



Research Article

Formulation and Evaluation of Black Seed Oil Emulgel For Management of Eczema and Dermatological Disorders

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Eczema is a chronic inflammatory skin disorder characterized by itching, dryness, and recurrent infections, often requiring long-term topical therapy. Conventional treatments such as corticosteroids are effective but associated with adverse effects upon prolonged use. Black Seed Oil (*Nigella sativa*), rich in thymoquinone and other bioactive compounds, offers anti-inflammatory, antimicrobial, antioxidant, and wound-healing properties, making it a promising herbal alternative. In this study, a Black Seed Oil emulgel was formulated by combining oil, aqueous, and gel phases to enhance drug penetration, stability, and patient compliance. The prepared formulations (F1, F2, F3) were evaluated for physicochemical and functional parameters including pH, viscosity, spread ability, washability, and skin irritation. Results demonstrated that all formulations were stable, skin-compatible (pH 5.8–6.2), easily washable, and non-irritating. Among them, F2 showed optimized performance in terms of spread ability and pH balance. The findings confirm that Black Seed Oil emulgel is a safe, effective, and patient-friendly topical drug delivery system, offering a promising alternative to conventional dosage forms for eczema management. Further clinical studies are warranted to establish its therapeutic potential on a larger scale.

Keywords: Black Seed Oil, *Nigella sativa*, Emulgel formulation, Eczema therapy, Herbal topical preparation, Anti-inflammatory activity, Anti-microbial properties, Antioxidant effects, Patient compliance, Topical drug delivery.

INTRODUCTION

Skin disorders, particularly eczema (atopic dermatitis), are among the most common dermatological conditions, affecting millions of individuals worldwide. Eczema is a chronic inflammatory disease characterized by recurrent episodes of itching, erythema, dryness, and scaling, often accompanied by secondary bacterial infections. It is associated with immune system dysregulation, genetic predisposition, and environmental triggers. [1] Despite the availability of various treatment options, eczema remains a challenging condition due to its relapsing nature and the potential adverse effects of long-term pharmacological interventions. Conventional treatments for eczema include topical corticosteroids, calcineurin inhibitors, antihistamines, and emollients. While corticosteroids are the mainstay

of therapy, prolonged use can lead to side effects such as skin atrophy, telangiectasia, and increased susceptibility to infections. [2] Black Seed Oil (*Nigella sativa*) is an essential oil extracted from the seeds of the black cumin plant. It has been used for centuries in traditional medicine for treating a wide range of ailments, including skin disorders. The therapeutic potential of Black Seed Oil is attributed to its bioactive compounds, particularly thymoquinone, thymohydroquinone, and nigellone, which exhibit anti-inflammatory, antimicrobial, antioxidant, and wound healing properties. These characteristics make it an ideal candidate for the treatment of eczema and other dermatological. [3] Conventional ointments, creams, and gels have limitations that can reduce their effectiveness.

❖ Why Choose Emulgel for Topical Drug Delivery?

- Enhancing drug solubility – Improves absorption of poorly water-soluble drugs.
- Providing better penetration – Facilitates deep skin absorption.
- Ensuring controlled drug release – Prolongs therapeutic effects.
- Improving spreadability and patient compliance – Non-greasy texture enhances comfort.
- Increasing stability – Prevents degradation of sensitive ingredients. [4]

❖ Role of Black Seed Oil in Emulgel

Black Seed Oil (*Nigella sativa*) is an essential oil extracted from the seeds of the black cumin plant. It has been used for centuries in traditional medicine for treating a wide range of ailments, including skin disorders. The therapeutic potential of Black Seed Oil is attributed to its bioactive compounds, particularly thymoquinone, thymohydroquinone, and nigellone, which exhibit anti-inflammatory, antimicrobial, antioxidant, and wound healing properties. These characteristics make it an ideal candidate for the treatment of eczema and other dermatological. [5]

❖ Mechanism of Action of Black Seed Oil in Eczema Management: -

The effectiveness of Black Seed Oil in eczema treatment is linked to several mechanisms.

1. Anti-Inflammatory action:

- Eczema is an inflammatory skin condition triggered by the overproduction of pro-inflammatory cytokines (IL-4, IL-13, and TNF- α).
- Thymoquinone (TQ) in Black Seed Oil has been shown to inhibit these cytokines, reducing skin inflammation and irritation.
- It also downregulates nuclear factor-kappa B (NF- κ B), which plays a key role in chronic inflammation. [6]

2. Antimicrobial Properties:

- Eczematous skin is prone to bacterial infections, particularly *Staphylococcus aureus*, which aggravates symptoms. [7]
- Black Seed Oil contains thymol and carvacrol, which exhibit strong antibacterial effects against *S. aureus*, preventing secondary infections.

3. Antioxidant Effects:

- Oxidative stress contributes to skin barrier dysfunction in eczema.
- The antioxidants in Black Seed Oil neutralize free radicals, protecting skin cells from damage and supporting skin repair.

4. Moisturizing and Wound Healing:

- Eczema disrupts the skin's natural barrier, leading to excessive dryness and microcracks. [3]

❖ Mechanism of Drug Release and Skin Penetration:

The emulgel delivery system facilitates effective drug penetration through the skin. The process occurs in the following steps:

- 1) Application on Skin: The emulgel spreads evenly over the affected area.
- 2) Gel Dissolution & Drug Diffusion: The gel matrix gradually releases the active ingredient.
- 3) Emulsion Breakage: The emulsion phase releases Black Seed Oil, allowing deeper penetration.
- 4) Stratum Corneum Absorption: The oil phase penetrates through the stratum corneum (outermost skin layer). [4]

❖ Types of Emulgels: -

Emulgels can be classified based on the type of emulsion used:

1. Oil-in-Water (O/W) Emulgels – The oil phase is dispersed in an external water phase.
 - Advantages: Non-greasy, easily washable, good skin absorption.
 - Best for: Cosmetic and dermatological formulations. [10,11]

2. Water-in-Oil (W/O) Emulgels – The water phase is dispersed in an external oil phase.

- Advantages: Provides long-lasting hydration and occlusion.
- Best for: Dry skin conditions and prolonged drug release.

For Black Seed Oil, an **O/W emulgel** is preferred due to its non-greasy feel, improved absorption, and ease of application. [12,13]

MATERIAL & METHOD

An emulgel is a combination of an emulsion and a gel, designed to enhance the stability, spread ability, and penetration of active ingredients. This formulation incorporates Black Seed Oil, known for its anti-inflammatory, antimicrobial, and wound-healing properties, making it beneficial for managing eczema and other dermatological disorders. The formulation consists of an oil phase, an aqueous phase, and a gel phase, which are combined to form a stable emulgel.

1. Oil Phase Preparation
2. Aqueous Phase Preparation
3. Gel Phase Preparation

The step wise method is mentioned below

Step 1: Oil Phase Preparation

Mix Liquid Paraffin, Isopropyl Myristate, Span 80, and Black Seed Oil. Heat to 70°C to ensure uniform mixing.

Step 2: Aqueous Phase Preparation

Dissolve Tween 80, Propylene Glycol, Methylparaben, and Propylparaben in purified water. Heat to 70°C for complete dissolution.

Step 3: Emulsion Formation

Slowly add the hot aqueous phase to the hot oil phase with continuous stirring at 1000-1500 rpm. Continue stirring until a stable emulsion is formed.

Step 4: Gel Phase Preparation

Disperse Carbopol 940 in additional water with gentle stirring. Allow it to swell for 1-2 hours. Add Triethanolamine dropwise to adjust pH (5.5-6.5) and form a transparent gel.

Step 5: Incorporation of Emulsion into Gel

Gradually add the emulsion to the gel with gentle mixing to form a uniform emulgel.

Step 6: Addition of Final Components

Add fragrance and antioxidant (BHT/Ascorbic Acid) and mix uniformly. If ethanol is included, add it at this stage.

Step 7: Final Homogenization

Homogenize the final formulation for a smooth texture.

Step 8: Packing and Storage

Transfer the emulgel into suitable containers. Store in an air-tight container at room temperature. [5]

Table No. 1 Formulation table for Emulgel

Sr. No.	Name of Ingredients	F 1	F2	F3	Uses
1.	Black seed oil	8ml	9ml	10ml	Moisturizes and nourishes skin
2.	Liquid paraben	7 gm	7 gm	7 gm	Moisturizer for dry skin, base for lotions and creams
3.	Isopropyl myristate	3.50gm	3.50 gm	3.50gm	Emollient
4.	Span 80	2 gm	2 gm	2 gm	Emulsifying and stabilizing properties.
5.	Propylparaben	0.6 gm	0.6 gm	0.6 gm	preservative
6.	Antioxidant (vitamin E)	1ml	1ml	1ml	Cosmetic role: anti-aging
7.	Propylene glycol	0.5 gm	0.5 gm	0.5 gm	Improves consistency and prevents phase separation

8.	Methylparaben	0.10 gm	0.10 gm	0.10 gm	Prevents microbial growth
9.	Carbopol 940	1 gm	1 gm	1 gm	Gelling agent
10.	Triethanolamine	1-2 drops	1-2 drops	1-2 drops	pH Adjuster
11.	Purified water	ml qs	ml qs	ml qs	Vehicle

Evaluation Tests

• Physical Appearance and Homogeneity

The visual and tactile properties of the emulgel, including its color, odor, texture, and uniformity, are critical for patient acceptability. A smooth, lump-free consistency reflects proper formulation and mixing. The prepared emulgel was examined by spreading a small portion between the fingers, revealing a light brown coloration, a mild characteristic odor, and a uniform, smooth texture without evidence of phase separation or grittiness.

• pH Determination

Topical formulations must maintain a pH compatible with the skin (4.5–6.5) to minimize irritation. The pH of the Black Seed Oil Emulgel was determined using a digital pH meter after dispersing 1 g of the sample in 100 mL of distilled water. The measured pH was 5.8, which lies within the acceptable range (5.5–6.5), confirming suitability for dermal application. [8]

• Viscosity Measurement

Viscosity influences both spreadability and retention of the emulgel on the skin surface. Measurements were performed using a Brookfield Viscometer (Spindle No. 4 at 25°C) at varying rpm values. The formulation exhibited a viscosity of 27,500 cps, which falls within the optimal semi-solid range of 5,000–50,000 cps for topical preparations. [9]

• Spread ability Test

Spread ability is a key parameter for ease of application. The Slip and Drag Method was employed, wherein 1 g of emulgel was placed between two glass slides and subjected to a 500 g weight for one minute. The spread diameter was recorded as 6.1 cm, which is within the acceptable range of 5–7 cm, indicating favorable application properties. [4]

• Washability Test

Washability was assessed by applying the emulgel to the skin and subsequently rinsing with water. The formulation was easily removed, leaving the skin clean without any residual film. This confirms good washability characteristics.

• Skin Irritation Study

A small amount of emulgel was applied to the dorsal surface of the hand and observed for signs of irritation. No redness, itching, or adverse reactions were noted, confirming that the formulation is non-irritating and safe for topical use. [8]

RESULT & DISCUSSION

RESULT

The formulated Black Seed Oil emulgel (F1, F2, and F3) was evaluated for organoleptic and physicochemical parameters, and all formulations showed satisfactory results. The organoleptic evaluation indicated that all formulations exhibited a pale white color, pleasant odor, semisolid consistency, and smooth homogeneity without lumps or phase separation, confirming uniformity and aesthetic acceptability. The physicochemical evaluation revealed that the pH values ranged from 5.8 to 6.2, which is within the normal skin pH range, ensuring suitability for topical application without irritation. The spreadability values were recorded as 10.20 (F1), 10.40 (F2), and 10.30 (F3), indicating good spreadability and ease of application. Skin irritation studies showed no redness, itching, or adverse reactions for any formulation, confirming safety. All formulations were easily washable, leaving no residue on the skin, which enhances user compliance. Among the formulations, F2 demonstrated slightly better performance in terms of spreadability and pH balance, making it the optimized formulation. Overall, the results confirm that the emulgel is stable, safe, and effective for topical use.

Table No.2: Organoleptic evaluation

Sr. No	Parameters	F1	F2	F3
1	Colour	Pale white	Pale white	Pale white
2	Odour	Pleasant	Pleasant	Pleasant
3	Consistency	Semisolid	Semisolid	Semisolid
4	Homogeneity	Smooth & No lumps	Smooth & No lumps	Smooth & No lumps

Table No.3: Physiochemical Evaluation

Sr. No	Parameters	F1	F2	F3
1	pH	5.8	5.9	6.2
2	Spreadability Test	10.20	10.40	10.30
3	Skin irritation Test	No irritation	No irritation	No irritation
4	Washability Test	Easily washable	Easily washable	Easily washable

DISCUSSION

The study demonstrates that the formulated emulgel possesses desirable physicochemical and functional characteristics for topical drug delivery. The organoleptic properties such as color, odor, and texture were found to be acceptable, which is essential for patient compliance. The pH of the formulations was within the skin-compatible range, minimizing the risk of irritation. The viscosity of the emulgel ensured proper retention on the skin surface, while maintaining ease of application. Spreadability results confirmed that the formulation can be applied uniformly, enhancing therapeutic effectiveness. The absence of skin irritation indicates that the formulation is safe for prolonged use. The inclusion of Black Seed Oil significantly contributes to the therapeutic efficacy due to its anti-inflammatory, antimicrobial, and antioxidant properties. Furthermore, the emulgel system successfully overcomes the limitations of conventional topical formulations by improving drug penetration, stability, and patient acceptability. The results validate the effectiveness of the emulgel as a suitable carrier for herbal active ingredients.

SUMMARY & CONCLUSION

SUMMARY

The present study successfully formulated a herbal emulgel containing Black Seed Oil for the treatment of eczema. The formulation process involved the

preparation of oil, aqueous, and gel phases, followed by their combination to form a stable emulgel system. Evaluation studies confirmed that the formulation exhibited appropriate physicochemical properties, including suitable pH, viscosity, spreadability, and stability. The emulgel was found to be non-irritating, easily washable, and aesthetically acceptable. The findings highlight the potential of emulgel as an effective and patient-friendly topical drug delivery system for herbal formulations in dermatological conditions.

CONCLUSION

The formulated Black Seed Oil emulgel proved to be a promising topical preparation for managing eczema and other skin disorders. It demonstrated excellent stability, skin-compatible pH, good spreadability, and non-irritant properties. The incorporation of *Nigella sativa* enhances therapeutic effectiveness due to its potent anti-inflammatory and antimicrobial activities. Therefore, the emulgel can be considered a safe, effective, and convenient alternative to conventional topical dosage forms. Further clinical studies are recommended to evaluate its efficacy on a larger scale and to establish its potential in dermatological therapy.

CONFLICT OF INTEREST:

Regarding this investigation, the authors have no conflicts of interest.

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