

REVIEW ARTICLE

A Review on Niosome: A Promising Tool for Novel Drug Delivery

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ABSTRACT

Niosomes are essential for medication delivery. Niosomes are vesicles made of non-ionic surfactants, which are more stable, less expensive, biodegradable, and generally harmless. It consisted of a non-ionic surfactant vesicle, which is created by hydrating cholesterol and non-ionic surfactant. Niosomes improve the bioavailability of medications by extending their residence time and reducing their clearance. Niosomes, a type of pill encapsulation, are used to deliver medication. may serve as a dermal depot for the local solubilization matrix topically, as in niosomes. As membrane rate-limiting barriers or as penetration enhancers for the extended release of active substances, they are used to regulate the systemic absorption of medications. An overview of niosomes is given in this thorough review article, which covers their types, structure, characterization, formulation techniques, applications, and currently available formulations on the market.

Keywords: Niosomes, Non-Ionic surfactant, Drug delivery, Drug entrapment.

Received 22.06.2025

Revised 25.07.2025

Accepted 29.08.2025

How to cite this article:

Mamta K, Soumya R M, Parul N, Anushka V, Sayantan D, Ashish K G, Anubhav D, Seema S. A Review on Niosome: A Promising Tool for Novel Drug Delivery. Adv. Biores., Vol 16 (5) September 2025: 86-96.

INTRODUCTION

To improve absorption and distribute the active ingredient to the intended region, niosomes, a novel drug delivery system (NDDS), are designed to release the medication at a controlled pace determined by the body's needs during the course of treating a disease. [1] Among these carriers, niosomes are among the best. Researchers in the cosmetics sector originally reported on the self-assembly of non-ionic surfactants into vesicles in the 1970s. When non-ionic surfactants of the alkyl or dialkyl polyglycerol ether family are combined with cholesterol, microscopic lamellar structures known as niosomes (non-ionic surfactant vesicles) are created. [2] Because of their amphiphilic nature, non-ionic surfactants use energy, such as heat or physical agitation, to create a closed bilayer vesicle in aqueous fluids. While the hydrophilic heads stay in touch with the aqueous solvent, the hydrophobic portions of the bilayer structure are oriented away from it. Varying the vesicles' composition, size, lamellarity, tapping volume, surface charge, and concentration can alter their characteristics. The vesicle is subject to a variety of forces, including the van der Waals forces between surfactant molecules, the entropic repulsive forces of the head groups of surfactants, the short-acting repulsive forces, and repulsive forces arising from the electrostatic interactions among charged groups of surfactant molecules. These forces are responsible for preserving niosomes' vesicular structure. However, the kind of surfactant, the medication contained, the storage temperature, detergents, the use of membrane-spanning lipids, the interfacial polymerization of surfactant monomers in situ, and the presence of charged molecules all have an impact on the stability of niosomes. The structure's hydrophilic, amphiphilic, and lipophilic components can accommodate drug

molecules with a broad range of solubility. [3] These could serve as a depot, allowing the medication to be released gradually. Delaying the medication's removal from circulation, shielding it from the biological environment, and limiting its effects to target cells can all enhance the therapeutic performance of the drug molecules. [4]

Numerous pharmaceutical agents may benefit from niosomal medication delivery in order to combat a range of illnesses. Additionally, it can be utilized to create new drug delivery systems for poorly absorbed medications. By transcytosing M cells of Peyer's patches in the intestinal lymphatic tissues, it overcomes the gastrointestinal tract's anatomical barrier and increases bioavailability. [5] The reticulo-endothelial system absorbs the niosomal vesicles. Diseases like leishmaniasis, in which parasites infiltrate liver and spleen cells, are treated with this type of localized medication accumulation. [6,7] The lipid surface of this delivery mechanism is also recognized by certain non-reticulo-endothelial systems, such as immunoglobulins. [8,9] The anti-tumor activity has been maintained or even increased in certain cases due to the reduction of harmful side effects caused by the encapsulation of several antineoplastic drugs in this carrier vesicle. The broad-spectrum antitumor antibiotic doxorubicin exhibits an irreversible cardio-toxic impact that is dose-dependent. [10,11]

MERITS

- Niosomes can be administered topically, orally, or parenterally.
- Surfactants can be handled and stored without the requirement for particular conditions. - Targeted and regulated medication administration
- Osmotically active and stable.
- Enhanced oral bioavailability and cutaneous penetration; -Enhanced therapeutic efficacy.
- Niosomes have better patent compliance than fatty dosage forms because of their water base. [12-13]

DEMERITS

- May show signs of drug fusion, leaching, or hydrolysis, which would shorten its shelf life.
- The drug loading capacity is insufficient
- Specialized equipment is needed for manufacturing
- The drug leaks when entrapped
- The formulation takes a long time
- Aggregation is costly, and so on.

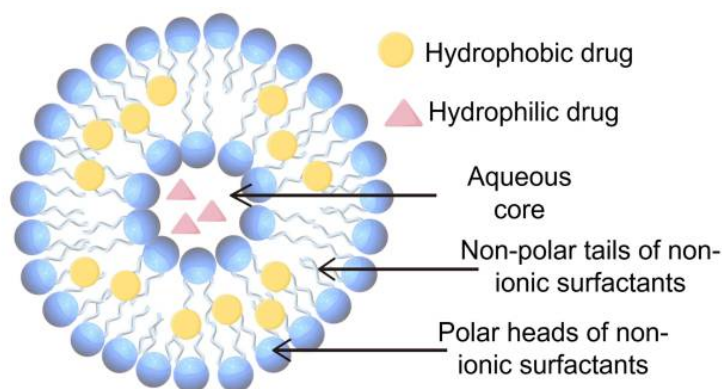


Fig. 1. Structure of Niosomes [53]

VARIOUS TYPES OF NIOSOME

Niosomes can be categorized into three types according to the size of their vesicles. Multilamellar vesicles (MLV, size $\geq 0.05 \mu\text{m}$), large unilamellar vesicles (LUV, size $\geq 0.10 \mu\text{m}$), and small unilamellar vesicles (SUV, size $0.025\text{--}0.05 \mu\text{m}$) are among them. [14]

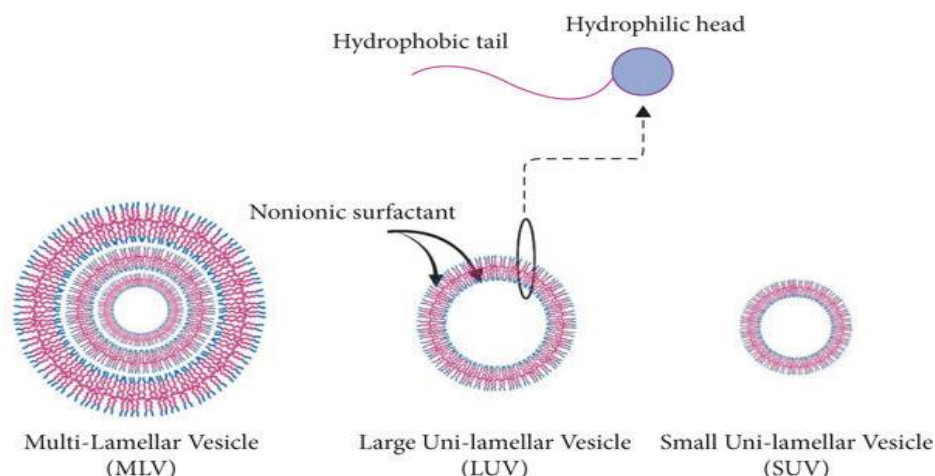


Fig.2. Types of Niosome[51]

NIOSOME PREPARATION METHODS:

Different techniques are used to manufacture niosomes depending on the vesicle sizes and distribution, the number of double layers, the aqueous phase's entrapment efficiency, and the permeability of the vesicle membrane. Non-ionic surfactant and cholesterol dissolve in an organic solvent. The answer for organics is to dry them on a spinning evaporated surface at 40°C to 60°C and 60 RPM. The hydration was produced using thin film dispersion and phosphate buffer. Niosome suspension develop.[15]

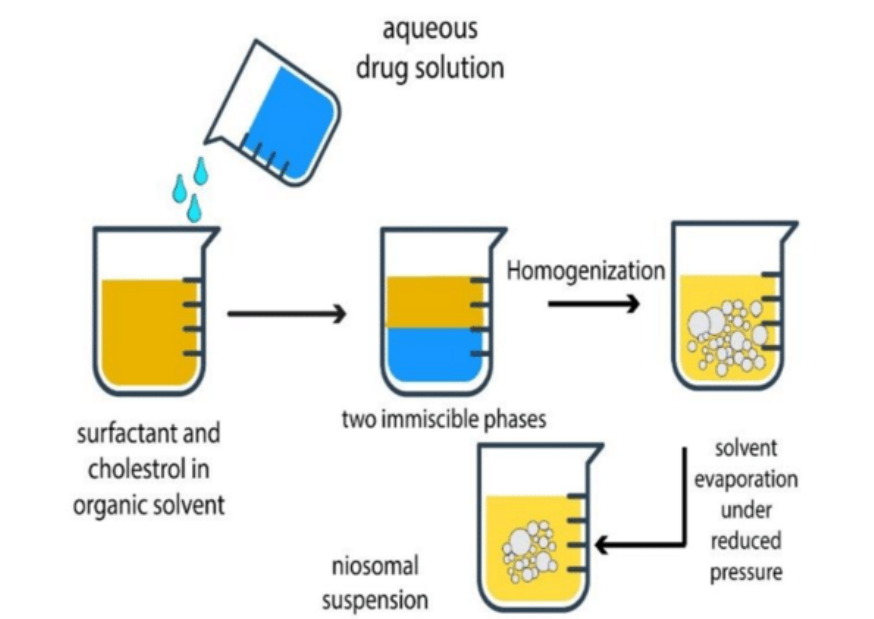


Fig.3. Preparation of Niosome[52]

➤ **The Bubble Method**

The bubble procedure is used to create niosomes without the need of organic solvents. The mixture is transferred to a flask with three necks and a circular bottom once the surfactants and additives have been combined in an aqueous phase, such as PBS.[16]

➤ **Ether for injection method**

The ether injection method essentially uses a 14-gauge needle to slowly introduce Niosomal components in diethyl ether at a rate of approximately 0.25 ml/min into a heated aqueous phase that is maintained at 60°C. The slow vaporization of the solvent, which produces an ether gradient that stretches towards the aqueous-non-aqueous boundary, is probably the cause of the formation of larger unilamellar vesicles. The former may have led to the formation of the bilayer structure. One of the disadvantages of this approach is that there is typically a very little quantity of ether in the vesicle suspension, which is difficult to remove.[17]

➤ **Sonication Method**

Sonication is a popular technique for producing niosomes. A 10-ml glass vial containing the drug, cholesterol, and surfactants is opened, and the contents are mixed with buffer. In order to produce Niosomes, the liquid is then sonicated with a titanium probe for around three minutes. Tiny, unilamellar vesicles are present in the finished product. Making small vesicles is the most popular use of this technique. Probe and bath sonicators are the two types used in the sonication process. Depending on the circumstance, either kind may be used.[18]

➤ **Multiple Membrane Extrusion Method**

A mixture of surfactant, cholesterol, and diacetyl phosphate in chloroform is evaporated to produce a thin film. After hydrating the film with an aqueous drug solution, the suspension is extruded through a series of polycarbonate membranes with a maximum of eight passages. This method works well for controlling vesicle sizes.[19]

➤ **Reversed-Phase Evaporation**

The surfactants are dissolved in a solution of ether and chloroform and then added to an emulsified medication to create a water phase. The organic phase is eliminated by evaporating the liquid after it has been homogenized. The lipid or surfactant first forms a gel before being hydrated to produce spherical, stable, homogeneous vesicles.[20]

CHARACTERISATION OF NIOSOMES

➤ **Size**

Niosomal vesicles are thought to have a spherical shape, and the laser light scattering method can be used to calculate their mean diameter. [21] Additionally, electron microscopy, molecular sieve chromatography, ultracentrifugation, photon correlation microscopy, optical microscopy, and freeze fracture electron microscopy can all be used to measure the diameter of these vesicles [22, 23]. A fusion of vesicles during the cycle may be the cause of the increase in vesicle width caused by the freeze-thaw of Niosomes.

➤ **Bilayer formation**

Under light polarization microscopy, the creation of an X-cross indicates the assembly of non-ionic surfactants to create a bilayer vesicle. [24]

➤ **Number of lamellae**

Small angle X-ray scattering, electron microscopy, and nuclear magnetic resonance (NMR) spectroscopy are used to ascertain this. [25]

➤ **Membrane rigidity**

The mobility of a fluorescent probe as a function of temperature can be used to determine membrane stiffness.[26]

➤ **Entrapment efficiency**

The untrapped drug is separated after the niosomal dispersion is prepared, and the drug that is still entrapped in niosomes is identified by completely disrupting the vesicles with 50% n-propanol or 0.1% Triton X-100, then analyzing the resulting solution using the drug's suitable test method. [27] It can be shown as:

Entrapment efficiency (EF) = (Amount entrapped / total amount) × 100

➤ **In vitro Release Study**

Dialysis tubing was used to describe an in vitro release rate study technique. [28] After washing, distilled water was used to immerse a dialysis sac. After pipetting the vesicle suspension into a bag composed of the tubing, it was sealed. After that, the vesicle-containing bag was continuously shaken at 25°C or 37°C in a 250 ml beaker filled with 200 ml of buffer solution. Using a suitable assay technique, the buffer's drug content was examined at different intervals. In a different technique, isoniazid-encapsulated niosomes were separated using gel filtration on powdered Sephadex G-50 that had been swelled for 48 hours in double-distilled water. [29] Initially, the column was covered with 1 milliliter of the produced niosome suspension, and elution was performed using regular saline. First, the slightly dense, white, opalescent dispersion of isoniazid encapsulated in niosomes elutes, followed by the free drug. A sigma dialysis sac was fastened to one end of a dialysis tube, which was then filled with separated niosomes. Using a magnetic stirrer, the dialysis tube was suspended in a phosphate buffer with a pH of 7.4. Samples were taken out at predetermined intervals and subjected to high-performance liquid chromatography (HPLC) analysis.

➤ ***In vivo* Release Study**

For this study, albino rats were employed. These rats were separated into several groups. Using the proper disposal syringe, the niosomal suspension utilized in the *in vivo* investigation was administered intravenously (via the tail vein).[30]

APPLICATION OF NIOSOMES

Numerous pharmacological treatments that target a range of disorders may be administered effectively by niosomal drug delivery. Below is a discussion of several therapeutic applications.

Niosomes Drug Carriers:

It has been investigated to use niosomes as carriers, such as when delivering the diagnostic drug iobitridol, which is used in X-ray imaging. Topical niosomes can improve penetration, serve as a membrane barrier that affects the systemic absorption of medications, serve as a solubilization matrix, or offer a local depot for the prolonged release of dermally active substances. Furthermore, iobitridol, a diagnostic agent used in X-ray imaging, has been transported by niosomes. [31,32]

Drug Targeting:

The ability of niosomes to distribute drugs precisely is one of its main benefits. Drugs can be selectively targeted by niosomes to the reticuloendothelial system (RES), which preferentially absorbs niosome vesicles. Opsonins, which are circulating serum factors that mark niosomes for clearance, control the uptake of niosomes. Animal cancers that are prone to spreading to the liver and spleen have been treated with this targeted medication localization. It can also be used to treat liver-damaging parasite infections. Niosomes can be used to direct medications to organs other than the RES. Since immunoglobulins easily attach to the lipid surface of niosomes, enabling selective organ targeting, one strategy is to attach a carrier system, such as antibodies, to niosomes.[33]

Anti-neoplastic Treatment:

Serious adverse effects are linked to most antitumor medications. By altering drug metabolism and increasing drug circulation and half-life, niosomes provide a potential remedy by lessening the negative effects of these medications. Higher medication plasma levels and a slower clearance process result from Niosomes' contribution to a slower pace of tumor proliferation.[34]

Delivery of Peptide Drugs:

Overcoming the gastrointestinal tract's enzymatic breakdown is the issue of oral peptide medication administration. The use of Niosomes to successfully shield peptides from gastrointestinal breakdown is being investigated in current research. The entrapment of the medicine considerably improved the stability of the peptide, according to an *in-vitro* investigation on the oral delivery of a vasopressin derivative encapsulated in Niosomes. Research is being done to see if Niosomes might act as a useful barrier against gastrointestinal peptide degradation, as overcoming the problem of enzymatic breakdown of peptides in oral drug administration is a persistent obstacle. [35,36]

Study of Immune Response:

Because of their improved stability, minimal toxicity, and immunological selectivity, Niosomes are presently used in the study of immune responses. When given parenterally with different antigens and peptides, this non-ionic surfactant vesicles have demonstrated their capacity to act as adjuvants, improving our knowledge of the characteristics of immune responses.[37]

Diagnostic Imaging with Niosomes:

When 99mTc-labeled DTPA-containing Niosomes are used in imaging studies, they show site specificity for the liver and spleen, serving as carriers for radiopharmaceuticals. The formulation of Gado enate with conjugated Niosomes, which incorporates N-palmitoyl glucosamine, NPG, PEG 4400, and a mixture of PEG and NPG, has improved tumor targeting of a paramagnetic drug.[38]

Niosomes as Hemoglobin Carriers:

In the bloodstream, Niosomes can be used as haemoglobin carriers, offering a permeable vesicle for the transportation of oxygen. Because of this characteristic, Niosomes can be used as haemoglobin carriers in anaemic patients.[39]

Magnetic Targeting in Drug Delivery:

Niosomes demonstrate effective magnetic targeting for drug delivery, particularly in cancer treatment applications. The encapsulation of an EMG 707 magnetic ferrofluid and a model anti-tumor within the aqueous core of Niosomes has led to the creation of doxorubicin-loaded atom-loaded formulations without further toxicity.[40]

Ophthalmic Applications:

The water-soluble antibiotic gentamicin sulfate showed significant heterogeneity in release rates in ocular drop experiments. In contrast to traditional drug samples, the niosomal formulation showed

delayed release. Furthermore, as compared to commercially available goods, timolol maleate niosomes (0.25%) made with chitosan coating have shown a more significant influence on intraocular pressure with less side effects. [41]

Transdermal Drug Delivery:

In transdermal medication delivery, niosomes have been used to address the slow drug penetration through the skin. One significant disadvantage of the transdermal approach has been addressed by incorporating medications inside niosomes, which has increased the penetration rate.[42]

Cosmetic Applications:

The first product, 'Niosome,' was introduced by Lancôme in 1987 after L'Oreal was the first to use non-ionic surfactant vesicles (niosomes) for cosmetic purposes. Benefits of niosomes in cosmetics include better skin penetration, increased stability of entrapped medications, and increased bioavailability of poorly absorbed substances.[43]

Hormone Delivery:

Oestradiol's in vitro penetration through the human stratum corneum has been investigated using niosomes made of non-ionic n-alkyl polyoxymethylene ether surfactants. The impact of vesicular structures at the stratum corneum suspension interface and the penetration-enhancing action of surfactant molecules are two of the mechanisms at play.[44]

Vaccine Delivery:

Although niosomes are not very immunogenic, they are being investigated as vaccine carriers, especially for topical and oral vaccinations. The effects of varying niosome surfactant, cholesterol, and dicetyl phosphate quantities on shape, particle size, entrapment efficiency, and in-vitro antigen release were examined. Topical niosomes showed immune-stimulating action that was similar to that of topical liposomes and intramuscular recombinant HBsAg.[45]

Prolonged Release Capability of Niosomes:

Drugs with a low therapeutic index and poor water solubility can benefit from the sustained release feature of niosomes. This is due to the fact that niosomal encapsulation makes it possible to keep these medications in circulation. [46,47]

Targeted Drug Action at Specific Sites:

One way to accomplish localized pharmacological action is by using niosomes for drug delivery. Niosomes' intrinsic properties, such as their size and restricted capacity to pass through connective tissue and epithelium, help to maintain the medication localized at the precise administration location. [48,49]

MARKETED FORMULATIONS OF NIOSOMES [50]

Table 1: List of marketed formulation

| Sr. No. | Brand | Name of Products |
|---------|--------------------------------|--|
| 1. | Britney Spears – Curious | Curious Coffret: Edp Spray 100ml +Dual ended Perfume & Pink Lipgloss + Body soufflé 100 ml |
| 2. | Orlane – Lipcolor and Lipstick | Lip Gloss |
| 3. | Loris Azzaro – Chrome | Chrome Eau De Toilette Spray 200 ml |

APPLICATIONS OF NIOSOMES

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Niosomes as Hemoglobin Carriers: In the bloodstream, niosomes can be used as hemoglobin carriers, offering a permeable vesicle for the transportation of oxygen. Because of this characteristic, niosomes can be used as hemoglobin carriers in anemic patients.

Magnetic Targeting in Drug Delivery: When it comes to medication delivery, niosomes exhibit efficient magnetic targeting, especially in cancer therapy applications. The production of doxorubicin-loaded atom-loaded formulations without extra toxicity has resulted from the encapsulation of both an EMG 707 magnetic ferrofluid and a model anti-tumor within the aqueous core of niosomes.

Ophthalmic Applications: The water-soluble antibiotic gentamicin sulfate showed significant heterogeneity in release rates in ocular drop experiments. In contrast to traditional drug samples, the niosomal formulation showed delayed release. Furthermore, as compared to commercially available goods, timolol maleate niosomes (0.25%) made with chitosan coating have shown a greater influence on intraocular pressure with less side effects.^{23,24}

Treatment of Leishmaniasis: Drugs for diseases like leishmaniasis, where the infectious organism resides in the reticuloendothelial system (RES), may be targeted by niosomes. Niosomal formulations have shown increased efficacy and reduced side effects, especially for sodium stibogluconate, a commonly administered drug associated with arsenic.

Anticancer Drug Delivery: Anticancer medications such as methotrexate, vincristine, bleomycin, and paclitaxel have been encapsulated in niosomes, which are made of cholesterol, dicetyl phosphate, and non-ionic surfactants. When taken orally, this encapsulation has improved anticancer activity, decreased toxicity, and enhanced absorption from the gastrointestinal system.

Transdermal Drug Delivery: In transdermal medication delivery, niosomes have been used to address the slow drug penetration through the skin. One significant disadvantage of the transdermal approach has been addressed by incorporating medications inside niosomes, which has increased the penetration rate.

Cosmetic Applications: The first product, 'Niosome,' was introduced by Lancôme in 1987 after L'Oreal was the first to use non-ionic surfactant vesicles (niosomes) for cosmetic purposes. Benefits of niosomes in cosmetics include better skin penetration, increased stability of entrapped medications, and increased bioavailability of poorly absorbed substances.

Hormone Delivery: Estradiol's in vitro penetration through the human stratum corneum has been investigated using niosomes made of non-ionic n-alkyl polyoxymethylene ether surfactants. The impact of vesicular structures at the stratum corneum suspension interface and the penetration-enhancing action of surfactant molecules are two of the mechanisms at play.

Neoplasia Treatment: Doxorubicin, an anthracyclic antibiotic, was delivered niosomally to mice with S-180 tumors, extending their survival and reducing the growth of sarcoma. Niosomal entrapment changed the drug's metabolism, extended circulation, and improved half-life. When methotrexate entrapped in niosomes was administered intravenously to S-180 tumor-bearing mice, the tumor completely disappeared, plasma levels rose, and the removal process took longer.

Vaccine Delivery: Although niosomes are not very immunogenic, they are being investigated as vaccine carriers, especially for topical and oral vaccinations. The effects of varying niosome surfactant,

cholesterol, and dicetyl phosphate quantities on shape, particle size, entrapment efficiency, and in-vitro antigen release were examined. Topical niosomes showed immune-stimulating action that was similar to that of topical liposomes and intramuscular recombinant HBsAg.

Diagnostic Imaging with Niosomes: Niosomes are thought to be efficient delivery systems for the X-ray imaging diagnostic drug iobitridol. In diagnostic imaging studies, niosomes prepared by the film hydration process and then sonicated provide improved vesicle stability and encapsulation.

Prolonged Release Capability of Niosomes: Drugs with a low therapeutic index and poor water solubility can benefit from the sustained release feature of niosomes. This is due to the fact that niosomal encapsulation makes it possible to keep these medications in circulation.^{30,31,33,34}

Targeted Drug Action at Specific Sites: One way to accomplish localized pharmacological action is by using niosomes for drug delivery. Niosomes' intrinsic properties, such as their size and restricted capacity to pass through connective tissue and epithelium, help to maintain the medication localized at the precise location of administration [54].

Other Applications

Additionally, niosomes are essential for imaging and diagnosis. To enhance contrast and image visibility, imaging agents or contrast agents are used in a variety of imaging procedures, including computed tomography (CT), magnetic resonance imaging (MRI), and ultrasound imaging. To improve diagnostic imaging accuracy and reduce side effects, niosomes can be designed to deliver contrast or imaging chemicals precisely to target tissues or cells. With the use of magnetic and active targeting, niosomes modified with transferrin (Tf) and featuring integrated magnetic iron oxide nanoparticles (MIONs) and quantum dots (QDs) were created for efficient glioma imaging. The generated niosomes shown a strong promise for dual imaging (fluorescent and magnetic resonance imaging) and cell-specific dual targeting (active and magnetic targeting) in gliomas. High cancer-cell integration capacity and good in vitro stability were shown by niosomes made using the thin-film hydration process and labeled with the radioactive technetium-99m isotope.¹⁶³ Additionally, niosomes can be engineered to transport both therapeutic and diagnostic substances, allowing for simultaneous therapy and imaging, which is very helpful for monitoring treatment outcomes. At low doses, theranostic pH-responsive niosome formulations for doxorubicin administration and breast cancer bioimaging demonstrated strong anti-cancer action. When administered directly intratumorally, theranostic niosomes demonstrated markedly improved anti-cancer and tumor retention properties. Furthermore, probes or biomarkers that bind selectively to disease signals can be delivered via niosomes, aiding in the early diagnosis and tracking of illnesses. Using HPLC-FLD devices, niosomes made up of Tween 20 and Tween 21—which are colloidal nanocarriers used to transport medicinal drugs and molecular probes—were detected with great sensitivity and precision.

Applications of Artificial Intelligence

Nanomedicine and artificial intelligence (AI) are essential to the development of personalized medicine. AI has been used to a number of noteworthy aspects of nanomedicine, such as pharmacokinetics and the prediction of Niosome composition, safety, efficacy, and structure-activity connections (Figure 4). AI algorithms can more accurately interpret, manage, and analyze complex functions or data.

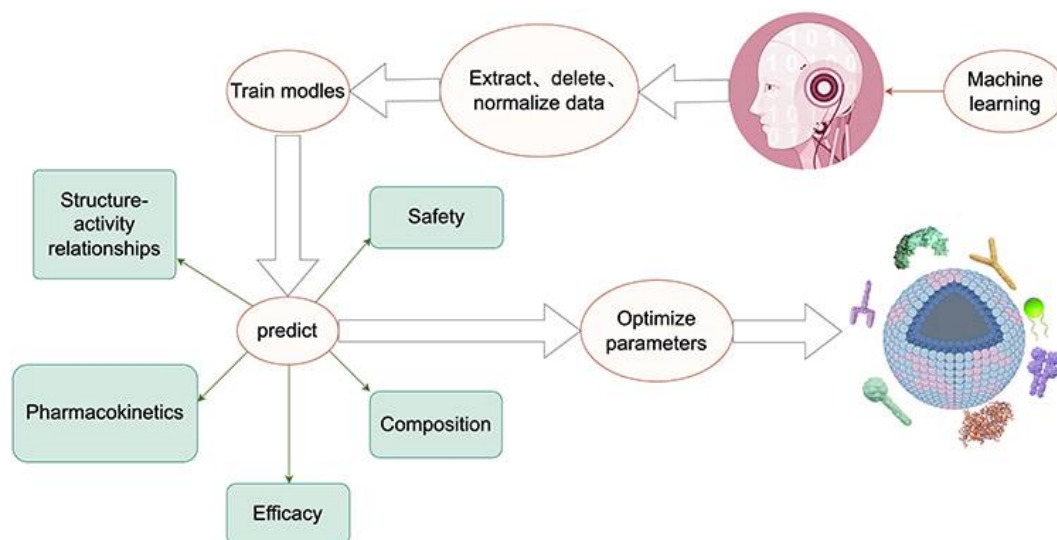


Figure 4- Machine learning optimization of niosomes[53]

There are currently a number of artificial intelligence methods, such as machine learning, that can help with niosome preparation. For instance, niosome medication compositions were optimized using a machine learning technique. 114 niosome formulations were examined by screening the literature using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) approach. A neural network model with a hyperbolic tangent sigmoid transfer function and the Levenberg-Marquardt backpropagation algorithm was trained using eleven properties that were shown to affect the particle size and drug entrapment. The model's prediction accuracy for particle size and drug entrapment was high. The drug/lipid and cholesterol/surfactant ratios were identified as important variables by sensitivity analysis. By creating batches of donepezil hydrochloride niosomes, the model's accuracy was confirmed, showing a prediction accuracy of more than 97%. The study found that for niosome formulations, the global artificial neural network performs better than the local response surface methods. By optimizing the composition, structure, and characteristics of niosomes, machine-learning algorithms can anticipate their stability, drug loading capacity, and release, improving medication release and absorption effects at a reduced cost and time. Compared to conventional procedures, these artificial intelligence techniques provide more accurate and efficient ways to prepare and enhance niosome performance. To guarantee the viability and safety of these technologies, however, experimental validations are required before implementation.[53]

CONCLUSION

Recent technical developments called niosomes show promise for treating infectious diseases and cancer. They provide benefits like improved purity, higher chemical stability, and lower cost as an alternative to liposomes. Non-ionic surfactant vesicles called niosomes have an impact on cellular contact, metabolism, tissue distribution, and drug plasma clearance. They are already used in cosmetics, but they have potential for a variety of medication delivery uses, including topical, parenteral, ophthalmic, and targeted. Compared to ionic drug carriers, which are inappropriate and relatively hazardous, it offers a potential carrier system. Nonetheless, Niosome technology is still in its early stages of development. Because it is a promising targeted medication delivery method, research is being done to create a technology that can be produced in big quantities.

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