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Proniosomes: A review on provesicular drug delivery system

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Abstract

Proniosomes are a novel provesicular system used for delivering hydrophobic as well as hydrophilic drugs. They are non-ionic surfactant vesicles that, upon hydration, form niosomes. The incorporation of the drug within the vesicular structure of the proniosomes improves its bioavailability, extending its duration in systemic circulation. Proniosomes are a better alternative to the other vesicular systems due to their superior physicochemical stability and effective drug delivery capability. Proniosomes represent promising drug delivery technologies for delivering the drug through various routes. This review describes structural components and their effect on proniosomes vesicle formation and application of proniosomes in drug delivery.

Keywords: proniosomes, drug carrier, provesicular, drug delivery, non-ionic surfactant

Introduction

Vesicular drug delivery systems are used as drug carriers where both lipophilic as well as lipophobic drugs can be encapsulated in amphiphilic vesicles. This encapsulation of drugs in vesicles can prevent drug degradation as well as prolong the drug residence time in the systemic circulation. It includes liposomes, niosomes, ethosomes, transfersomes, pharmacosomes, proliposomes and proniosomes etc. Among these, proniosomes is one of the provesicular approaches gaining popularity[1,2].

These are vesicular structures with non-ionic surfactants as a main component, present in free-flowing powder or semi-solid gel form [3,4]. Hydration of proniosomes leads to formation of niosomes [5]. These have been successfully employed for drug delivery through various administration routes such as oral, transdermal, ocular, intranasal, parenteral, pulmonary etc.[5–10].

Proniosomal formulation offers prolonged drug release, which reduces the need for frequent dose administration and improves patient compliance. Targeted administration of proniosomes to particular organs or tissues increases therapeutic efficacy while lowering systemic toxicity [11].

Based on method of preparation, proniosomes are classified as dry granular form and liquid crystalline or gel form. Dry granular proniosomes are water-soluble carrier particles such as maltodextrin, sorbitol, mannitol etc. which are coated with nonionic surfactant and can be hydrated to produce niosomes. Whereas liquid crystalline proniosomes/proniosomal gel possess a highly organized liquid crystalline structure, which enhances the drug permeation through the biological membranes [12].

Composition of proniosomes

The essential and common components of the proniosomal drug delivery system are as follows:

Nonionic Surfactant

Nonionic surfactants are the important structural component in the preparation of proniosomes. These molecules are more stable, compatible and less toxic compared to cationic and anionic surfactant types[13]. Apart from vesicle formation, nonionic surfactants help in controlled drug release, play a part as penetration enhancers in transdermal medication and can be used to improve the bioavailability of poorly water-soluble drugs in oral proniosomal formulation[14]. Vesicle formation and entrapment efficiency depend on various parameters like Hydrophilic Lipophilic Balance (HLB) value, chemical nature, phase transition temperature, chain length and the size of the hydrophilic group of the surfactant. Surfactants with longer alkyl chains and lower HLB values (between 4-8) were found to have high encapsulation efficiency whereas surfactants

with high HLB values having large polar head groups cannot form vesicles. Phase Transition temperature (Tc) increases as the length of the alkyl chain increases providing the highest entrapment for the drug[15–18].

The most common nonionic surfactants used for vesicle formation are alkyl ethers, alkyl esters and esters of fatty acids as given below.

Sorbitan fatty acid esters

Sorbitan fatty acid esters are usually referred to as Spans. The polar head groups are similar in all Spans, while the alkyl hydrocarbon chains are varied. Spans surfactants with different fatty acid chain lengths like Span 20, Span 40, Span 60, Span 80 have been used alone or in combination in preparation of proniosomes. Spans with lower HLB values and increased alkyl chain length exhibit high entrapment efficiency[19]. Span 60 showed higher entrapment efficiency than the other spans[21].

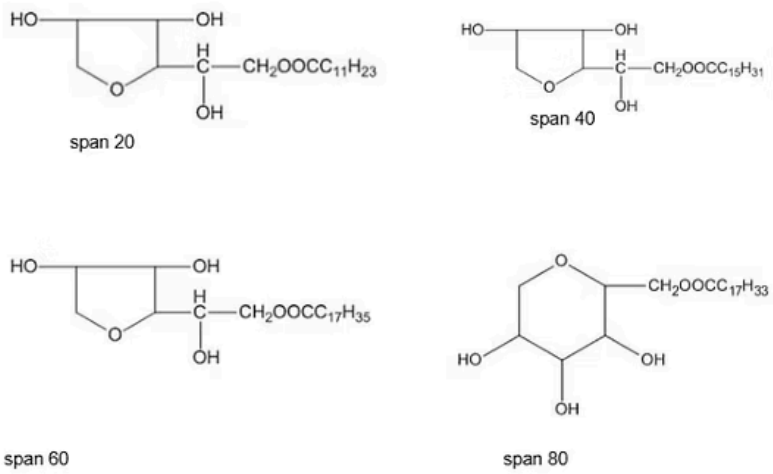

Figure 1. Chemical structure of sorbitan fatty acid esters

Polyoxyethylene fatty acid esters

Tweens, commonly referred to as polysorbates, are polyoxyethylene sorbitan esters. Tween 20 and Tween 60, Tween 80 have been used in proniosomal formulation. However, Tween 80 being a hydrophilic surfactant with a high HLB value elucidates the lower entrapment efficiency in proniosomal formulations[22]. However, a few articles reported that the drug entrapment efficiency of Tween is superior compared to different Spans containing proniosomes[23,24].

Sugar esters

These are non-ionic surfactants with sucrose as the polar head group and fatty acids as non-polar groups. Different grades of sugar esters, such as sucrose stearate S-1670, S-970, S-370, sucrose palmitate P-1670, sucrose myristate, M-1695, and sucrose laurate L-1695 have been used as permeation and absorption enhancers. These have excellent safety profiles and are non-irritants[25].

Cremophor

Cremophor is hydrogenated castor oil. Cremophor has been successfully used in proniosomal gel formulation as a permeation enhancer. The use of cremophor provided proniosomes with favourable physicochemical characteristics and a sustained release pattern suitable for ocular delivery[26–27].

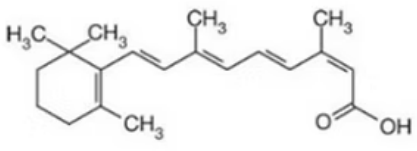

Figure 2. Chemical structure of Cremophor RH-40

Poloxamer

Poloxamer is a polyethylene-propylene glycol copolymer nonionic surfactant that acts as a penetration enhancer by removing the mucus layer and breaking junctional complexes and thus improving the solubility of drug[28–29].

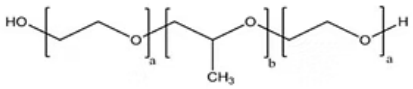

Figure 3. Chemical structure of poloxamer 188

Polyoxyethylene alkyl ether

Polyoxyethylene alkyl ethers, such as Brij-35, Brij 72, Brij 78 Brij 92, are nonionic surfactants used as good vesicle forming nonionic surfactants in the proniosomes formulation. Proniosomal gel prepared using Brij 35 showed better entrapment and the highest in vitro drug release with an equimolar ratio (1:1) of Brij 35 and cholesterol[30]. Proniosomal gel containing Brij 72, Brij 92 having long alkyl chain and lower HLB values showed better vesicle forming ability and higher entrapment efficiency (EE) of the drug within the hydrophobic core[31].

Nonionic surfactant	Examples	HLB	Nonionic surfactants	Examples	HLB
Polyoxyethylene fatty ether (Brij series)	Brij 30	9.7	**Sorbitan fatty acid esters**	Span 20	8.6
	Brij 35	16.9		Span 40	6.7
	Brij 52	5.3		Span 60	4.7
	Brij 56	12.9		Span 80	4.3
	Brij 58	15.7	**Sugar esters**	sucrose stearate S-1670	16
	Brij 72	4.9		sucrose stearate S-970	9
	Brij 76	12.4		sucrose stearate S-370	3
	Brij 78	15.3		sucrose palmitate P-1670	16
	Brij 92	4.9		sucrose myristate M-1695	16
Polyoxyethylene fatty acid esters	Tween 20	16.7		sucrose laurate L-1695	16
	Tween 60	15	**Cremophor**	Cremophor RH 40	15.65
	Tween 80	15	**Poloxamer**	poloxamer 188	29

Table 1. Common nonionic surfactants used in proniosomal formulations

Cholesterol

Although, non-ionic surfactants represent the essential component of proniosomal vesicles, the incorporation of cholesterol influences stability and permeability in the vesicle. Cholesterol makes the membrane more ordered by interaction with surfactants through hydrogen bonding and hence able to effectively prevent leakage of drugs from bilayer vesicles. Cholesterol provides rigidity to the bilayer and enhances the entrapment efficiency of proniosomes. The increased drug entrapment is most likely due to increased vesicle size and increased width of lipid bilayer which increase the vesicle volume and entrapment efficiency[21,32].

The concentration of cholesterol in the formulation depends on the HLB value of the surfactants. Surfactants with high HLB values such as Brij 35, Brij 92, Tween 80 and Pluronic F68 will need higher concentration of cholesterol to form vesicles. On the other hand, proniosomes can be

produced even at low cholesterol concentration in case of surfactants with low HLB value such as Brij 72, Span 65[33].

Lecithin

Lecithin is a phospholipid that acts as a membrane stabilizer and penetration enhancer in proniosomes formulations. It forms a tightly packed bilayer, decreases membrane permeability and prevents drug leakage, thus improving the drug entrapment of the vesicles. Soya lecithin is derived from soybean, while egg lecithin obtained from egg yolk, is most commonly utilized in proniosomal formulations. Soya lecithin is a good penetration enhancer compared to egg lecithin, due to the presence of unsaturated fatty acids in soya lecithin, whereas egg lecithin contains saturated fatty acids[19],[34],[35].

Solvent

Solvents like ethanol, isopropyl alcohol, butanol, propanol have been employed in the preparation of proniosomes. Alcohol acts as penetration enhancer 36. The rate of drug penetration and vesicle size are affected by the different alcohols. The rate of permeation increases with the longer chain length of the alcohol. Maximum drug permeation was observed with isopropanol, possibly due to branched chain structure. Vesicles formed from different alcohols differ in size. Vesicles with ethanol result in the highest size while isopropanol results in vesicles of the smallest size, which may be due to branched chains present in it[37–39].

Carrier

Dry Granular Proniosomes are prepared using carriers that are coated with suitable noisome-forming surfactants. The carrier should be non-toxic, water soluble but poorly soluble in the solvent used in the formulation. Commonly used carriers include maltodextrin, sorbitol and mannitol and to a lesser extent magnesium aluminium silicate, spray dried lactose and sucrose stearates are used[40],[41].

Hydration medium

Formation of niosomes from proniosomes is carried out by the addition of a suitable hydration medium such as water, phosphate buffer saline. Hydration media affect the vesicle size and entrapment efficiency of the proniosomes[42],[43].

Charge inducer

The addition of charge inducers affects the drug encapsulation efficiency and vesicle size. Stearyl amine and dicetyl phosphate are commonly employed as positive and negative charge inducers in the membrane bilayers of proniosomal vesicles.[44],[45].

Pharmaceutical application of proniosome

Proniosome technology is the effective delivery of a wide range of therapeutic agents through different routes, such as oral, parenteral, dermal, transdermal, ocular, pulmonary, vaginal, and mucosal routes.

Oral route

Administration of the poorly soluble drug through the oral route in the proniosomal form showed increased solubility and bioavailability[46].

Drugs	Disease treatment	Types of formulation	Major Outcomes	Reference
Celecoxib	Nonsteroidal Anti-Inflammatory drug (NSAID)- COX-2 inhibitor	proniosomal capsule	proniosomal formulation showed enhanced drug dissolution rate than pure drug powder	47
Valsartan	high blood pressure, congestive heart failure, post myocardial infraction and Alzheimer's disease	proniosome powders	Increased dissolution efficiency and improved Permeation across the rat intestine with proniosome formulation	48
Telmisartan	Angiotensin-II receptor (type AT1) blocker	Tablet	Provides a controlled release profile. The proniosomes might enhance the gastrointestinal absorption of poorly water-soluble drugs	49

Glipizide	Antidiabetic		sustained the drug release and reduced gastrointestinal irritation	50

Table 2. Research work on proniosome administration through the oral route

Transdermal route

Transdermal drug delivery is a promising alternative to the oral and parenteral route. Proniosomes offer a versatile vesicle delivery concept with the potential for drug delivery via the transdermal route[51].

Drugs	Therapeutic use	Type of formulation	Major Outcomes	Reference
Vinpocetine	cerebrovascular disorder	proniosomal patch	promising carrier for vinpocetine, provides controlled drug release	25
Lacidipine	calcium channel blocker	proniosomal gel	Provided absorption and penetration enhancement of drug formulated transdermally	26
Risperidone	schizophrenia and other psychiatric disorder	transdermal patch	an increase in mean residence time ensures about its prolonged blood circulation	52
Ketorolac	NSAID	proniosomal gel	Maintains extended blood levels of Ketorolac for an extended period	53
Glimepiride	Diabetes	proniosomal gel	Provided controlled release and a significantly higher hypoglycemic activity	54
Frusemide	Diuretic	proniosomal gel	provided controlled systemic transdermal drug delivery	55

Table 3. Research work on proniosome administration through transdermal route

Ophthalmic delivery

Proniosomes offer a promising solution for ocular drug delivery. It improves bioavailability by increasing ocular residence time of drug [56,57].

Drugs	Therapeutic use	Type of formulation	Major Outcomes	Reference
Voriconazole	fungal keratitis	ocular inserts	prolonged release up to 8 hours	56
Dorzolamide Hydrochloride	anti-glaucoma	proniosomal gel	Sustained drug release and increased bioavailability	57

Levofloxacin	Antibiotic	proniosomal gel	enhanced contact time and retention in the eye and provided sustained release action and better availability of drug	58

Table 4. Research work on proniosome administration through ophthalmic route

Intranasal delivery

Proniosomal gel through the nasal route shows a potential platform for the delivery of drugs to the brain [59,60].

Drugs	*Therapeutic use*	*Type of formulation*	*Major Outcomes*	*Reference*
Duloxetine	*antidepressant*	*proniosomal gel*	*provided improved permeation enhancement and stability with controlled drug release*	*59*
Artemether	*cerebral malaria*	*proniosome powder*	*better stability and penetration of drug with controlled drug release for a longer duration*	*60*

Table 5. Research work on proniosome administration through intranasal route

Conclusion

Proniosomes represent promising technologies to deliver medications with improved stability in a controlled, targeted manner. Proniosomal formulations offer improved bioavailability of drugs with poor solubility and reduced adverse effects. A wide range of drugs can be encapsulated in vesicular structures and can be effectively designed for different routes of administration.

Conflicts Of Interest Declaration

Authors report no conflicts of interest.

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