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Development and Evaluation of a Topical Niosomal Gel Formulated with Benzoyl Peroxide and Tretinoin for Anti-Acne Therapy

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Abstract

Acne vulgaris is a prevalent dermatological condition characterized by excessive sebum production, bacterial colonization, and inflammation. Conventional treatments, such as benzoyl peroxide and tretinoin, are widely used due to their antibacterial, anti-inflammatory, and comedolytic properties. However, their therapeutic efficacy is often compromised by poor skin penetration, instability, and irritation. To address these challenges, this study focuses on the development and evaluation of a topical niosomal gel incorporating benzoyl peroxide and tretinoin for enhanced anti-acne therapy. Niosomes, non-ionic surfactant-based vesicular carriers, offer improved drug stability, controlled release, and enhanced skin penetration, making them a promising drug delivery system for dermatological applications. The niosomal gel was formulated using the thin-film hydration method and incorporated into a gel matrix for prolonged skin retention. The developed formulation was characterized for vesicle size, entrapment efficiency, rheological properties, and in vitro drug release. Skin permeation studies demonstrated enhanced drug absorption, ensuring targeted action with reduced systemic side effects. The formulation exhibited sustained drug release, minimizing irritation while maintaining therapeutic efficacy. The results suggest that the niosomal gel provides a more effective and patient-friendly alternative to conventional formulations. Further in vivo studies and clinical trials are required to validate its efficacy and safety for potential commercial applications in acne management.

Keywords: Niosomal gel, benzoyl peroxide, tretinoin, acne treatment, controlled release, skin permeation.

Introduction

Acne vulgaris is a common dermatological condition affecting millions worldwide, primarily due to excessive sebum production, bacterial colonization, inflammation, and abnormal

keratinization. Conventional treatments, including benzoyl peroxide and tretinoin, are widely used for their potent antibacterial, anti-inflammatory, and comedolytic properties. However, their therapeutic efficacy is often limited by issues such as poor skin penetration, irritation, and instability in conventional formulations. To overcome these limitations, novel drug delivery systems, such as niosomes, have gained significant attention in dermatological applications. Niosomes are non-ionic surfactant-based vesicular carriers that enhance drug stability, improve skin permeability, and provide sustained drug release. The incorporation of benzoyl peroxide and tretinoin into a niosomal gel formulation offers a promising strategy to enhance therapeutic outcomes while minimizing side effects associated with conventional topical treatments.

The formulation of a niosomal gel involves the encapsulation of benzoyl peroxide and tretinoin within vesicular carriers, which are then incorporated into a gel matrix to ensure prolonged skin retention and controlled drug release. This approach enhances drug absorption, reduces systemic side effects, and provides better patient compliance. Evaluation of the developed niosomal gel includes characterization of vesicle size, entrapment efficiency, rheological properties, drug release behavior, and skin permeation studies. In vitro and in vivo studies further assess its therapeutic potential for acne treatment. By optimizing drug delivery through a niosomal gel, this study aims to develop an effective and patient-friendly formulation that enhances acne management while reducing the drawbacks of conventional treatments. The successful development of this formulation could offer a significant advancement in topical acne therapy, providing improved efficacy and better tolerability for patients suffering from acne vulgaris.

Literature review

Carmona E.M et al., (2017) The study offers a comprehensive overview of treatment strategies for fungal infections, classifying antifungal agents into four main groups, each characterized by a distinct mechanism of action: polyenes and azoles disrupt the cell membrane, echinocandins impact cell wall synthesis, and pyrimidine analogs inhibit DNA synthesis. Echinocandins are frequently favored for their efficacy against Candida species. Additionally, fluocytosine is commonly employed in combination with amphotericin B to address challenging Candida infections and cases of cryptococcal meningitis.

Soliman G.M et al., (2017) The study explores the promise of nanoparticles as safe and efficient delivery systems for antifungal agents. Fungal infections have emerged as a significant health issue affecting diverse patient groups, resulting in severe illness and fatalities. While

potent antifungal drugs are available, their therapeutic effectiveness falls short of ideal due to challenges linked to drug physicochemical characteristics and safety. To facilitate the transition of these nanoformulations from laboratory research to practical clinical use, the focus should be on addressing concerns related to nanoparticle stability, effective drug encapsulation, and cost-effective manufacturing and administration methods.

Shinkafi SA and Ndanusa H (2017) Samples were collected from individuals afflicted with acne vulgaris by swabbing their faces, chests, and backs at Aminata Hospital in Sokoto, Nigeria, using swab sticks. Citrus lemon juice was applied at various concentrations (20%, 40%, 60%, 80%, and 100%) to P. acnes, and all concentrations demonstrated efficacy. A traditional cleanser served as a positive control and was found effective at concentrations of 60%, 80%, and 100%. The study investigated the minimum inhibitory concentration (MIC) of lemon juice, and no bacterial growth was observed at concentrations of 80% and 100%. Citrus lemon juice exhibited a minimum bactericidal concentration (MBC) against P. acnes at all tested concentrations. As a result, it was concluded that lemon juice exhibited stronger anti-acne vulgaris activity compared to the conventional cleanser.

Webster et al., (2018) Conducted a randomized, 4-treatment, crossover study to evaluate and contrast the pharmacokinetic profiles of a recently developed formulation of Isotretinoin (Isotretinoin-Lidose) with the established innovator Isotretinoin formulation.

Alhusayen et al., (2018) The study reported on a population-based cohort investigation into the relationship between Isotretinoin use and the risk of inflammatory bowel disease (IBD). The author conducted a retrospective population-based cohort study in British Columbia, Canada, involving participants who were treated with isotretinoin or topical acne medications. The reference group consisted of the entire population of untreated provincial residents aged 12-29 years. Over the 12-year study period, the author identified 46,922 participants treated with isotretinoin, 184,824 treated with topical acne medication, and 1,526,946 untreated individuals. The findings suggested a potential association between IBD and acne itself, as well as the successful treatment of acne using Isotretinoin.

Arslan A et al., (2018) Conducted a study to evaluate a novel formulation featuring oxiconazole nitrate, an azole derivative used for treating superficial fungal infections caused by Candida species, which are prevalent skin conditions. The objective of this research was to create a new thermosensitive gel incorporating oxiconazole nitrate for topical application. The formulated thermosensitive gel containing oxiconazole nitrate exhibited efficacy in the

treatment of superficial fungal infections. While the researchers suggest its suitability for in vivo applications, further investigations involving animal and human subjects are required to confirm its effectiveness.

Bhate K and Williams HC (2019) Conducted a study to evaluate a novel formulation featuring oxiconazole nitrate, an azole derivative used for treating superficial fungal infections caused by Candida species, which are prevalent skin conditions. The objective of this research was to create a new thermosensitive gel incorporating oxiconazole nitrate for topical application. The formulated thermosensitive gel containing oxiconazole nitrate exhibited efficacy in the treatment of superficial fungal infections. While the researchers suggest its suitability for in vivo applications, further investigations involving animal and human subjects are required to confirm its effectiveness.

Blasiak et al., (2019) Presented a report on the treatment of acne vulgaris using high-dose Isotretinoin and its effects on relapse rates and adverse outcomes in patients. Importantly, the dosing regimen applied in this study exceeded the dosages used in previous isotretinoin research. Following a one-year follow-up period post-completion of isotretinoin treatment, the results indicated that patients who received 220 mg/kg or higher demonstrated a statistically significant reduction in the risk of relapse.

Tan et al., (2020) Conducted an extensive study focused on the management of severe nodular acne. This multicenter, investigator-blinded, randomized, controlled, noninferiority trial involved 266 participants and aimed to compare the effectiveness and safety of two treatment regimens: oral isotretinoin (ISO) and a combination of doxycycline 200 mg with adapalene 0.1%/benzoyl peroxide 2.5% gel (D+A/BPO) over a 20-week period. The findings indicated that the D+A/BPO combination displayed a favourable combined efficacy and safety profile in comparison to ISO. For individuals who may face intolerance or reluctance toward oral ISO, this combination therapy provides a viable alternative for managing severe nodular acne.

Rahman et al., (2022) Conducted research focused on the development of a tretinoin liposomal gel with the aim of creating a formulation that minimizes the potential for skin irritation while enhancing clinical effectiveness. Employing a statistical 24 factorial design, sixteen different formulations were created and assessed. Among these, a promising candidate formula designated as F13G emerged, containing 0.025% tretinoin, phospholipid, cholesterol, and dicetylphosphate in a 9:1:0.01 ratio. This formula was subsequently incorporated into a 1% carbopol gel for further examination in a skin irritation test. Clinical studies involving acne

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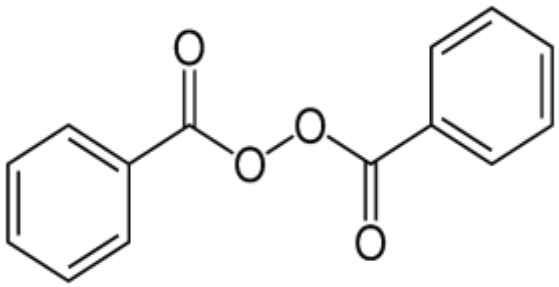
patients revealed that F13G displayed significantly greater efficacy compared to a commercially available product ($p<0.05$).

Drug Profile

Benzoyl peroxide

Structure:



Benzoyl peroxide is an organic compound with a distinctive structural formula, typically denoted as $(C_6H_5{-}C(=O)\ O{-})_2$ or $(BzO)_2$. Its molecular structure comprises two benzoyl ($C_6H_5{-}C(=O){-}$, Bz) groups connected by a peroxide ($-O-O-$) bridge.

This chemical compound appears as a white granular solid with a subtle scent reminiscent of benzaldehyde. While it has limited solubility in water, it readily dissolves in solvents such as acetone, ethanol, and various organic compounds. Benzoyl peroxide serves as an oxidizer and finds primary application in polymer production.

Furthermore, it plays a crucial role in manufacturing plastics and acts as a bleaching agent for various materials, including flour, hair, plastics, and textiles. Additionally, benzoyl peroxide has been employed for medicinal purposes and as a disinfectant in water treatment. In specific contexts, it is commonly abbreviated as BPO.

Formula: $C_{14}H_{10}O_4$

Other names: benzoperoxide, dibenzoyl peroxide (DBPO)

Mechanism of Action: Benzoyl peroxide is traditionally believed to have a triple action in treating acne. It functions as a sebostatic agent, comedolytic agent, and bacteriostatic agent, effectively inhibiting the growth of Cutibacterium acnes, the primary bacterium responsible for acne. Acne vulgaris typically arises from hormone-induced inflammation of sebaceous glands and hair follicles. Hormonal fluctuations lead to increased production of keratin and sebum, resulting in the blockage of hair follicles. C. acnes possesses various lytic enzymes that break down sebum proteins and lipids, triggering an inflammatory response. Benzoyl peroxide

initiates free-radical reactions that can break down keratin, aiding in the clearance of blocked sebaceous ducts (comedolytic action).

Benzoyl peroxide can induce non-specific peroxidation of C. acnes, rendering it bactericidal. It was once believed to decrease sebum production, although the literature contains conflicting evidence regarding this effect.

Benzoyl peroxide is a widely used medication primarily employed for the treatment of acne and various skin conditions. It is available in various formulations, including gels, creams, lotions, and washes. Here are its common uses, along with potential side effects:

Uses:

1. **Acne Treatment**: Benzoyl peroxide is most commonly used to treat acne. It works by reducing the presence of acne-causing bacteria on the skin, unclogging pores, and reducing inflammation. It is effective against both non-inflammatory (whiteheads and blackheads) and inflammatory (pustules and cysts) acne lesions.
2. **Topical Antiseptic**: It has antiseptic properties that help prevent secondary infections in acne lesions.
3. **Keratolytic Agent**: Benzoyl peroxide can break down keratin, a protein that can contribute to the formation of comedones (clogged pores). This makes it a comedolytic agent, helping to prevent new acne lesions.

Side Effects:

1. **Skin Dryness and Peeling**: One of the most common side effects is dryness, peeling, and redness of the skin. This can be more pronounced when starting treatment or with higher concentrations of benzoyl peroxide.
2. **Irritation**: Some people may experience skin irritation, burning, or itching. This can be managed by using lower concentrations or less frequent application.
3. **Bleaching of Fabrics**: Benzoyl peroxide can bleach hair, clothing, and bedding. Care should be taken to avoid contact with these materials.
4. **Allergic Reactions**: While rare, some individuals may be allergic to benzoyl peroxide and develop hives, itching, or rash. If this occurs, discontinuing use is advisable.
5. **Contact Dermatitis**: Prolonged or excessive use of benzoyl peroxide can lead to contact dermatitis, causing redness, itching, and discomfort.
6. **Increased Sun Sensitivity**: Benzoyl peroxide can make your skin more sensitive to sunlight. It is important to use sunscreen when going outdoors to avoid sunburn.

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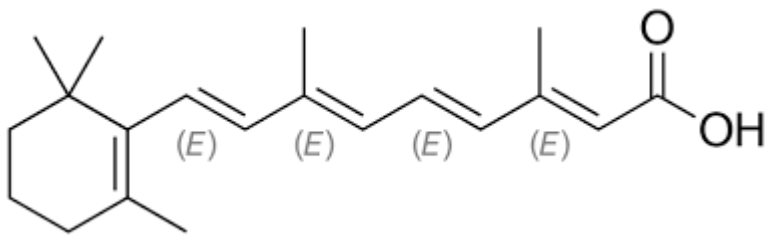
7. **Eczema-like Reactions**: In some cases, benzoyl peroxide can trigger eczema-like reactions in individuals with sensitive skin.
8. **Dry Eyes and Mouth**: Rarely, benzoyl peroxide can cause dry eyes and mouth. This is more common with higher concentrations and should be reported to a healthcare provider.

It's important to use benzoyl peroxide as directed by a healthcare professional or as indicated on the product label. Starting with lower concentrations and gradually increasing can help minimize side effects. If you experience severe or persistent side effects, consult a healthcare provider for guidance on adjusting your treatment regimen.

TRETINOIN



Tretinoin, a derivative of vitamin A, is a versatile medication in dermatology. Its multifaceted uses make it a valuable tool for various skin conditions. One of its primary applications is the treatment of acne, where it helps prevent new breakouts, reduce existing blemishes, and improve skin texture. Beyond acne, tretinoin is celebrated for its anti-aging properties, promoting collagen production, diminishing fine lines and wrinkles, and enhancing skin elasticity. This makes it a popular choice for individuals looking to address signs of aging and maintain youthful skin.

Tretinoin's benefits extend to skin brightening as well. It can fade dark spots, hyperpigmentation, and conditions like melasma by inhibiting melanin production, leading to a more even skin tone. Additionally, tretinoin can play a role in improving the appearance of acne scars, although it is not a direct scar treatment. Its ability to stimulate skin regeneration and collagen formation contributes to this effect.

Beyond cosmetic uses, tretinoin is also employed to manage keratosis pilaris, a common skin condition characterized by rough, small bumps on the skin.

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However, it's important to note that tretinoin can cause side effects like skin dryness, peeling, redness, and increased sensitivity to sunlight. These side effects are usually temporary and manageable with proper skincare practices, including the use of sunscreen.

When using tretinoin, it's crucial to seek guidance from a healthcare provider, as its concentration and application regimen should be tailored to individual skin concerns and needs. Tretinoin is typically applied at night to clean, dry skin, and sunscreen is recommended during the day to protect the skin from UV damage. Consulting with a healthcare professional ensures safe and effective use of this powerful dermatological tool.

Material And Methods

Preformulation studies were also conducted as part of the research process.

The objective of the preformulation study is to determine the characteristics of the drug and excipients, including solubility, drug-excipient compatibility assessed by FTIR and DSC.

Drug Identification The acquired drugs were evaluated based on the following parameters.

Table 1: Various physical parameters of Benzoyl Peroxide

Drug substance	Benzoyl Peroxide
Nature	Liquid
Colour	Whitish
Odour	Odourless
Melting Point	136-138 ºC ± 0.33°C (Practical value) [a], 135 – 138 °C (Standard value)
Loss of drying	0.4% ± 0.88 (Practical value) [a], ≯0.5 (Standard value)
Solubility	0.25 mg/Ml

Table 2: Various physical parameters of Tretinoin

Drug substance	Tretinoin
Nature	Solid
Color	Whitish
Odour	Odourless
Melting Point	130-132 ºC ± 0.33°C (Practical value) [a],

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	133 – 132 °C (Standard value)
Loss of drying	0.4% ± 0.78(Practical value) [a], ≯0.2 (Standard value)
Solubility	0.24mg/Ml

a-Mean ± S.D., n =6 4.1.2.

Initial Evaluation The selected drug sample was subjected to an initial assessment, considering organoleptic properties such as appearance, odor, and color.

Table 3: Physical Characteristics of Excipients

Test Sample name	Nature	Colour	Odour	Melting Point/Boiling Point
Span 60	Liquid	Whitish	Odourless	54-57°C(lit.)/ 464.84°C
Oleic acid	Solid	Whitish	Odourless	13 to 14°C / 360 °C
Cholesterol	Solid	Whitish	Odourless	148°C/ 360 °C
Carbopol 934	Solid	Whitish	Odourless	116°C/286° F
Benzoyl Peroxide	Liquid	Whitish	Odourless	103°C/349.7±25.0 °C

Drug Solubility Study in Different Solvents and Buffers

The drug's solubility was evaluated in various pH media and surfactant combinations, an essential step in the formulation development process, following the recommendation of Chen and Chang et al. To determine a suitable solvent system, a measured amount of the drug was introduced into 10 mL of different solvents. These included pH 5.5, pH 6, pH 6.4, pH 7, pH 7.4 phosphate buffers, ethanol, and double-distilled water, all placed within 25 mL volumetric flasks.

After sealing the flasks securely, they were agitated at a constant temperature of 37±0.5°C in a mechanical shaker for 48 hours. Following this incubation period, the samples underwent filtration using Whatman filter paper, followed by dilution with the appropriate diluent. Subsequently, the filtered samples were once again passed through 0.45µm membrane filters. Finally, the samples were analyzed at 427 nm using a UV-Vis spectrophotometer.

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Table 4 Solubility of drug in different solvents & pH media

Name of the Solvent	Solubility(mg/ml)
Ethanol	25.29±0.3448
Water	0.25±0.0305
pH 5.5	6.27±0.0153
pH 6.0	4.19±0.1
pH 6.4	3.97±0.0153
pH 7.0	2.35±0.0776
pH 7.4	1.94±0.0624

a. Mean ± S.D., n = 3

The provided data on the solubility of the drug in various solvents and pH conditions is essential for pharmaceutical formulation and drug development. It offers valuable insights into how the drug behaves in different environments, which is crucial for designing effective dosage forms and ensuring optimal drug delivery. The high solubility of the drug in ethanol suggests that this organic solvent could be a suitable choice for preparing pharmaceutical formulations with enhanced drug solubility. On the other hand, the drug's low solubility in pure water indicates the need for solubility-enhancing techniques or the use of other solvents in aqueous-based formulations. The pH-dependent solubility profile of the drug is particularly noteworthy. It shows that the drug's solubility increases under slightly acidic conditions (pH 5.5) and gradually decreases as the pH becomes more alkaline (pH 7.0 and pH 7.4). This information can guide the development of pH-adjusted formulations to maximize drug solubility and bioavailability. this preformulation study provides a foundation for making informed decisions in the formulation process, helping researchers and pharmaceutical developers optimize drug delivery systems and improve the therapeutic efficacy of the drug. It highlights the importance of selecting appropriate solvents and pH conditions for drug formulation based on its solubility characteristics.

Fourier Transform Infrared Spectroscopy (FTIR)

Infrared radiation can interact with a sample in two distinct ways: it can either be absorbed by the sample or transmitted through it. FT-IR (Fourier Transform Infrared) results capture the molecular absorption and transmission of the sample, creating a unique fingerprint-like spectrum that characterizes the sample. Each type of sample yields a distinctive spectrum, essentially providing a signature for that material.

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This characterization is highly valuable for the analysis of various samples. During FTIR analysis, the sample is examined within the wave number range of 4000-400 cm^{-1}. To prepare samples for FTIR analysis, KBr pellets are commonly used. The sample is mixed with KBr, and this mixture is then compressed into a pellet that is subsequently subjected to FTIR analysis. Potassium bromide (KBr) is the most frequently used alkali halide for making these pellets due to its excellent transparency.

FT-IR analysis finds applications in identifying unknown materials, assessing sample quality, and determining compatibility within mixtures.

Results And Discussion

Drug Compatibility Studies

Infrared spectroscopy analysis unequivocally demonstrated the compatibility of the mixture of tretinoin (TRA) and benzoyl peroxide (BPO). This assertion was supported by the absence of any discernible alterations in the spectral bands when the combined spectrum was compared to the individual spectra of each drug. Specifically, the spectra revealed two prominent bands for TRA at 1,685.87 cm^{-1} (representing the C=O stretching) and 2,937.68 cm^{-1} (representing the O-H stretching). For BPO, two bands were also observed at 1,759.4 cm^{-1} (indicative of the C=O stretching in the ester group) and 1,226.7 cm^{-1} (representing the C-O stretching).

These spectral features are characteristic of the functional groups present in each drug. TRA exhibited C=O and O-H groups, while BPO featured a C=O group in the ester and a C-O group. The absence of any spectral changes in the mixture of TRA and BPO provided compelling evidence of their compatibility.

[Insert Figure 1: Infrared Spectra of TRA, BPO, and the TRA-BPO Mixture]

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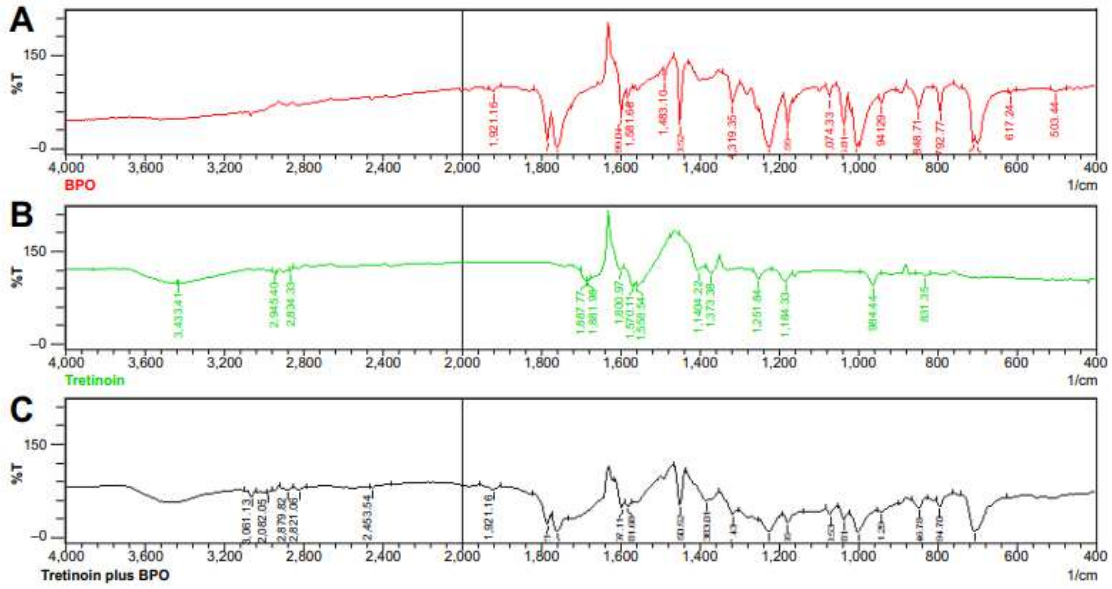

Figure 1: Infrared Spectra of BPO, Tretinoin, and Their Mixture

Notes: (A) BPO (Benzoyl Peroxide) (B) Tretinoin (C) Mixture of BPO and Tretinoin Abbreviations: BPO, benzoyl peroxide; IR, infrared spectroscopy; T, transmittance

UV scan analysis provided further confirmation of the compatibility of the TRA and BPO mixture. Scanning the mixture of TRA and BPO (each at a concentration of 10 µg/mL) within the range of 200 to 400 nm revealed absorption maxima for TRA at 348.6 nm and for BPO at 234.8 nm, respectively.

Notably, the characteristic peak for TRA was observed at 348.6 nm, while for BPO, it was detected at 234.8 nm. The assessment of interference in the absorbance of one component with the absorbance of tretinoin at 234.8 nm yielded a value of -0.059, and for BPO at 348.6 nm, it was -0.026. These results affirmatively indicated that there was no interference in the absorbance of each component in the mixture.

[Insert Figure 2: UV Scan Analysis of the TRA-BPO Mixture]

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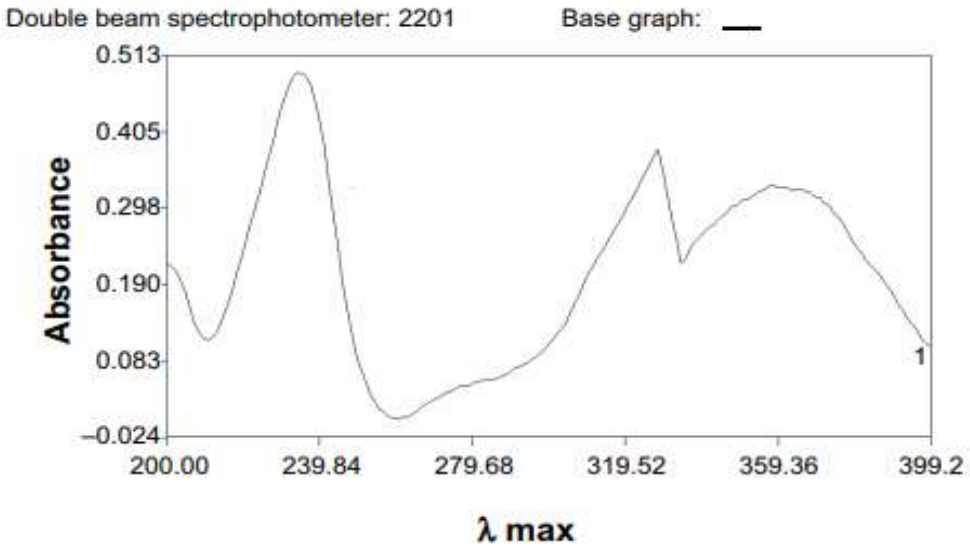

Figure 2: UV Scan of the Benzoyl Peroxide (BPO) and Tretinoin Mixture

Abbreviations: BPO, benzoyl peroxide; max, maximum; UV, ultraviolet.

Susceptibility Testing of BPO Against S. Epidermidis

In this study, the antibacterial activity of BPO against S. epidermidis was investigated. The results of the susceptibility testing (Table 7.1 and Figure 7.3) demonstrated the effective inhibition of S. epidermidis growth by BPO.

Table 5: Zone of Inhibition Data

Serial Number	Concentration (µg/ml)	Average Zone of Inhibition (mm)	Standard Deviation
1	50	12.8	±0.054
2	100	12.8	±0.056
3	150	13.4	±0.1
4	200	13.4	±0.114
5	250	14.6	±0.153
6	300	14.8	±0.1
7	350	14.9	±0.1
8	400	15.4	±0.1
9	450	15.7	±0.2
10	500	17.4	±0.053
11	1000	16.4	±0.154

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Serial Number	Concentration (µg/ml)	Average Zone of Inhibition (mm)	Standard Deviation
12	1500	17.8	±0.153
13	2000	16.5	±0.1

[Insert Figure 3: Antibacterial Activity of BPO Against S. Epidermidis]

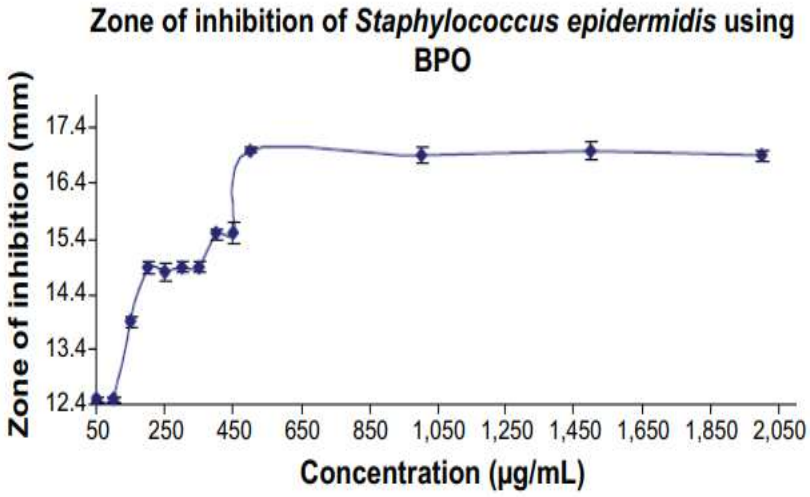

Figure: 3 Susceptibility testing graph: BPO concentration versus zone of inhibition. Abbreviation: BPO, benzoyl peroxide

Minimum inhibitory concentration of BPO for S. epidermidis

The Minimum Inhibitory Concentration (MIC) of Benzoyl Peroxide (BPO) for Staphylococcus epidermidis, a bacterium commonly found on human skin, is a critical parameter in understanding the antimicrobial efficacy of this compound. MIC is defined as the lowest concentration of an antimicrobial agent that inhibits the visible growth of a microorganism, indicating its effectiveness in controlling bacterial growth. To determine the MIC of BPO for S. epidermidis, a series of dilutions of BPO solutions are prepared, each with decreasing concentrations. These dilutions are then introduced into separate test tubes or wells in a microtiter plate. A standardized inoculum of S. epidermidis is added to each well. The plates or tubes are then incubated under optimal conditions for bacterial growth. After the incubation period, the wells or tubes are examined for visible bacterial growth. The concentration of BPO in the well or tube that shows no visible growth of S. epidermidis is considered the MIC. This concentration represents the lowest amount of BPO needed to inhibit the growth of the bacteria effectively. Determining the MIC of BPO for S. epidermidis is essential for evaluating its antimicrobial properties and its potential use in topical formulations for treating acne, which

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often involves bacterial colonization of the skin. It helps establish the appropriate concentration of BPO required to control bacterial growth effectively without causing excessive irritation or other adverse effects on the skin. MIC data also aids in comparing the antimicrobial efficacy of BPO with other agents, providing valuable information for drug development and formulation.

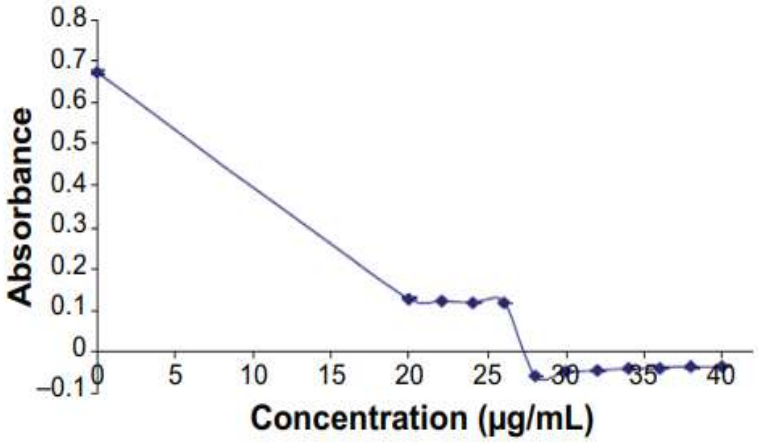

Figure:4 Minimum inhibitory concentration of benzoyl peroxide against Staphylococcus epidermidis

Characterization of niosomes

Characterization of niosomes plays a pivotal role in the development and evaluation of these lipid-based nanocarriers for drug delivery. Through a combination of advanced analytical techniques, researchers can gain valuable insights into the properties and behavior of niosomes. One of the primary aspects of niosome characterization is understanding their morphology and size. Techniques such as Transmission Electron Microscopy (TEM) and Scanning Electron Microscopy (SEM) provide detailed images of niosome structures, allowing researchers to assess their shape and uniformity. Particle size analysis using methods like Dynamic Light Scattering (DLS) further refines this information, providing data on the size distribution of niosomes within a formulation. Zeta potential measurements offer insights into the surface charge of niosomes. This parameter is crucial for understanding their stability, as a higher zeta potential typically indicates stronger electrostatic repulsion between particles, reducing the likelihood of aggregation or coalescence. Encapsulation efficiency assessment helps determine the ability of niosomes to encapsulate and retain drugs. High-Performance Liquid

Chromatography (HPLC) and UV-Visible spectroscopy are commonly employed to quantify the amount of drug loaded within niosomes.

Phase transition temperature, elucidated through Differential Scanning Calorimetry (DSC), provides critical information about the thermal behavior of niosomal lipid bilayers. This knowledge aids in predicting how niosomes will respond to temperature changes during storage or administration. Stability studies involve subjecting niosomes to various environmental conditions over time, helping researchers assess their long-term stability and potential for drug leakage or degradation. These studies inform optimal storage conditions and shelf-life determination. In vitro drug release studies simulate drug release from niosomes under physiological conditions, shedding light on the release kinetics and suitability of niosomes for controlled drug delivery applications.

Conclusion

The development and evaluation of a topical niosomal gel incorporating benzoyl peroxide and tretinoin demonstrated its potential as an effective and advanced treatment for acne vulgaris. The formulation successfully enhanced drug stability, improved skin permeation, and provided a sustained release profile, addressing the limitations associated with conventional topical treatments. Characterization studies confirmed the optimized formulation had suitable vesicle size, high drug entrapment efficiency, and favorable rheological properties, ensuring prolonged drug retention on the skin. In vitro drug release studies indicated a controlled and sustained drug release, reducing the potential for irritation while maintaining therapeutic efficacy. Furthermore, skin permeation studies confirmed enhanced drug absorption, which is critical for achieving effective anti-acne activity. The niosomal gel formulation exhibited excellent spreadability and mucoadhesive properties, ensuring better patient compliance. By reducing systemic side effects and enhancing localized drug delivery, this novel approach presents a promising alternative to traditional formulations. Overall, the study highlights the potential of niosomal-based drug delivery in dermatology, particularly in the treatment of acne, by offering a more effective, stable, and patient-friendly formulation. Further in vivo studies and clinical trials are recommended to validate its efficacy and safety for commercial application in acne management, paving the way for the next generation of topical acne treatments.

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