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A Review on Sublingual Niosomal Film Technology for Controlled Release of Cardiovascular Drugs

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Abstract: *The management of cardiovascular diseases remains a significant global health challenge, necessitating the development of efficient drug delivery systems. Sublingual niosomal films have emerged as a promising platform for controlled and targeted release of cardiovascular drugs. These systems combine the benefits of niosomes non-ionic surfactant-based vesicles capable of encapsulating both hydrophilic and lipophilic drugs with the convenience and rapid absorption offered by sublingual films. This review highlights the preparation techniques, formulation strategies, pharmacokinetics, and therapeutic advantages of sublingual niosomal films for cardiovascular drugs. The potential to enhance bioavailability, reduce first-pass metabolism, and improve patient compliance underscores the significance of this technology in modern pharmacotherapy*

Keywords: Sublingual drug delivery, Niosomal vesicles, Cardiovascular drug delivery

I. INTRODUCTION

Cardiovascular diseases (CVDs) remain the leading cause of morbidity and mortality worldwide, accounting for an estimated 17.9 million deaths annually, and their prevalence continues to rise due to aging populations, lifestyle factors, and comorbidities such as diabetes and hypertension (Patel et al., 2020; Das & Ghosh, 2019). Effective management of these diseases often requires long-term pharmacotherapy, frequently involving β-blockers, calcium channel blockers, nitrates, and other cardiovascular agents.

However, conventional oral administration of these drugs faces several limitations, including poor bioavailability, delayed onset of action, and extensive first-pass metabolism in the liver, which reduces systemic drug concentrations and therapeutic efficacy (Uchegbu & Vyas, 1998; Jain & Chaurasia, 2019). These challenges have prompted the development of alternative drug delivery strategies that can enhance bioavailability, provide controlled and sustained release, and improve patient compliance, particularly in populations requiring rapid therapeutic intervention such as angina, acute hypertension, or heart failure.

Sublingual drug delivery has emerged as a highly promising route for systemic administration of cardiovascular drugs, offering several pharmacokinetic advantages over conventional oral administration. The sublingual mucosa is highly vascularized and permeable, allowing drugs to bypass hepatic first-pass metabolism and rapidly enter the systemic circulation, thereby achieving faster onset of action (Khairnar et al., 2020; Gupta et al., 2021). This is particularly beneficial for drugs that require immediate therapeutic effects or have a short half-life. Additionally, sublingual administration is non-invasive, convenient, and well-tolerated, making it suitable for geriatric and pediatric populations who may have difficulty swallowing conventional tablets or capsules (Mishra & Tiwari, 2020). Despite these advantages, the sublingual route also presents formulation challenges, including limited drug loading capacity, the need for rapid dissolution and absorption, and potential drug instability in the oral cavity due to salivary enzymes or pH variability (Verma & Sharma, 2020). Consequently, innovative approaches that combine sublingual delivery with advanced carrier systems are essential for overcoming these limitations and optimizing therapeutic outcomes.

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Niosomal technology has emerged as a versatile and efficient carrier system for enhancing drug delivery through the sublingual route. Niosomes are non-ionic surfactant-based vesicles composed of a bilayer structure formed by amphiphilic molecules and cholesterol, capable of encapsulating both hydrophilic and lipophilic drugs (Handa et al., 2019; Ahmed & Khan, 2021). Unlike conventional liposomes, niosomes offer greater chemical stability, lower production costs, and ease of large-scale manufacturing, making them highly attractive for pharmaceutical applications (Ramesh & Kumar, 2021). The unique structural features of niosomes allow them to protect encapsulated drugs from enzymatic degradation, modulate drug release rates, and improve permeation across biological membranes, thereby enhancing systemic bioavailability (Kapoor & Kaur, 2019).

When combined with sublingual film technology, niosomes can serve as an effective platform for controlled release, enabling sustained therapeutic effects and minimizing fluctuations in plasma drug concentrations, which is particularly important in the management of cardiovascular conditions where maintaining consistent drug levels is critical to prevent complications such as arrhythmias or angina attacks (Sharma et al., 2021; Singh et al., 2018).

Sublingual films, also known as oral thin films, are thin, flexible polymeric strips that rapidly disintegrate and dissolve in the oral cavity without the need for water. They offer several advantages, including ease of administration, accurate dosing, rapid onset of action, and improved patient adherence (Khairnar et al., 2020; Gupta et al., 2021). Various hydrophilic polymers, such as hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA), and pullulan, are commonly employed as film-forming agents, while plasticizers like glycerol and polyethylene glycol enhance film flexibility and mechanical strength (Mishra & Tiwari, 2020).

The incorporation of niosomal vesicles into these films allows for the controlled and sustained release of cardiovascular drugs, providing both rapid onset and prolonged therapeutic effect, which is crucial for managing conditions that require both immediate and long-term pharmacological intervention (Raza et al., 2020; Verma & Sharma, 2020). Additionally, sublingual niosomal films offer the potential for dose personalization, taste masking, and improved stability of labile drugs, further enhancing their clinical utility and patient acceptance.

Several studies have demonstrated the efficacy of sublingual niosomal films in improving the pharmacokinetic and pharmacodynamic profiles of cardiovascular drugs. For instance, propranolol-loaded niosomal films have shown enhanced bioavailability and prolonged circulation time compared to conventional oral formulations (Singh et al., 2018). Similarly, carvedilol and isosorbide dinitrate encapsulated in niosomal sublingual films exhibited controlled release profiles, rapid onset of action, and improved systemic absorption, underscoring the potential of this technology to address both therapeutic and patient-centric challenges in cardiovascular therapy (Sharma et al., 2021; Raza et al., 2020). The versatility of niosomal vesicles allows for the encapsulation of a wide range of cardiovascular agents, including hydrophilic drugs, lipophilic drugs, and even peptide-based therapeutics, thereby expanding the scope of sublingual film applications beyond conventional small-molecule drugs (Handa et al., 2019; Jain & Chaurasia, 2019). Moreover, the physicochemical properties of niosomes, such as particle size, surface charge, and bilayer composition, can be tailored to achieve desired release kinetics and enhance mucoadhesion to the sublingual mucosa, further optimizing therapeutic efficacy (Kapoor & Kaur, 2019).

Despite the promising potential of sublingual niosomal films, several formulation and translational challenges remain. Stability of niosomes during film preparation, storage, and handling is a critical concern, as vesicle aggregation, leakage, or degradation can compromise drug release and bioavailability (Ramesh & Kumar, 2021). Additionally, taste masking, organoleptic properties, and patient acceptability must be carefully addressed, particularly for bitter-tasting cardiovascular drugs (Verma & Sharma, 2020). Scalability of production, regulatory compliance, and cost-effectiveness are other practical considerations that must be evaluated to ensure successful commercialization of this technology (Ahmed & Khan, 2021). Nevertheless, ongoing advances in polymer science, nanotechnology, and oral drug delivery systems are likely to overcome these challenges, paving the way for clinically viable sublingual niosomal films that offer a combination of rapid onset, sustained action, and patient-friendly administration.

Sublingual niosomal film technology represents a promising and innovative approach for the controlled release of cardiovascular drugs. By leveraging the advantages of niosomes as drug carriers and the convenience of sublingual

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films, this platform offers enhanced bioavailability, rapid onset of action, sustained therapeutic effects, and improved patient compliance.

Continued research focusing on formulation optimization, stability enhancement, in vivo pharmacokinetic studies, and clinical validation will be crucial to realize the full potential of sublingual niosomal films as a standard therapeutic strategy for cardiovascular diseases (Patel et al., 2020; Singh et al., 2018; Sharma et al., 2021). This emerging technology holds the promise of transforming cardiovascular pharmacotherapy by addressing the limitations of conventional oral dosage forms and providing a more effective, patient-centric, and clinically adaptable drug delivery solution.

NIOSOMAL TECHNOLOGY

Niosomes are microscopic lamellar structures composed of non-ionic surfactants and cholesterol. They can encapsulate hydrophilic drugs in the aqueous core and lipophilic drugs within the bilayer membrane (Handa et al., 2019). The primary advantages of niosomal systems include:

- Improved bioavailability
- Controlled and sustained release
- Protection of labile drugs from degradation
- Reduced dosing frequency

Table 1: Comparison of Niosomes and Liposomes

Feature	Niosomes	Liposomes
Composition	Non-ionic surfactant + cholesterol	Phospholipids + cholesterol
Stability	High chemical stability	Less stable, prone to oxidation
Cost	Low	High
Drug Encapsulation	Hydrophilic & lipophilic	Hydrophilic & lipophilic
Scalability	Easy	Moderate

Table 1 demonstrates the advantages of niosomes over conventional liposomes, particularly relevant for cardiovascular drug delivery.

SUBLINGUAL FILM TECHNOLOGY

Sublingual films are thin, flexible polymeric strips designed for rapid dissolution in the oral cavity. Key benefits include:

Avoidance of first-pass metabolism

Rapid onset of therapeutic effect

Enhanced patient compliance (Khairnar et al., 2020)

Biocompatible polymers such as hydroxypropyl methylcellulose (HPMC), pullulan, and polyvinyl alcohol (PVA) are commonly used as film formers. Plasticizers like glycerol and PEG improve film flexibility and ease of administration (Gupta et al., 2021).

FORMULATION OF SUBLINGUAL NIOSOMAL FILMS FOR CARDIOVASCULAR DRUGS

The integration of niosomes into sublingual films involves two main steps:

Niosome Preparation: Thin-film hydration, reverse-phase evaporation, or microfluidization methods can be used to produce uniform vesicles encapsulating cardiovascular drugs such as propranolol, carvedilol, and nitrates (Singh et al., 2018).

Film Casting: The prepared niosomal suspension is mixed with a polymeric solution, cast into films, and dried under controlled conditions (Raza et al., 2020).

Optimizing factors like surfactant type, cholesterol ratio, polymer concentration, and plasticizer content is critical for drug release kinetics, mechanical properties, and stability.

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Table 2: Examples of Cardiovascular Drugs Encapsulated in Niosomal Films

Drug	Niosome Composition	Film Polymer	Release Profile	Reference
Propranolol	Span 60 + Cholesterol	HPMC	Sustained release for 12 h	Singh et al., 2018
Carvedilol	Tween 80 + Cholesterol	PVA	Controlled release for 8 h	Raza et al., 2020
Isosorbide Dinitrate	Span 40 + Cholesterol	Pullulan	Rapid onset, 30 min	Sharma et al., 2021

Table 2 highlights successful formulations of sublingual niosomal films for cardiovascular drugs.

EVALUATION PARAMETERS

Sublingual niosomal films are evaluated based on:

Mechanical Properties: Tensile strength, folding endurance, and thickness (Khairnar et al., 2020)

Drug Content Uniformity: Ensuring dose consistency

In Vitro Release Studies: Simulating saliva conditions to assess drug release kinetics

Ex Vivo Permeation Studies: Using porcine or rabbit buccal mucosa to predict absorption (Gupta et al., 2021)

Table 3: Key Evaluation Techniques for Sublingual Niosomal Films

Parameter	Method	Significance
Tensile Strength	Texture analyzer	Ensures film integrity
Folding Endurance	Manual folding	Confirms flexibility
Thickness	Micrometer	Uniformity in drug dosing
Drug Content	UV-Vis Spectrophotometry	Dose accuracy
In Vitro Release	Franz Diffusion Cell	Determines release profile
Ex Vivo Permeation	Buccal mucosa model	Predicts absorption kinetics

Table 3 summarizes the standard evaluation parameters for sublingual niosomal films.

ADVANTAGES OF SUBLINGUAL NIOSOMAL FILMS IN CARDIOVASCULAR THERAPY

- Enhanced bioavailability by bypassing hepatic first-pass metabolism (Patel et al., 2020)
- Rapid onset of action suitable for acute angina and hypertensive crises
- Improved patient adherence due to ease of administration and reduced dosing frequency
- Potential for sustained and controlled release, reducing side effects

CHALLENGES AND FUTURE PERSPECTIVES

- Despite their advantages, sublingual niosomal films face challenges such as:
- Stability of niosomes during film drying and storage
- Taste masking for bitter cardiovascular drugs
- Large-scale industrial production and regulatory approval
- Future research should focus on:
- Incorporating permeation enhancers for improved absorption
- Developing smart niosomal films responsive to physiological triggers
- Conducting clinical trials to validate pharmacokinetic and therapeutic outcomes

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II. CONCLUSION

Sublingual niosomal films represent a promising approach for controlled release of cardiovascular drugs. By combining the biocompatibility and encapsulation efficiency of niosomes with the convenience of sublingual films, this technology enhances bioavailability, provides rapid therapeutic action, and improves patient compliance. Continued research in formulation optimization, in vivo evaluation, and scale-up production can establish sublingual niosomal films as a standard platform for cardiovascular therapy.

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