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Ufasomes: A comprehensive review of design, characterization and applications

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Abstract

Ufasomes are vesicular systems composed of unsaturated fatty acids that self-assemble into bilayer structures in aqueous environments. These vesicles offer a promising approach to drug delivery, particularly for enhancing skin penetration and bioavailability. Ufasomes are advantageous due to their cost-effectiveness, biocompatibility, and ability to encapsulate both hydrophilic and lipophilic drugs. Their superior drug retention and controlled release properties make them ideal carriers for antifungal, anti-inflammatory, anticancer, and osteoarthritic treatments. However, their susceptibility to oxidation and colloidal instability poses challenges for long-term storage and formulation stability. Various preparation techniques, such as thin-film hydration, ensure optimized vesicle formation and drug entrapment. Characterization methods, including particle size analysis, zeta potential measurement, and in vitro release studies, help assess their efficacy and stability. Additionally, in vivo and ex vivo studies demonstrate their potential for enhanced therapeutic outcomes, particularly in transdermal and targeted drug delivery applications. This review provides an in-depth analysis of the formulation, advantages, limitations, and pharmaceutical applications of ufasomes, highlighting their emerging role in modern drug delivery systems.

Keywords: Ufasomes; Vesicular drug delivery; Unsaturated fatty acids; Thin-film hydration; Transdermal delivery

1. Introduction

Ufasomes are vesicles composed of long-chain unsaturated fatty acids, formed through mechanical agitation of an evaporated lipid film in the presence of a buffer solution. These vesicles exist as colloidal suspensions, consisting of fatty acids and their ionized counterparts. Due to their structural properties, ufasomes serve as an efficient drug delivery system, ensuring targeted transport of therapeutic agents to infection sites while minimizing toxicity and adverse effects.[1]

Unlike liposomes, which are primarily made from phospholipids, ufasomes benefit from the abundance and ease of sourcing fatty acids, whereas synthetic phospholipids can be challenging to produce in large quantities. These vesicles can be derived from both unsaturated fatty acids, such as oleic and linoleic acids, and saturated fatty acids, including octanoic and decanoic acids. One of the key advantages of ufasomes is their ability to enhance drug penetration through

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the skin. Unsaturated fatty acids, like oleic and linoleic acids, naturally act as permeation enhancers, further improving drug absorption.[2]

Additionally, incorporating surfactants alongside fatty acids increases skin flexibility, facilitating more efficient drug transport across the skin barrier. Ufasomes also help retain drugs within skin cells, leading to prolonged drug action and sustained therapeutic effects. These features make ufasomes a promising and versatile approach to enhancing drug delivery and skin penetration.[3]

Unsaturated fatty acids, such as oleic and linoleic acids, are known to form vesicular structures in aqueous environments. Similarly, saturated fatty acids with chain lengths between C8 and C12 can also self-assemble into vesicles in a pH-dependent manner. Due to their high solubility, fatty acids can easily integrate into biological membranes, promoting drug absorption in the gastrointestinal tract. This enhancement in bioavailability is likely due to the formation of mixed micelles or their incorporation into chylomicrons.[4] Figure 1 provides the structure of ufasomes.

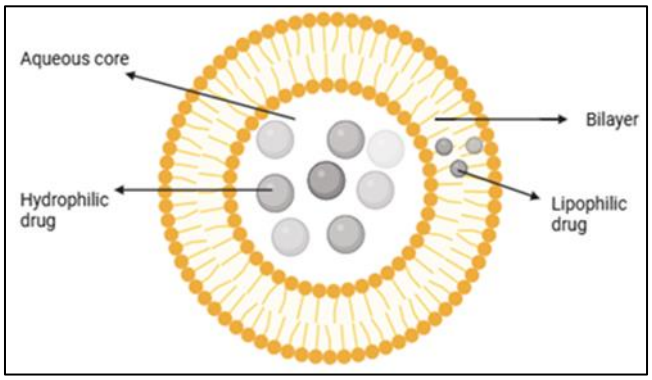

Figure 1 Structure of Ufasomes

Fatty acids play a significant role in enhancing the penetration of bioactive compounds through the stratum corneum. Their ability to improve permeation is influenced by chain length and molecular configuration, with penetration efficiency increasing with chain length up to C18. Unsaturated fatty acids generally exhibit superior skin permeability compared to saturated ones, with cis-isomers being more effective than trans-isomers. However, the potential for skin irritation limits the direct application of fatty acids as penetration enhancers. This challenge is addressed by using fatty acid-based vesicles, such as ufasomes, which serve as efficient carriers for drug delivery.[5]

Ufasomes, composed of fatty acid bilayers, enhance drug transport by merging with skin lipid bilayers, leading to controlled drug release. This strategy not only improves drug permeation but also reduces toxicity, making ufasomes a cost-effective and promising approach for topical drug administration. This study explores the encapsulation of drug in oleic acid vesicles to evaluate their effectiveness as an advanced transdermal drug delivery system.[5]

Ufasomes, made from unsaturated fatty acids, are pH-sensitive vesicles suitable for topical delivery but have lower stability. Transferosomes are highly deformable lipid vesicles designed for excellent transdermal penetration. Liposomes, composed of phospholipid bilayers, are versatile carriers but prone to instability and oxidation. Niosomes use non-ionic surfactants, offering better chemical stability and cost-effectiveness. Ethosomes, containing ethanol, enhance skin permeability but may cause irritation. Solid lipid nanoparticles (SLNs) provide controlled release and high stability, ideal for lipophilic drugs.[6] Table 1 provides a comparison of Ufasomes with other carrier vesicles

Table 1 Comparison of Ufasomes with other carrier system [7–10]

Feature	**Ufasomes**	**Liposomes**	**Niosomes**	**Ethosomes**
Composition	Unsaturated fatty acids	Phospholipids	Non-ionic surfactants	Phospholipids + ethanol
Cost	Low	High	Moderate	High
Skin penetration	High	Moderate	Moderate	Very High

Colloidal stability	Moderate (Prone to oxidation)	High	High	Low (Ethanol-induced instability)
Ease of preparation	Simple	Moderate	Simple	Complex
Encapsulation	Both hydrophilic & hydrophobic drugs	Both hydrophilic & hydrophobic drugs	Both hydrophilic & hydrophobic drugs	Primarily hydrophilic drugs
Applications	Drug delivery, gene therapy, vaccine carriers	Drug delivery, cosmetics, food	Drug delivery, cosmetics	Transdermal drug delivery

1.1. Advantages of Ufasomes

- Prolonged Drug Retention and Reduced Side Effects: Ufasomes enhance drug retention in systemic circulation, enabling sustained release and minimizing adverse effects. This leads to more effective treatments and improved patient outcomes.[11]
- Enhanced Targeted Drug Delivery and Bioavailability: These vesicles facilitate targeted drug delivery, significantly improving the bioavailability of poorly soluble drugs by enhancing their solubility and absorption. This makes ufasomes particularly useful for drugs with low inherent solubility.[12]
- Versatile Drug Encapsulation: Ufasomes can encapsulate both hydrophilic and lipophilic drugs, making them suitable for a broad range of therapeutic applications. Their adaptability allows for the development of various drug formulations.[13]
- Efficient Skin Penetration: Ufasomes exhibit excellent skin penetration properties, making them particularly effective in topical applications. This characteristic is advantageous for dermatological treatments requiring localized drug delivery.[1]
- High Drug Entrapment Efficiency: Ufasomes demonstrate a high drug entrapment efficiency, ensuring a significant portion of the drug remains encapsulated and reaches the target site, thereby enhancing therapeutic efficacy.[13]
- Cost Effectiveness: Unsaturated fatty acids, the primary components of ufasomes, are relatively inexpensive and widely available. This makes ufasomes a cost-effective alternative to other vesicular systems, such as liposomes, which require more expensive lipids and surfactants.[14]

1.2. Disadvantages of Ufasomes

- Susceptibility to Oxidation: Ufasomes are highly prone to oxidation, which compromises their structural integrity and stability, particularly in lipid-based formulations. This susceptibility shortens their shelf life and limits their suitability for long-term storage and therapeutic applications.[15]
- Potential Toxicity from Oxidation of Byproducts: The oxidation of unsaturated fatty acids in ufasomes can generate harmful byproducts, such as peroxides and aldehydes, which may induce cytotoxicity. This poses a significant concern, particularly for systemic applications, where oxidative degradation could impact patient safety.[11]
- Colloidal Instability: Ufasomes are susceptible to colloidal instability, leading to vesicle aggregation, fusion, or rupture. This instability can result in inconsistent drug release, reduced bioavailability, and compromised efficacy, limiting their reliability in drug delivery and other biomedical applications.[16]

1.3. Key Features of Ufasomes

- Self-Assembly: Ufasomes form naturally when unsaturated fatty acids (e.g., oleic, linoleic, or linolenic acid) are diffused in water with an adequate pH.[17]
- Bilayer Structure: Unlike micelles, which are single-layered structures, ufasomes consist of bilayers, making them functionally like liposomes.[18]
- Stability: Ufasomes are generally less stable than conventional phospholipid liposomes and require stabilizing agents or careful control of environmental conditions.[14]
- Encapsulation Properties: They can encapsulate both hydrophilic and lipophilic drugs, making them suitable for drug delivery applications.[15]
- Biocompatibility: Since they are composed of naturally occurring fatty acids, they exhibit good biocompatibility and biodegradability.[19]

1.4. Application of Ufasomes

Ufasomes, vesicles composed of unsaturated fatty acids, have been explored for various biomedical applications.[16] Table 2. exemplifies various drugs incorporated into ufasomal carrier.

- Anti-Cancer Drug Delivery: Ufasomes have been utilized to deliver 5-Fluorouracil for the topical treatment of basal cell carcinoma. This approach aims to reduce side effects such as eczema, itching, and redness by encapsulating the drug within the vesicles.[20]
- Enhanced Skin Penetration: Due to their composition, ufasomes can adhere to the skin's surface, facilitating the transport of lipids from the stratum corneum to the skin's outermost layer, thereby enhancing transdermal drug delivery.[11]
- Improved Bioavailability of Poorly Soluble Drugs: Ufasomes can improve the bioavailability of poorly soluble drugs by encapsulating them within their vesicular structure, ensuring better solubility and absorption.[3]
- Sustained Release Systems: Ufasomes can delay the elimination of rapidly metabolizable drugs, functioning as sustained release systems and maintaining therapeutic drug levels over extended periods.[11]
- Cosmetic Applications: Ufasomes have potential uses in cosmetic development, particularly in formulations aiming for enhanced delivery and efficacy of active ingredients.
- Nutrient Encapsulation: Ufasomes can be employed for the encapsulation of nutrients, protecting them from degradation and improving their bioavailability.

Table 2 Ufasomal drug carrier system prepared by thin film hydration

Drug	Therapeutic Uses	Excipients
Dexamethasone[5]	Dexamethasone is an anti-inflammatory drug which is used for treating ocular disorders such as uveitis, allergic conjunctivitis, and post-corneal surgery recovery. It is also used for skin conditions like atopic dermatitis, allergic dermatitis, eczema, psoriasis, acne rosacea, and phimosis.	Unsaturated fatty acid: Oleic acid Surfactant: Span 20 Solvent: Methanol Hydrating solvent: Phosphate buffer solution (pH 7.4) Gelling agent: Carbopol 940
Terbinafine hydrochloride[4]	Terbinafine hydrochloride is used to treat various skin infections caused by fungi, particularly dermatophytes.	Unsaturated fatty acid: Glyceryl tri oleate Solvent: Dichloromethane Hydrating solvent: pH 5.5 phosphate buffer solution
Clotrimazole[21]	Clotrimazole is a broad-spectrum, less toxic imidazole antifungal agent which is widely used to treat candidiasis.	Unsaturated fatty acid: Oleic acid Solvent: methanol Hydrating solvent: Phosphate buffer solution (pH 7.4) Gelling agent: Hydroxy propyl methyl cellulose
Cinnarizine[22]	Cinnarizine is commonly used to treat cerebral arteriosclerosis, thrombosis, and vertigo disorders.	Unsaturated fatty acid: oleic acid Lipid: Cholesterol Solvent: methanol Hydrating solvent: phosphate buffer of pH 8

		Gelling agent: Hydroxy propyl methyl cellulose K100
Itraconazole hydrochloride[23]	This drug is effective against *Candida albicans* and works by inhibiting lanosterol 14α-demethylase, which disrupts the synthesis of fungal ergosterol. It is used to treat fungal infections such as candidiasis, including systemic and superficial infections.	Unsaturated fatty acid: Oleic acid Lipid: Cholesterol Solvent: Methanol Hydrating solvent: borate buffer (pH 8.5)
Propranolol hydrochloride[24]	Propranolol hydrochloride is a non-selective β-adrenoreceptor blocker used to treat hypertension. It helps regulate cardiac contractions and relaxations, and exhibits immunomodulatory, anti-inflammatory, and antioxidant effects.	Lipid: Cholesterol Surfactant: Span 20, Span 60, Solvent: Chloroform Hydrating solvent: Phosphate buffer solution (pH 7.4)
Etodolac[3]	Etodolac is a non-steroidal anti-inflammatory drug which is recommended for direct application to the affected area to provide localized pain relief, minimizing the systemic side effects typically associated with oral NSAIDs.	Unsaturated fatty acid: Oleic acid Surfactant: Tween 80 Solvent: Methanol, Triethanolamine Hydrating solvent: phosphate buffer (pH 7.4) Gelling agent: Carbopol 940
Oleuropein[19]	Oleuropein has been found to possess antiviral activity against certain viruses, hypoglycaemic effects beneficial for diabetes treatment, anti-aging properties like vitamin E, and anti-inflammatory effects by inhibiting lipoxygenase activity.	Unsaturated fatty acid: Oleic acid, linoleic acid, phospholipid 90 G Hydrating solvent:
Voriconazole[25]	Voriconazole is a broad-spectrum triazole antifungal agent that inhibits fungal cytochrome P450-mediated 14α-sterol demethylation, a key step in ergosterol biosynthesis. It has high antifungal potency against Candida species and fungicidal activity against all Aspergillus species.	Unsaturated fatty acid: Sodium oleate Other Lipid: cholesterol Solvents: chloroform, methanol Hydrating solvent: phosphate buffer (pH 7.4) Gelling agent: HPMC
Methotrexate[1]	Methotrexate is a commonly used disease modifying anti-rheumatic drug in the treatment of Rheumatoid arthritis and effectively reduces associated inflammation.	Unsaturated fatty acid: Oleic acid Surfactant: span 80 Solvent: methanol Hydrating solvent: alkaline borate buffer (pH 7.4) Gelling agent: Carbopol 940

2. Methods of Preparation

- Thin film hydration method: The thin film hydration method is a widely used approach for the preparation of ufasomes. In this technique, essential vesicle components, including fatty acids, surfactants, and stabilizers, are dissolved in an organic solvent system, typically a 1:1 mixture of chloroform and methanol. The prepared solution is then subjected to rotary vacuum evaporation to ensure complete solvent removal and the device is then set to a specific Rotation Per Minute and temperature, beginning to rotate under vacuum conditions, resulting in the formation of a thin lipid film. This film is subsequently hydrated with phosphate-buffered saline (PBS) pH 7.4 to generate a vesicular dispersion.
- To obtain uniform and stable vesicles, the dispersion is sonicated for a specific duration. For improved permeation and topical application, the optimized vesicular dispersion is incorporated into a hydrogel matrix using a suitable polymer such as hydroxypropyl methylcellulose (HPMC) or Carbopol 940. This method enhances drug stability, retention, and controlled release, making ufasomes an effective carrier for drug delivery.[25]
- Reverse phase evaporation method: In the reverse phase evaporation method, lipids and surfactants are first dissolved in an organic solvent to form the oil phase. Simultaneously, an aqueous phase containing the desired component is prepared separately. These phases are then combined to create an emulsion, followed by solvent evaporation under reduced pressure to produce a water-in-oil emulsion. To achieve a thick, gel-like consistency, an aqueous solution is introduced, and the mixture is homogenized and vortexed. The system is then allowed to stabilize, promoting vesicle formation. Further processing steps, such as sonication or extrusion, are performed to refine the size and uniformity of the vesicles.[26]
- Vortex mixing: In the vortex mixing method, a fresh stock solution containing 10% oleic and linoleic acid in chloroform is prepared and maintained at 200ºC. To form a thin lipid film, 0.2 mL of this stock solution is placed in a test tube and dried using a nitrogen stream, followed by evaporation under a water pump. Once dried, 0.2 mL of a 0.1 M Tris-hydroxymethyl aminomethane buffer (pH 8-9) is introduced, completely dissolving the fatty acid layer and resulting in the formation of a ufasome solution.[26] Table 2. delivers various excipients in the preparation of Ufasomes.

2.1. Significance of Ufasome Components

Ufasomes are composed of several key components, each contributing to their structural integrity and functionality. Phospholipids form the bilayer membrane, ensuring stable encapsulation of drugs and bioactive compounds. Unsaturated fatty acids, the primary building blocks, self-assemble at specific pH ranges, allowing the formation of vesicular structures capable of carrying both hydrophilic and hydrophobic molecules. To regulate vesicle flexibility and permeability, cholesterol is incorporated, modulating the membrane's physical properties. Stability is further enhanced by stabilizers, which prevent vesicle aggregation, and surfactants, which improve dispersibility and uniform distribution. The formulation process often involves solvents, excipients, and co-solvents, which facilitate lipid dissolution and enhance the solubility of poorly water-soluble drugs. Additionally, buffer solutions help maintain an optimal pH environment, preserving vesicle stability, while antioxidants protect the formulation from oxidative damage, prolonging the shelf life of ufasomes.[18]

2.2. Characterization of Ufasomes

- Particle Size (PS) and Polydispersity Index (PDI) Measurements: Diluted ufasome formulations were analysed using a Malvern Zetasizer at 25°C, measuring PS and PDI in triplicate. The PS of ufasomes typically ranges from 200 to 500 nm for different ufasomes formulation. Factors such as lipid composition, pH, and preparation methods influence the size distribution.[27]
- Determination of Encapsulation Efficiency (%EE): The %EE of drug loaded ufasomes was determined using the direct method and indirect method like ultracentrifugation, dialysis and analyzed spectrophotometrically at predetermined λmax. EE values for ufasomes range from approximately 50% to 80% for different formulations.[23]
- %EE = Measured amount of drug / Theoretical amount of drug× 100
- Surface morphology: Scanning electron microscopy and transmission electron microscopy is used to study the surface morphology. Ufasomes were roughly spherical with smooth surfaces.[21]
- Zeta potential (ZP): The electrophoretic mobility of particles was measured to quantify the surface charge, or zeta potential using Nano-particle analyser. Each measurement was performed at least in triplicate. ZP values in the range of -30 mV to -60 mV, indicating good colloidal stability. Terbinafine-loaded ufasomes: - 45.37 ± 0.42 mV, suggesting high stability, Itraconazole-loaded ufasomes: -40 mV to -55 mV, depending on the fatty acid composition.[12]

- Differential Scanning Calorimetry (DSC) Analysis: The thermal properties of pure components and lyophilized formulations were evaluated using a DSC instrument, providing insights into their thermal stability and phase transitions. Terbinafine-loaded ufasomes exhibited a disappearance of the drug's melting peak at 178.43°C, confirming successful encapsulation and reduced crystallinity.[28]
- Fourier Transform Infrared (FTIR) Spectroscopy: FTIR spectroscopy was employed to explore potential interactions between the drug and its excipients. The analysis was carried out using the Brucker IR-Affinity-1 FTIR spectrophotometer.[25]
- Percentage Yield: The percentage yield was then calculated using the formula:

$$\text{Percentage Yield} = (\text{Practical Yield} / \text{Theoretical Yield}) \times 100$$

Typical values range between 60% and 90%, indicating good formulation yield.[3]

2.3. *In Vitro* Drug Release Studies

For the in vitro dialysis of ufasomes, a dialysis tubing cellulose membrane with a flat width of 10 mm (0.4 in) is utilized. The withdrawn samples were filtered and analysed spectrophotometrically at 283 nm to determine the drug release profile.[4]

The drug release rate and kinetics from ufasomes using Franz diffusion cells, which have donor and receptor compartments separated by a 50 nm polycarbonate membrane. The donor compartment contains 1 ml of ufasomal dispersion, and the receptor compartment holds PBS at pH 7.4, stirred continuously at 37°C. At specific time intervals, aliquots were withdrawn from the receptor compartment and replaced with fresh PBS.[3] Glyceryl oleate ufasomes encapsulating terbinafine hydrochloride[4], the optimized formulation demonstrated a cumulative drug release of approximately 55.48% over 30 hours, following zero-order kinetics.[4]

Preparation of Gel: Various polymers, such as Carbopol 934 and 940, HPMC, etc., were used in varying ratios as the gelling agent during the preparation of the gel. The agents were combined while being stirred continuously to create a gel of the right consistency. The conventional gel was prepared by dispersing the drug into the gel matrix.[3] Evaluation parameters for the gel are listed in Table 3.

Table 3 Evaluation parameters for Ufasomal gel

Evaluation of Ufasomal Gel	Method
Physical Evaluation	The prepared formulations were confirmed by its properties like colour, clarity, appearance.
Determination of pH	Digital pH meter
Spread ability	Slip and drag method S= m × l/t where, S - spread ability, m - weight tied to upper slides, l - length of the glass slide t - time taken in sec
In Vitro Drug Release	Franz diffusion cell by applying cellophane membrane And Measured Using UV-spectrophotometer
Drug Content	measured spectrophotometrically slope Drug content = Absorbance/ × Dilution factor × 1/1000
Percentage Yield	Percentage yield = Practical yield/Theoretical yield*100

2.4. *Ex Vivo* permeation studies

For permeation studies, the dorsal skin of newborn rats (weighing 70 ± 20 g) is carefully excised after euthanasia. Any excess fat attached to the dermal surface is carefully removed. The skin samples are then stored in a freezer at −20°C until needed for subsequent permeation experiments. Rat skin was equilibrated in phosphate buffer for 3 hours before diffusion testing. Propranolol HCl ufasomes, chitosan-ufasomes, or a control solution were applied, with receptor fluid sampled at intervals and analysed at 290 nm. The cumulative drug permeation was plotted, and key parameters, including the permeability coefficient, drug flux, and 24-hour cumulative amount, were calculated. The enhancement index was determined by comparing the Kp of ufasomes to the control solution. Chitosan– ufasomes significantly

enhanced the skin permeation of propranolol HCl compared to the propranolol HCl solution, shows higher drug diffusion and retention.[24]

2.5. Histopathological and confocal imaging

Sheep nasal mucosa tissue was excised through a longitudinal incision along the lateral nasal wall, washed with distilled water, and stored frozen for up to two weeks before use in histopathological studies and confocal imaging. Histopathological examination compared the effects of a Cinnarizine-loaded ufasomal gel and PBS on nasal mucosa. Tissues were treated for 12 hours, processed, stained, and analyzed microscopically. The gel caused mild epithelial changes without severe irritation, and the lamina propria remained intact, indicating good intranasal tolerability.[22]

2.6. *In Vivo* studies

2.6.1. Anti-inflammatory activity

Male Wistar rats (150–200 g, n = 15) were used in a carrageenan-induced paw edema model. Baseline paw volumes were measured, and topical formulations (plain gel, ufasomal gel 0.5% w/w, and marketed formulation 0.5% w/w) were applied at 1 mg/kg over a 1 cm^2 area. Inflammation was induced by injecting 0.05 mL of 1% carrageenan into the right hind paw, with saline in the contralateral paw as a control. Paw volumes were recorded hourly for six hours. The ufasomal gel of dexamethasone showed superior anti-inflammatory effects. The ufasomal gel demonstrates superior anti-inflammatory efficacy in a carrageenan-induced paw edema model, significantly it reduces paw swelling compared to the plain gel and marketed formulation.[5]

2.6.2. Antifungal activity

Male guinea pigs (400–450 g) Animals were divided into three groups (n=4): one received a marketed gel (Sample A), another received drug loaded oleic acid vesicles (Sample B), and the control group received phosphate buffer (pH 5.5). Treatment was applied once daily for three days. Colony counts were assessed at baseline (Day 0) and post-treatment (Days 1, 3, and 5) by culturing excised skin homogenates on Sabouraud Dextrose Agar plates. Oleic acid vesicular dispersion of clotrimazole shows a significant colony count reduction even after five days, likely due to its reservoir effect in the dermal layer, makes it more effective than the marketed gel.[2]

3. Conclusion

Ufasomes have emerged as a promising drug delivery system due to their ability to enhance drug penetration, improve bioavailability, and provide controlled drug release. Their structural composition, made from readily available unsaturated fatty acids, makes them a cost-effective alternative to phospholipid-based vesicles like liposomes. The ability of ufasomes to encapsulate both hydrophilic and lipophilic drugs further expands their potential applications in pharmaceutical formulations.

Despite their many advantages, challenges such as oxidative degradation, colloidal instability, and potential toxicity from oxidation byproducts need to be addressed. Various formulation strategies, including the incorporation of stabilizers and surfactants, have been explored to improve the stability and efficacy of ufasomal formulations. Characterization studies confirm their efficiency in drug entrapment, sustained release, and permeation enhancement, making them a viable option for topical, transdermal, and systemic drug delivery.

Both in vivo and ex-vivo studies highlight the significant therapeutic potential of ufasomes in delivering antifungal, anti-inflammatory, and other bioactive agents. With further research and optimization, ufasomes can be refined for clinical applications, offering a novel and efficient approach to targeted drug delivery with reduced side effects and improved patient outcomes.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors report no conflicts of interest in this work.

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