

A REVIEW ON NANOEMULSION-BASED NASAL DRUG DELIVERY EMPHASIZING FEXOFENADINE AND NIGELLA SATIVA OIL

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ABSTRACT

Allergic rhinitis is a common inflammatory condition of the nasal mucosa that greatly impairs quality of life. Due to its effectiveness and lack of sedative effects, fexofenadine, a second-generation antihistamine, is frequently utilized; nevertheless, oral administration may cause delayed onset and decreased absorption. Intranasal drug administration promotes quick beginning of action, bypasses first-pass metabolism, and enables direct transport to the site of action. Nanoemulsion-based nasal medication delivery methods have attracted attention due to its capacity to improve drug solubility, stability, and nasal absorption. The use of natural oils in nanoemulsions has further enhanced formulation performance. *Nigella sativa* oil, rich in thymoquinone, exhibits anti-inflammatory and antioxidant properties and serves as effective oil phase in nanoemulsion formulations. This review discusses allergic rhinitis, nasal drug delivery systems, nanoemulsion

technology, and formulation components, with emphasis on fexofenadine and the supportive role of *Nigella sativa* oil in nanoemulsion-based nasal delivery for improved management of allergic rhinitis.

KEYWORDS: Allergic rhinitis; Fexofenadine; Nanoemulsion; Nasal drug delivery; *Nigella sativa* oil.

INTRODUCTION

Allergic disorders are among the most common chronic health conditions globally and continue to pose a significant public health challenge. These disorders arise from an inappropriate immune response to normally harmless environmental substances known as allergens, such as pollen, house dust mites, animal dander, fungal spores, and various occupational irritants. The increasing incidence of allergic diseases has been due to factors including urbanization, environmental pollution, climate change, reduced exposure to microorganisms, and genetic predisposition. Beyond clinical symptoms, allergic conditions adversely affect patient's quality of life by disrupting sleep, limiting daily activities, reducing work productivity, and increasing healthcare expenditure.^[1]

Allergic rhinitis is primarily mediated through an immunoglobulin E (IgE)-dependent mechanism. Upon exposure to allergens, mast cells become activated and release inflammatory mediators such as histamine, leukotrienes, and prostaglandins. Among these, histamine plays a central role in the development of classical symptoms including sneezing, nasal congestion, itching, and rhinorrhea. Consequently, antihistamines remain a fundamental component in the therapeutic management of allergic rhinitis.^[2]

Fexofenadine, a second-generation H₁ receptor antagonist, is widely prescribed due to its high antihistaminic efficacy and minimal central nervous system penetration, which reduces sedative effects. Despite these advantages, conventional oral administration of fexofenadine may result in a delayed onset of action and variable bioavailability, largely attributed to gastrointestinal absorption limitations and hepatic first-pass metabolism.^[3]

Intranasal drug delivery has emerged as an effective alternative to oral administration, offering rapid onset of action, bypass of first-pass metabolism, and direct delivery to the site of inflammation. The use of nanoemulsion-based delivery systems further enhances these benefits by improving drug solubility, physicochemical stability, and mucosal permeation. As a result, nanoemulsion-based nasal sprays represent a promising strategy for optimizing therapeutic efficacy in the management of allergic rhinitis.^[4]

Nigella sativa oil, commonly referred to as black seed oil, is known to contain several

bioactive constituents, particularly thymoquinone, which has been reported to possess anti-inflammatory, antioxidant, and immunomodulatory activities. While *Nigella sativa* oil is not used as a primary active pharmaceutical ingredient in the present formulation approach, its incorporation as the oil phase in a nanoemulsion may offer supportive therapeutic effects in addition to its functional role as a carrier. The integration of fexofenadine with *Nigella sativa* oil in a nanoemulsion-based nasal delivery system therefore represents a logical and potentially beneficial strategy for enhancing the overall management of allergic rhinitis.

ALLERGIC RHINITIS

Allergic rhinitis (AR), commonly known as hay fever is an inflammatory disorder of the nasal mucosa. It is induced by allergen exposure triggering IgE-mediated inflammation.^[5]

Allergic Rhinitis is the most common chronic condition worldwide, and affects individuals of all age groups. It is provoked by either seasonal or perennial inhalant allergens.^[6]

Classification

Allergic rhinitis (AR) is classified by ARIA (Allergic Rhinitis and its Impact on Asthma) guidelines:

1. On the basis of duration as “intermittent” or “persistent” disease
2. On the basis of severity of symptoms and quality of life as “mild” or “moderate-severe”.^[9]

Etiology

Allergic rhinitis is primarily caused by the harmful airborne substances (allergens like pollen, dust mites, pet dander, and mold), triggering histamine release and inflammation in nasal passages, leads to sneezing, itching and runny nose.^[5]

Individuals with a family history of atopy are more susceptible, indicating a strong genetic predisposition.^[11]

Pathophysiology

Allergic rhinitis is characterized by inflammatory cells, includes mast cells, CD₄ positive T-cells, B cells, macrophages and eosinophils. It infiltrates the nasal lining upon exposure to an inciting allergen. The synthesis and secretion of prostaglandins, leukotrienes, cytokines and chemokines produce the late-phase reaction, includes bronchoconstriction, vasodilation and inflammation, thereby causing congestion. Continuous allergen exposure may lead to chronic disease.^[7,8]

Symptoms

The major symptoms of allergic rhinitis are anterior or posterior rhinorrhea, sneezing, nasal itching and nasal congestion. Allergic rhinitis symptoms may result in sleep disturbance, fatigue and depressed mood.^[5]

Diagnosis

Diagnosis is based on a typical history of allergic symptoms (sneezing, rhinorrhea, nasal obstruction, itching) and nasal examination (anterior rhinoscopy or endoscopy). Objective assessment of nasal obstruction may include peak nasal inspiratory flow or rhinomanometry.

Confirmation relies on IgE-mediated testing, including skin prick tests and serum allergen-specific IgE assays, which identify sensitization to specific allergens. Nasal allergen challenge is mainly used in research or occupational cases. CT imaging is reserved for excluding sinusitis, structural abnormalities or tumors.^[5]

Treatment

1. Environmental Control

Avoidance of triggers (dust mites, pets, molds, pollen, and pollutants) through allergen-proof bedding, humidity control, air filtration, pest control and improved ventilation.

2. Pharmacotherapy

- a) First-line: Second-generation oral antihistamines and intranasal antihistamines or corticosteroids.
- b) Persistent/moderate-severe AR: Intranasal corticosteroids (most effective), alone or with intranasal antihistamines.
- c) Adjuncts: Leukotriene receptor antagonists, saline nasal irrigation.
- d) Systemic corticosteroids: Short course only for severe acute exacerbations.

3. Immunotherapy

Indicated for patients with confirmed IgE-mediated sensitization who experience persistent symptoms despite optimal therapy. Includes subcutaneous and sublingual immunotherapy, which reduces symptoms and may prevent disease progression.^[9]

Complications

Allergic rhinitis may lead to asthma, sinusitis, otitis media with effusion (due to Eustachian tube dysfunction) and recurrent upper respiratory infections, resulting from persistent airway

inflammation and impaired mucosal drainage.^[10]

NASAL DRUG DELIVERY SYSTEM

Nasal drug delivery systems are gaining importance due to their rapid onset of action, non-invasive administration, improved patient compliance, and reduced systemic side effects. Common nasal formulations include sprays, drops, gels, and powders, with nasal sprays being the most preferred because they bypass first-pass metabolism, provide rapid absorption, and improve bioavailability.

Nasal sprays are widely used for treating local conditions such as allergic rhinitis and sinusitis, as well as systemic disorders including pain and hormonal deficiencies. Recent advances such as mucoadhesive formulations, Nano emulsions, and nanoparticles have enhanced drug residence time, mucosal penetration, and enabled nose-to-brain delivery, expanding the therapeutic potential of the nasal route.^[4,12,14]

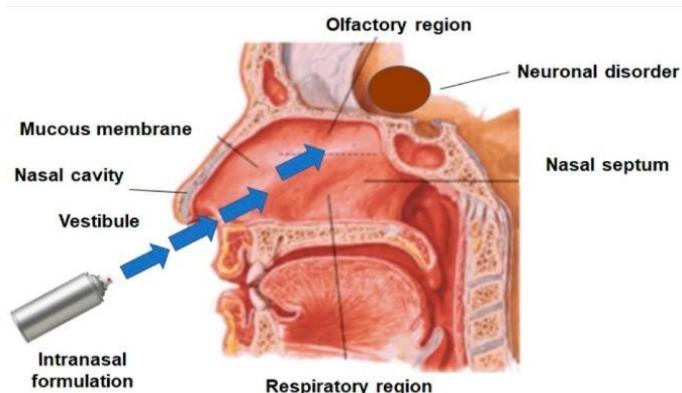


Fig. 1: Schematic Representation of Intranasal Drug Administration.

Why Nasal Spray Formulation?

Among intranasal dosage forms, nasal sprays are the most favored due to their simplicity, precise dosing, and reliable drug delivery. They enable rapid therapeutic onset, making them effective for acute conditions such as allergic rhinitis, sinus congestion, and migraine. Direct deposition onto the nasal mucosa allows sprays to circumvent gastrointestinal degradation and first-pass metabolism, thereby enhancing bioavailability. Their non-invasive, portable, and patient-centric nature makes them suitable across all age groups. Recent innovations, including mucoadhesive systems and nano emulsions, further optimize nasal residence time and absorption efficiency.^[13]

Nasal Mucosa: A Strategic Target for Drug Delivery

The nasal mucosa serves as a strategic drug delivery site owing to its extensive surface area, dense vascular network, and thin epithelial barrier, enabling rapid absorption and efficient local and systemic therapeutic action.^[11,14]

The nasal cavity consists of three regions: vestibular, olfactory, and respiratory. The vestibular region has minimal involvement in drug absorption due to its limited surface area and vascularization. The olfactory region, located at the nasal roof, contains specialized epithelial cells and provides a potential nose-to-brain transport pathway. The respiratory region is the primary site for nasal drug delivery, characterized by a large surface area, rich vascular supply, and mucus-secreting epithelium, enabling rapid systemic absorption.^[11]

Physiological barriers include the nasal mucus layer and variable pH, which can affect drug diffusion and ionization, as well as mucociliary clearance, which rapidly remove deposited drugs. These limitations can be minimized using mucoadhesive formulations to enhance nasal residence time and absorption.^[11,15]

Mechanism of Nasal Absorption

After intranasal administration, drugs must traverse the nasal mucus layer, which acts as the primary barrier to absorption. Drug permeability is influenced by molecular size, charge, and lipophilicity, as well as mucus composition and pH.

Nasal absorption occurs predominantly via two pathways: the Paracellular pathway, involving passive diffusion of small hydrophilic molecules through intercellular spaces, and the transcellular pathway, which facilitates transport of lipophilic drugs across epithelial cell membranes. The use of absorption enhancers, such as chitosan, can transiently modulate tight junctions and improve drug permeation.^[11,15]

NANO EMULSION

A nano emulsion is a nanosized (typically 20-200 nm) system composed of two immiscible liquids made into a single-phase system using emulsifying agents such as surfactants.

An emulsion is a thermodynamically unstable biphasic system in which internal phase is dispersed in the external phase in the form of minute droplets ranging from 0.1 to 100 μm in diameter. The dispersed phase is also known as discontinuous phase while the external phase is called dispersion medium or continuous phase. This system can be stabilized by using an

emulsifying agent.

Properties of nano emulsion

1. Droplets size ranges from 1-100 nm
2. Optically transparent
3. Low viscosity
4. Large surface-to-volume ratio
5. Large elastic moduli should present
6. Exhibit enhanced stability against creaming or sedimentation

Types of nano emulsion^[16]

- a) **O/W nano emulsion:** Oil is dispersed in a continuous aqueous phase. Commonly used for oral, nasal, IV delivery.
- b) **W/O nano emulsion:** Water droplets are dispersed in a continuous oil phase. Used in topical and transdermal formulations.
- c) **Bi-continuous nano emulsions:** Both water and oil phases form continuous domains.

Advantages of nanoemulsion^[17]

1. As substitute for liposomes and vesicles
2. Improves the bioavailability of drug
3. Small dose can achieve better therapeutic effects
4. Non-toxic and non-irritant
5. Improved physical stability
6. Have greater surface area providing greater absorption
7. Can carry both hydrophilic and lipophilic drug
8. Helpful in taste masking
9. Suitable for multiple routes

Disadvantages of nanoemulsion^[17]

1. Cost of high energy equipment
2. Thermodynamic instability
3. Use of large amount of surfactant
4. Not suitable for large volume drug loading

Pharmaceutical applications of nanoemulsion^[17,18,19]**1) Drug delivery systems**

- a) Oral delivery: Enhances solubility and absorption of poorly water-soluble drugs. E.g., Cyclosporine
- b) Nasal drug delivery: Rapid action for allergic rhinitis and CNS drug delivery.
- c) Ocular drug delivery: Enhances corneal penetration. E.g., Piroxicam
- d) Parenteral delivery: Suitable for hydrophobic drugs, reduces irritation at injection sites.
- e) Transdermal & Topical delivery: Improves drug permeation via skin. E.g., Corticosteroids, anti-fungal, anti-bacterial, etc.
- f) Pulmonary delivery: Used in inhalable formulations for faster lung absorption.

2) Improved bioavailability: Increased dissolution rate and intestinal lymphatic uptake.**3) Controlled & targeted drug Release:** Designed to release drugs on-target. E.g., brain delivery, nasal sprays.**4) Vaccines:** Act as adjuvant systems to enhance immune response. E.g., MF59 used in influenza vaccines.**5) Cancer therapy:** Encapsulate anti-cancer drugs to reduce its side effects. E.g., Paclitaxel, Doxorubicin.**6) Gene & protein delivery:** Can deliver fragile biomolecules like siRNA, DNA, or peptides.**7) Cosmeceuticals:** Enhances moisturizing, anti-ageing, UV-protection effects, etc.**Components of nanoemulsion**

Nanoemulsions are colloidal delivery systems consisting of an oil phase, surfactant, co-surfactant, and aqueous phase, stabilized by a thin interfacial film. The selection of formulation components is critical, as it directly influences droplet size, physical stability, drug solubilization, and overall performance of the nanoemulsion system.^[20]

Oil phase: The oil phase is used to dissolve lipophilic drugs and helps in forming nano-sized droplets. It also affects the stability and drug release behavior of the nanoemulsion.^[21,22]

Common examples include isopropyl myristate, oleic acid and medium-chain triglycerides. Natural oils are also widely reported because they are safe and well tolerated.^[21]

Examples of some natural oil include castor oil, black seed oil, coconut oil, etc.

Surfactant: Surfactants helps to reduce the surface tension between the oil and water phases. This allows the formation of small and stable droplets. Non-ionic surfactants are commonly preferred in pharmaceutical nanoemulsions because they are less irritating and more stable.^[20,21]

Common examples include Tween 20, Tween 60, Tween 80, Span 20, and Span 80.

Co-surfactant: Co-surfactants support the action of surfactants by further reducing surface tension and improving flexibility of the droplet surface. This helps in forming smaller droplets and improves stability of the nanoemulsion.^[20,21]

Commonly used co-surfactants are ethanol, propylene glycol, polyethylene glycol (PEG 400), and Transcutol® P.

Aqueous phase: The aqueous phase forms the main continuous phase of oil-in-water nanoemulsions, which are suitable for nasal drug delivery. It usually consists of purified or distilled water.^[21]

For nasal formulations, the pH and isotonicity should be suitable to avoid irritation. Phosphate buffer and normal saline are commonly used as the aqueous phase.^[20]

Stabilizing agent: Stabilizing agents are sometimes added to prevent droplet aggregation and improve the physical stability of nanoemulsions during storage. They may also increase viscosity and improve retention in the nasal cavity.^[23]

Commonly used stabilizing agents include Carbopol®, hydroxypropyl methylcellulose (HPMC), and chitosan.

FEXOFENADINE AS AN ANTIHISTAMINE

Fexofenadine is a second-generation antihistamine classified as a BCS Class III drug with high solubility and low permeability. Unlike first-generation antihistamines, it does not cross the blood–brain barrier and therefore does not cause sedation. The drug has a rapid onset of

action, a long duration of effect, and an excellent safety profile. It is minimally metabolized and is mainly excreted unchanged through feces and urine, making it suitable for use in both pediatric and elderly patients.

Mechanism of action

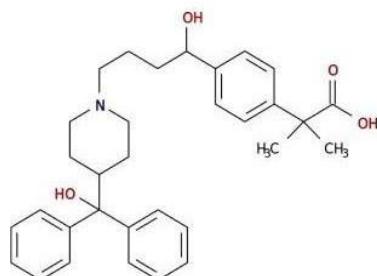


Fig. 2: Structure of Fexofenadine.

Fexofenadine acts as an inverse agonist at the histamine H₁ receptor by stabilizing the receptor in its inactive form. This prevents histamine-mediated allergic responses. It is highly selective for H₁ receptors and does not produce anticholinergic, sedative, or central nervous system effects.

Pharmacokinetics

Fexofenadine shows low oral bioavailability (~33%) due to poor membrane permeability and active efflux by P-glycoprotein transporters. Intranasal administration improves drug absorption by delivering it directly to the nasal mucosa and avoiding first-pass metabolism. The drug has minimal hepatic metabolism (about 5%) and is mainly eliminated in unchanged form, with approximately 80% excreted through feces and around 11% excreted in urine. The elimination half-life ranges from 11 to 15 hours.

Uses

Fexofenadine is commonly used in the management of seasonal allergic rhinitis and chronic idiopathic urticaria. It relieves symptoms such as sneezing, nasal itching, rhinorrhoea, and pruritus by selectively blocking H₁ histamine receptors.

ROLE OF NIGELLA SATIVA OIL (BLACK CUMIN SEED)

Recent pharmaceutical research has shown increasing interest in the use of natural bioactive compounds with therapeutic potential. Thymoquinone, a major active constituent of black seed oil derived from *Nigella sativa*, exhibits significant antioxidant, anti-inflammatory, and

immunomodulatory effects.^[24]

When combined with antihistaminic drugs in nanoemulsion systems, thymoquinone can provide synergistic therapeutic benefits. It helps reduce oxidative stress and inflammatory responses associated with allergic rhinitis, thereby enhancing overall treatment efficacy.

Preparation methods of nanoemulsion

Formulation of nano emulsion includes active drug, additive and emulsifier. Nanoemulsions can be prepared using either low-energy or high-energy methods.

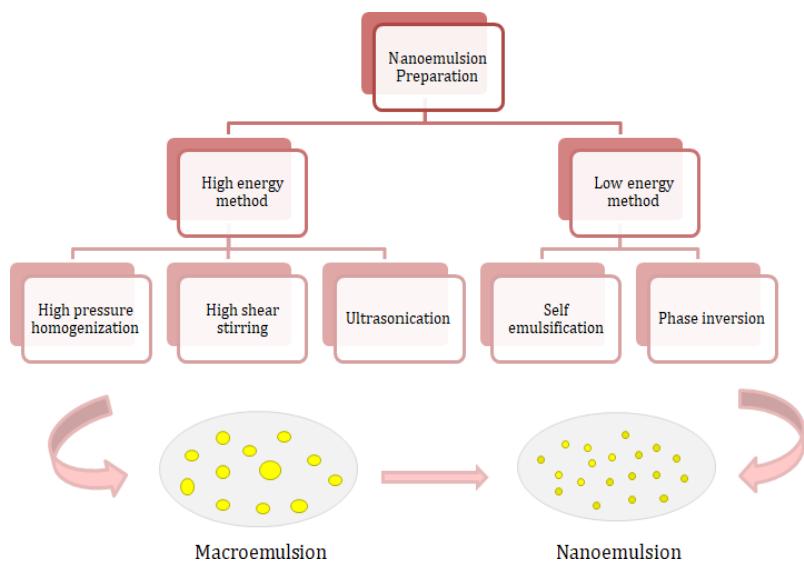


Fig. 3: Flow chart of Nanoemulsion preparation.

High-Energy Method

High-energy methods involve the use of external mechanical devices to produce intense forces that reduce droplet size. Techniques such as ultrasonication, high-speed homogenization, and high shear stirring are commonly used. These methods convert coarse emulsions into nanoemulsions by breaking droplets into nano-sized particles. Higher energy input results in smaller droplet size and improved stability.

The sequence of phase addition and the final emulsification step significantly influence nanoemulsion stability. Adding the aqueous phase into the oil phase followed by high-energy treatment helps in obtaining a stable and uniform nanoemulsion.

Low-Energy Method

Low-energy methods rely on the internal interaction of formulation components, mainly

surfactants, during the emulsification process. These methods do not require specialized equipment.

Common low-energy techniques include self-emulsification and phase inversion methods. In self-emulsification, nanoemulsions form spontaneously due to surfactant diffusion between oil and aqueous phases. Phase inversion occurs due to changes in temperature or composition of the system.^[25]

Evaluation of nanoemulsion

Physical Appearance

The nanoemulsion nasal spray will be visually examined for color, clarity, and phase separation to ensure uniformity and stability.

Measurement of pH

The pH of the nanoemulsion nasal spray will be measured using a digital pH meter to confirm compatibility with nasal mucosa (around 4.5-6.5), preventing irritation or discomfort upon administration.

Measurement of Viscosity

Viscosity will be measured using Brookfield viscometer to ensure suitable flow and spray ability. An optimum viscosity facilitates uniform dosing and better retention in the nasal cavity.

Zeta Potential Analysis

Zeta potential will be determined using a Zetasizer to evaluate the surface charge of the droplets. High positive or negative zeta potential indicates good electrostatic repulsion, predicting enhanced stability of the nanoemulsion.

Droplet Size and Polydispersity index

The average droplet size and size distribution of the nanoemulsion will be determined. Nano-sized droplets (<200 nm) ensure uniform dispersion, enhanced absorption, improved physical stability, and consistent therapeutic performance of the formulation.

Measurement of Osmolality

Osmolality will be determined using an osmometer to ensure the formulation is isotonic with nasal fluids (around 290 to 320 mOsm/kg), preventing nasal irritation.

Drug Content

Fexofenadine nanoemulsion was centrifuged for 10 minutes at 10,000 rpm. After dilution using a spectrophotometer, the supernatant was collected, filtered, and the drug content in the formulation was calculated.

In Vitro Drug Release

The drug release profile will be studied using a diffusion membrane method. It determines the rate and extent of fexofenadine release, reflecting its potential therapeutic performance.

Spray Pattern

The spray pattern of the nasal spray will be evaluated to ensure uniform dispersion of the formulation during spraying. A uniform spray pattern ensures proper dosing and effective deposition in the nasal cavity.

CONCLUSION

Nasal drug delivery systems provide an effective alternative to oral therapy in the management of allergic rhinitis by offering rapid onset and improved drug absorption. Nanoemulsion-based nasal formulations further enhance these benefits by improving solubility, stability, and mucosal permeation. Fexofenadine is a suitable candidate for intranasal delivery due to its safety and antihistaminic efficacy. The use of *Nigella sativa* oil as the oil phase supports nanoemulsion formulation and may provide additional anti-inflammatory benefits. Overall, nanoemulsion- based nasal delivery represents a promising approach for improving allergic rhinitis management.

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