Research Article **ISSN:2456-1622**

Asia Pacific Journal of Pharmaceutical and Applied Sciences

FORMULATION AND EVALUATION OF NIGELLA SATIVA BASED EMULGEL

Jasneek Kaur Kaloti[1], Aryan[2], Rajwant Kaur[3]*

[1]University Institute of Pharma Science, Chandigarh University, Mohali, Punjab, India

ABSTRACT

In addition to meeting basic nutritional requirements, plant-based diets play a pivotal role in enhancing immune function, thereby supporting overall health and providing protection against various diseases. With growing recognition of the link between nutrition and life expectancy, there has been a significant rise in interest surrounding nutraceuticals and functional foods among health-conscious individuals. *Nigella sativa* (black cumin) seeds have garnered considerable attention due to their diverse range of pharmacological activities, "including anticancer, gastroprotective, cardioprotective, antioxidant, antimicrobial, neuroprotective, antihypertensive, immunomodulatory, antidiabetic, anti-inflammatory, nephroprotective, and liver protective effects". These therapeutic properties are largely attributed to its diverse phytochemical constituents, such as "thymohydroquinone, thymol, thymoquinone (TQ), carvacrol, α-hederin, nigellidine, and nigellicine." The present study aimed to develop and evaluate a topical emulgel formulation incorporating *Nigella sativa* seed extract. The formulation was prepared using the cold process method with Carbopol as the gelling agent. Key parameters such as stability, spreadability, and pH were assessed to determine the suitability of the emulgel for dermal application. The results demonstrated that the prepared formulation exhibited satisfactory physicochemical characteristics, including appropriate pH for topical use, good spreadability, and excellent stability, indicating its potential as a promising herbal topical delivery system.

Keywords: Black cumin, carbopol, emulgel, herbal medicine, *Nigella sativa*, phytochemicals, skin application, stability, thymoquinone, topical formulation.

Submitted: 2 April 2025; Revised: 17 April 2025; Accepted: 28 April 2025

INTRODUCTION

Over the past few decades, the resurgence of interest in traditional medicine has highlighted the therapeutic potential of medicinal plants, which serve as rich sources of pharmacologically active compounds. Among these, "*Nigella sativa* L. (often called as black seed or black cumin), belonging to family Ranunculaceae, stands out due to its wide-ranging pharmacological activities and historical usage across various cultures in South Asia, North Africa, and the Middle East."

The seeds obtained from *Nigella sativa* contain a complex mixture of bioactive constituents, including "fixed and volatile oils, proteins, saponins, alkaloids, and essential fatty acids." Thymoquinone, the primary constituent of the volatile oil fraction, exhibits potent antioxidant, anti-inflammatory, antimicrobial, and anticancer properties. Other bioactive compounds, such as thymohydroquinone, carvacrol, dithymoquinone, and α-hederin, contribute to the synergistic pharmacological effects coming from the seed.

Antioxidative potential, a hallmark of *N. sativa*, is crucial in mitigating oxidative stress— an underlying factor in numerous chronic conditions including cancer, diabetes, neurodegenerative diseases, and cardiovascular disorders. TQ had been shown to "boost the function of internal antioxidant enzymes such as superoxide dismutase (SOD), catalase, and glutathione peroxidase."

Nigella sativa also indicate potent inflammation-modulating effects through modulation of key mediators such as prostaglandins, leukotrienes, and inflammatory cytokines such as TNF-α, IL-1β, and IL-6, making it beneficial for treating asthma, arthritis, and dermatitis. Its immunomodulatory, antimicrobial, and regenerative properties further enhance its therapeutic relevance, especially in skin disorders and cosmeceutical applications.

Traditional systems like Unani and Ayurveda consider *N. sativa* a "cure-all" remedy, corroborated by modern pharmacological studies. The increasing shift towards natural and sustainable remedies, coupled with scientific validation of their efficacy and safety, underscores the significance of exploring innovative delivery systems for herbal actives.

The ongoing study highlights formulation and evaluation of the topical emulgel incorporating *Nigella sativa* seed extract. Emulgels, which combine the advantages of both emulsions and gels, offer improved stability, ease of application, and enhanced skin penetration, making them ideal for delivering lipophilic plant actives like thymoquinone.

Reported Literature

Shaukat et al. (2023): This comprehensive review assessed the antidiabetic mechanisms of *Nigella sativa* seeds and their bioactive component, thymoquinone. The article elaborated on how thymoquinone improves insulin sensitivity, enhances pancreatic β-cell proliferation, and modulates glucose transporter (GLUT-4) expression. It also addressed its involvement in attenuating systemic

inflammation and oxidative stress, which are hallmarks of type 2 diabetes mellitus. The authors emphasized *N. sativa*'s role in glycemic control and proposed it as an adjunct in diabetes therapy.

Ferizi et al. (2023): This review explored the diverse therapeutic applications of *Nigella sativa*, consisting of "antioxidant, hepatoprotective, anti-inflammatory, nephroprotective, cardioprotective, and anticancer characteristics." It highlighted the key phytochemicals—especially thymoquinone, thymol, and nigellidine—as being responsible for modulating multiple cellular pathways, including cytokine inhibition, free radical scavenging, and apoptosis induction. The article also suggested its potential integration into evidence-based herbal medicine.

Navidshad et al. (2024): This research assessed the effectiveness of Nigella sativa seed extract and oil as a natural enhancer of growth and immune system modulator in poultry.. Results indicated enhanced weight gain, feed conversion ratio, and reduced mortality in broilers. The immunomodulatory action was attributed to improved leukocyte function and cytokine balance. The antimicrobial properties also led to better gut microbiota regulation, suggesting potential in organic livestock production.

Lim et al. (2024): This study evaluated methanolic extracts of *Nigella sativa* for antibacterial and antioxidant activities using DPPH and ABTS assays. The extract demonstrated significant inhibition against "E. coli, S. aureus, P. aeruginosa, and other Gram-positive and Gram-negative bacteria." The antioxidant activity was dose-dependent and attributed to phenolics, flavonoids, and thymoquinone. The authors proposed its application in natural preservative formulations and topical antimicrobial products.

Shad et al. (2021): This review emphasized the inflammation-modulating and antimicrobial mechanisms of thymoquinone, the leading bioactive of *Nigella sativa*. It described its inhibition of TNF-α, COX-2, IL-6, and IL-1β, and its effectiveness against multi-drug-resistant bacteria and fungi. The compound also showed promise in treating respiratory infections, urinary tract infections, and systemic inflammation. Molecular docking studies supported its potential in drug development.

Bhatia et al. (2022): The researchers analyzed the seed extract of *Nigella sativa* using GC-MS and FTIR spectroscopy. A broad spectrum of bioactive compounds, such as alkaloids, terpenoids, and phenolics were identified. The extract exhibited potent antibacterial effects against *Staphylococcus aureus* and *Klebsiella pneumoniae*. The study linked these effects to the synergistic interactions among thymoquinone, carvacrol, and thymol.

Ramadan et al. (2023): This article detailed *Nigella sativa*'s effect on chronic diseases including hypertension, asthma, neurodegenerative diseases, and cancer. The authors discussed its capacity to modulate gene expression (e.g., Nrf2, NF-κB), enhance detoxification pathways, and inhibit tumor growth. The safety profile was also examined, confirming minimal toxicity at therapeutic doses.

Clinical trials cited demonstrated improved patient outcomes when *N. sativa* was used as an adjuvant.

Kulyar et al. (2023): This paper reviewed randomized controlled trials where *Nigella sativa* supplementation resulted in decreased BMI, LDL cholesterol, and markers of insulin resistance. The plant was found to regulate lipid metabolism by modulating PPAR pathways. Furthermore, improvements in liver enzyme levels suggested hepatoprotective potential in obese individuals

Hajhashemi et al. (2023): The study explored thymoquinone's impact on neurodegenerative disorders, including Alzheimer's and Parkinson's. It showed the compound's ability to inhibit β-amyloid aggregation, reduce neuronal inflammation, and enhance mitochondrial function. The authors suggested *Nigella sativa* as a potential preventive strategy for age-associated cognitive decline.

Abou El Naga et al. (2023): This clinical trial assessed the efficacy of *Nigella sativa* oil for treating atopic dermatitis. Application of a cream containing 10% oil led to significant improvements in itching, redness, and lesion size within four weeks. The results were attributed to its anti-inflammatory and antimicrobial effects, suggesting its use in natural skincare and dermatology.

MATERIALS AND METHODS

Chemicals: Glycerine, Carbopol (940), methylparaben, Polyethylene glycol 6000 and triethanolamine were provided by pharmaceutics lab at Chandigarh University, Punjab, India, Black cumin oil was obtained from the local market in Punjab, India.

Instruments and Equipment: Beakers, measuring cylinder, mortar and pestle, glass rod, glass slides, magnetic stirrer, water bath and weighing balance.

Formulation of emulgel

The emulgel was prepared using the Cold method [13]

1. Weighed 0.3 g of Carbopol (940) accurately. Slowly sprinkled into 10ml of distilled water. Stirred gently using a magnetic stirrer until, it fully dispersed. Allowed it to hydrate for 1 hour or until the mixture was slightly hazy or clear.
2. Heated 5ml of distilled water to 70-80 ◦C and dissolved 0.06 of methylparaben.
3. Weighed 1g of PEG 6000 accurately. Melted at 60-65 ◦C using a water bath. Once melted, mixed it with the methylparaben solution.
4. Mixed 10 ml of black cumin oil and 10ml of glycerine. Heated to enhance mixing.
5. Added the melted PEG 6000 and methylparaben solution to the oil and glycerine one and stirred. Now slowly added this mixture to the hydrated Carbopol dispersion, stirred gently to avoid air bubbles.

6. Added triethanolamine further to adjust both the consistency and the pH. The final formulation is depicted in Figure 1. [14]

Figure 1. *Nigella sativa* emulgel

RESULTS AND DISCUSSION

Organoleptic property evaluation: The assessment involved examining a number of organoleptic characteristics of the prepared emulgel, such as the preparation's colour, feel, and odour. [15] The emulgel was observed to be light brown colour and found to be homogeneous and phase separation was not observed. The consistency was found to be smooth and it had a distinct herbal aroma characteristic of *Nigella sativa* oil; no foul or synthetic odour.

Spreadability evaluation: A 1 g sample that was produced 48 hours before to the test is sandwiched between two 20 × 20 cm glass plates. For one minute, a 125 g weight (50–500 g) is set on top. The sample's diameter within the plates is then being measured. [17] The spreadability was determined by parallel plate method was found to be 2096.7 mm2 indicating good spreading ability under light pressure (Figure 2).

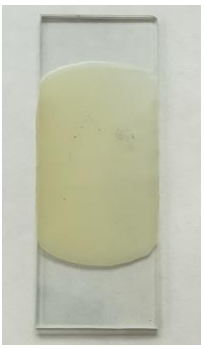

Figure 2. Spreadability test.

Dilution test: The prepared emulgel sample (Emulsions A and B) was diluted with either water or oil. This test relies on the notion that adding a dispersion medium to an emulgel prevents phase separation. [15] The emulgel stayed stable on addition of water. However, it showed coalescence on addition of NS oil

Thermal stability test: From day 1 to day 5, both emulgel preparations were being exposed to sunlight and refrigerated at 4°C. [15] Phase separation occurred in emulgel after Day 5.

pH: pH was determined using the pH paper and digital p meter [16]

Using pH Paper*:* The pH paper had turned light green to yellowish-green (Figure 3)**,** indicating a pH in the range of 6.0 to 6.5**,** suitable for topical application.

Figure 3. pH test using pH paper

Using pH Meter*:* The pH of the emulgel was found to be 6.12 ± 0.05 (mean of three readings), confirming its compatibility with the skin's pH.

Viscosity: A Brookfield viscometer was used to measure the created gel's viscosity. 50 revolutions per minute were used to rotate the gels. The dial reading that corresponded to each speed was recorded. By multiplying the dial reading by the factor listed in the Brookefield Viscometer catalogues, the viscosity of the emulgel was determined. [16] The emulgel's consistency was ideal for topical use it wasn't overly stiff or runny. Throughout storage, the consistency remained consistent.

The successful incorporation of *Nigella sativa* oil into a stable emulgel base highlights the feasibility of developing a topical delivery system that preserves the bioactivity of its key constituents, especially thymoquinone. The formulation offers the benefits of both emulsion-based penetration and gel-based retention on the skin, ensuring sustained localized delivery of actives. The use of Carbopol 940 provided an appropriate gel consistency without compromising the spreadability or user comfort. The pH adjustment ensured compatibility with skin physiology, which is critical in preventing adverse reactions. The findings corroborate previous studies supporting a topical application of *N. sativa* extracts in inflammatory and microbial skin conditions.

CONCLUSION

The present study successfully demonstrated the formulation and evaluation of a topical emulgel incorporating *Nigella sativa* seed oil, known for its broad pharmacological benefits, particularly anti-inflammatory, antioxidant, and antimicrobial properties. The emulgel was prepared using a cold method with Carbopol 940 as the gelling agent, resulting in a stable, pH-balanced, and cosmetically acceptable formulation. The physicochemical assessments—including organoleptic evaluation, spreadability, viscosity, pH, and thermal stability—confirmed its suitability for dermal application. The formulation maintained its consistency, showed good spreadability, and was stable under

moderate conditions, indicating its potential as an effective herbal delivery system. Importantly, the pH of the final product was within the ideal range for skin application, ensuring minimal risk of irritation. These findings support the integration of *Nigella sativa* oil in topical preparations and highlight the potential of emulgel systems in enhancing skin penetration and sustained delivery of phytochemicals for therapeutic and cosmeceutical applications.

REFERENCE

[1] Hannan, M. A., Rahman, M. A., Sohag, A. A. M., Uddin, M. J., Dash, R., Sikder, M. H., ... & Kim, B. Black cumin (Nigella sativa L.): A comprehensive review on phytochemistry, health benefits, molecular pharmacology, and safety. Nutrients., 2021; 13(6): 1784.

[2] Dalli, M., Bekkouch, O., Azizi, S. E., Azghar, A., Gseyra, N. & Kim, B. Nigella sativa L. phytochemistry and pharmacological activities: A review (2019–2021). Biomolecules, 2021; 12(1): 20.

[3] Shafodino, F. S., Lusilao, J. M. & Mwapagha, L. M. Phytochemical characterization and antimicrobial activity of Nigella sativa seeds. PloS One, 2022; 17(8): e0272457.

[4] Derosa, G., D'Angelo, A., Maffioli, P., Cucinella, L. & Nappi, R. E. The use of Nigella sativa in cardiometabolic diseases. Biomedicines, 2024; 12(2): 405.

[5] Wahab, S. & Alsayari, A. Potential pharmacological applications of Nigella seeds with a focus on Nigella sativa and its constituents against chronic inflammatory diseases: Progress and future opportunities. Plants, 2023; 12(22): 3829.

[6] Hossain, M. S., Sharfaraz, A., Dutta, A., Ahsan, A., Masud, M. A., Ahmed, I. A. & Ming, L. C. A review of ethnobotany, phytochemistry, antimicrobial pharmacology and toxicology of Nigella sativa L. Biomedicine & Pharmacotherapy, 2021; 143: 112182.

[7] Pandey, R., Pandey, B. & Bhargava, A. Morphological and anatomical studies in Nigella sativa L. (Ranunculaceae). Journal of Applied Horticulture, 2024; 26(2).

[8] Tiji, S., Benayad, O., Berrabah, M., El Mounsi, I. & Mimouni, M. Phytochemical profile and antioxidant activity of Nigella sativa L growing in Morocco. The Scientific World Journal, 2021; 2021(1): 6623609.

[9] Manoharan, N., Jayamurali, D., Parasuraman, R. & Govindarajulu, S. N. Phytochemical composition, therapeutical and pharmacological potential of Nigella sativa: A review. Tradit Med Res, 2021; 6(4): 32.

[10] Shaukat, A., Zaidi, A., Anwar, H. & Kizilbash, N. Mechanism of the antidiabetic action of Nigella sativa and Thymoquinone: a review. Frontiers in Nutrition, 2023; 10: 1126272.

[11] Alberts, A., Moldoveanu, E. T., Niculescu, A. G. & Grumezescu, A. M. Nigella sativa: A Comprehensive Review of Its Therapeutic Potential, Pharmacological Properties, and Clinical Applications. International Journal of Molecular Sciences, 2024; 25(24): 13410.

[12] Ciesielska-Figlon, K., Wojciechowicz, K., Wardowska, A. & Lisowska, K. A. The immunomodulatory effect of Nigella sativa. Antioxidants, 2023; 12(7): 1340.

[13] Sailaja, A. K. & Supraja, R. An overall review on topical preparation-gel. Innovat International Journal Of Medical & Pharmaceutical Sciences, 2016; 1(1): 17-23.

[14] Jangdey, M. S., Gupta, A. & Sah, A. K. Formulation and evaluation of sustained release topical gel of flurbiprofen using natural polymers. Research Journal of Topical and Cosmetic Sciences, 2014; 5(1): 7-11.

[15] Alodhaibi, A., Alanazi, A., Alharbi, A. & Hashmi, S. Development and characterization of the emulsion formulation of herbal extract of Nigella sativa for topical application and evaluation of its antimicrobial activity. International Journal of Medicine in Developing Countries, 2022; 6(4): 586-586.

[16] Bhalani, U. & Shah, K. Preparation and evaluation of topical gel of Nigella sativa (KALONJI). International Journal of Research and Development in Pharmacy & Life Sciences, 2015; 4(4): 1669-1672.

[17] Alexander, I. & Krasnyuk, I. I. Dermatologic gels spreadability measuring methods comparative study. Int J Appl Pharm, 2022; 14(1): 164-8.

***Corresponding Author: Rajwant Kaur, University Institute of Pharma Sciences, Chandigarh University, Mohali, Punjab, India**