Review Article

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NIOSOMAL DRUG DELIVERY SYSTEM

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ABSTRACT

Niosomes are a novel and efficient drug delivery carrier. These are non-ionic surfactant vesicles obtained by hydrating mixture of cholesterol and nonionic surfactants. It can be utilized to transport both amphiphilic and lipophyilic drugs. The drug is enclosed in niosomal vesicle which is made up with non ionic surfactance. Niosomes are flexible in their structural characterization, biodegradable, biocompatible, and non-immunogenic. The liposome are the most commonly used bilayer vesicular system, however due to some shortcoming such as limited shelf-life, high formulation cost, susceptibility to oxidation and economy it is necessary to develop the better vesicular structure which is free from the all limitations. Whereas Niosomes ideally a bilayer vesicles structure which over come from all this limitations. Niosomes proved to be a promising drug carrier and has potential to reduce the side effects of drugs and increased therapeutic effectiveness in various disease. These have great drug delivery potential for targeted delivery of anti-cancer, anti-infective agents and for topical application. The mean objective of this review article is to acknowledge the structure, advantages, disadvantage, components of niosomes, preparation method, applications and marketed products of niosomes.

KEYWORDS

Niosomes, Non ionic surfactance, Composition, Method of preparation and Novel drug delivery system.

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INTRODUCTION

From many years the treatment of acute and the chronic illness have been involved by giving a patient they suitable medication in a various pharmaceutical doses form such as cream, ointment, liquids, tablet, capsules, emulsion, suspension, injectables and suppositories as carriers. To achieve and maintain the bioavailability of drug within therapeutically effective range these type of drug is often necessary to be administered several time in a

day in order to get a desirable pharmacological effect which lead to a fluctuation of drug levels and the undesirable toxicity and poor efficiency of medication. To minimize these fluctuations and undesirable toxicity novel drug delivery system have been developed¹. Any drug delivery systems that tend to alter the release of drug rate or site of absorption of drug is broadly categorized under the delivery system. novel drug Ideally this novel Delivery system should be able to fulfill two prerequisite which are unable to fill by the conventional drug delivery systems that is the capacity of delivery the payload or required drug rate over the treatment duration and delivering of payload or drug to the site specific at which it is required. The novel drug delivery approach attends to sustain the release of drug in predetermined pattern by maintaining the relative constant, effective level of API in a body with a minimum side effect at targeted tissue or organ with the help of some carriers such as niosomes, liposomes, nanoparticles microspheres, micro emissions, impalatable pumps and magnetic micro-capsules. Among these niosomes are the one of the best carrier². The first concept of niosomes was introduced by L'Oreal in 1970's and 1980s .In the year of 1987 the first niosomal product was developed by the L'Oreal (US patent 48308547, 1989) in cosmetic industry, for better penetrations, bioavailability and stability of entrapped drug³.

STRUCTURE OF NIOSOMES

Niosomes are non ionic microscopic lamellar vesicular structure of size range between the 10 to 1000nm formed by the admixture of non ionic effect surfactants and charge inducing agents which are stabilized by the addition of cholesterol with consequent hydration in aqueous media³. A typical niosome vesicle consists of vesicle forming amphiphile i.e non ionic surfactant such as alkyl or dialkyl polyglycerol ether. The self assembling of non ionic surfactants into a vesicle was firstly reported in 70s by the researchers in cosmetic industry⁴. As niosomes are amphiphilic in nature. This tends to oriented the hydrophilic drug into a

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cavity and hydrophobic drug into non polar region within the bilayer. Niosomes vesicle properties can be altered by the factors such as vesicle composition, size lemellarity, tapped volume, surface charge and concentration. The various type of force are involved inside the niosomes in order to maintain its vesicular structure such as Vander walls force among the surfactant molecule repulsive force emerging from the electrostatic interaction among the charged groups of surfactants molecules, entropic repulsive force of head group of surfactants and a short acting repulsive forces. The stability of niosomes can be affected by the type of surfactants used, the nature of encapsulated drug, storage temperature, detergents, use of membrane spanning lipids and interfacial polymerization of surfactants monomers in a situ are inclusions of charged molecule. The solubility of niosomal drug is a very high due to the presence of hydrophilic, amphiphilic and lipophilic moieties in the structure. The Non-ionic surfactants used in the niosomal preparation must be biodegradable, bio- compatible and Immunogenic⁵.

Image No.1: Structure of Niosomes



COMPARISON OF NIOSOMES WITH LIPOSOMES

Niosomes and liposomes are bilayer microscopic lamellar vesicular structures which have equiactive in the drug delivery potentials but higher stability and economy of niosomes make superior then the liposome. Basic difference between the niosomes Table No.1.

nposomes			
S.No	Niosomes	Liposomes	
1	Less expensive	More expensive	
2	Non ionic surfactants are stable toward oxidative degradation.	Phospholipids are prone to oxidative degradation	
3	Non ionic surfactant are neutral charged	Phospholipids may by neutral charged	
4	No special methods are required.	Require special method for handling and storage.	
5	Prepared from uncharged single chain surfactant and cholesterol.	Prepared from double chain phospholipids.	
6	Prolonged circulation of entrapped drug and altering its organ distribution and metabolic stability.	The properties of liposomes depend upon the composition of the bilayer and their method of production	

Table No.1: Comparison of niosomes with linosomes^{5,6}

COMPONENTS OF NIOSOMES

They are three main constituent uses in the formulation of niosomes.

Non ionic surfactance

Cholesterol

Hydration medium.

Non-ionic surfactance^{7,8}

Non ionic surfactance are main component use in preparation of niosomes. Which are converted into a lamellar microscopic are nanoscopic basils upon the hydration. This is depending up on HLB value of surfactants, CPP value and the chemical structure. These non ionic surfactance are less toxic, less hemolytic and less irritative to a cellular surface and more stable and more compatible when compared to anionic and cationic counterparts. This all properties are lead to maintain the physiological PH in the solution. The non ionic surfactance can also act as a solubilizer, wetting agent, emulsifiers and permeability enhancers.

Example

Poly glycerol, alkyl Ether, glycosyl di alkyl Ether, crown ether, span (span 20, 40, 60, 80, 85) and Brij (brij 30, 35, 52, 58, 72, 76) and etc and shown Table No.2.

Table No.2: Different types of non ionic
surfactants ⁴

S.No	Type of Non Ionic Surfactants	Examples
1		Cetyl alcohol,stearyl
	Fatty alcohol	alcohol,cetostearyl
		alcohol
2	Ethers	Brij, lauryl glycoside,
	Ethers	nonoxynol-9
3	Block copolymers	Poloxamers
4	Esters	Glyceryl laurate,
		spans, polysorbates

Cholesterol^{9,10}

Cholesterol is steroid derivative which is influence the physical and structural properties of niosomes. As it is interact with non-ionic surfactants during the formulation niosomes. It does not form the bilayer itself but it can be incorporate in a large molar ration and these incorporation of cholesterol will affect the various properties of niosomes such as membrane permeability, rigidity, encapsulation efficiency, easy of rehydration of freeze dried niosomes and their Toxicity. It also prevent the leakage problem which is major drawback in niosomal formulation.

Hydration medium⁵

The different PH phosphate buffer are used in niosomes formulation. The PH of hydration medium depends on the solubility of encapsulated drug. Phosphate buffers of PH 7.4 respectively are used to prepare ketoconazole niosomes and Meloxicam niosomes.

ADVANTAGES AND DISADVANTAGES OF NIOSOMES Adventages^{5,11}

- Niosomes provide the Sustained release of drug in predetermined manner. There by it enhances the oral bioavailability of drug.
- As it is the non ionic surfactance it will entrapped the hydrophilic, lipophylic and amphiphilic drugs, which leads to the enhance the stability of drug.
- The renal clearance of drug can be reduce by protecting the drug from the biological environment and restricting the transfer of drug to non specific cells or organ.
- Niosomes are flexible in nature, so it can be easily modified into the various route of administration such as oral, parenteral, as well as topical.
- As it is non ionic surfactants it will improve the skin penetration of drug.
- The presence of non ionic surfactance in niosomes structure makes it biodegradable, bio –compatible and non immunogenic.
- Niosomes product do not required the any specific storage condition as it is a more stable.

DISADVANTAGES^{11,12}

- It is expensive.
- Leaking of entrapped drug, fusion and aggregation may cause the physical instability of aqueous suspension.
- The preparation of multilamellar vesicles by the extrusion and the sonication are time consuming process and required the specialized equipments and experience person for the process.
- The self-life of dispersion is shortened by hydrolysis of the encapsulated medication.

Classification of niosome^{5,13}

Niosomes are classified based on number of bilayer or size or by method of preparation. The various types of niosomes are Table No.3. Small unilamellar vesicles Large unilamellar vesicles

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Multi lamellar Vesicles
Table No 3. Classification of niosomes

Table 10.3. Classification of mosomes				
S.No	Parameters	Small unilamellar vesicles	Large unilamellar vesicles	Multi lamellar vesicles
1	Vesicle size	0.025- 0.05μm	Greater than 0.10μm	Greater than 0.05µm
2	Method of preparation	Sonication Micro fluidization Solvent dilution techniques	Reverse phases evaporation technique Ether injection	Hand shaking method Remote loading

Method of preparation of niosomes Common stages of all methods of preparation of Niosomes⁵

Cholesterol + non ionic surfactant

Dissolve in organic solvent Solution in organic solvent

Drying

Thin film

Uspersion [hydration]

Niosomes suspension

Preparation of small unilamellar vesicles Sonication¹⁴

Niosomes using sonication method were prepared by Baillie *et al*, 1986. In this method, Surfactant and cholesterol (150micro.mol.) mixture was dispersed in 2ml aqueous phase in vial. The dispersion is subjected to probe sonication for 3 min. at 60c. This method involved the formation of SUVs which are subjected to ultrasonic vibration. Sonicator is two type Probe and Bath sonicator. Probe sonicator is use when sample volume is small and Bath sonicator is use when sample volume is large.

Micro Fluidization¹⁵

This technique, known as the "submerged jet principle," involves the interaction of two fluidized Streams (one containing a drug and the other a surfactant) at extremely high viscosities in precisely

defined micro channels inside an interaction chamber. This results in better uniformity, the smallest size, and reproducibility in a formulation of niosomes.

Preparation of large unilamellar vesicles Reverse phases evaporation technique¹⁶

A mixture of ether and chloroform is used to dissolve the surfactants, which are then added to the aqueous phase to emulsify the drug. After 296 hours homogenized the resulting mixture, an emulsion is created. It evaporates the organic phase. Lipid or surfactant initially creates a gel, then hydrates to create spherical stable identical vesicles.

Ether injection⁵

A solution of surfactant mixture is prepared first and then slowly introduced into warm water maintain at 60c. The surfactant mixture in ether is injected through 12-gauge needle into an aqueous solution of material. Single layer vesicles are formed by the vaporization of ether. The vesicle diameter range from 50 to 1000nm. The small amount of ether is often present in vesicle is major disadvantage of this Method.

Preparation of multilamellar vesicles

Hand shaking method (Thin film hydration Technique)¹⁷

The mixture of the surfactant and the other vesiclesforming components, such as cholesterol, is dissolved in a volatile organic solvent such as diethyl ether, chloroform, or methanol in a flask with a flat bottom. Rotating the evaporator when the organic solvent is eliminated at 20°C room temperature, this causes the production of multilamellar niosomes. When a thin layer of solid mixture is applied to the wall of an aqueous phase at 60°C while being gently stirring and Rehydrating the dried surfactant film¹⁷.

Remote loading^{1,5}

Surfactant and cholesterol are ready in chloroform and evaporated under reduced pressure and stream of N2 to yield a tinny lipid film on the wall of a round-bottomed bottle. The obtained lipid film is hydrated with an acidic compound (usually citric acid). The resulting preparation (multilamellar

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vesicles) is exposed to freeze-thaw cycles. The pH of the sample is then elevated to 7.2.

Miscellaneous

The Bubble method^{5,18}

Without the use of organic solvents, liposomes and niosomes can be created using this one-step method. With its three necks, a round-bottomed flask serves as a bubbling unit. Placed in the water bath to regulate the temperature. А water-cooled thermometer and reflux gauge are located in the first and third neck, whereas nitrogen is supplied via the second neck. At 70°C Surfactant and cholesterol are distributed simultaneously in the buffer (pH 7.4) was combined for 15 seconds with a high shear homogenizer before being instantly "bubbled" with nitrogen gas at 70°C.

The Handjani - Vila method¹²

In this method, a homogeneous lamellar phase is produced by mixing a lipid or lipid mixture with an aqueous solution containing and equivalent amount of active substance. The resultant mixture is homogenized at a controlled temperature by the means of ultra centrifugation or agitation.

Formation of niosomes from proniosomes^{5,18}

In this method of niosome production, sorbitol and water-soluble carrier are coated with a surfactant to create a dry formulation that covers each watersoluble particle in a thin layer of dry material surfactant. The word "Proniosomes" refers to this preparation. Then a screw-capped vial is filled with proniosome powder and Vortexing at 80°C with water or saline mixture, then by stirring for two minutes causes the development of niosomal suspension.

Separation of unentrapped drug^{5,6}

The removal of unentrapped drug from the niosomes can be achieved by following methods,

Dialysis

Niosomes in aqueous solution are dialyzed in dialysis tubing at normal temperature in opposition to an appropriate dissolving medium. The samples are removed from the medium at appropriate intervals, centrifuged, and the drug content is determined using the appropriate analytical method.

Gel filtration

Niosomal dispersion is put through a Sephadex-G-50 column for gel filtration, then it is eluted with the right mobile phase and subjected to the right analytical procedures.

CHARACTERIZATION OF NIOSOMES
Table No.4: Characteristics of niosomes

A valutical				
C N	Characteristi	Evaluation	Analytical	
S.No	cs	Parameters	Methods	
			/Instruments	
			Transmission	
			electron	
		Morphology	microscopy, SEM	
			and freeze-	
			fracture electron	
			Photon correlation	
		Vesicle size	spectroscopy,	
		and size	dynamic light	
		distribution	scattering,	
			zetasizer	
		Surface	Free flow	
		charge	electrophoresis	
1	Physical	C	Amount	
1	characteristics	Entrapment	entrapped/total	
		efficiency	amount added	
		5	*100	
			Freeze -fracture	
			electron	
		Phase behavior	microscopy,	
			differential	
			scanning	
			colorimetry	
		Electric	Zeta potential	
		surface	measurement and	
		potential and	PH sensitive	
		surface PH	probes	
			Cholesterol	
	Chemical characteristics	Cholesterol	oxidase assay and	
		concentration	HPLC	
2		Osmolarity	Osmometer	
2		Cholesterol		
		and auto	HPLC and TLC	
		oxidation		
		OAldation	Monitoring	
	Biological	Animal	survival rates,	
3	characteristics	toxicity	histology and	
	characteristics	toxicity		
			pathology	

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Sterility	aerobic or anaerobic cultures
Pyrogenicity	Limulus amebocyte lysate [LAL] test

Table No.5: Nature of drug and its effect on stability⁸

~•j			
S.No	Nature of drug	Leakage from the vesicle	Stability
1	Hydrophobic drug	Decreases	Increases
2	Amphiphilic drug	Decreases	-
3	Hydrophobic drug	Increases	Decreases
4	Macromolecules	Decrease	Increases

Centrifugation

After separating the supernatant from the proniosome-derived niosomal suspension, the suspension is centrifuged. To create a niosomal suspension free of unentrapped medication, the pellet is first cleaned and then re-suspended.

FACTORS AFFECTING NIOSOMES FORMULATION

Drug

Drug entrapment in niosomes causes an increase in vesicle size, which is most likely caused by an Increase in the charge and mutual repulsion of surfactant bilayers or by the interaction of the solute with surfactant head groups. However, certain drugs are caught in the lengthy PEG chains. In cases where vesicles are coated with polyoxyethylene glycol (PEG), the inclination to become larger is lessened. The drug's hydrophilic lipophilic balance influences the level of entrapment⁵.

Nature and type of surfactants

Since the surface free energy of a surfactant lowers as its hydrophobicity increases, the mean size of niosomes rises correspondingly as HLB surfactants like Span 85 (HLB 1.8) to Span 20 (HLB 8.6) are used. Hydrophilic head and hydrophobic tail are necessary characteristics of a surfactant. One, two, or perhaps one or more alkyl, perfluoroalkyl, or in

July – August

297

certain situations, steroidal groups may make up the hydrophobic tail⁹.

Cholesterol content and charge

The chain order of bilayers in the liquid state is increased by cholesterol, whereas the chain order of bilayers in the gel state is decreased. With a lot of cholesterol present, the gel state changes into a liquid-ordered phase. The bilayers' stiffness increased with increasing cholesterol content because it reduced the rate at which material was released from its encapsulation. Due to the existence of charge and other factors, the interlamellar distance between subsequent bilayers tends to grow in multilamellar vesicles which lead to increases the total volume of air trapped¹⁰.

Membrane composition

The creation of stable niosomes is aided by the addition of various chemicals, surfactants, and medications. Several morphologies' permeability and stability qualities change as a result of the addition of various chemicals. For instance, when a small amount of Solulan C24 (a cholesterol poly 8248 oxyethylene ether) is added, the shape of polyhedral niosomes formed from the antimicrobial peptide C16G2: cholesterol: solution produces spherical niosomes (49:49:2). The composition of the membrane has an impact on the mean niosome size. For instance, polyhedral niosomes created by C16G2 and solution C24 in the ratio (91:9) are larger (8.0 0.03mm) than spherical/tubular niosomes formed by C16G2 and solution C24 in the ratio (49:49:2) (6.6 0.2mm). Niosomes become stiff when the cholesterol molecule is $added^{16}$.

Method of preparation

Smaller vesicles are produced by the ether injection method (50-1,000nm) than by the hand shaking method (0.35-13nm). Small-sized niosomes can be created using the reverse phase evaporation (REV) approach, although microfluidisation results in smaller vesicles and more uniform distribution⁵.

Resistance to osmotic stress

Reduction in niosomes diameter is observed upon the addition of a hypertonic salt solution. However, an initial slow release with slight swelling of vesicles is observed due to inhibition of eluting

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fluid from vesicles, followed by faster release, which may be due to mechanical loosening of vesicles structure under osmotic stress^{5,12}.

Temperature of hydration

The hydration temperature can also affect the size and shape of niosomes; in ideal circumstances, it should be higher than the system's gel-to-liquid phase transition temperature. Niosomal system temperature changes have an impact on how surfactants are assembled into vesicles and also cause vesicle shape changes. C16G2: Solulan C24 (91:9) was shown to create polyhedral vesicles at 25°C, which changed into spherical vesicles at 48°C after heating, but on cooling from 55°C, the vesicle developed a cluster of smaller spherical niosomes at 49°C before converting to the polyhedral structures at 35°C. Vesicles made of C16G2: cholesterol: solulanC24 (49:49:2), in contrast, do not change shape when heated or cooled. Niosome hydration duration and volume, in addition to the previously mentioned parameters, are also important. Improper selection of these factors may result in the formation of fragile niosomes or creation of drug leakage problem⁶.

APPLICATIONS

Niosomes in oral drug delivery

Comparison to the conventional medication in mice, the oral administration of methotrexate in niosomal form results in higher serum drug concentrations and greater liver uptake. Niosomal insulin formulation made from the Span 20, 40, 60 and 80 demonstrated lesser insulin releas in vitro in simulated intestinal fluid from Span 40 and 60 than Span 20 and 80. When sodium deoxycholate and storage temperature are present, niosomes made from Span 60 exhibit the highest level of preservation of insulin against proteolytic enzymes¹⁹.

Niosomes in transdermal drug delivery

The main disadvantage of transdermal administration is the slow absorption of drugs through the skin. Transdermal administration of a medicine contained in niosomes may boost the penetration rate. The greatest technique to prevent

stomach problems when taking NSAIDs is by transdermal administration. Diclofenac diethyl ammonium niosomes for topical distribution demonstrated positive activity for the topical, noninvasive treatment of inflammation in a published study. Because niosomes can enter the deeper layers of the skin, Meloxicam niosomal gel demonstrated greater anti-inflammatory effect in the carrageenaninduced rat model²⁰.

Niosomes in ophthalmic drug delivery

The fundamental drawback of ocular dose forms such ophthalmic solutions, suspensions and ointments is poor bioavailability because of tear formation, corneal epithelial impermeability, nonproductive absorption, and brief residence duration. Niosome application is a wonderful choice to increase the bioavailability. Bioadhesive-coated niosomal formulations of acetazolamide made from Span 60, cholesterol, stearylamine, or dicetyl phosphate showed a stronger tendency to lower intraocular pressure when compared to conventionally marketed forms of dorzolamide. In comparison to a commercial formulation with a lower risk of cardiovascular side effects, the chitosan-coated niosomal formulation of Timolol maleate (0.25%) has a greater impact on lowering intraocular pressure².

Niosomes in neoplastic drug delivery

The anthracyclic antibiotic Doxorubicin exhibits a dose-dependent irreversible cardiac damaging impact in addition to its broad spectrum anti-tumor activity. Due to the drug's niosomal entrapment, its half-life was extended, and its circulation and metabolism were also changed. When this medicine is administered by niosomal administration to mice with the S-180 tumour, it has been found that both the mice's lifespan and the pace at which sarcomas proliferate have diminished. When methotrexate is entrapped in niosomes and given intravenously to mice carrying the S-180 tumour, the tumour completely regresses, as well as having a higher plasma level and a slower rate of clearance¹³.

Niosomes in brain delivery

Mice received intravenous injections of niosomes containing radiolabelled 1251 vasoactive intestinal

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peptide (VIP) and glucose. Higher VIP brain absorption than control is shown by encapsulated VIP within glucose-bearing niosomes^{5,13}.

Other applications

Sustain release

Ketoprofen Niosomes were prepared by lipid hydration method and then dried and compressed into sustained release tablets (100mg)⁹.

Targeted drug delivery systems

The colon is a site where both local and systemic delivery of drugs can take place. Local delivery allows topical treatment of inflammatory bowel disease. However, treatment can be made effective if the drugs can be targeted directly into the colon, thereby reducing the systemic side effects^{7,21}.

ROUTES OF ADMINISTRATION OF NIOSOMAL DRUGS^{5,11}

Niosomes have been demonstrated to be effective in controlled drug delivery systems for the transdermal, parenteral, oral, and ocular routes Table No.6 and Figure No.2.

different routes in mosonial drug denvery			
S.No	Route of administration	Example of drugs	
	Intravenous	Diclofenac sodium, Ipromide, rifampicin, insulin, cisplatin,	
1	route	zidovudine, transferrin,	
		amphotericin B, Vincristine.	
2	Ocular route	Timolol maleat, cyclopentolate.	
		Enoxaci, ketaconazole,	
3	Transdermal	flurbiprofen, piroxicam,	
3	route	cyclosporine, erythromycin,	
		DNA loaded niosomes.	
4	Nasal route	Sumatriptan, influenza viral	
4	Inasai ioute	vaccine	
5	Peroral route	DNA vaccine, protein, peptides	
6	Pulmonary	Chloroquine, gemcitabine and	
	route	cisplatin	
7	Treatement of leishmaniasis	stilbogluconat	

Table No.6: List of drugs administered through different routes in niosomal drug delivery



MARKETED PRODUCTS OF NIOSOMES

Lancôme firstly has come out with the developing the various niosomal products in market which is based on anti ageing product. Still research is going on the anti ageing costamic by loreals and various pharmaceutical dosages are developing bv researcher based on their bioavailability and safety shown Figure No.3 to Figure No.5.

Image No.3¹³



Image No.4¹³







CONCLUSION

One of the clearest illustrations of the rapid advancement of nanotechnology and drug delivery systems is the niosomal drug delivery system. The fact that niosomes are largely stable dosage forms. These are much potential to encapsulate harmful anti-cancer, anti-infective, anti-AIDS, anti-viral, and other drugs in niosomes and use them as promising drug carriers to improve the bioavailability and targeting properties of the drugs while lowering their toxicity and side effects. To develop a commercially valuable niosomal preparation, these aspects need further systematic thought and research. Researchers and academicians generally agree that putting the drug into a niosomal formulation will improve its ability to target the drug to the proper tissue destinations. The niosomal carriers are safer, while ionic drug carriers are more hazardous and inappropriate. Niosomes handling and storage also don't need any specific circumstances. As compared to liposomes, they are thought to be better Candidates for drug delivery due to various factors like cost, stability etc. Overall Noisome are very effective tool for Sustained, targeted, opthalmic and Topical drug delivery systems. They have potential to provide better treatment than the conventional drug delivery systems. Niosomes are very useful in bright future for pharma industries.

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CONFLICT OF INTEREST

We declare that we have no conflict of Interest.

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