Research Article

Formulation, optimization and in-vitro evaluation of niosome-loaded nasal drops for the treatment of multiple sclerosis

Siya Kapoor*, Satinder Kakar,Ramandeep Singh

Himachal Institute of Pharmacy, Paonta Sahib, Himachal Pradesh,India

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Abstract

Multiple sclerosis (MS) is a long-term autoimmune disorder that progressively damages the central nervous system, leading to demyelination, axonal loss, and neurological disability. One of the primary challenges in MS therapy is achieving effective drug concentrations within the brain due to the restrictive nature of the blood–brain barrier (BBB). Conventional drug delivery routes often result in limited brain uptake and increased systemic adverse effects.To address these limitations, nanocarrier-based systems such as niosomes have been extensively investigated. Niosomes are vesicular structures formed from non-ionic surfactants and cholesterol, capable of encapsulating diverse therapeutic agents and enhancing their stability and permeability.Their structural flexibility and biocompatibility make them suitable candidates for targeted drug delivery to the central nervous system.Intranasal administration has emerged as a promising alternative route for brain targeting, allowing drugs to bypass the BBB via olfactory and trigeminal neural pathways. When combined with niosomal encapsulation, this approach can significantly improve drug transport efficiency and therapeutic outcomes.This review provides a comprehensive overview of the formulation strategies, optimization variables, and in-vitro evaluation techniques for niosome-loaded nasal drug delivery systems. Emphasis is placed on critical parameters such as vesicle size, entrapment efficiency, and drug release behavior.Overall, the integration of niosomal technology with nasal delivery offers a promising platform for improving the management of multiple sclerosis.

Keywords: Sclerosis,niosomes

Introduction

Multiple sclerosis (MS) is a complex neuroinflammatory disease characterized by immune-mediated destruction of the myelin sheath surrounding neuronal axons. This pathological process leads to impaired nerve transmission, resulting in a wide spectrum of clinical symptoms, including motor dysfunction, sensory disturbances, and cognitive decline. Despite advances in disease-modifying therapies, effective management remains limited due to challenges in delivering drugs across the blood–brain barrier (BBB).The BBB is a highly selective barrier composed of tightly packed endothelial cells, which restricts the entry of most therapeutic molecules into the brain. As a result, many conventional treatments fail to achieve adequate concentrations at the target site. This has driven the exploration of novel drug delivery systems capable of enhancing brain targeting while minimizing systemic exposure. Among these, niosomes have gained attention as efficient vesicular carriers. Structurally similar to liposomes but more stable and cost-effective, niosomes are formed from non-ionic surfactants and cholesterol. These vesicles can encapsulate both hydrophilic and lipophilic drugs, protect them from degradation, and provide sustained release profiles.Parallel to carrier development, alternative routes of administration have been explored. Intranasal delivery has emerged as a viable strategy for direct drug transport to the brain. Drugs administered through the nasal cavity can reach the CNS via olfactory and trigeminal nerve pathways, effectively bypassing the BBB and first-pass metabolism. This route also offers advantages such as rapid onset of action, ease of administration, and improved patient compliance.The combination of niosomal carriers with intranasal delivery systems represents a synergistic approach for enhancing drug delivery to the brain. This review focuses on formulation considerations and in-vitro evaluation methods for such systems, highlighting their potential in improving therapeutic outcomes in MS.[1-5]

***Correspondence**
Siya Kapoor
Himachal Institute of Pharmacy,Paonta Sahib,H.P,India
E-Mail: siyakapoor@gmail.com

Formulation of Niosome-Loaded Nasal Drops

The development of niosome-based nasal formulations requires a systematic approach to ensure optimal drug delivery performance.

1.Selection of Components

Niosomes are primarily composed of:

1.Non-ionic surfactants: These form the bilayer structure. Surfactants with appropriate hydrophilic–lipophilic balance (HLB), such as Span 60 and Tween 80, are commonly used to achieve stable vesicles.

2.Cholesterol: Incorporated to enhance membrane rigidity and reduce permeability, thereby improving stability.

3.Charge modifiers: Agents like dicetyl phosphate or stearylamine are added to prevent vesicle aggregation through electrostatic repulsion.

4.Aqueous phase: Contains the drug and buffering agents to maintain physiological pH suitable for nasal administration.

2.Preparation Techniques

Several methods are employed to prepare niosomes:

1.Thin-film hydration: A widely used method where surfactants and cholesterol are dissolved in an organic solvent, evaporated to form a thin film, and subsequently hydrated with an aqueous drug solution.

2.Reverse-phase evaporation: Produces vesicles with higher encapsulation efficiency by forming emulsions followed by solvent removal.

3.Sonication or extrusion: Applied to reduce vesicle size and achieve uniform distribution.[6-8]

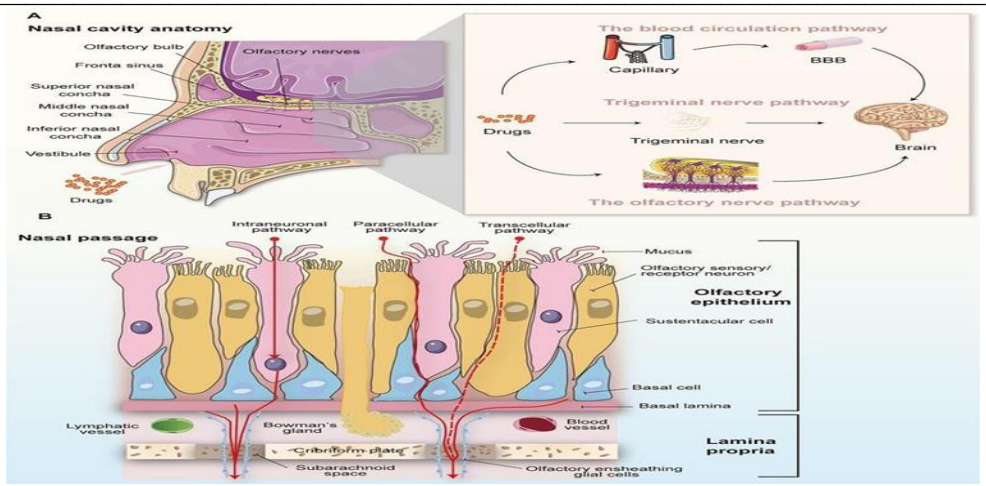

Fig 1:Brief view of delivery through nasal cavity

3.Optimization Parameters

Key formulation variables include:

1.Surfactant-to-cholesterol ratio

2.Hydration conditions (temperature and duration)

3.pH and ionic strength

4.Use of viscosity enhancers for nasal retention

Optimization aims to achieve nanosized vesicles, high drug entrapment, and controlled release characteristics.

Evaluation – In Vitro

In-vitro characterization is essential to assess the quality, stability, and performance of niosomal formulations.

1.Particle Size and Surface ChargeParticle size influences drug absorption and distribution. Dynamic light scattering is commonly used for measurement. Zeta potential provides insight into formulation stability, with higher values indicating better resistance to aggregation.[9-11]

2.Morphological Analysis

Electron microscopy techniques such as TEM and SEM are used to visualize vesicle shape and confirm structural integrity.

3.Entrapment Efficiency

This parameter indicates the percentage of drug encapsulated within the vesicles. It is determined by separating free drug from vesicle-associated drug and quantifying it using analytical methods.[12-14]

4.In-Vitro Drug Release

Release studies are conducted using diffusion systems to evaluate the rate and mechanism of drug release. Niosomes typically exhibit a biphasic release pattern, with an initial burst followed by sustained release.

5.Permeation Studies

Ex-vivo studies using nasal mucosa help assess drug permeability and predict in-vivo behavior.

6.Stability Testing

Formulations are stored under various conditions to monitor changes in physical appearance, particle size, and drug content over time.

7.Mucoadhesion Studies

Mucoadhesive properties are evaluated to determine the residence time of the formulation in the nasal cavity, which directly impacts drug absorption.[16-19]

Conclusion

Niosome-based intranasal drug delivery systems present a promising approach for overcoming the limitations associated with conventional therapies for multiple sclerosis. Careful formulation and thorough in-vitro evaluation are essential to ensure optimal performance and stability. Although further research and clinical validation are required, this approach holds strong potential for future pharmaceutical applications in CNS disorders.

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