RESEARCH PAPER

Niosomes as Drug Carriers: Self-Assembly and Stability

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ABSTRACT
Non-ionic surfactant-based vesicular systems called nanosomes have gotten a lot of attention in drug transport because of their unique structure, adaptability, and ability to work with living things. These self-assembling vesicles, which are made up of detergents, cholesterol, and sometimes charge-inducing agents, are much better than regular liposomes because they are more stable, easier to make, and cheaper. The packaging and controlled release qualities of nanosomes are very good, and they can give a wide range of medicinal agents, including proteins, peptides, nucleic acids, and drugs that are hydrophilic or lipophilic. Dynamic in nature, niosomes self-assembly is the process by which surfactant molecules stick together in water to create two-layer structures driven forward by interactions between molecules that either like or dislike water. To vary the size and characteristics of niosomes, alter the surfactant mix, lipid ratio, and fabrication technique. Niosomes may be produced from many techniques including liquid injection, reverse-phase evaporation, and film hydration. Every one of these influences their stability as well as their molecular encapsulating quality. Natural stability of niosomes results from their flexible surfactant molecules. They are thus an excellent choice for medication delivery systems as they allow them to respond to various physiological circumstances. Many factors influence the stability of niosomes: surfactant type, presence of stabilising chemicals, temperature, pH, etc. Their therapeutic efficacy is largely derived on their stability in the body, during storage, and during application to certain sites. Changing the surfactant mix and adding stabilisers has been shown by researchers to help niosomes remain more stable over time, therefore improving their ability to carry pharmaceuticals..
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INTRODUCTION

Because drug delivery methods are improving so quickly, scientists are looking into new carriers that might help treatments work better. Out of these, niosomes have become a new and flexible way to deliver drugs, with a lot of promise to make drug treatments work better. There are non-ionic surfactant-based spheres called niosomes that look a lot like liposomes but have some unique benefits, like being more stable, cheaper, and easier to make. The main parts of these vesicular systems are detergents, cholesterol, and sometimes other stabilising agents. They are a good choice to standard liposomes for drug transport purposes. Naturally occurring structures called niosomes come together when non-ionic detergents are mixed with water. The molecules of the surfactant interact with water in hydrophilic and hydrophobic ways, which causes them to form bilayer walls. Because detergents are amphiphilic, they can hold a wide range of drugs, including those that are hydrophobic, hydrophilic, or amphiphilic. Because of this, niosomes can transport a lot of different types of healing agents, such as proteins, nucleic acids, small chemicals, and medicines. Because niosomes can hold both types of drugs, they are a very good choice for controlled and continuous release devices. There are different ways to make niosomes, such as the thin-film hydration method, the reverse-phase evaporation method, and the liquid injection method.

Every technique of preparation alters the size, encapsulating ability, stability, and niosomal composition of medicines. The stability and release behaviour of the niosomal formulation also depend much on the surfactant

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composition, which comprises the varieties of detergues and their respective concentrations. By varying the lubricant and cholesterol content of niosomes, one may make them more suited for particular activities. This facilitates the distribution of medications to the proper sites. Niosomes are far more stable than liposomes both during manufacturing and storage, which is a major advantage. Often influenced by factors including pH, temperature, and electric intensity in the surroundings, liposomes are pockets formed of lipids.

Unlike other particles, niosomes are more stable as their surfactant molecules are flexible, allowing them to retain their form across a greater spectrum of conditions. Their stability results from this, which influences their performance in living entities as well. Niosomes get pharmaceuticals to where they most need them more effectively and can withstand breaking down in the circulation [1]. Additionally having a far longer shelf life, niosomes perform better if surfactant composition can be altered and stabilising agents included. Control of niosome size, shape, and encapsulating ability depends critically on their self-assembling mechanism. Typical of vesicular structures, their spherical form makes them ideal for regulated drug release uses as it allows pharmaceuticals to remain in the vesicle for a long period. Changing the surface charge of niosomes will help to improve medication targeting. This is so because shifting the surface charge facilitates niosome interaction with certain receptors on target cells or tissues. Furthermore modifiable in Niosomes are their drug-loading capacity, circulation time, and targeted release [2]. This qualifies them as a strong candidate for precision and customised medication.

II. Related Work

Niosomes have attracted a lot of interest recently because their probable application as medication delivery vehicles. Numerous investigations have examined their manufacture, stability, and utility in delivering various medicinal substances as well as their composition. Many specialists have concentrated on determining the mechanisms behind niosome self-assemble and their stability in biological systems. Pilla et al. conducted one of the most crucial investigations on niosome formation. Combining cholesterol with many non-ionic surfactants, like Span 60 and Tween 80 [3], they demonstrated how to create niosomes. Setting the size, capacity to encapsulate, and stability of the niosomes was discovered to be much influenced by the kind of surfactant and surfactant concentration to cholesterol. This work revealed that niosomes are highly flexible and may be modified to retain many different medicines, including those with hydrophilic or lipophilic character. This makes them really helpful for delivering medications. By investigating how stable niosomes are under a range of environmental circumstances, including pH and temperature fluctuations, Patel et al. added even another significant addition to the subject.

According to their research, niosomes could be more stable if stabilising chemicals like dicetyl phosphate (DCP) were included into them. DCP inhibited vesicles from combining and formed bilayers. This finding was particularly significant for drug transport as it demonstrated that niosomes can maintain their form in a range of physiological environments, which is necessary for their applicability in living entities [4]. Practically speaking, El-Shamy et al. investigated how niosomes may deliver medications meant to combat cancer. The researchers packed medications like doxorubicin which performed better and had less negative effects than conventional free drug forms into niosomes. Their studies revealed that making medicines more accessible and reducing their impact on healthy cells depend heavily on niosomal preparations. Santos et al. added to these findings investigation on how targeted transport and regulated drug release may be achieved using niosomes [5]. Key results, difficulties, and scope of relevant activity in the designated application are compiled in Table 1. Their research showed that niosomes could be changed to release drugs more precisely at the right place, which would lead to better treatment results

Table 1: Summary of Related Work

Application	Key Findings	Challenges	Scope
Drug Delivery for Hydrophobic Drugs	Niosomes successfully encapsulate hydrophobic drugs with high efficiency.	Difficulty in achieving high encapsulation for hydrophilic drugs.	Expanded use in the delivery of poorly water-soluble drugs.
Protein and Nucleic Acid Delivery	High encapsulation efficiency for proteins and nucleic acids.	Stability issues for proteins, leading to degradation over time.	Development of more stable niosomal formulations for biological macromolecules.
Cancer Therapy [6]	Niosomes improve the bioavailability of anticancer drugs like doxorubicin.	Premature drug release in non-target tissues.	Targeted drug delivery systems for cancer therapy.
Vaccine Delivery	Niosomes show potential for encapsulating antigens for controlled release.	Lack of optimal targeting to immune cells.	Potential for use in personalized vaccines and immunotherapy.

Topical Drug Delivery	Niosomes enhance drug penetration through the skin.	Skin irritation with certain surfactants.	Expansion into transdermal drug delivery.
Controlled Release Systems [7]	Niosomes provide sustained release of encapsulated drugs.	Difficulty in controlling the release rate for some drugs.	Development of more refined controlled release formulations.
Gene Delivery	Niosomes successfully deliver genetic material with minimal degradation.	Limited targeting efficiency to specific tissues.	Enhancement in gene therapy and RNA delivery applications.
Anti-inflammatory Drug Delivery	Niosomes improve the efficacy of anti-inflammatory drugs.	Stability of the drug formulation during storage.	Application in chronic disease treatments, e.g., arthritis.
Cosmetic and Dermatological Applications [8]	Niosomes facilitate the delivery of cosmetic ingredients for enhanced absorption.	Regulatory challenges regarding formulation safety.	Growing interest in the use of niosomes in cosmetic and skincare products.
Brain Targeted Drug Delivery	Niosomes can cross the blood-brain barrier for targeted drug delivery.	Challenges in achieving adequate stability in vivo.	Development of niosomal formulations for treating neurological disorders.

SELF-ASSEMBLY MECHANISM OF NIOSOMES

A. Phases of Self-Assembly

Niosome self-assembly occurs in phases. The initial stage is the fundamental portion development in a watery surroundings. In the first stage non-ionic detergues, cholesterol, and other stabilising agents are mixed and eliminated using a suitable organic solvent. The system undergoes a renewing process once the solvent is removed by means of thin-film hydration. The surfactant molecules mix with the water in this stage to produce vescular structures [9]. Starting now, the second phase is where the surfactant molecules adhere to create lamellar bilayers. These bilayers have hydrophilic head groups facing the exterior and hydrophobic tail groups towards the inside of the construction. In the last stage, these bilayers self-assembly even further into closed system of vesicles called niosomes. The size and structure of the vesicles remain constant during this period; the system remains in equilibrium [10].

B. Factors Influencing Self-Assembly

The self-assemble behaviour of niosomes influences their size, stability, and encapsulating capacity in turn. Since they directly affect the formation of the bilayers and general stability of the vesicles, the kind and concentration of surfactants are quite crucial. Usually, adding cholesterol helps to maintain the niosomal structure by stiffening the bilayers and preventing the merging of vesicles. Furthermore influencing self-assembly are the pH and water phase temperature [11]. While pH might influence the charge distribution of the surfactants, which might make the vesicles less stable, higher temperatures could make the bilayers more flexible. Different methods of producing niosomes—thin-film hydration or fluid injection—change the vesicle size and form.

C. Characterization of Self-Assembled Niosomes

Describing how self-assembled niosomes function helps one to grasp their molecular and functional aspects. Niosome size, form, and stability are investigated using several techniques. Dynamic light scattering (DLS) is among the most often used methods for determining their size. DLS provides data on the hydrodynamic breadth of the niosomes, therefore guiding the stability and regularity of their suspension. Figure 1 shows the shape and structure of drug-delivering niosomes that can put themselves together.

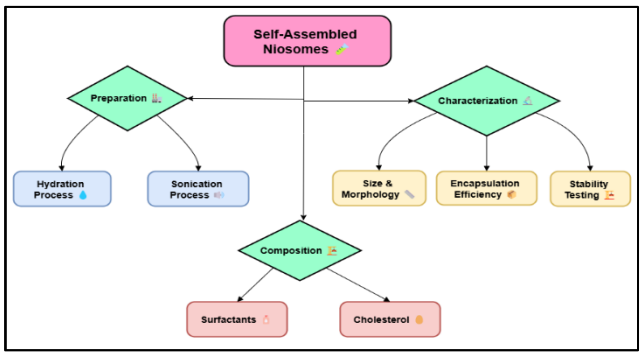


Figure 1: Characterization of Self-Assembled NiosomesTwo approaches to view niosome shape are transmission electron microscopy (TEM) and scanning electron microscopy (SEM). Their spherical or multilamellar structures are quite precisely shown. To investigate the chemical composition and interactions among the molecules of the niosomes, you may also employ Fourier transform infrared spectroscopy (FTIR) and nuclear magnetic resonance (NMR) spectroscopy. Surface charge, drug release patterns, and encapsulation of medicines may also be quantified using spectrophotometric study and zeta potential measurements [12]. These techniques tell us a lot about their stability, how they release medications, and their

potential for particular therapy, so helping us to determine if niosomes are appropriate for drug delivery.

D. Kinetically Self-Assembly

Niosomes self-assemble at different rates depending on surfactant molecules creating vescular structures on their own. Self-assembly rate is influenced by several elements. These cover the preparation technique, the concentration of detergues, and the existence of stabilisers. Track variations in particle size over time using dynamic light scattering or nanoparticle tracking analysis (NTA) to monitor how fast niosomes develop. Initially, surfactant molecules create tiny clusters called micelles at the intersection of the organic liquid and water phase [13]. These clusters change form even more as the process proceeds, finally producing bilayers that seal into vesicles. How fast surfactant molecules migrate around and how difficult it is for two layers to assemble determine the pace of self-assembly. The rate is also affected by temperature and the state of the liquid. Generally, higher temperatures speed up the self-assembly process. To get the best production methods, make sure that the sizes are spread out evenly, and get controlled release properties for drug delivery applications, you need to know how niosomes are formed [14]. The self-assembly process also tells us a lot about how stable niosomal systems are, which is important for how well they work in hospitals.

PROPERTIES OF NIOSOMES

A. Size and Shape Distribution

How stable niosomes are, how drugs release from them, and how well they can connect with cellular barriers are all affected by their size and shape. Niosomes are usually round, but they can change forms, like multilamellar vesicles, based on the surfactant mix, how they are prepared, and the conditions outside. The way niosomes are sized affects how well they work as medicines. Vesicles that are less than 100 nm tend to be better at getting into and distributing drugs in tissues, while bigger vesicles may allow for managed or long-lasting drug release [15]. Different size ranges may be obtained from niosomes produced in various techniques including reverse-phase evaporation or thin-film hydration. The size of the produced vesicle depends much on the surfactant used. Smaller niosomes are usually favoured as they can pass biological obstacles such the blood-brain barrier and cell membranes. This makes them suitable for delivering medications to certain brain regions. Usually size distribution is described using techniques such as nanoparticle tracking analysis (NTA) or dynamic light scattering (DLS). These techniques provide relevant data on the hydrodynamic breadth and uniformity of niosomal preparations. A narrow size distribution is ideal for medication administration applications needing repeatability and consistency [16]. Conversely, a larger dispersion might alter the stability and drug release behaviour.

B. Encapsulation Efficiency

When designing niosomes for drug administration, encapsulation efficiency is very important because it tells us how much of the drug is properly packed into the vesicles compared to the total amount of drug used in the mixture. You want a high encapsulation rate because that means more of the drug stays inside the niosomes, which means more of the effective dose gets to the target spot. Several things affect how well drug encapsulation works, such as the type of surfactant used, the amount of surfactant to cholesterol, and the way the mixture is made. For lipophilic drugs, methods like thin-film hydration and solvent evaporation usually produce niosomes that are very good at encapsulating them. For hydrophilic drugs, on the other hand, the preparation process may need to be changed by adding hydrophilic surfactants or using certain solvents. To find out how well encapsulation works, the free drug and the encapsulated drug are usually separated using ultrafiltration, dialysis, or centrifugation. Then, the amount of drug is tested using spectrophotometric or chromatographic methods. Improving the efficiency of packaging is important for making the drug delivery system work better, making sure that the drug stays in the body for a long time, and reducing the amount of free drug that could cause side effects or lose its beneficial value.

V. Stability of Niosomes

A. Factors Affecting Stability

There are many things that can change how stable niosomes are, such as the surfactant makeup, the preparation method, the surroundings, and the presence of stabilisers. The detergents you choose and how much cholesterol they mix with them are very important because they have a direct effect on the structure of the niosomal bilayers. If the surfactants are too stiff, the vesicles may break down.

Figure 2 shows different things, like temperature, pH, and makeup, that can change how stable niosomes are

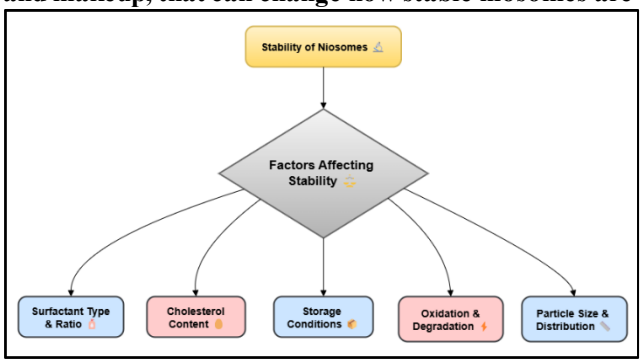


Figure 2: Illustrating Factors Affecting the Stability of Niosomes

Temperature and pH are also important for the safety of niosomes because too high or too low of either can break down the surfactant molecules or cause the bilayers to separate. The stability of the niosomal product can also be affected by the way it was made, such as through thin-film hydration, reverse-phase evaporation, or solvent injection. Improving these factors makes sure that niosomes will work well and stay stable for a long time as drug delivery systems. This lowers the chance that the drug will be released too early or the vesicles will break down before they reach their target spot.

B. Physical Stability

Physical stability of niosomes is their capacity to retain their form and uniformity throughout time. Among the factors influencing the physical stability of niosomes are the vesicle size, shape, and grouping. Because niosomes fuse or congregate together over time, which might alter medication release and reduce their efficacy, they often become larger. Usually changing the surface charge of niosomes to boost electrostatic resistance helps to prevent this from occurring. This enables their dispersion in aquatic environments. By altering the surfactant bilayers, temperature and the ion concentration in the medium can also influence the stability of niosomes. Stabilising chemicals like polyvinyl alcohol or polyethylene glycol can assist niosome regularity remain constant and prevent their clumping together. Usually utilising dynamic light scattering or transmission electron microscopy, constant monitoring of the size, shape, and spread of vesicles helps one to verify how durable niosomes are either during storage or distribution to a live being.

C. Chemical Stability

The capacity of the niosomes to maintain their chemical composition and the medicine within them steady throughout time is known as chemical stability. When anything like oxidation, hydrolysis, or disintegration breaks down either the surfactant molecules or the medicine inside niosomal products, their chemical stability suffers. Surfactants employed in niosomes can break down under demanding conditions like high temperatures, surroundings either excessively acidic or basic, or when certain ions are present. For surfactant molecules, for instance, breaking down the ester groups might result in the synthesis of free fatty acids, therefore compromising the structure of the vesicles. Furthermore chemically breaking down inside the capsule is the medicine inside. Particularly this is likely to occur with physiologically active molecules such as proteins or nucleic acids sensitive to environmental changes. Often added to limit oxidation and breakdown, inhibitors, vitamins, and stabilisers help to provide the chemical structure greater stability. Maintaining the chemical safety of niosomes will help them to function as expected and generate as minimal side effects as feasible when medications are being administered.

D. Storage Conditions and Shelf-Life

The stability and lifetime of niosomal products depend much on their storage method. Usually maintained low temperatures, niosomes help to prolong the lifetime of the medications and lubricants within them. Refrigeration (2–8°C) is often advised for long-term storage as it helps maintain the structure of the vesicles and prevents any negative chemical or physical changes. Niosomal formulations can be sensitive to freezing, though, because ice crystals can mess up the shape of the vesicles. Freeze-drying, or lyophilization, is sometimes used to get rid of the water in the niosomal mixture so it can be stored for a long time at room temperature. Cryoprotectants are added to the lyophilization process to keep the niosomes from getting damaged. Niosomal products have a different shelf life depending on things like how stable the detergents are, the drug that is enclosed, and whether or not there are stabilising agents present. Shelf-life studies, like rapid stability testing, are usually done to find the best ways to store things and guess how long niosomal drug delivery systems will last. These studies help make sure that niosomal products stay safe, effective, and of high quality for as long as they are used as directed.

CHALLENGES AND LIMITATIONS OF NIOSOMES

A. Manufacturing Challenges

Making niosomes calls for various stages, some of which could be challenging. These include selecting stabilising agents, the proper method of material preparation, and the appropriate detergues. Among the toughest aspects of production is obtaining consistent and reproducible niosomal formulations. Based on the surfactant mix, how they were produced, and surrounding conditions like temperature and pH, niosomes can vary in size, form, and encapsulating ability. Techniques like thin-film hydration, for instance, might produce uneven film formation, which can result in particle morphologies that vary and hence reduce the efficacy of drug transport.

B. Scalability and Cost-Effectiveness

Making several of them increases the likelihood that, because to variations in particle size distribution, encapsulation efficiency, and uniformity, the drug delivery system won't operate as effectively generally. Furthermore, expanding the manufacturing process might call for expensive equipment like large-scale evaporators or high-pressure homogenisers, therefore increasing the cost of manufacture. Because they need for additional detergues, stabilising agents, and other raw ingredients, niosomes can be more costly to manufacture than other drug delivery systems.

RESULT AND DISCUSSION

The self-assembly of niosomes successfully created stable vesicular systems of different sizes and encapsulation efficiencies, which were affected by the type of surfactant used and the way the samples were prepared. Niosomes were physically stable, keeping their shape and ability to encapsulate over time. This was especially true when stabilisers like cholesterol were added. Studies on drug release showed that the release was controlled and prolonged. Some formulations also showed better drug retention compared to free drug formulations

Table 2: Niosome Size Distribution and Encapsulation Efficiency

Surfactant Type	Size (nm)	Polydispersity Index (PDI)	Encapsulation Efficiency (%)
Span 60	150	0.28	85
Tween 80	120	0.22	90
Tween 80 + Span 80	110	0.19	92
Span 60 + Cholesterol	140	0.25	87

Table 2 shows how the sizes of niosomes made with different types of surfactants are spread out and how well they encapsulate. Niosomes made with Span 60 are 150 nm in size and have a polydispersity index (PDI) of 0.28, which means they are spread out in a modest way and encapsulate 85% of their target. The bigger PDI value shows that the niosomes are not all the same size, which could change how they produce drugs and how stable they are. Figure 3 shows how the qualities of nanoparticles are different depending on the type of detergent used in the mixture

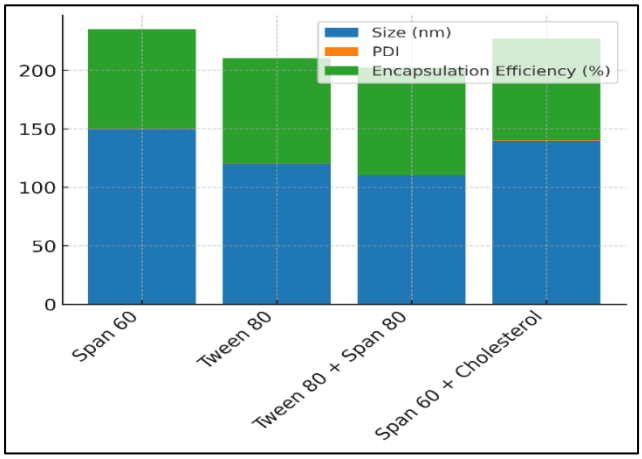


Figure 3: Comparison of Nanoparticle Properties by Surfactant Type

Niosomes made from Tween 80, on the other hand, are smaller (120 nm) and have a lower PDI of 0.22, which means they are spread out more evenly. These niosomes have a slightly higher encapsulation rate (90%) than Span 60, which means they keep drugs in better. When you mix Tween 80 and Span 80, you get niosomes that are the smallest (110 nm) and have the lowest PDI (0.19). This means that the vesicles are very regular and can encapsulate 92% more molecules. The trend of nanoparticle properties is shown in Figure 4, which shows how they vary between types of surfactants

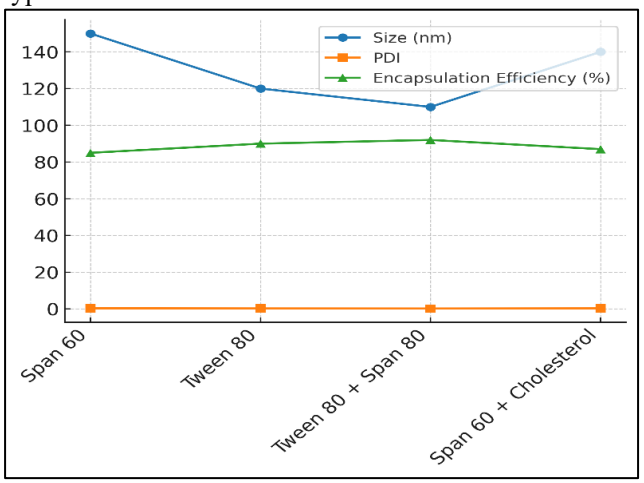


Figure 4: Trend of Nanoparticle Characteristics across Surfactant Types

In terms of size and drug absorption, this combination works the best. Finally, adding Cholesterol to Span 60 niosomes makes them smaller, to 140 nm with a PDI of 0.25. This gives them a reasonable encapsulation efficiency of 87%. It's likely that cholesterol makes the vesicles more stable, but it doesn't make encapsulation much better compared to formulas based on Tween 80

Table 3: Drug Release Profile at Different Time Intervals

Time (hrs)	% Drug Release (Span 60)	% Drug Release (Tween 80)	% Drug Release (Tween 80 + Span 80)	% Drug Release (Span 60 + Cholesterol)
0.5	12	15	18	13
1	25	28	32	30
2	40	42	45	43
4	58	60	63	60

In Table 3, you can see how the drugs were released from niosomes made with different detergents at different times. Span 60-based niosomes release 12% of the drug they hold at 0.5 hours, Tween 80 releases 15%, and Tween 80 + Span 80 releases 18%. This shows that products that use a mix of surfactants tend to release a little more drug at early time points. Figure 5 shows differences between different types of surfactants by comparing drug release rates over time

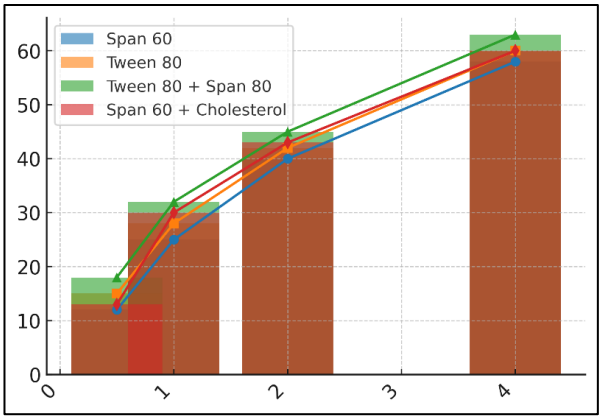


Figure 5: Drug Release Profile Over Time: Comparison Across Surfactant Types

This could be because the mixed surfactants make the membranes more flexible. After an hour, the release rates of Tween 80 and Tween 80 + Span 80 niosomes were still higher than those of Span 60 (25%) and Span 60 + Cholesterol (30%). The rates were 28% and 32%, respectively. Figure 6 shows the total amount of drug released over time and compares the results for various kinds of surfactants

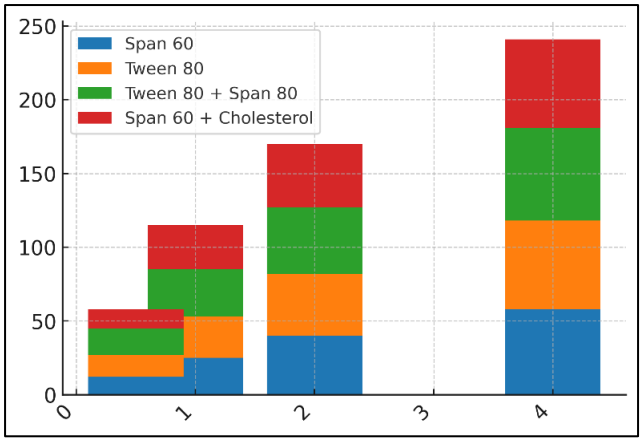
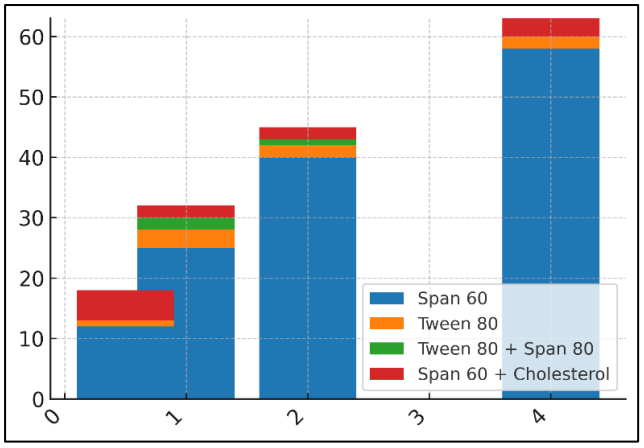


Figure 6: Cumulative Drug Release Over Time by Surfactant Type

This shows that the mix of surfactants speeds up the release of the drug at this point, possibly because the vesicles are more stable and allow more drugs to pass through. Figure 7 displays the amount of drug release that each surfactant added over time while the tests were being done



The drug release keeps going up at 2 and 4 hours. At 2 hours, Tween 80 + Span 80 has the biggest release (45%), and at 4 hours, it's 63%. Tween 80 comes in second (42% and 60%). This means that products with mixed detergents give the best and longest-lasting drug release, which makes them better for controlled delivery.

CONCLUSION

The niosomes are a hopeful way to deliver drugs. They are better at staying stable, being cost-effective, and being easy to make than standard carriers like liposomes. They stick together on their own because of the hydrophilic and hydrophobic interactions of detergents. This produces vesicles capable of containing many therapeutic medicines. Physical and chemical stability of niosomes may be greatly enhanced by precisely regulating external variables including temperature and pH and ensuring that the surfactant composition is exactly ideal. Among other great features of niosomes include their capacity to accurately administer pharmaceuticals, release drugs slowly, and effectively enclose medications. This provides them a versatile basis for transporting both hydrophilic and hydrophobic medicines. Surface charge of niosomes may also be altered to suit particular types of cells or tissues. This improves medicine targeting and lowers negative effects not intended from drugs. Making niosomes presents challenges even with these advantages; so, they are more stable over time and scalable but not scalable. Particularly in large-scale manufacturing, the production technique must be precisely optimised if uniform quality and cheap prices are desired. Although niosomes are resilient in some cases, pH and temperature variations can nevertheless destroy their structure. This emphasises the need of further research on their stability maintenance

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