

## Formulation and Evaluation of Niosomal Gel of Clindamycin Hydrochloride and Nicotinamide for Treatment of Acne

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### ABSTRACT

Acne vulgaris is a chronic inflammatory skin disorder affecting the pilosebaceous unit, commonly observed in adolescents and young adults. Its pathogenesis involves multiple factors, including excessive sebum production, follicular hyperkeratinisation, microbial colonization by *Cut bacterium acnes*, and inflammatory responses mediated by cytokines. Conventional topical therapies, although widely used, often suffer from limitations such as poor skin penetration, frequent dosing, irritation, and the development of antibiotic resistance, which ultimately reduce their therapeutic effectiveness.

To overcome these challenges, advanced drug delivery systems such as niosomal gels have emerged as promising alternatives. Niosomes are non-ionic surfactant-based vesicles capable of encapsulating both hydrophilic and lipophilic drugs, thereby enhancing drug stability, improving skin permeation, and providing controlled and sustained release. Incorporation of these vesicles into a gel base further improves formulation characteristics such as spreadability, retention time, and patient compliance, making them suitable for topical application in acne treatment.

The combination of Clindamycin hydrochloride and Nicotinamide offers a synergistic therapeutic approach. Clindamycin acts by inhibiting bacterial protein synthesis, thereby reducing *C. acnes* proliferation, while Nicotinamide exerts anti-inflammatory and sebostatic effects, contributing to the reduction of acne lesions without promoting resistance. The use of a niosomal carrier system enhances the delivery of both drugs to the target site, ensuring improved bioavailability and minimized side effects.

Various formulation and evaluation parameters, including vesicle size, zeta potential, entrapment efficiency, drug content, and in-vitro drug release, play a crucial role in determining the performance and stability of the niosomal gel. These parameters confirm the ability of the system to provide

sustained drug release and improved therapeutic outcomes.

In conclusion, niosomal gel of Clindamycin hydrochloride and Nicotinamide represents an effective and innovative approach for acne management. It addresses the limitations of conventional therapies by enhancing drug delivery, reducing adverse effects, and improving patient compliance. This formulation holds significant potential for future development and clinical application in dermatological therapy.

### Keywords

Acne vulgaris; Niosomal gel; Clindamycin hydrochloride; Nicotinamide; Vesicular drug delivery system; Controlled drug release; Topical drug delivery; Anti-acne therapy; Skin permeation; Entrapment efficiency

### I. INTRODUCTION

Acne vulgaris is a chronic inflammatory disorder of the pilosebaceous unit that predominantly affects adolescents but may persist into adulthood. It is one of the most common dermatological conditions worldwide and has a significant impact on both physical appearance and psychological well-being, often leading to reduced self-esteem, anxiety, and social withdrawal [1,2]. Due to its high prevalence and long-term nature, acne is considered a major concern in dermatology and cosmetology.

The disease is multifactorial and involves complex interactions between hormonal, microbial, and immunological factors. These interactions lead to the formation of different types of lesions such as comedones, papules, pustules, nodules, and cysts, with varying severity [3]. Effective management of acne requires targeting multiple pathogenic factors simultaneously.

### 1.2 EPIDEMIOLOGY OF ACNE

Acne affects nearly 80–90% of adolescents at some stage of their life. Although it is more common during teenage years, adult acne is increasingly

being reported, especially among females. The global burden of acne highlights the need for effective and safe treatment strategies [1].

### 1.3 TYPES OF ACNE LESIONS

Acne vulgaris presents with a wide spectrum of lesions that are broadly classified into **non-inflammatory** and **inflammatory** types. The type and severity of lesions depend on the stage of disease progression and the underlying pathological mechanisms involved [3].

#### 1.3.1 Non-inflammatory Lesions (Comedonal Acne)

Non-inflammatory lesions represent the earliest stage of acne and occur due to follicular blockage caused by excess sebum and keratin accumulation.

**Open Comedones (Blackheads):** These are formed when the follicular opening remains dilated. The dark appearance is not due to dirt but results from oxidation of melanin and lipids on exposure to air. They are typically seen on the nose, forehead, and chin.

**Closed Comedones (Whiteheads):** These occur when the follicular opening is completely blocked. The trapped sebum and keratin form small, white or skin-colored bumps beneath the skin surface. Closed comedones are more prone to progression into inflammatory lesions.

Non-inflammatory lesions are generally mild but act as precursors to more severe forms of acne if left untreated [3].

#### 1.3.2 Inflammatory Lesions

Inflammatory lesions develop when blocked follicles become infected with *Cutibacterium acnes*, triggering an immune response.

**1.3.1.1 Papules:** Small, red, raised lesions without visible pus. They result from inflammation of the follicular wall and are often tender to touch.

**1.3.1.2 Pustules:** These are similar to papules but contain visible pus at the center. They appear as red lesions with a white or yellowish core due to accumulation of neutrophils.

**1.3.1.4 Nodules:** Larger, solid, and painful lesions that extend deeper into the dermis. They are formed due to severe inflammation and can persist for a long duration.

**1.3.1.5 Cysts:** The most severe form of acne lesions, cysts are pus-filled, deep-seated, and highly inflamed. They often lead to permanent scarring if not treated properly.

#### 1.3.3 Severity Grading of Acne Lesions

Based on lesion type and number, acne can be classified into different severity levels:

**1.3.3.1 Mild Acne:** Predominantly comedones with few papules

**1.3.3.2 Moderate Acne:** Presence of papules and pustules

**1.3.3.3 Severe Acne:** Nodules, cysts, and widespread inflammation

#### 1.3.4 Clinical Significance of Lesion Types

Understanding the type of lesion is important for:

- Selecting appropriate treatment
- Predicting disease progression
- Preventing complications like scarring
- Evaluating therapeutic response

Non-inflammatory lesions respond well to keratolytic agents, whereas inflammatory lesions require anti-inflammatory and antimicrobial therapy.



Fig1.1 Clinical Presentation of Acne

### 1.4 PATHOPHYSIOLOGY OF ACNE

The pathogenesis of acne vulgaris involves multiple interconnected factors that collectively lead to the formation of acne lesions. These mechanisms occur simultaneously and influence each other, resulting in disease progression [3].

#### 1.4.1 Sebum Overproduction

Sebum production is stimulated by androgens, especially during puberty. Excess sebum accumulates in the hair follicles, creating an oily environment that promotes bacterial growth and contributes to pore blockage [3].

#### 1.4.2 Follicular Hyperkeratinization

Abnormal shedding and increased proliferation of keratinocytes lead to blockage of the follicular opening. This results in the formation of comedones, which act as the initial stage of acne development [3].

#### 1.4.3 Microbial Colonization

*Cutibacterium acnes* colonizes the blocked follicles and utilizes sebum as a nutrient source. Its metabolic activity releases enzymes and inflammatory substances that aggravate acne lesions [5].

### 1.4.4 Inflammatory Response

The immune response triggered by bacterial activity leads to the release of inflammatory mediators such

as interleukins and TNF- $\alpha$ . This causes redness, swelling, and pain, resulting in inflammatory lesions like papules and pustules [5].

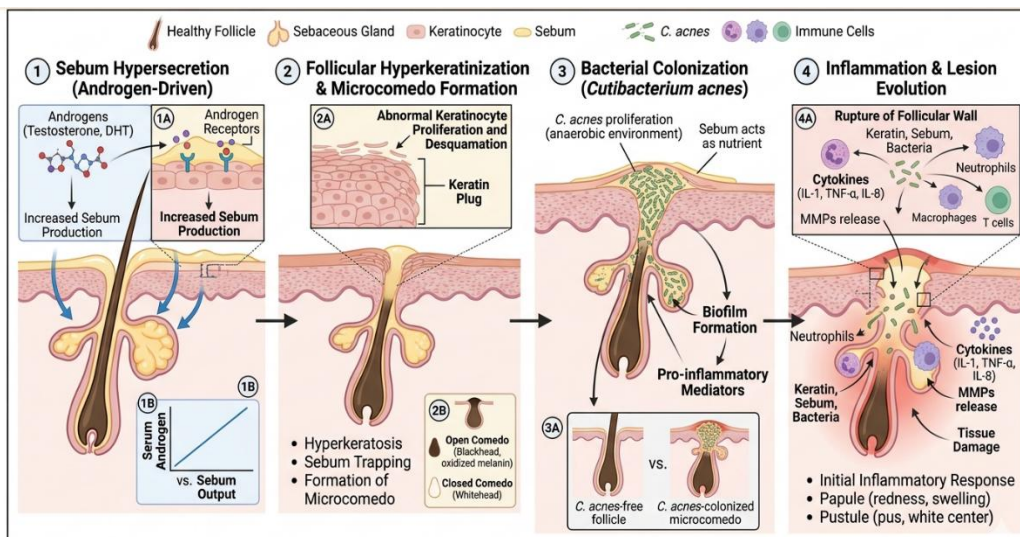


Fig.1.2 Pathophysiology of Acne Vulgaris

## II. CLINDAMYCIN HYDROCHLORIDE

Clindamycin hydrochloride is a semi-synthetic lincosamide antibiotic widely used in the topical treatment of acne vulgaris. It is particularly effective against anaerobic bacteria, including *Cutibacterium acnes*, which plays a central role in acne pathogenesis. Due to its antibacterial and anti-inflammatory properties, clindamycin is commonly incorporated into topical formulations for managing inflammatory acne lesions [6].

### 2.1 PHARMACOLOGICAL PROFILE

Clindamycin acts by inhibiting bacterial protein synthesis, thereby preventing bacterial growth and reducing infection at the site of application.

#### 2.1.1 Mechanism of Action

Clindamycin binds to the 50S ribosomal subunit of susceptible bacteria, inhibiting peptide chain elongation during protein synthesis. This action suppresses bacterial proliferation and reduces the production of inflammatory mediators released by *C. acnes* [6].

In addition to its antibacterial activity, clindamycin also exhibits indirect anti-inflammatory effects by decreasing the release of free fatty acids and inflammatory cytokines, thereby helping in the reduction of acne lesions.

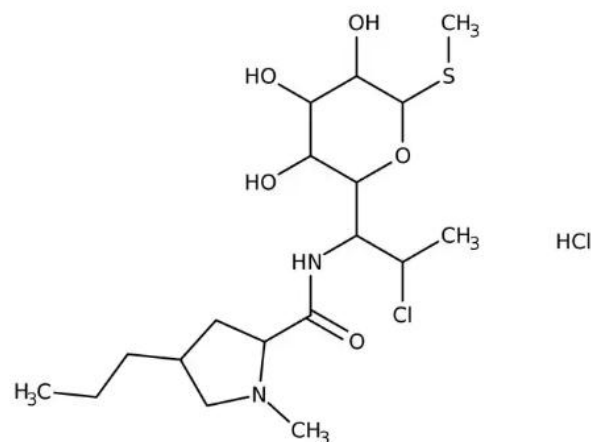


Fig.2.1 Chemical Structure of Clindamycin

#### 2.1.2 Spectrum of Activity

Clindamycin is mainly active against:

- *Cutibacterium acnes*
- Anaerobic Gram-positive bacteria
- Some aerobic Gram-positive organisms

Its effectiveness against *C. acnes* makes it a preferred choice in acne therapy [6].

#### 2.1.2 Role in Acne Treatment

Clindamycin is primarily used for mild to moderate inflammatory acne. It helps in:

- Reducing bacterial colonization
- Decreasing inflammation

- Preventing progression of lesions

Topical clindamycin is often combined with other agents such as benzoyl peroxide or nicotinamide to enhance therapeutic efficacy and reduce the risk of resistance <sup>[7]</sup>.

## 2.2 PHARMACOKINETIC

When applied topically:

- Systemic absorption is minimal
- Drug concentrates in sebaceous follicles
- Provides localized action at the site of infection

However, penetration through the stratum corneum may be limited in conventional formulations, which reduces its overall effectiveness <sup>[7]</sup>.

## 2.3 Limitations of Clindamycin Therapy

Despite its clinical usefulness, clindamycin therapy has several limitations:

### 2.3.1 Antibiotic Resistance

Prolonged use of clindamycin may lead to the development of resistant strains of *C. acnes*, which decreases treatment effectiveness over time. This is a major concern in acne management <sup>[7]</sup>.

### 2.3.2 Skin Irritation

Topical application may cause:

- Dryness
- Redness
- Burning sensation

These side effects may reduce patient compliance.

### 2.3.3 Poor Skin Penetration

Conventional formulations may not effectively deliver the drug into deeper skin layers, limiting its therapeutic potential. This necessitates the use of advanced delivery systems like niosomes<sup>[7]</sup>.

### 2.3.5 Need for Improved Delivery of Clindamycin

To overcome the above limitations, novel drug delivery systems such as niosomal formulations are being explored. These systems help in:

- Enhancing skin penetration
- Providing controlled drug release
- Reducing dosing frequency
- Minimizing side effects

Thus, incorporating clindamycin into a niosomal gel system can significantly improve its therapeutic performance in acne treatment.

## III. NICOTINAMIDE

Nicotinamide, also known as niacinamide, is a water-soluble form of Vitamin B3 widely used in dermatology due to its anti-inflammatory and skin-protective properties. It is considered a safe and effective agent for the management of acne, especially when used in topical formulations <sup>[8]</sup>.

### 3.1 Pharmacological Profile

Nicotinamide plays an important role in cellular metabolism and skin health. It enhances the skin barrier function and helps in maintaining hydration.

#### 3.1.1 Mechanism of Action

Nicotinamide exerts its effects primarily through:

- Anti-inflammatory action: Reduces production of inflammatory cytokines
- Sebum regulation: Controls excess oil secretion from sebaceous glands
- Antioxidant activity: Protects skin from oxidative stress

These combined actions help in reducing acne severity <sup>[8]</sup>.

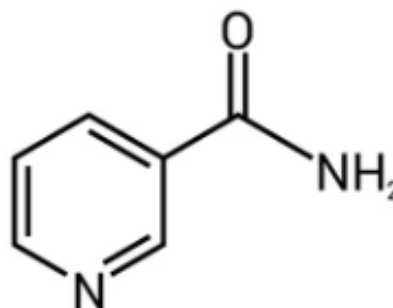


Fig3.1 Chemical Structure of Nicotinamide

#### 3.1.2 Role in Acne Treatment

Nicotinamide is effective in managing acne due to its multiple benefits:

- Reduces inflammatory lesions
- Controls sebum production
- Improves skin texture and barrier function

It is often used as an alternative or adjunct to antibiotics in acne therapy <sup>[9]</sup>.

#### 3.1.3 Advantages Over Antibiotics

Unlike antibiotics, nicotinamide:

- Does not cause bacterial resistance
- Is suitable for long-term use
- Has minimal side effects

This makes it a safer option for chronic acne management <sup>[9]</sup>.

#### 3.1.4 Limitations

Although nicotinamide is well tolerated, it has some limitations:

- Mild efficacy when used alone
- Requires combination with other agents for better results

#### 3.1.5 Rationale for Use in Combination

The combination of nicotinamide with clindamycin provides a synergistic effect:

- Clindamycin → Antibacterial action
- Nicotinamide → Anti-inflammatory & sebum control

This combination enhances overall therapeutic effectiveness while reducing side effects.

#### IV. NIOSOMES

Niosomes are non-ionic surfactant-based vesicular systems that act as carriers for both hydrophilic and lipophilic drugs. They enhance drug stability, improve skin penetration, and provide controlled release, making them suitable for topical drug delivery in acne treatment<sup>[10]</sup>.

##### 4.1.1 Composition

Niosomes are mainly composed of:

- Non-ionic surfactants (e.g., Span, Tween)
- Cholesterol (for membrane stability)
- Aqueous phase (for drug loading)

##### 4.1.2 Advantages

Niosomes offer several advantages over conventional drug delivery systems, particularly in topical applications. They significantly enhance drug penetration by interacting with the lipid components of the stratum corneum, thereby facilitating deeper drug delivery into the skin layers. Additionally, niosomes provide controlled and sustained release, which helps maintain therapeutic drug levels for an extended period and reduces the need for frequent application.

Another important advantage is their ability to improve drug stability, especially for drugs that are prone to degradation in conventional formulations. Niosomes also minimize systemic absorption and side effects, ensuring that the drug acts primarily at the target site. Furthermore, they are biocompatible, non-immunogenic, and relatively easy to prepare, making them suitable for large-scale pharmaceutical applications<sup>[10]</sup>.

##### 4.1.3 Mechanism of Action

Niosomes enhance drug delivery through multiple mechanisms. Upon application, they adhere to the skin surface and interact with the stratum corneum lipids, leading to disruption and increased permeability of the skin barrier. This facilitates the penetration of the encapsulated drug into deeper layers of the epidermis and dermis.

In addition, niosomes act as drug reservoirs, gradually releasing the drug over time, which contributes to sustained therapeutic action. The vesicles may also fuse with skin lipids, allowing direct transfer of the drug into the target site. This dual mechanism of enhanced permeation and controlled release improves overall drug bioavailability and effectiveness in acne treatment<sup>[10]</sup>.

#### V. NIOSOMAL GEL

Niosomal gel is a novel topical delivery system in which drug-loaded niosomes are incorporated into a suitable gel base. This combination merges the benefits of vesicular carriers with the convenience of gel formulations, resulting in improved therapeutic performance. The gel matrix enhances viscosity, stability, and ease of application, while niosomes ensure efficient drug delivery to the target site.

Such systems are particularly beneficial in acne treatment, as they allow localized delivery of active agents with minimal systemic exposure. The formulation also improves patient compliance due to its non-greasy nature and ease of spread on the skin<sup>[11]</sup>.

##### 5.1.1 Advantages

Niosomal gels provide multiple formulation and therapeutic benefits. They offer better spreadability and uniform application, ensuring that the drug is evenly distributed across the skin surface. The presence of a gel base increases the residence time of the formulation, allowing prolonged contact with the skin and improved drug absorption.

Additionally, these systems reduce the frequency of application due to their sustained release properties, which enhances patient adherence to therapy. Niosomal gels also help in reducing irritation and dryness, commonly associated with conventional topical formulations, thereby improving overall patient comfort<sup>[11]</sup>.

##### 5.1.2 Role in Acne Treatment

In acne management, niosomal gels play a significant role by improving the delivery of active agents such as clindamycin and nicotinamide. They enhance penetration into sebaceous glands, which are the primary sites of acne development.

The controlled release of the drug helps maintain effective concentrations over a longer duration, leading to better reduction of bacterial load and inflammation. Moreover, the targeted delivery minimizes unwanted side effects such as irritation and dryness, making niosomal gels a more effective and patient-friendly alternative to conventional formulations<sup>[11]</sup>.

#### VI. FORMULATION OF NIOSOMAL GEL

##### 6.1.1 Method

Dissolve Surfactant + Cholesterol  
in Organic Solvent (Chloroform/Methanol)

↓

Evaporation of Solvent  
(using Rotary Evaporator)

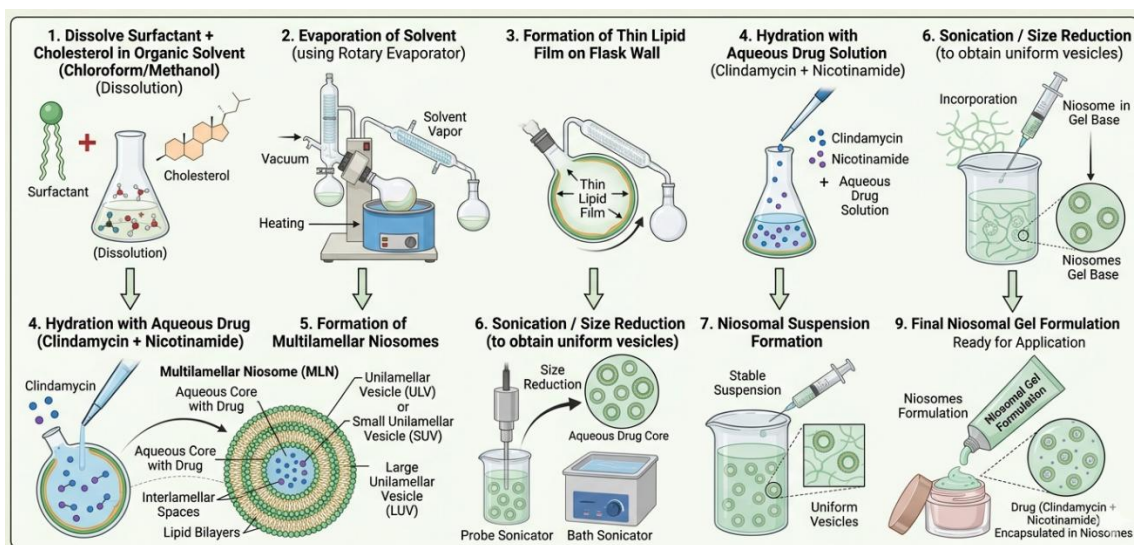
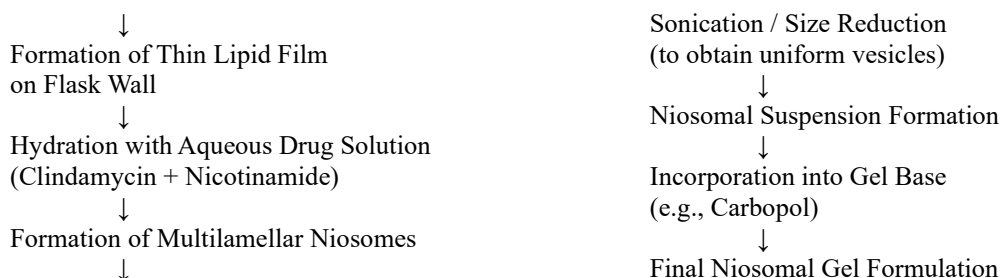


Fig.6.1 Formulation of Niosomal Gel

The thin film hydration method is the most widely used technique for preparing niosomes due to its simplicity and reproducibility. In this method, non-ionic surfactants and cholesterol are first dissolved in a suitable organic solvent such as chloroform or methanol. The solvent is then evaporated under reduced pressure using a rotary evaporator, forming a thin, uniform lipid film on the inner wall of the flask.

This dried film is subsequently hydrated with an aqueous solution containing the drug, leading to the formation of multilamellar vesicles. The dispersion is then subjected to sonication or mechanical agitation to reduce vesicle size and obtain a more uniform distribution. Finally, the prepared niosomal suspension is incorporated into a gel base such as Carbopol to obtain the final niosomal gel formulation.

This method ensures high entrapment efficiency, uniform vesicle formation, and reproducibility, making it suitable for pharmaceutical applications [12].

### 6.1.2 Factors Affecting Formulation

Several formulation variables influence the characteristics and performance of niosomal gel:

- Type of surfactant: Determines vesicle formation, size, and stability
- Surfactant-to-cholesterol ratio: Affects membrane rigidity and drug entrapment
- Hydration temperature and time: Influence vesicle size and drug loading
- Sonication time: Controls particle size and uniformity
- pH of hydration medium: Impacts drug stability and encapsulation efficiency

Proper optimization of these parameters is essential to achieve a formulation with desired vesicle size, stability, and controlled drug release profile [12].

## VII. EVALUATION OF NIOSOMAL GEL

Evaluation of niosomal gel is a critical step to ensure quality, stability, efficacy, and safety of the formulation. Multiple physicochemical and biological parameters are assessed.

### 7.1.1 Physical Appearance

The prepared gel should be visually inspected for:

- Colour
- Homogeneity
- Presence of lumps
- Phase separation

An ideal niosomal gel should be smooth, transparent (or slightly opaque), and free from grittiness, ensuring uniform drug distribution<sup>[13]</sup>.

### 7.1.2 pH Determination

The pH of the gel is measured using a calibrated digital pH meter.

- Ideal pH range: 5.5–7
- Ensures compatibility with skin
- Prevents irritation and dryness

Maintaining proper pH is essential for patient comfort and stability of formulation<sup>[14]</sup>.

### 7.1.3 Viscosity

Viscosity is determined using a Brookfield viscometer.

- Indicates flow behaviour
- Affects spreadability and drug release
- Higher viscosity → prolonged retention
- Lower viscosity → easy spread

Optimized viscosity ensures balance between retention and ease of application<sup>[15]</sup>.

### 7.1.4 Spreadability

Spreadability is evaluated using glass slide method:

$$S = \frac{M \times L}{T}$$

Where:

M = weight applied

L = length moved

T = time taken

Good spreadability ensures uniform application and patient compliance<sup>[16]</sup>.

### 7.1.5 Drug Content

Drug content analysis ensures uniform distribution of:

- Clindamycin hydrochloride
- Nicotinamide

It is determined using UV spectrophotometry. Uniform drug content is essential for dose accuracy and therapeutic effectiveness<sup>[17]</sup>.

### 7.1.6 Entrapment Efficiency

Entrapment efficiency determines the amount of drug encapsulated within niosomes.

$$EE\% = \frac{\text{Entrapped Drug}}{\text{Total Drug}} \times 100$$

Higher entrapment efficiency indicates better formulation performance and sustained drug release<sup>[18]</sup>.

### 7.1.7 In-vitro Drug Release Study

Performed using Franz diffusion cell:

- Determines release profile
- Shows sustained drug release
- Helps compare with conventional formulations

Niosomal gels typically exhibit controlled and prolonged drug release<sup>[19]</sup>.

### 7.1.8 Zeta Potential

Zeta potential indicates stability of niosomes.

- High value → better stability
- Prevents aggregation
- Indicates surface charge

Stable formulations generally show values above  $\pm 30$  mV<sup>[20]</sup>.

### 7.1.9 Particle Size Analysis

Measured using dynamic light scattering:

- Influences penetration
- Smaller size → better absorption
- Uniform size distribution improves consistency

### 7.1.10 SEM (Scanning Electron Microscopy)

SEM analysis provides:

- Surface morphology
- Shape of vesicles
- Structural integrity

Niosomes generally appear spherical and smooth.

### 7.1.11 FTIR Studies

FTIR is used to:

- Detect drug-excipient interaction
- Confirm chemical stability
- Ensure compatibility

No major peak shifts indicate stable formulation.

### 7.1.12 Stability Studies

Stability testing is conducted under:

- Different temperatures (4°C, 25°C, 40°C)
- Humidity conditions

Parameters evaluated:

- Drug content
- pH
- Appearance

Ensures long shelf-life and product reliability

## VIII. CONCLUSION

The present review highlights the significant potential of niosomal gel as an advanced drug delivery system for the effective management of acne vulgaris. Acne, being a multifactorial skin disorder, requires a therapeutic approach that can simultaneously target microbial growth,

inflammation, and excessive sebum production. The combination of Clindamycin hydrochloride and Nicotinamide fulfills this requirement by providing both antibacterial and anti-inflammatory actions, thereby improving overall treatment efficacy.

However, conventional topical formulations of these drugs are often associated with limitations such as poor skin penetration, instability, frequent application, and the risk of antibiotic resistance. The incorporation of these drugs into niosomal vesicles offers a promising solution by enhancing drug stability, improving penetration through the stratum corneum, and providing controlled and sustained drug release.

Furthermore, the conversion of niosomal dispersion into a gel formulation enhances patient compliance by improving ease of application, spreadability, and retention time on the skin. The evaluation parameters such as particle size, zeta potential, entrapment efficiency, and in-vitro drug release confirm the effectiveness and stability of the formulation, making it a suitable candidate for topical delivery.

Overall, niosomal gel of Clindamycin hydrochloride and Nicotinamide represents a **superior** alternative to conventional acne therapies, offering enhanced therapeutic outcomes with reduced side effects. This formulation strategy not only improves drug delivery but also addresses key challenges associated with current acne treatments.

## IX. FUTURE PROSPECTS

The development of niosomal gel systems opens new avenues in the field of topical drug delivery, particularly for dermatological conditions like acne vulgaris. Although promising results have been observed in formulation and in-vitro evaluation studies, further advancements are required to fully explore the clinical potential of this system.

One of the major future directions includes conducting extensive in-vivo and clinical studies to establish the safety, efficacy, and long-term benefits of niosomal gels in human subjects. This will help in validating their superiority over conventional formulations and support their commercialization.

In addition, there is growing interest in the development of targeted and stimuli-responsive niosomal systems, which can release drugs in response to specific skin conditions such as pH, temperature, or enzymatic activity. Such smart delivery systems can further improve therapeutic precision and minimize side effects.

The incorporation of herbal or natural anti-acne agents into niosomal formulations is another

promising area of research. Combining phytoconstituents with conventional drugs may enhance therapeutic outcomes while reducing the risk of resistance and adverse effects.

Moreover, advancements in nanotechnology can lead to the development of nano-niosomes with improved size control, stability, and penetration efficiency, thereby further enhancing drug delivery performance. Optimization of formulation variables using modern techniques such as design of experiments (DoE) can also contribute to more efficient and reproducible formulations.

From an industrial perspective, efforts should be directed toward scale-up production, stability optimization, and regulatory approval to ensure successful commercialization of niosomal gel formulations. Development of cost-effective and patient-friendly products will further increase their acceptance in the pharmaceutical market.

In conclusion, niosomal gel systems hold great promise as next-generation topical drug delivery platforms. With continued research and technological advancements, they have the potential to revolutionize acne treatment by providing safer, more effective, and patient-compliant therapeutic option.

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