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REVIEW ARTICLE

A Vesicular Drug Delivery for Futuristic Drug Delivery Applications: Ufasomes

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ABSTRACT

In vesicular drug delivery devices, aqueous cubicles are covered by one or more concentric bilayers comprised of amphiphilic molecules. Due to their ability to localise drug exercise to the website online or organ of action, they are an incredible distribution strategy for focused medicine transport. The vesicular drug delivery method keeps the drug motion moving at a steady pace. The body's opioid frequency is thereafter maintained while the negative side effects are diminished. Vesicles made of unsaturated fatty acids are known as ufasomes. They are closed lipid bilayer suspensions of fatty acids and their ionised species that have their pH regulated. Fatty acid vesicles are regularly produced by the lipid movie hydration system. Oleic acid is the fatty acid that produces ufasomes most frequently. Unsaturated fatty acid vesicles are suspensions of fatty acid-based closed lipid bilayers, with the pH range in which their ionised species can exist being between 7 and 9. Recent developments might make it possible to create ufasomes with customizable properties such a wider pH range, resistance to divalent cations, and greater stability.

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INTRODUCTION

Ufasome is a novel method for improving opioid skin absorption. In the production of ufasomes, unsaturated fatty acids like linoleic and oleic acids are used as herbal permeability enhancers. Fatty acids and surfactants are frequently used to improve skin flexibility and medication delivery through the skin membrane. Ufasomes have increased medicinal drug retention characteristics inside the skin cell membrane for a considerable amount of time. Little fatty acid vesicles are known as ufasomes. While the carboxyl groups of membrane fatty acids are in touch with water, their hydrocarbon tails are orientated closer to the interior of the membrane, forming a bilayer structure. Ufasomes are closed lipid bilayer solutions made primarily of fatty acids, and they have a soapy consistency. In nature, they normally stay between the pH range of 7 to 9.¹

Colloidal suspensions of closed lipid bilayers made up of fatty acids and their ionised species are known as fatty acid vesicles (soap). They are situated in a tiny area inside the ternary section layout of the appropriate fatty acid-soap mixture's chain melting temperature (Tm). The nonionized impartial structure and the ionised structure are the two types of amphiphiles that are typically present in fatty acid vesicles (the negatively charged soap). The stability of the vesicle depends on the ratio of nonionized unbiased structure to ionised structure. Fatty acid vesicles are

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undoubtedly "fatty acid/soap vesicles," but we just refer to them as fatty acid vesicles for the sake of simplicity. Gebicki and Hicks first described the creation of fatty acid vesicles in 1973, and the vesicles formed were initially known as "ufasomes" or "unsaturated fatty acid liposomes"^{1,2} Later studies have demonstrated that fatty acid vesicles now contain saturated fatty acids like octanoic acid and decanoic acid in addition to unsaturated fatty acids like oleic acid and linoleic acid. Phospholipids are frequently employed in the manufacture of liposomes.

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Figure 1: Structure of Ufasomes

Advantages of Ufasomes

- 1. Decreases toxicity while lengthening the duration a medication is in the bloodstream.
- 2. The medicine can also be absorbed selectively because it is quickly delivered to the source.
- 3. Enhances bioavailability, particularly for medications that are poorly soluble.
- 4. Medicines that are lipophilic or hydrophilic can also be incorporated into ufasomes.
- 5. Acts as a constant launch mechanism by delaying the eradication of quickly metabolizable compounds.
- 6. If applied topically, the chemical will surprisingly permeate.
- 7. Because fatty acids are widely available, ufasomes are substantially less expensive than liposomes and niosomes.
- 8. The medicine's great entrapment is satisfactory.2

METHODS OF PREPARATION

The additives used in the preparation of ufasomes

are depicted (table 1).

Thin Film Hydration Method

Vesicle production happens in this method over a limited pH range. Fatty acids are combined with a natural solvent in a flask with a circular rim. For this approach, considerable fatty acid attention is necessary. The liquid is vaporized before the natural solvent has completely evaporated. Finally, using a pH-appropriate buffer, a thin fatty acid layer is formed and hydrated.

By Addition of Alcohol

This method creates fatty acid vesicles by including an alcohol with the same chain length as the fatty acid. The fatty acid vesicles are secure with this method over a wide pH range, which is a significant advantage. The presence of liposomes and pre-added fatty acid vesicles may also

Table 1: Additives used in ufasome preparation

enhance vesicle production. This method saves time because it takes a while to complete this process.

Autopoetic Process

Fatty acid vesicles form as a result of the random pH change that occurs when an aqueous fatty acid solution is added to a water-buffered solution. Vesicles are capable of forming when 50% of a fatty acids carboxylic acids ionize. In opposition to the aqueous compartment, the hydrocarbon chain forms a bilayer relationship that reduces water contact.⁴

Key Issues in Manufacturing of Ufasomes

Selection of fatty acid

12 to 22 carbon fatty acids seem suitable for the introduction of secure ufasomes, according to investigations of herbal membrane phospholipids and data from stress area measurements on fatty acid floor films. In reality, since C-18 acids showed the greatest promise in preliminary studies, the majority of knowledge used to be focused on them. These requirements are only met by oleic acid (cis-9-octadecenoic acid) and linoleic acid (cis-9,12 octadecenoic acid), which can form membranes. In an oleic acid membrane, palmitic acid can be tolerated up to 33 percent by weight but stearic acid can only be tolerated up to 5 percent. Low concentrations of oleic, linoleic, or stearic acid amides in charged membranes had minimal effect on the preparations. The results of stability tests showed that oleic acid was free of peroxide disease for at least 6 weeks while linoleic acid created significant amounts of peroxide within 2-3 weeks.

Addition of Cholesterol

LDL cholesterol has a unique power to change the fluidity, flexibility, and permeability of membranes in lipid vesicles. It simply closes the gaps caused by the uneven packing of various lipid molecules. When ldl cholesterol levels are multiplied, vesicles' capacity to retain solute quickly

declines. In addition, there is no increase in membrane impermeability at any level of ldl cholesterol. Researchers compared glucose leakage from ufasomes with built-in ldl cholesterol of 17 percent to leakage from spheres with included cholesterol of 17 percent. According to their findings, glucose leakage from vesicles containing 17 percent more ldl cholesterol was once shown to be greater than glucose leakage from oleic and linoleic acid ufasomes without cholesterol.

pH

Fatty acid vesicles may also develop at a specific pH range (7-9), where around half of the carboxylic acids are ionised. Fatty acids form unstructured precipitates below this range while becoming too soluble above it. At a full concentration of 80 mM, the oleic acid/oleate method titration curve will distinguish three zones for the production of micelles, vesicles, and oil droplets. The most frequent aggregation species at higher pH values are micelles, which have a higher ratio of ionised to protonated molecules. At lower pH values, oil droplets become stronger. Just slightly higher concentrations than the integral vesiculation concentration, or CVC, at which vesicle production is observed make fatty acid vesicle shapes much easier to detect. Monomers and non-vesicular aggregates combine at the necessary vesiculation concentration to form colloidal vesicle suspensions with a bilayer structure. It's also important to mention that vesicles form in a random sample with a wide size range when a fatty acid micellar solution is diluted to an unbiased pH.

Selection of buffer

The ufasome education buffer tris hydroxymethyl aminomethane is frequently utilized. On the other hand, spheres are formed using solutions of borates, glycinehydroxide, and bicarbonate. The type of solute to be included determines the buffer to be utilized. For instance, ufasomes made in bicarbonate no longer retained glucose in vesicles, while preparations made in borate may no longer need to be tested for retention due to the development of a glucose buffer complex. 1 mg of fatty acid needs to be converted into ufasomes using 0.1 ml of pH 8 0.1 M tris.

Electrolyte

The majority of electrolytes inhibit ufasome production. The spheres may also be exposed to phosphate or chloride solutions after stabilizing them in the appropriate buffer, as long as the occluded glucose is maintained.

Peroxidation

The normal bilayer form of fatty acid molecules is disrupted by peroxidation, which has a significant effect on the membranes of ufasomes. By oxidizing a heavy hydrophilic group, the hydrophobic membrane inside is distorted, allowing water-soluble molecules to flow more easily. The way of practise may also have a significant impact on the amount of fatty acid peroxidation. For the brief period needed for hand vortexing, peroxidation stopped progressing. After being exposed to 30-W irradiations at some point in a more intense ultrasonic resuspension, linoleic acid began to oxidize at a rate of 0.1 percent per minute in air-saturated buffers. Even though the maximum exposure time was three minutes, this method shouldn't result in significant oxidation of oxidation-sensitive linoleic acid. However, according to Hicks and Gebicki, it has been demonstrated that nitroxide radicals, butylated hydroxytoluene, and -tocopherol could resist linoleic acid membrane peroxidation.

Divalent Cations

Both enzymatic and nonenzymatic catalytic processes are used in lipid peroxidation (LPO). In non-enzymatic lipid peroxidation, transition steel ions play a crucial role. Only a few number of metals can accelerate the peroxidation of unsaturated lipids with a valency alternative that only calls for one electron transition. It has been established that nonvariable valence kingdom metals, like calcium, magnesium, and zinc, which are not capable of redox-coupled homolysis, affect lipid peroxidation. LPO is affected by calcium ions in a biphasic manner, with the potential for both stimulation and inhibition. Researchers looked into the biphasic motion of calcium in ufasomes and liposomes, which are made from egg yolk lecithin (from linoleic acid and methyl linolenate). Previously, the presence of ascorbate, hydroperoxide, and iron all contributed to the occurrence of LPO in liposomes and ufasomes. Ca displaced some Fe ions and increased awareness of free Fe ions, which are immediately concerned in LPO catalysis at low concentrations, by interfering with negatively charged lipid agencies (phosphate organizations of lecithin, carboxyl businesses of linolenic acid). This caused LPO to precipitate in lipids. It used to be necessary for Ca to interact with superoxide anion radicals at high quantities in order for it to have an inhibitory impact. This biphasic effect on LPO is no longer limited to Ca ions because other cations with highcost densities can also release Fe ions attached to negatively charged lipid structures and interact with superoxide free radicals. In the absence of Ca ions, LPO was activated by adding La ions to linolenic acid ufasomes at a rate equal to Fe ions. The mixed motion of equimolar Ca and La concentrations used to be affected by the prevention of linolenic acid peroxidation (where their whole awareness surpassed that of Fe).5

Characterization of Ufasome

Particle Size and Size Distribution

Using photon correlation spectroscopy, a particle dimension analyzer is used at constant angles of 90° and 25° to assess the common diameter and measurement dispersion of ufasome suspensions. The suspensions had been surpassed across a polycarbonate membrane following phosphate buffer dilution (pH 7.4). This is done to limit interference from particulate count numbers till sizing.

Shape and Surface Morphology

With the aid of transmission electron microscopy, the morphological characteristics of sphericity and the accumulation of drug-loaded ufasomal dispersion may also be investigated (TEM). One drop of the selected ufasomal dispersion can also be tested on a copper grid covered in carbon film and negatively stained with phosphotungstic acid at a 1 percent concentration. The pattern is allowed to dry at room temperature for 10 minutes prior to TEM inspection.

Differential Scanning Calorimetry

Comparative Scanning Calorimetry is used to determine the physical state of the material inside the oleic acid vesicles. Positioning the vesicles in a conventional aluminum pan and scanning them at a rate of 2°C/min.

Entrapment Efficiency

The effectiveness of the drug's entrapment may also be evaluated by ultracentrifugation at 25000 rpm for three hours at 4°C. UV spectroscopy can be used to measure the supernatant's entrapment efficiency as well. The following calculation can also be used to determine the proportional amount of the entrapped medication:

Entrapment effectivity $(%) = (Amount of drug brought)$ at the start - Amount of drug decided in the filtrate

spectrophotometrically) / Amount of drug brought at the beginning \times 100

In-vitro Drug Release

The goal of this research is to determine a drug's release kinetics the rate at which it leaves ufasomes and how rapidly it does so. Franz diffusion cells can also be used to do this. The Franz diffusion cell has two cubicles: one for the donor and one for the receptor. These two compartments are separated by a polycarbonate membrane with pores that are 50 nanometers wide. The receptor compartment contained phosphate-buffered saline (PBS), pH 7.4, which was stored at 37°C and stirred on a regular basis using a magnetic stirrer. The donor compartment contained 1 ml of ufasomal dispersion. At predetermined times, aliquots of the samples are taken out and replaced with equal amounts of sparkling PBS (pH 7.4).⁶

pH-Dependent Stability

The effect of pH on balance and drug launch activity was examined by incubating optimized vesicular dispersion with buffers of pH 8.5, 7.4, 6.5, and 5.5. The samples are collected at regular intervals and centrifuged for 30 minutes at 14,000 rpm. The utilization of the supernatant may also be studied together with the free medication produced. Use the following method to determine how much of a medication has been leached:

% Drug subtle = Amount of free drug / Total drug \times 100

Dynamic Nature of Ufasomes

Fatty acid vesicles have a complicated structure that is one of their most distinctive features since they are made of single-chain amphiphiles. Fatty acid vesicles differ from conventional vesicles made of double-chain amphiphiles and micelles made of single-chain surfactants due to their dynamic properties. The fact that a variety of fatty acid aggregates can be created by changing the protonation/ ionization ratio of the terminal carboxylic acid. The kinetics of ufasome production is a topic of research. By dialyzing fatty acid/soap monomers through a cellulose acetate membrane, the formation kinetics of micelles and vesicles from a saturated fatty acid/soap monomer solution have been contrasted. Starting with an uneven distribution of fatty acid/soap molecules between two chambers separated by way of a dialysis membrane, one containing aggregates (micelles or vesicles) and the different containing simply the buffer solution, the price of attainment of equilibrium was once determined. The fatty acid/soap contents in each chamber were the same, and the diffusate chamber generated micelles. But in the case of vesicles, reaching an equilibrium used to be seriously hampered (the awareness in the diffusate accelerated very slowly after the answer used to be saturated with monomers). Micelles are significantly less cognizant of amphiphiles than are vesicles. According to the findings of dialysis tests using fatty acid vesicles, producing fatty acid vesicles has a significantly higher power barrier than generating fatty acid micelles. Combining an intermediate pH buffer solution with an alkaline cleaning soap solution is a common method for producing fatty acid vesicles. Oleic acid/sodium oleate vesicles form spontaneously when sodium oleate micelles are added to a buffered solution with a pH of 8.5 due to the partial protonation of the oleate molecules caused by the pH reduction from roughly 10.5 to 8.5. Measurement and lamellarity of the vesicles produced are polydisperse. When buffered vesicles are exposed to alkaline micelles, fatty acid vesicles increase on their own.7

Stability Consideration in Ufasome Formulation

It is crucial to reduce the free electricity of the fatty acid-water device for the long-term survival of ufasome membranes. Because the acids begin a separate portion at pH eight, the membrane no longer increases on its own. Under the right conditions, even moderate mechanical agitation may encourage the production of bilayers. The increased entropy of water brought on by the hydrophobic interactions of the directed hydrocarbon chains accounts for a sizeable portion of the power released in this phase. The intriguing contact is inverted in the bilayer as a result of the ionised carboxyl head groups' mutual attraction for one another. Electrolytic dissociation reduces the stability of fatty acid films and may also result in rupture. The presence of screening counter ions minimizes cost repulsion by lowering the degree of head team dissociation, creating secure complexes between protonated and ionised carboxyl headgroups, or lowering the degree of head team dissociation. Any of these mechanisms may also help to stabilize the ufasome membrane. When the pH at the particle floor is dropped, the discount of lateral cost repulsions occurs, which is advantageous to membrane stability. In many cases, ionization reduces membrane stability. To begin with, in contrast to anions, protonated molecules are almost insoluble in water. The common distance between fees will increase by around 40%, decreasing columbic repulsions, when the second cost is removed from a movie of tightly packed headgroups. This reduces lateral headgroup repulsion. Third, a series of closely bound complexes are produced by protonated acid molecules and anions, with a 1:1 complex being the most frequent. The entropy of demixing associated with dimer formation, free strength decrease caused by the formation of hydrogen bonds between protonated and ionised carboxyl groups, and changes in free electricity caused by hydrophobic contacts make up the strength for binding. The headgroup hydrogen bonding with water, difficult synthesis of ionised and impartial acid molecules, and hydration of dissociated carboxyl groups all contribute to the stability of ufasome membranes. Additionally, the same hydrophobic and dispersion associations that bind micelles and membrane interior regions also bind fatty acid hydrocarbon regions.⁸

Microscopic Studies

Using electron microscopy on sectioned vesicular structures, the connection of organic membrane components like fatty acids and phospholipids was previously shown.

However, it was long widely believed that the necessary staining and fixing required strong chemicals, which might also cause distortion of these intricate structures, resulting in loss of definition and the fabrication of items. Much fewer abrasive techniques may also be used to allay these worries. Freeze-fracture is one of the most successful methods for addressing herbal causes. The method of detecting birefringence is much more delicate. According to electron microscopy, negatively stained specimens that were utilized to learn about the ufasomes form were no longer able to survive the educational processes. Both attempts to stain ufasomes for electron microscopy with neutralized potassium phosphotungstate failed to yield specimens with any indoor structure.

Freeze fracturing and etching

After being equilibrated with 17 percent glycerol for 10 minutes, the ufasome suspension is frozen. The Ufasome suspensions are then abruptly frozen in copper helmets filled with Freon and subsequently preserved in liquid nitrogen. Fracturing occurs in a Balzers microtome at 110 °C and 2 10-6 Torr pressure. Etching occurs in the neighborhood of 100 °C for one minute. After cutting, a three nm-thick platinum and carbon coating is applied to the fracture face at a 45° angle. The most amazing method of cleaning them involves floating copies off the steel helmet into water that has been mixed with methanol till the result is 80 percent alcohol. Each fatty acid warning indication disappeared in less than 30 minutes. The copies are then examined using an electron microscope from Hitachi, model HS8. The researchers claim that there used to be no distinction between ufasomes generated from oleic or linoleic acids in terms of appearance. Because ufasome preparations had an excessive amount of water, ice made up a significant portion of the freeze-damaged face, which had a very uneven surface. Etching the surface produced a distinct separation of the ice and particle surfaces, especially if the ufasomes had been pre-equilibrated in glycerol. While the underlying ice is typically grainy, the fatty acids that have been exposed on the outer and internal surfaces are smooth. The area between the membranes is additionally rough, indicating that it was once in the past flooded.

Birefringence

The wide variety of intermembrane lengths found in ufasomes can also be used to characterize the difference in birefringent particle frequency. Various varieties of birefringence seen in multi-lamellar particles often have outstanding or dreadful intrinsic variables. Lipid molecules placed perpendicular to the membrane surface generate a high-quality signal aspect, but membranes next to one another aligned parallelly give a poor "shape" aspect. The

degree of birefringence increases with the distance between adjacent membranes. Large water-filled spheres or irregular multi-membrane particles are significantly more regular than symmetrical particles with strong birefringence, according to freeze-etched ufasome preparations.⁹

Recent Innovations in Conventional Ufasomes

Due of concerns about the colloidal stability of carboxylic acid vesicles, ufasome applications in pharmaceutical shipping have largely gone untapped. However, several recent studies have shown that utilizing unique fatty acid types or combining a number of surfactants may also improve the dispersion of a given treatment.

New Type of Fatty Acids

Between pH 8.5 and 9, the fatty acid cis-4,7,10,13,16,19 docosahexaenoic acid (DHA) self-assembles into vesicles.

Extension of the pH Range

Given that only about half of the carboxylic acid needs to be ionised, a narrow pH range is typically ideal for the formation of fatty acid vesicles. However, the pH spectrum may also be broadened by using the following new techniques.

Amphiphilic additives, such as linear alcohols or a surfactant containing a sulfate or sulfonate head group

Decanoic acid and decanoate mixes are used to make vesicles at pH values between 6.4 and 7.8, however sodium dodecylbenzene sulfonate can also be added to lower the pH to at least 4.3. (SDBS).

Alter the scale of the hydrophilic head team of fatty acids synthetically

Fatty acids with an oligo (ethylene oxide) unit intercalated between the hydrocarbon chain and the carboxylate head team have been shown to enhance vesicle balance at lower pH levels. A large polar neighborhood has two effects: it lowers the pH range where vesicles may also grow and the segment switch temperature.

Insensitivity towards Divalent Cation

Even at low concentrations, divalent cations like Ca and Mg cause vesicle precipitation. Fatty acid glycerol esters can also be added to stabilize fatty acid vesicles when ionic solutes are present.

Enhancement of Stability by means of Cross-linking Fatty Acid Molecules by means of Chemical Bonds

To improve the consistency, a polymerizable fatty acid (such as sodium 11-acrylamidoundecanoate: SAU) may also be used. It was discovered that polymeric SAU vesicles *Mixture of Fatty Acid Vesicle and Surfactant-Based Vesicles* Tetradecyltrimethylammonium hydroxide (TTAOH) and fatty acids serve as the structural foundation for mixed vesicles. Unilamellar and multilamellar vesicles appeared after TTAOH and fatty acid had been combined in almost equal amounts.¹⁰

Application of Ufasomes

It is also possible to transdermally administer a variety of therapies using drug-loaded ufasomes. Anti-inflammatory, antifungal, anti-osteoarthritic, anti-cancer, and other medications loaded in ufasomes have all been administered transdermally.

Anti-fungal Drugs

For the transdermal delivery of these medications, innovative formulations such as niosomes, liposomes, ethosomes, microemulsions, and micelles have been created to solve the limitations of conventional formulations, such as allergic reactions and low penetration capability. Ufasomes are more sophisticated devices created specifically for this use. According to an in-vitro drug launch investigation, the medication that was once released from the ufasomal dispersion was sustained. An in vivo experiment showed a five-day drug release from ufasomes. This shows that it is suitable for long-term treatment, unlike other commercially available formulations.

Anti-cancer Drugs

The US Food and Drug Administration has approved the topical treatment for basal cell carcinoma with 5-fluorouracil (5-FU) (BCC). The advertised recipe has a history of causing skin irritation, eczema, redness, and poor skin penetration. Since the drug is contained inside the vesicles, ufasomes are used to reduce adverse effects. They have the potential to both delay the administration of medications while also increasing opioid penetration. The fatty acid vesicles had remained largely intact in the refrigerator. Ex-vivo investigations on skin and pores penetration revealed that the fatty acid vesicles entered the stratum corneum and preserved the epidermal layer's fabric.

Anti-inflammatory Drugs

The use of non-steroidal anti-inflammatory medicines (NSAIDs) is the first phase of rheumatoid arthritis (RA) therapy (NSAIDs). Slow-acting disease-modifying antirheumatic drugs (DMARDs) are now recommended for the early treatment of RA in order to prevent or limit

joint deterioration. When fatty vesicles were used instead of a basic drug solution or Carbopol gel, a three to four times greater amount of medication entered through rat skin. According to a study on the penetration of fatty acid vesicles into the skin, when they are used, up to 50% of the prescribed amount can be found there. Consequently, applying this technique may also aid in reducing RA inflammation. When fatty acid vesicular gel was combined with pure treatment gel, the transdermal penetration was found to be 4.7 times higher. When the fatty acid vesicular gel was administered in conjunction with an equivalent amount of commercial product, there was once a significant reduction in edoema. In order to cure inflammation, pharmaceutical gels based solely on fatty acid vesicles may also be superior to currently available gels.

Anti-osteoarthritic drugs

The existence of synovial fluid, which lubricates joints, and the generation of collagen and proteoglycans, both of which are present in the human body, are essential for joint regeneration. Taking glucosamine supplements promotes the body to create more of them. Glucosamine has so long been recommended for the treatment of osteoarthritis. As a result, fatty glucosamine sulphate vesicles are packaged and administered in carbopol gel for topical use to treat osteoarthritis. Rats responded to the treatment six times more favorably in the vesicle-based gel than in the straightforward carbopol gel. The medication used to frequently be printed on a gel made of fatty acids. This combination can therefore be used as a depot treatment for osteoarthritis.¹¹

CONCLUSION

The pH range of ufasomes, which are fatty acid-based solutions, is constrained. Fatty acid molecules in ufasomes have their carboxyl ends in contact with water and their hydrocarbon tails orientated against the membrane interior. The balance of ufasome formulation is influenced by a number of variables, including fatty acid preference, ldl cholesterol level, buffer, pH change, and others. In terms of medicine, ufasomes offer a lot of potential. They may also be used to treat a variety of skin problems. When you consider that the medication is released in a controlled or delayed manner, swelling, itching, and other allergic

reactions on the skin may also be reduced. Due to the controlled release of the medication, fatty acid vesicles have also been shown to be particularly helpful in the treatment of skin problems in diseases like AIDS. Due to their superior entrapment performance, quick penetration ability, and more affordable price, ufasomes are preferred to liposomes for topical drug administration.

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