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Review Article

The Noisome Revolution: Redefining Pharmaceutical Delivery

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ABSTRACT

Background: Noisome are nanometric vesicular systems made of cholesterol and non-ionic surfactants that were created to enhance drug delivery through reduced toxicity, increased bioavailability, and tailored therapy. Their structural resemblance to liposomes, together with their increased stability and affordability, have sparked interest in their application in a number of therapeutic fields. **Method:** The scientific literature from databases including PubMed, ScienceDirect, and Google Scholar was systematically evaluated to create this review. Comprehensive data on noisome composition, preparation methods, characterization techniques, drug targeting mechanisms, and pharmaceutical uses were gathered through an analysis of research publications, clinical studies, and reviews. **Results:** The results demonstrate that noisome can encapsulate medicines that are hydrophilic, lipophilic, or amphiphilic, providing enhanced targeting efficiency and controlled release. Numerous preparation techniques, including sonication, micro fluidization, and thin-film hydration, have an impact on the stability, size, and drug loading capability of vesicles. Since they are biocompatible and less immunogenic, noisome have shown promise in peptide, anticancer, ophthalmic, and transdermal drug delivery systems. **Conclusion:** By combining enhanced therapeutic results with formulation flexibility, noisome offer a viable platform for sophisticated drug delivery. Despite issues with sterilizing and physical stability, more study and improvement can realize their full promise in vaccine administration, diagnostics, and pharmaceuticals.

INTRODUCTION

Back in 1909, Paul Ehrlich came up with a groundbreaking idea: targeted drug delivery. He envisioned a system that could send medications straight to the sick cells, leaving healthy ones

untouched [1]. This concept, which we now call drug targeting, focuses on delivering drugs right where they're needed, reducing the risk of affecting healthy tissues. One exciting way to make this happen is through noisome [2]. These are tiny vesicles created by mixing non-ionic

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surfactants with water, and sometimes adding cholesterol or other lipids. They look a lot like liposomes and can hold both fat-loving and water-loving drugs, making them a fantastic option for precise and effective drug delivery [3]. The cosmetics industry was the first to use noisome [4]. Because of their lower irritating power—which falls in the order of cationic > anionic > ampholytic > non-ionic non-ionic surfactants are recommended. As seen in Fig. 1, non-ionic surfactants are made up of polar and non-polar segments with strong interfacial activity that,

when hydrated, create a bilayer to entrap both hydrophilic and hydrophobic medications [2]. Noisome can be used for a variety of medication delivery methods, including topical, ophthalmic, targeted, parental, and more [1]. Recent years have seen a great deal of research on noisome's potential as a vehicle for the transfer of hormones, antigens, medications, and other bioactive substances. In addition, noisome have been employed to address the issues of drug instability, insolubility, and fast degradation [5].

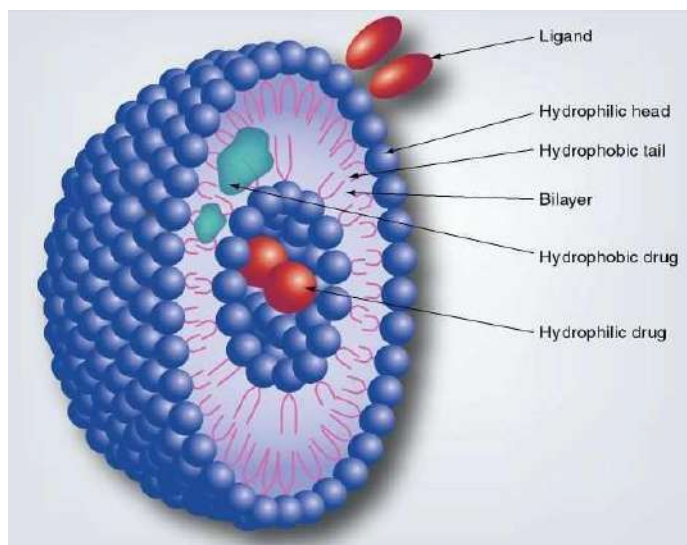


Fig No.1. Noisome structure [11]

Definition

Noisome are tiny vesicles, just a few nanometres in size, crafted from a blend of cholesterol and non-ionic surfactants. This unique combination gives them better structural stability than liposomes. Plus, because they use non-ionic surfactants, noisome are less toxic, making them a safer and more stable option for pharmaceutical uses. Noisome have particle sizes ranging from 20 nm to 100 nm⁻¹[6].

STRUCTURAL FEATURES AND COMPOSITION OF NOISOME

A typical noisome vesicle would have a vesicle-forming amphiphile, or non-ionic surfactant like Span860, which is typically stabilized by adding cholesterol, along with a tiny quantity of anionic surfactant, such diacetyl phosphate, which also aids in vesicle stabilization [7]. Selecting a surfactant for noisome synthesis primarily depends on the surfactant's HLB value, which ranges from 4 to 8. The procedure utilized to prepare the noisome determines whether its structure is uni-lamellar or multi-lamellar. All different kinds of medicines, including hydrophilic, lipophilic, and amphiphilic ones, can be included into the noisome structure. Figure 1

displays the locations of every drug kind in the noisome structure [6].

The noisome is mostly composed of the following elements:[8]

- Non-ionic surfactants
- Cholesterol
- Charge inducer
- Hydration medium
- **Non-ionic surfactants-**

Noisome production is significantly influenced by surfactants. When preparing noisome, the following non-ionic surfactants are typically utilized.

For instance,

spans (60, 40, 20, 85, 80)

Brij's (Brij 30, 35, 52, 58, 72, 76)

Tweens (tween 20, 40, 60, 80).

Non-ionic surfactants have a unique structure made up of two different parts: a hydrophilic head that loves to mingle with water and a hydrophobic tail that prefers to stay away from it [11].

- **Cholesterol-**

Cholesterol is employed to give the noisome preparations stiffness and the right shape and conformity [6].

- **Charge inducer-**

To prevent noisome aggregation, a charge molecule is introduced to the noisome formulation. e.g. Molecules with a negative charge- Di hexadecyl phosphate, lipoamino acid, phosphatidic acid, and diethyl phosphate. Molecule with a positive charge- Stearyl pyridinium chloride and stearyl amine [8].

- **Hydration medium-**

Phosphate buffer is the most widely utilized hydration medium while making noisome. At different pHs, these phosphate buffers are employed. The pH level of the hydration medium can change based on how well the encapsulated drug dissolves in the solution [10].

TYPES OF NOISOME [12]

Noisome can be categorized into three main types based on their size and structural features:

- **Small Unilamellar Vesicles (SUVs):** These tiny vesicles have a diameter that ranges from about 10 to 100 nanometres.
- **Large Unilamellar Vesicles (LUVs):** These are larger, typically measuring between 100 and 3000 nanometres.
- **Multilamellar Vesicles (MLVs):** These consist of several lipid bilayers stacked together in concentric layers.

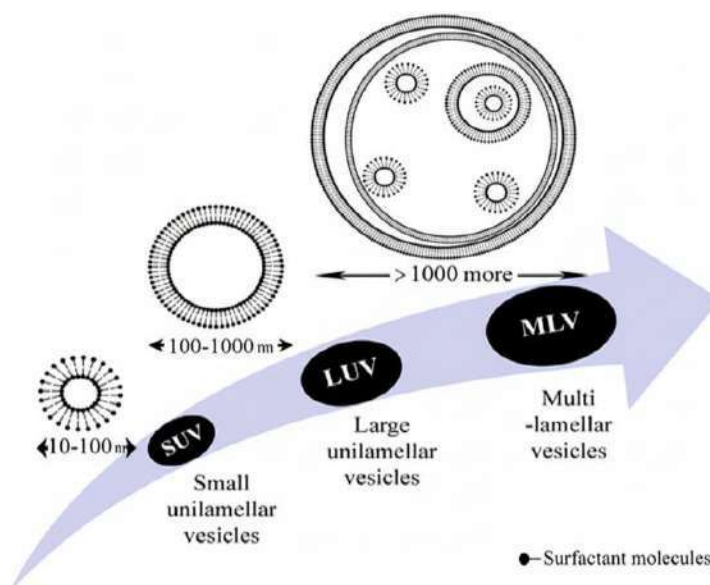


Fig No.2.Schematic structure of SUVs, LUVs and MLVs

Table No:1- Comparison with liposomes [6]

Sr. no	Noisome	Liposome
1	Surfactant	Phospholipid
2	Size 10-100nm	Size 10-3000nm
3	Inexpensive	Expensive
4	Not required special storage condition	Required special storage condition
5	Less toxic	More toxic
6	Cholesterol present	Not contain cholesterol

can improve a drug's skin penetration [4]	Entrapped medication leakage [16]
Noisome have a better bioavailability than traditional dosage formulations [5].	Encapsulated medication hydrolysis that reduces the dispersion's shelf life [11]
The surfactants are non-immunogenic, biodegradable, and biocompatible [14].	Fusion [17]

Table No:2- Advantages and Disadvantages of Noisome

Advantages	Disadvantages
Compared to liposomes, noisome have a longer storage period, are chemically stable, and are osmotically active [12]	Physical instability [19]
When you compare oil-based formulations to aqueous vesicular suspensions, you'll often find that patients tend to tolerate the latter much better. This leads to higher compliance rates [1].	Combination [15]

Salient features [10]

- Noisome make it simple to deliver sensitive and labile medications.
- Noisome typically have structural flexibility, their design can be tailored to the specific circumstance.

PREPARATION METHOD OF NOISOME

The preparation techniques should be selected based on the noisome' intended application, as they affect the aqueous phase's entrapment efficiency, size distribution, number of bilayers, and membrane permeability of the vesicles. The benefits and drawbacks of noisome preparation techniques are described in Table 3. The method of preparation of noisome is shown in below,[6]

- | | |
|---------------------------------------|--|
| 1)Sonication | 6)Bubble method |
| 2)Micro fluidization | 7) Thin film hydration technique (Hand shaking method) |
| 3)Multiple membrane extrusion method | 8) Trans membranes pH gradient method (inside acidic) |
| 4)Ether injection method | 9) Formulation of noisome from proniosome |
| 5)Reverse phase evaporation technique | |

Table No:3- Preparation Methods

Sr. No	Types of noisome	Preparation technology	Advantages	Disadvantages
1	Small unilamellar vesicles [18,20]	Sonication	Green technique; no need for organic solvents	High energy consumption and costly equipment
		Micro fluidization	high level of consistency and reproducibility	Not suitable for heat-sensitive medications that are readily hydrolysed and/or oxidized
		Multiple membrane extrusion method	Less polydispersity	Higher drug losses
2	Large unilamellar vesicles [6,2,20]	Ether injection method	Basic technology.	Not suitable for use with heat-sensitive medications or organic solvent residue
		Reverse phase evaporation technique (REV)	High efficiency of encapsulating	Possible organic solvent residues
		Bubble method	Organic solvents are not used.	Low stability during long-term storage
3	Multilamellar vesicles [20,3]	Thin film hydration technique (Hand shaking method)	Basic technology	Organic solvents are challenging to eliminate.
		Trans membranes pH gradient method (inside acidic)	High encapsulation efficiency and stability	Organic solvents have a high polydispersity index, heterogeneity, and are challenging to remove.
		Formulation of noisome from proniosome	High levels of chemical and physical stability during extended storage	complicated and time-consuming procedure

Formulation of noisome from proniosome [3]

The pro-noisome can be converted into a noisome by adding an aqueous component, such water, to the pro-noisome. Figure 3 illustrates how the pro-noisome and noisome develop. It took a brief

period of agitation at a temperature higher than the surfactant's typical transition phase temperature for noisome to develop from pro-noisome. $T > T_m$.
were



T=temperature.

T_m = mean temperature at phase transition.

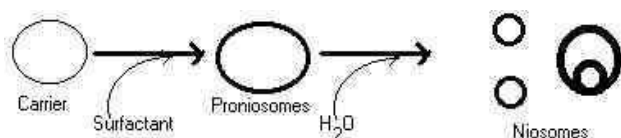


Fig No.3: Formation of niosome from proniosome [1]

Trans membranes pH gradient method [12]

In chloroform, cholesterol and surfactant dissolve. To create a thin layer on the flask's round bottom wall, the solvent is subsequently evaporated at

lower pressure. 300 mM citric acid (pH 4.0) is added to the film via vortex mixing. The multilamellar vesicles go through three rounds of freezing and thawing, and then they're sonicated. After that, this niosome dispersion is mixed with an aqueous drug solution that has 10 mg/ml of the active ingredient, using vortex mixing to ensure everything blends well. Finally, the pH of the mixture is fine-tuned to sit between 7.0 and 7.2 by adding a 1M solution of disodium phosphate. Niosome are then produced by heating this mixture for ten minutes at 60°C.

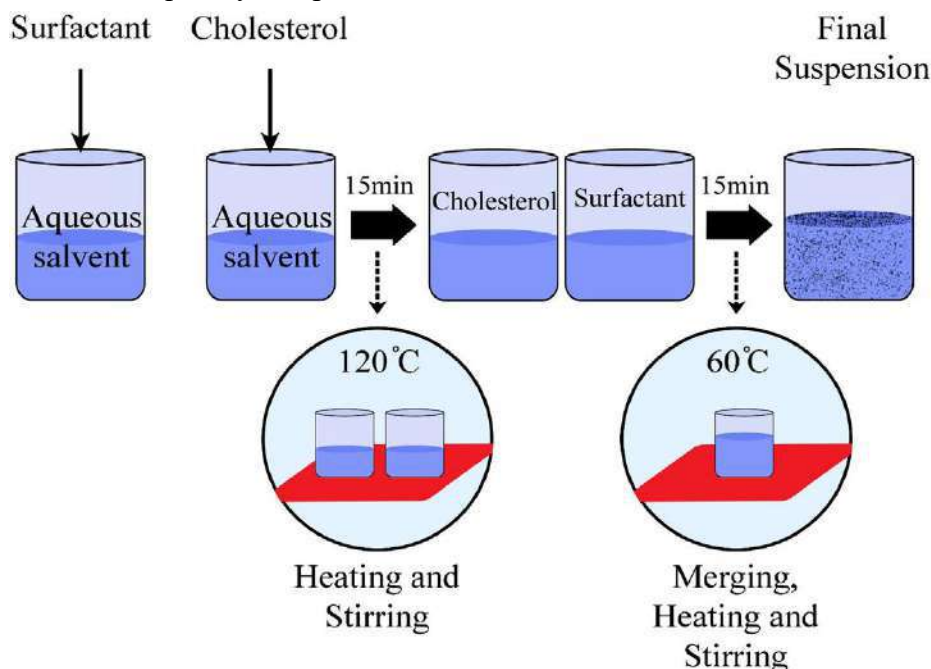


Fig No.4: Protocol for trans membranes pH gradient method [12]

Sonicator [21,30]

This approach initially disperses the mixture of cholesterol and surfactant in the aqueous phase. Multilamellar vesicles (MLV) are created when this dispersion is probe sonicated for ten minutes

at 60 °C. These MLVs undergo additional ultrasonication using a bath or probe sonicator, which causes unilamellar vesicles to develop.

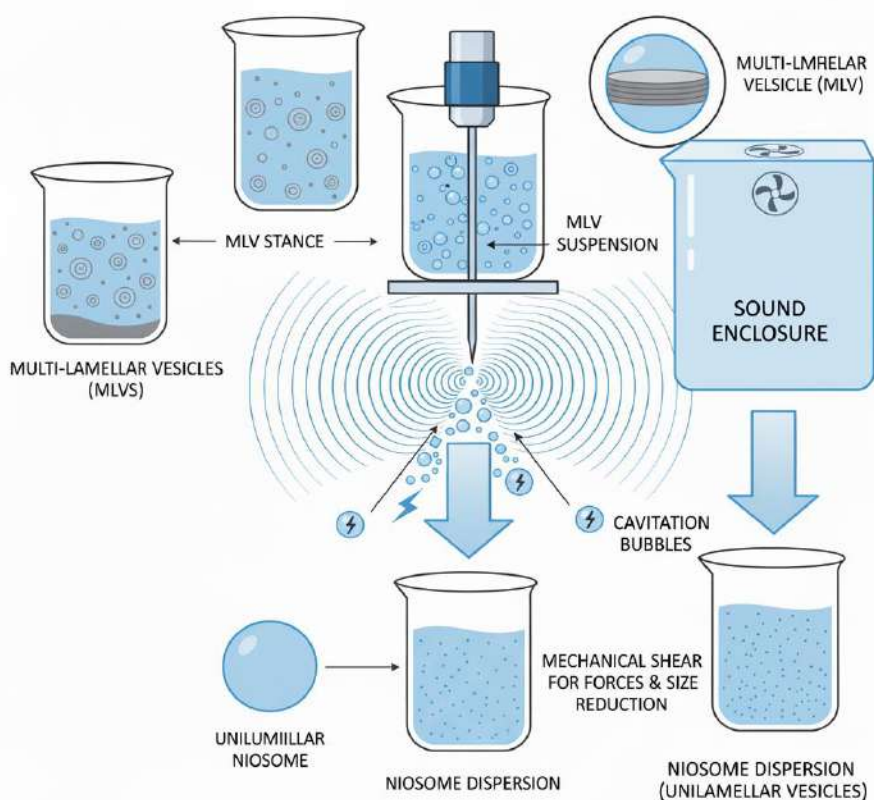


Fig No.5: Sonication

Micro fluidization [22]

Using this technique, two fluidized streams—one carrying a medication and the other a surfactant—interact at extremely high speeds in carefully crafted microchannels inside the interaction

chamber so that the energy delivered to the system stays in the region where niosome form. We refer to this as the submerged jet principle. Better homogeneity, reduced size, and reproducibility in niosome formulation are the outcomes.

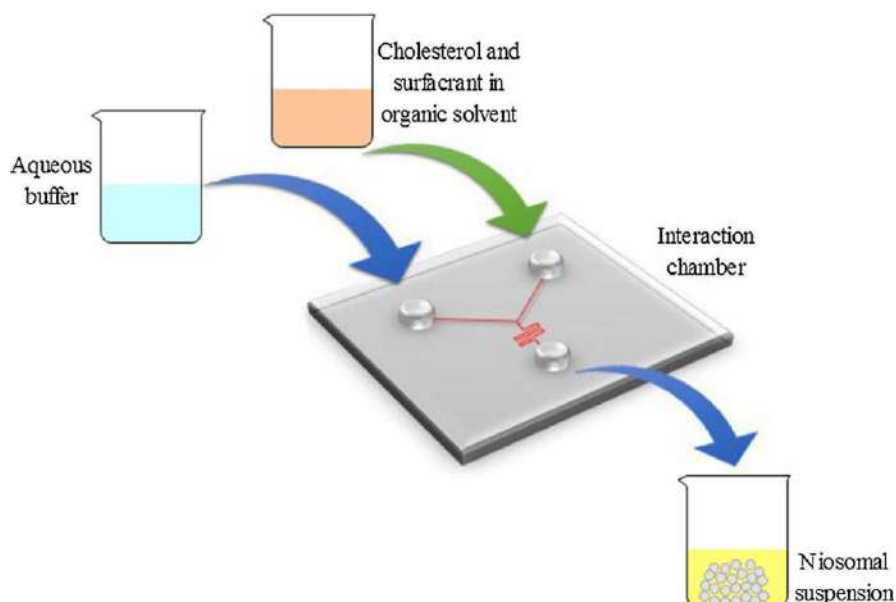


Fig No.6: The protocol for micro-fluidization [31]

The multiple membrane extrusion method [23]

To prepare the formulation, a mixture of surfactant, cholesterol, and diacetyl phosphate dissolved in chloroform is evaporated to form a thin lipid film. This film is then hydrated using an

aqueous drug solution, and the resulting suspension is passed through polycarbonate membranes to ensure uniformity in vesicle size. The film is then positioned in sequence for up to eight passages. It's a useful technique for managing noisome size.

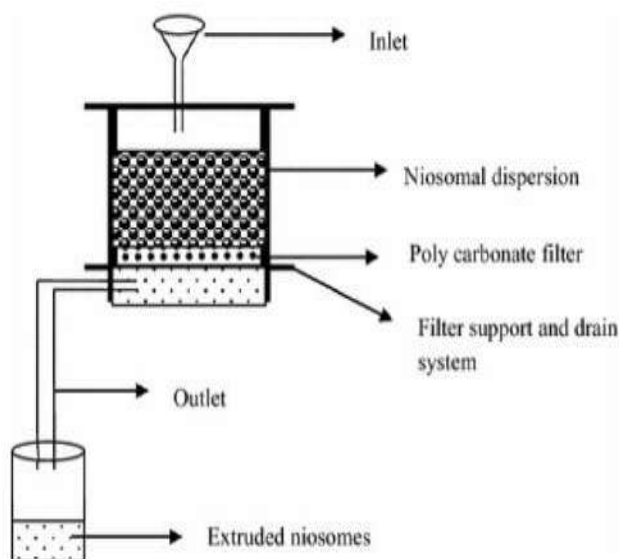


Fig No.7: Protocol for multiple membrane extraction method [23]

Ether injection method [12]

This method involves gradually adding a surfactant that's been dissolved in diethyl ether into water that's kept at 60°C. This process helps in creating noisome. A 14-gauge needle is used to inject a combination of ether-based surfactants into a solution of water. When the ether is

vaporized, it leads to the formation of single-layered vesicles. Vesicle diameters can vary quite a bit, ranging from 50 to 1000 nanometres, depending on the specific conditions during the formulation process. One downside of this method is that it might leave behind tiny traces of ether in the vesicle suspension, making it tricky to eliminate completely.

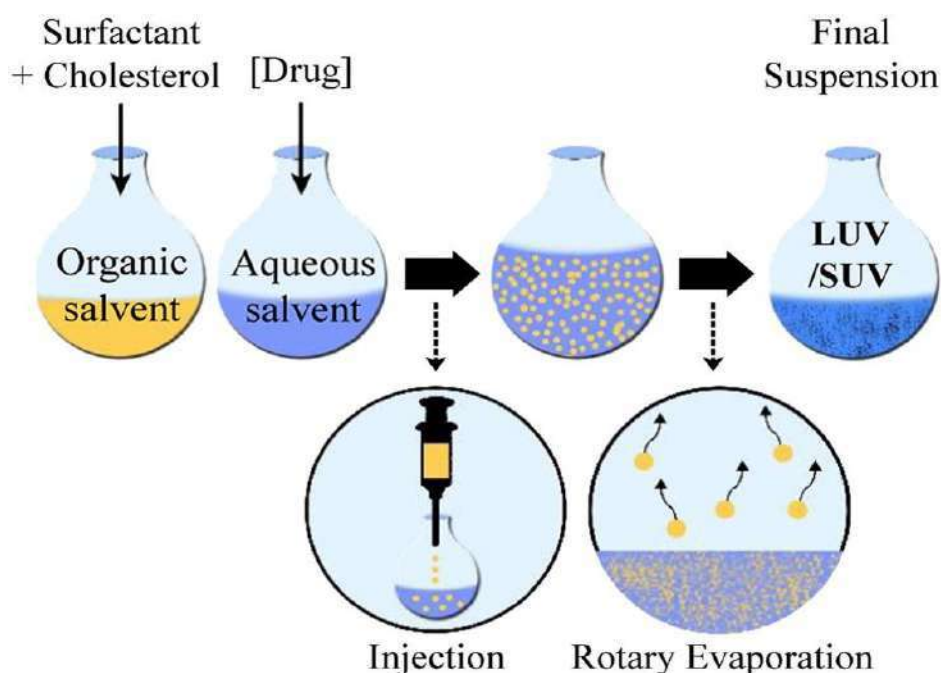


Fig No.8: Protocol for ether injection method [32]

Thin film hydration technique (Hand shaking method) [12]

When using the hand shaking method, a round-bottom flask is used to dissolve cholesterol and a non-ionic surfactant in a volatile organic solvent (such as methanol, diethyl ether, or chloroform). A thin coating of solid mixture is left on the flask

wall after the organic solvent is eliminated using a rotary evaporator set to room temperature (20°C). The drug-containing aqueous phase is added to the dry surfactant film at 50–60°C while being gently stirred. This process creates multilamellar noisome.

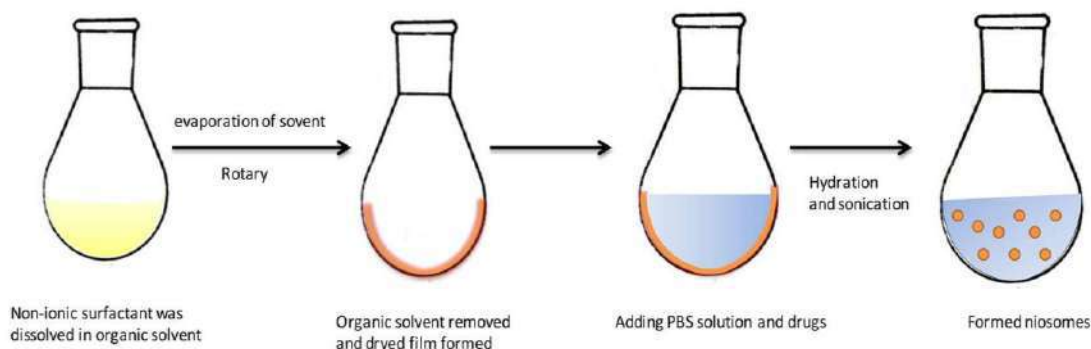


Fig No.9: Protocol for thin film hydration technique [27]

Bubble method [10]

The bubble method is a brand-new process that produces noisome without the use of organic solvents. This method involves a bubbling setup where we control the temperature using a three-

necked round-bottom flask that sits in a water bath. One neck connects to a water-cooled reflux condenser, another holds a thermometer, and the last one is for introducing nitrogen gas. We mix surfactant and cholesterol in a buffer solution with a pH of 7.4 and heat it up to 70°C. After that, we

subject the mixture to high shear homogenization for 15 seconds, and then we bubble nitrogen gas

through it right away while keeping it at the same temperature.

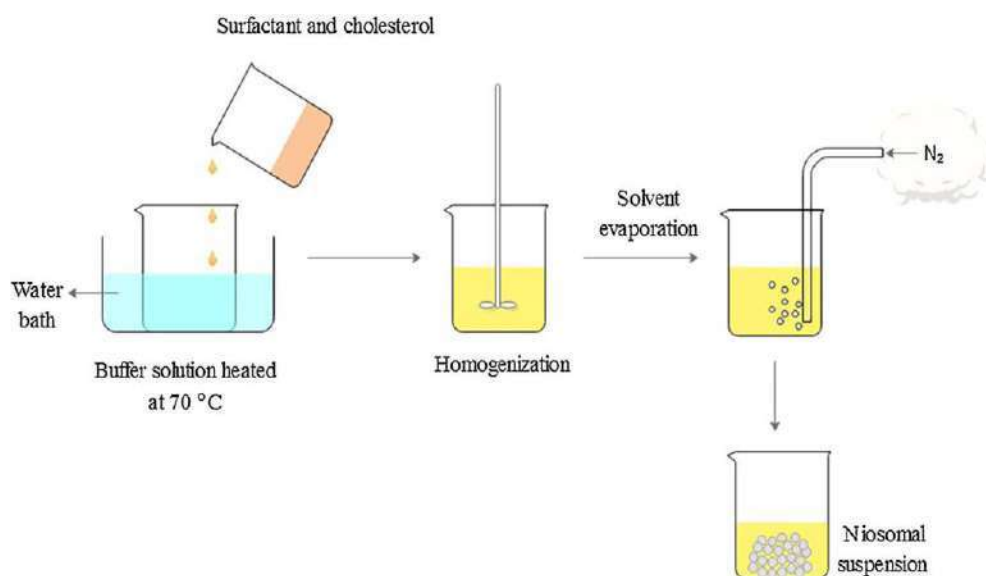


Fig No.10: Protocol for bubble method [31]

CHARACTERIZATION TECHNIQUES

The shape, size distribution, charge and zeta potential, entrapment efficiency, drug release curve, lamellarity, rigidity, stability, viscosity, conductivity, and homogeneity are all included in the physicochemical characterization and analysis of niosome.[32]

Table No:4- Method for Characterization of Niosome

Noisome parameter	Measurement
Particle size	DLS, SEM, AFM, STM, CLS [18,24]
Zeta potential	DLS, Electrophoretic mobility [12]
Encapsulation efficiency	Encapsulation efficiency = $\frac{\text{Encapsulated amount}}{\text{total amount}} \times 100\%$ The amount of the loaded drug is determined by HPLC, UV/VIS, Fluorescence [18]
Stability testing	DLS (determine size and zeta potential in 37 °C, or in serum to mimic the in vivo situation), Leaky of the loaded drugs [11]

Abbreviations: - DLS (Diameter Laser Scatter), SEM (Scanning Electron Microscope), AFM (Atomic Force Microscope), STM (Scanning Tunnelling Microscope), HPLC (High Performance Liquid Chromatography)

Particle size and Zeta potential [18,24,12]: -

Niosome are spherical in shape, and Table 4 summarizes the several methods that can be used to determine their size. The size of vesicles can vary from about 20 nm to over 50 μm . Zeta potential analysis is employed to ascertain the prepared formulations' colloidal characteristics.

Encapsulation efficiency [18]: -

The untrapped medication can be separated via gel filtration, centrifugation, or dialysis to increase the niosome dispersion's entrapment efficiency. The drug's ability to stay trapped in niosome is assessed by spectrophotometrically evaluating the sample after full vesicle destruction with 50% n-propanol or 0.1% Triton X-100.

Where,

percentage of entrapment= Total drug - diffused drug / total drug

Stability testing [11]: -

The ideal batch of noisome was kept in airtight, sealed vials at various temperatures to assess their stability.

In vitro drug release [34]: -

The dialysis bag method is a popular technique for assessing drug release in vitro. To get started, the dialysis tubing needs to be cleaned and soaked in distilled water for about half an hour. After that, the noisome formulation containing the drug is placed inside the bag. This bag is then submerged in a buffer solution, which is maintained at either 25°C or 37°C, and it's continuously shaken to ensure consistent conditions. At specific time intervals, samples are taken from the surrounding buffer and replaced with fresh buffer of the same volume. Finally, the amount of drug that has been released into the buffer is measured using a suitable assay technique.

MECHANISM OF DRUG TARGETING**Table No:5-Passive vs. Active Targeting [25]**

Passive targeting	Active targeting
modifies how drugs are biodistributed within the body	enhances target cells' absorption of drugs
Based on the Enhanced Permeability and Retention (EPR) effect in tumours, targeting	The basis for targeting is the molecular interactions between cancer receptors and NP's ligands.
Limited efficacy and modest specificity Limited in application	High effectiveness and specificity in use incredibly adaptable

More toxicity and adverse effects	Reduced toxicity and adverse consequences
Reduced engineering and synthesis effort	It is more difficult to synthesize NPs with ligands attached while preserving their capacity to connect with target receptors in order to accomplish the desired activity (active targeting).

Passive Targeting [26]

The term "passive targeting" typically describes drug delivery methods that aim to deliver the medication to the systemic circulation. Passive targeting takes advantage of the natural interactions between the body's environment and the physical and chemical properties of a drug or its delivery system. This process helps the drug to gather at the intended site (see Figure). For instance, Zhang and his team successfully targeted breast cancer and cancer stem cells by using salinomycin-loaded micelles through passive targeting.

Active Targeting [26]

Active targeting works by attaching specific ligands to the surface of a drug delivery system, allowing them to bind to receptors found on target cells. These ligands can be things like albumin, antibodies, or bio adhesive non-ionic surfactants. There are three levels of active targeting, as illustrated in the figure: first-order targeting focuses on organs, second-order targeting hones in on specific cells, and third-order targeting goes even deeper, targeting within cells. For example, Zwicke et al. used folate receptors to effectively deliver anticancer drugs.

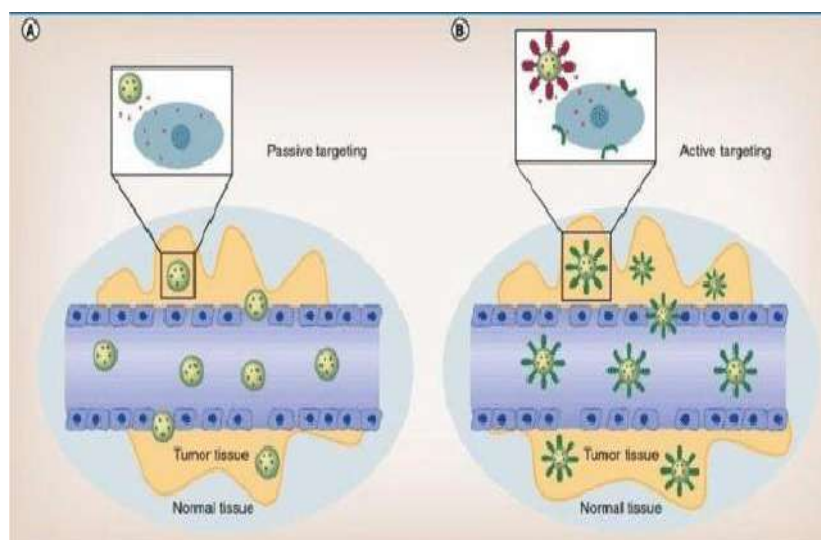


Fig No.11.Mechanism of active targeting and passive targeting [33]

APPLICATIONS

Table No:6-Application in Pharmaceutical Delivery

Application	Components	Drugs
Anticancer drug delivery [6,28,10]	Span 60, Cholesterol, DCP	Doxorubicin
Ophthalmic drug delivery [5,28,29]	Span 20, Span 60, Cholesterol	Pilocarpine hydrochloride
Transdermal drug delivery [3,5,10]	a, w-Hexadecyl-bis-(1-aza)18-crown-6(bola), Span 80, Cholesterol Brij 96, Cholesterol	Ammonium glycyrrhizinate
Nasal drug delivery [28]	Span20, Span40, Span80, Span85, Cholesterol, Phosphate buffered saline	Nefopam
Peptide drug delivery [3,5,10]	Span20, Span40, Span60, Tween20, Tween80, Cholesterol	Insulin
Pulmonary drug delivery [5,28]	Span40, Span60, Span85, Tween60, Cholesterol	Zanamivir
Diagnostic imaging [5,28]	N-Palmitoyl-glucosamine (NPG), Polyethylene glycol (PEG)-4400	Gadobenate
For anti-inflammatory effect [27,6]	Cholesterol (CH), Diacetyl phosphate (DCP) and Surfactants (Tween 85, Pluronic F108)	Diclofenac sodium

For brain targeting [5,28]	N-Palmitoyl glucosamine (NPG), Span 60, Cholesterol, Solulan C24	Vasoactive Intestinal Peptide
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TOXICITY [12,23]

Noisome' non-ionic composition is likely to contribute to their low toxicity. In actuality, non-ionic surfactants are less harmful and more compatible than their anionic, amphoteric, or cationic equivalents. On the other hand, non-ionic surfactant segregation could be harmful. Additionally, the location and concentration of released drug provide another rationale for toxicity when noisome are involved in lowering and targeting pharmacological side effects. Noisome also have the ability to target, which lessens the negative effects of the medication; but, in certain situations, the excessive concentration and improper placement of the released drug may still be harmful.

BIOCOMPATIBILITY [12]

The numerous benefits of noisome, including their biodegradability, non-immunogenicity, bioavailability, and ability to effectively modify drug release parameters, have garnered significant interest in controlled drug delivery systems. Furthermore, due to their non-ionic structure and remarkable biodegradability, noisome have demonstrated low toxicity and great biocompatibility. Therefore, there are many chances for future advancements in drug delivery due to noisome' diverse biological functions, such as their low immunogenicity.

FUTURE PERSPECTIVES

Noisome are a promising method of medication delivery. Noisome can be used to boost the bioavailability and targeting capabilities of

hazardous medications, such as antiviral, anti-AIDS, and anti-cancer medications, by encapsulating them. Noisome do not require particular handling or storage conditions. Use the noisome technology to prepare the cosmetics. The two main barriers to noisome' prospective use as drug delivery vehicles are their physical stability and sterilizing.

CONCLUSION

Noisome drug delivery is a successful approach of creating novel medication delivery. Noisome are mostly made up of cholesterol and non-ionic surfactants. Noisome, which have a structure similar to liposomes, offer a versatile vesicular system capable of encapsulating a diverse array of drugs within their multilayered design. For drug delivery, noisome are thought to be superior to liposomes for a number of reasons, including stability and affordability. Noisome are highly promising for targeted administration of anti-inflammatory, anti-cancer, and anti-infective drugs as well as transdermal drug delivery. More recently, they have been used as adjuvants in vaccines and as diagnostic agents.

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