream

Based on the likely active ingredients and their respective roles, Trishield Cream can be classified into the following categories:

A. Topical Corticosteroid

Hydrocortisone is a corticosteroid, which works as an anti-inflammatory agent, helping to reduce the redness, swelling, and irritation caused by inflammatory skin conditions.

- Classification: when used in concentrations like 0.5% or 1% (as in typical hydrocortisone creams).
- Indications: Treatment for inflammatory skin conditions such as eczema, dermatitis, psoriasis, and insect bites.

B. Topical Antibiotic

Neomycin or bacitracin (if present) are common topical antibiotics used to treat or prevent infection in minor cuts, burns, and scrapes.

 Classification: Antibiotic. These are typically broad spectrum antibiotics that target gram-positive and gram-negative bacteria.

• Indications: Used to treat minor bacterial skin infections and prevent infection in open wounds.

C. Topical Antifungal

Clotrimazole or miconazole (if present) are antifungal agents that inhibit the growth of fungi and yeasts on the skin.

- Classification: Topical Antifungal (Azole class antifungals).
- Indications: Treating superficial fungal infections like athlete's foot, ringworm, or candidiasis (yeast infections).

3. Uses of Trishield Cream

Trishield Cream is often used for various dermatological conditions that require a combination of anti-inflammatory, antimicrobial (antibacterial and antifungal), and sometimes antiitch properties. Common uses include:

- 1] Eczema and Dermatitis: To reduce inflammation, itching, and redness caused by inflammatory skin conditions like eczema or contact dermatitis.
- 2] Infections: To treat or prevent bacterial infections in cuts, burns, and abrasions, particularly when secondary infections are suspected.
- 3] Fungal Infections: For superficial fungal infections such as athlete's foot, ringworm, or jock itch.
- 4] Allergic Skin Reactions: In cases of skin allergies, to relieve swelling and redness while preventing infection or fungal growth.

4. Mechanism of Action of Active Ingredients

- Hydrocortisone (Corticosteroid): Works by suppressing the immune system's inflammatory response, reducing redness, swelling, and itching.
- Antibiotics: These kill or inhibit the growth of bacteria that may cause infections. Neomycin and bacitracin work by disrupting bacterial cell wall synthesis and protein synthesis, respectively.
- Antifungals: Clotrimazole and miconazole work by inhibiting the synthesis of ergosterol, a crucial component of fungal cell membranes, leading to fungal cell death.

MECHANISM OF ACTION

The formulation aims to accelerate healing for minor cuts, abrasions, insect bites, and joint discomfort while ensuring safety and tolerability for different skin types through thorough assessments.

Trishield cream is typically formulated to provide multiple benefits for skin health, particularly in treating various dermatological conditions. While specific formulations may vary, the mechanisms of action generally include the following components:

1. Anti-inflammatory Action

Key Ingredients: Often includes corticosteroids or natural anti-inflammatory agents (like aloe vera or chamomile). Mechanism: These ingredients help reduce inflammation by inhibiting the release of proinflammatory cytokines and mediators. This results in decreased redness, swelling, and irritation in affected areas.

2. Moisturizing and Barrier Repair

Key Ingredients: Emollients and occlusives (such as glycerin, petrolatum, or ceramides).

Mechanism: These components enhance the skin's moisture retention by creating a protective barrier that prevents trans epidermal water loss (TEWL). This is particularly beneficial for conditions like eczema or dry skin, where the skin barrier is compromised.

3. Antimicrobial Activity

Key Ingredients: Antimicrobial agents (like benzoyl peroxide or tea tree oil).

Mechanism: These ingredients can help reduce or eliminate harmful bacteria, fungi, and other pathogens on the skin surface, decreasing the risk of infections, especially in inflammatory conditions like acne or dermatitis.

4. Wound Healing Promotion

Key Ingredients: Growth factors, allantoin, or certain vitamins (like vitamin E).

Mechanism: These agents can promote cellular proliferation and migration, enhancing tissue repair and regeneration processes. They also help reduce scarring and improve overall skin texture.

5. Antioxidant Properties

Key Ingredients: Vitamins (such as C and E) or botanical extracts.

Mechanism: Antioxidants neutralize free radicals and reduce oxidative stress in skin cells. This helps protect the skin from damage caused by environmental factors (like UV radiation and pollution), promoting healthier skin.

6. Skin Soothing Effects

Key Ingredients: Ingredients like calendula, chamomile, or panthenol.

Mechanism: These agents provide soothing effects, alleviating discomfort associated with skin irritations, itching, or burning sensations. They can also enhance the overall skin feel and comfort.

7. Keratinocyte Regulation

Key Ingredients: Retinoids or alpha hydroxy acids (AHAs).

Mechanism: These compounds help regulate skin cell turnover and promote the shedding of dead skin cells. This is particularly useful in treating conditions like acne or psoriasis, where abnormal keratinocyte proliferation can lead to clogged pores and plaque Trishield cream is typically utilized for various dermatological applications due to its multifunctional properties.

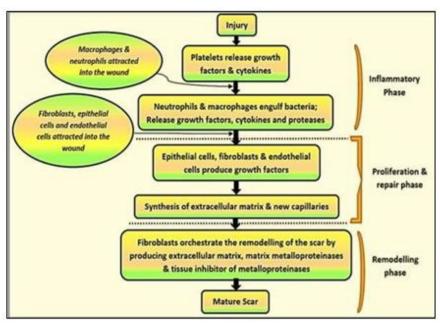


Fig. 2: Mechanism of Action.

MATERIAL AND METHODS OF PREPARATION Ingredients

Eucalyptus Oil: 3% is recognized for its soothing properties and ability to reduce inflammation.

Synonym: Eucalyptus globulus

Biological source: It is obtained from fresh leaves of Eucalyptus globulus Family: Myrtaceae

➤ Clove Oil: 3% offers potent antiseptic qualities and pain relief.

Synonym: Lavang, Caryophyllum

Biological source: It is obtained from dried flower buds of Eugenia caryophyllus Family: Myrtaceae

➤ **Tea Tree Oil:** 2% is renowned for its broad spectrum antimicrobial action, effectively combating a variety of pathogens.

Synonym: Melaleuca oil

Biological source: It is obtained from leaves of Melaleuca alternifolia Family: Myrtaceae

➤ **Lemongrass Oil**: 3% not only enhances the formulation with its refreshing scent but alsoprovides additional antimicrobial benefits.

Synonym: Citrus oil

Biological Source: It is volatile oil obtained by steam distillation from the leaves and aerial parts of the plants of Cymbopogon citratus.

Family: Germinae/Poaceae.

> Sandalwood Perfume

Sandalwood perfume is a fragrance that features sandalwood as a dominant note. Sandalwood is a type of wood derived mainly from the Santalum album tree, traditionally found in India, but also in Australia and other regions. It has been used in perfumery, religious rituals, and traditional medicine for centuries, prized for its warm, creamy, and woody scent.

METHODOLOGY Formulation of cream

a) Preparation of the Base



Fig. 3 Preparation of The Base.

b) Preparation of Active Pharmaceutical Ingredient (API) Mixture



Fig. 4: Preparation of oil phase.

Incorporation of API Mixture into the Base



Fig. 5: Mixing of oil and aqueous phase



Fig. 6 Addition of perfumery agent

d) Cooling, Texturization, and Storage



Fig. 7 Stirring process for homogenization.



Fig. 8 Final product.

FORMULATION BATCHES

Table 1: Formulation Batches.

Cu no	Inquadianta	Quantity Role		
Sr. no.	Ingredients	F1	F2	F3
1	Eucalyptus oil	4 ML	5 ML	6 ML
2	Clove oil	6 ML	5 ML	4 ML
3	Tea tree oil	3 ML	5 ML	4 ML
4	Lemongrass oil	1 ML	1 ML	1 ML
5	Sandalwood Oil	1 ML	1 ML	1 ML
6	Vitamin E	5 ML	5 ML	5 ML
7	Glycerin	4 ML	3 ML	5 ML
8	Bees wax	6 GM	5 GM	4 GM

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FORMULATION TABLE

Table 2: Formulation Table.

Sr. no.	Ingredients	Quantity	Role	
1	Eucalyptus oil	5 ML	Anti-inflammatory agent	
2	Clove oil	5 ML	Anti-septic agent	
3	Tea tree oil	5 ML	Anti-microbial agent	
4	Lemongrass oil	1 ML	Astringent / Anti-microbial Agen	
5	Sandalwood Oil	1 ML	Perfume	
6	Vitamin E	5 ML	Preservative	
7	Glycerin	3 ML	Moisturizing Agent	
8	Bees wax	5 GM	Emulsifying agent	

EVALUATION PARAMETERS

- **1. Physical Appearance:** The final formulation exhibited a smooth, creamy texture with a pleasant aroma from the essential oils. The color was a pale yellow, indicative of the natural ingredients
- 2. pH Analysis: The pH meter was calibrated using standard buffer solution. About 0.5 g of the cream was weighed and dissolved in 50.0 ml of distilled water and its pH was measured.
- **3. Viscosity:** Viscosity measurements indicated a stable formulation, with results falling within the desired range for a topical formulation, ensuring ease of application and spread ability.
- **4. Skin Irritation Test:** In preliminary efficacy safety tests, the cream showed slight irritation & warm effect as its anti-inflammatory, antiseptic & antimicrobial activity.
- **5. Homogeneity:** The formulations were tested for the homogeneity by visual appearance and by touch.
- **6. After feel:** Emolliency, slipperiness and amount of residue left after the application of fixed amount of

cream was checked.

- Removal: The ease of removal of the cream applied was examined by washing the applied part with tap water.
- **8. Spreadability:** Assess ease of application over the skin, to ensure uniform distribution of active ingredients & optimize viscosity and texture for consumer appeal.

The present study was conducted to formulate and evaluate a polyherbal ointment for its analgesic, antiinflammatory, and antimicrobial properties, along with essential physicochemical and dermatological assessments to ensure its safety, stability, and efficacy.

RESULT AND DISCUSSION

1. Physical Appearance: The final formulation exhibited a smooth, creamy texture with a pleasant aroma from the essential oils. The color was a pale yellow, indicative of the natural ingredients.

Table 3: Physical Appearance.

Description	F1	F2	F3
Color	Yellowish	Creamish Yellow	Yellowish Brown
Odour	Consistent	Mild & Pleasant	Strong
Appearance	Rough	Smooth	Smooth / Rigid

2. pH Analysis: The pH of the cream was found to be in range of 6.5 - 6.8 which is good for skin pH. All the formulations were shown pH nearer to skin required.

Table 4: pH Analysis.

Description	F1	F2	F3
pН	4.9	5.45	5.75

3. Viscosity: The viscosity of was cream was in the range of 27019 – 27023 cps which indicates that the cream is easily spreadable by small amounts of shear. But F1 and F2 shows good spreadable property than other formulations.

Table 5: Viscosity.

Description	F1	F2	F3
Viscosity(cps)	27019	27023	27021

4. Skin Irritation Test: The formulation F1, F2 and F3 shows no redness, edema, Inflammation and irritation during irritancy studies. These formulations are safe to use for skin.

Table 6: Skin Irritation Test.

Description	F1	F2		
Skin Irritation	No	No	Slightly Occurs	

5. Homogeneity: All formulations produce uniform distribution of extracts in cream. This was confirmed by visual appearance and by touch.

Table 7: Homogeneity.

Description	F1	F2	F3
Homogeneity	Satisfactory	Good	Satisfactory

6. After feel: Emolliency, slipperiness and amount of residue left after the application of fixed amount of

cream was found.

Table 8: After feel.

Description	Description F1		F3
After Feel	Easy	Easy	Easy

7. Removal: The cream applied on skin was easily removed by washing with tap water.

Table 9: Removal.

Description	$\mathbf{F_1}$ $\mathbf{F_2}$		\mathbf{F}_3	
Removal	Easy	Easy	Not Easy	

8. Spreadability: The cream applied on skin was easily spread.

Table 10: Spreadability.

Description	$\mathbf{F_1}$	$\mathbf{F_2}$	$\mathbf{F_3}$
Spreadability	Satisfactory	Good	Satisfactory

CONCLUSION

In conclusion, the formulation you developed shows a multifunctional topical treatment with anti-inflammatory, antiseptic, and antimicrobial properties. It may provide effective relief from pain, inflammation, and minor skin infections, making it a versatile option in topical therapy.

Comprehensive physicochemical evaluations confirmed the uniformity, spreadability, and pH suitability of the formulation for dermal application. The pH remained within the optimal range (6.0– 6.2), ensuring compatibility with human skin. Stability tests over 120 days revealed no significant changes in texture, colour, Odor, or viscosity, confirming the formulation's robustness under ambient conditions.

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