Journal of Pharma Research
Available online through
www.jprinfo.com

Review Article
ISSN: 2319-5622

Proniosome: A Preferable Carrier for Novel Drug Delivery System

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Received on: 13-08-2015; Revised and Accepted on: 26-08-2015

ABSTRACT

The aim of drug delivery system is to deliver the therapeutic agent to the desired site of action. Advancements in niosome lead to evolution of proniosomal delivery systems. From a technical point of view, niosomes are promising drug carriers as they possess greater stability and simple method for the routine and large scale production of niosomes, but proniosomes are recent development in novel drug delivery system. These are most advanced drug carrier in vesicular system. Proniosome is dry formulation using suitable carrier coated with nonionic surfactants and can be converted into niosomes immediately before use by hydration. The proniosomes minimize problems of niosomes physical stability such as aggregation, fusion, leaking and provide additional convenience in transportation, distribution, storage and dosing. The goal of this review is to introduce different aspects related to proniosome merits, preparation, characterization, entrapment efficiency, stability, drug release, application.

Keywords: *Proniosomes, Niosome, Liposome, Nonionic surfactant, Stability, Hydration.*

INTRODUCTION

Proniosomes are dry formulations of surfactant- coated carrier, which can be measured out as needed and rehydrated by brief agitation in hot water. Stability of dry proniosomes is expected to be more stable than a pre-manufactured niosomal formulation. In release studies proniosomes appear to be equivalent to conventional niosomes. Size distributions of proniosome-derived niosomes are somewhat better that those of conventional niosomes so the release performance in more critical cases turns out to be superior. Proniosomes are dry powder, which makes further processing and packaging possible. The powder form provides optimal flexibility, unit dosing, in which the proniosome powder is provided in capsule could be beneficial [1].

Proniosomes a versatile delivery system is their potential of entrapping a wide range of active compounds without showing any problems of physical stability (aggregation, fusion, leaking). They also provide the convenience of the transportation, distribution, storage, and dosing. Proniosomes upon hydration with water from skin after topical application get readily converted into niosomes of uniform size [2].

Niosomes are non-ionic surfactant vesicles that are capable to entrap hydrophilic as well as lipophilic drug candidates because they have an infrastructure consisting of both hydrophilic and hydrophobic moieties together. Niosomes are also osmotically active, stable, providing the stability of entrapped drug. They are advantageous than other vesicles as being cheap and chemical stability. All methods traditionally used for preparation of niosomes are time consuming and many of them need specialized equipment's. Most of these methods allow only for a predetermined lot size, so material is often wasted if smaller quantities are required for particular dose application. The size of niosomes is microscopic and lies in nano metric scale. The particle size ranges from 10-100 nm [3].

Niosomes are widely studied as an alternative to liposomes. These vesicles appear to be similar to liposomes in terms of their physical properties. From a technical point of view, niosomes are promising drug carriers as they possess greater stability and lack of many disadvantages associate with liposomes. These vesicular delivery systems have attracted considerable attention in topical/transdermal drug delivery for many reasons. These penetration enhancers are biodegradable, non-toxic, amphiphilic in nature, and effective in the modulation of drug release properties. Their effectiveness is strongly dependent on their physiological properties, such as composition, size, charge, lamellarity and application conditions. Most of these methods allow only for a predetermined lot size so material is often wasted if smaller quantities are required for particular dose application. L'Oreal had brought the first cosmetic product called 'Niosomes' containing niosome vesicles into the market. The product also had its successors like 'Niosome Plus' anti-ageing cream by Lancome, which reached the market in the early 1990's [4].

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Disadvantages of Niosomes: [4]

1. Physical instability
2. Aggregation
3. Fusion
4. Leaking of entrapped drug
5. Hydrolysis of encapsulated drugs which limiting the shelf life of the dispersion.

Advantages of Proniosomes over niosomes include: [5]

1. Avoiding problem of physical stability like aggregation, fusion, leaking.
2. Avoiding hydration of encapsulated drugs which is limiting the shelf-life of the dispersion.
3. Proniosomes are water soluble carrier particles that are coated with surfactant and can be hydrated to form niosomal dispersion immediately before use on brief agitation with hot aqueous medium. This has additional convenience of the transportation, distribution; storage and designing would be dry niosomes a promising industrial product.
4. Furthermore, unacceptable solvents are avoided in proniosomal formulations. The systems may be directly formulated into transdermal patches and doesn't require the dispersion of vesicles into polymeric matrix.
5. The storage makes Proniosomes a versatile delivery system with potential for use with a wide range of active compounds.

Comparison Between Niosome and Proniosome:

Niosomes are non-ionic surfactant bilayer vesicular structure ranging 10 to 100 nm in size. It provide several advantages such as low production cost, greater chemical and physical stability, ability to entrap both lipophilic and hydrophilic

drugs either in aqueous layer or in vesicular membrane, low toxicity because of their non-ionic nature, flexibility in their structural constitution, improved drug availability and controlled delivery at a particular site and ease of storage [2].

The Proniosomes are dry formulation which is water-soluble carrier particles that are coated with surfactant and can be measured out as needed and dehydrated to form niosomal dispersion immediately before use on brief agitation in hot aqueous media within minutes. The resulting niosomes are very similar to conventional niosomes and more uniform in size [6].

Components Used for the Preparation of Proniosomes:

Surfactants:

Surfactants are the surface active agents which are usually organic compounds that are amphiphilic in nature (having both hydrophobic and hydrophilic groups). Therefore, a surfactant molecule contains both a water insoluble (lipophilic) and a water soluble (hydrophilic) component. They have variety of functions including acting as solubilizes, wetting agents, emulsifiers and permeability enhancers (Sudhamani T et al., 2010). The most common non-ionic amphiphiles used for vesicle formation are alkyl ethers, alkyl esters, alkyl amides and esters of fatty acids [7].

Carrier materials:

The carrier when used in the proniosomes preparation or formulation permits the flexibility in the ratio of surfactant and other components that incorporated. In addition to this, it increases the surface area and hence efficient loading. The carriers should be safe, effective and non-toxic, free flowing, poor solubility in the loaded mixture solution and good water solubility for ease of hydration (Akhilesh D et al., 2012, Pandey N et al., 2011 [8].

Commonly used carriers are listed below: [8]

1. Maltodextrin
2. Mannitol
3. Sorbitol
4. Spray dried lactose
5. Lactose monohydrate
6. Sucrose stearate
7. Glucose monohydrate

Membrane stabilizer:

Carriers such as Cholesterol and lecithin components are mainly used as membrane stabilizer. Steroids are important components of cell membrane and their presence in membrane and bring about significance changes with regard to bilayer stability, fluidity and permeability. Cholesterol is a naturally occurring steroid used as membrane additive. It prevents aggregation, diffusion by the inclusion of molecules that stabilize the system against the formation of aggregate by repulsive steric or electrostatic effects. It leads transition from the gel state to liquid phase in niosome system. Phosphatidylcholine is a major component of lecithin. It has low solubility in water and can form liposomes, bilayer sheets, micelles or lamellar structures depending on hydration and temperature (Kumar K et al., 2011, Yadav K et al., 2010) [9].

Solvent and Aqueous phase:

Alcohol used in proniosome has a great effect on vesicle size and drug permeation rate. Vesicles formed from different alcohols are of different size and they follow the order: Ethanol > Propanol > Butanol > Isopropanol. Ethanol has greater solubility in water hence leads to formation of highest size of vesicles instead of isopropanol which forms smallest size of vesicle due to branched chain present. Phosphate buffer pH 7.4, 0.1% glycerol, hot water is used as aqueous phase in preparation or formulation of proniosomes (Yadav K et al., 2010) [10].

Method of Preparation of Proniosomes:

Spraying method:

Taken a 100 ml round bottom flask (RBF) containing desired amount of carrier can be attached to rotary flash evaporator.

↓

A mixture of cholesterol and surfactants is prepared and poured into RBF on rotary evaporator by sequential spraying of aliquots onto carrier, s surface. The evaporator is used to evacuate the vapour and rotating flask can be rotated in water bath under vacuum at 65- 70ºC for 15-20 min.

↓

This process is repeated until all of the surfactant solution has been applied. The evaporation should be continued until the powder becomes completely dry.

The prepared proniosomes by spraying the surfactant in organic solvent onto sorbitol powder and then evaporating the solvent. Because the sorbitol carrier is soluble in the organic solvent, it is necessary to be repeat the process until the desired surfactant load has been achieved. The surfactant coating on the carrier comes out to be very thin and hydration of this coating allows multilamellar vesicles to form [11].

Slurry method:

Powdered drug was poured into a 250-ml round-bottom flask and the specific volume of surfactant solution was added directly to the flask to form slurry. If the surfactant solution volume is less, then additional amount of organic solvent can be added to get slurry. The flask was attached to the rotary evaporator and vacuum was applied until the powder appeared to be dry. The flask was removed from the evaporator and kept under vacuum overnight. Proniosome dry powder was stored in sealed containers at 4°C (Srivastava AR et al., 2009) [12].

Coacervation phase separation method:

Accurately weighed or required amount of surfactant, carrier (lecithin), cholesterol and drug can be taken in a clean and dry wide mouthed glass vial (5ml) and solvent should be added to it. All these ingredients have to be heated and after heating all the ingredients should be mixed with glass rod. To prevent the loss f solvent, the open end of the glass vial can be covered with a lid. It has to be warmed over water bath at 60-70ºC for 5 minutes until the surfactant dissolved completely. The mixture should be allowed to cool down at room temperature till the dispersion gets converted to a pronisomal gel [13].

Characterization of Proniosomes:

Measurement of Angle of repose:

The angle of repose of dry proniosomes powder and maltodextrin powder was measured by a funnel method (Lieberman et al 1990). The maltodextrin powder or proniosomes powder was poured into a funnel which was fixed at a position so that the 13mm outlet orifice of the funnel is 2.5cm above a level black surface. The powder flows down from the funnel to form a cone on the surface and the angle of repose was then calculated by measuring the height of the cone and the diameter of its base [14].

Vesicle morphology:

Vesicle morphology involves the measurement of size and shape of proniosomal vesicles. Size of proniosomal vesicles can be measured by dynamic light scattering method in two conditions: without agitation and with agitation. Hydration without agitation results in largest vesicle size. Scanning electron microscopy (SEM) can also be used for the measurement of vesicle size and shape [15].

Zeta potential analysis:

Zeta potential analysis will be done for determining the colloidal properties of the prepared formulations. The suitably diluted proniosomes derived noisome dispersion will be determined using zeta potential analyzer based on Electrophorectic light scattering and laser Doppler Velocimetery method. The temperature will set at 25°C. Charge on vesicles and their mean zeta potential values with standard deviation of 5 measurements will be obtained directly from the measurement [16].

Determination of Encapsulation Efficiency:

Percent encapsulation efficiency (EE) was determined by centrifugal method56. The proniosomal gel was converted to niosomal dispersion, which was centrifuged (18000 rpm) for 40 min at 5ºC in order to separate unentrapped drug. The supernatant was taken and diluted with PBS (pH7.4). The drug concentration in the resulting solution was assayed spectrophotometrically at 293 nm. The percentage of drug encapsulation was calculated by the following: EE (%) = [(Ct - Cf)/ Ct] × 100, Where Ct is the concentration of total drug and Cf is the concentration of unentrapped drug [17].

Scanning electron microscopy:

Proniosomes, prepared as described above, were sprinkled on double-sided conductive car-bon tape on an aluminum stub. Excess sample was blown off with compressed air. The specimen was then coated with Au: Pd (60:40) using a Ladd Sputter

Coater at 2.5 KV and 20 mA for 45 s. The coated specimen was observed using a Philips 515 Scanning Electron Microscope at 50KV and recorded on Polaroid PIN 55 film [18].

Rate of hydration (spontaneity):

Spontaneity of niosome formation is described as number of niosome formed after hydration of proniosomes after 15 min. Proniosome were transferred to the bottom of a small stoppered glass tube and spread uniformly. One ml saline (0.154 M Nacl) was added carefully along the walls of the test tube and kept a side without agitation. After 15-20 min a drop of aqueous layer was withdrawn and placed on neubar's chamber. The number of niosomes eluted from proniosomes was counted [19].

Transmission Electron Microscopy (TEM):

For Transmission Electron Microscopy, the morphology of hydrated niosomal dispersion prepared from Proniosome was also determined using transmission electron microscope. A drop of noisome dispersion was applied to a carbon-coated 300 mesh copper grid and left for 1 min to allow some of the niosomes to adhere to the carbon substrate. The remaining dispersion was removed by absorbing the drop with the corner of a piece of filter paper. A drop of 2% aqueous solution of uranyl acetate was applied for 35 sec. The remaining solution was removed by absorbing the liquid with the tip of a piece of filter paper and the sample was air dried. The sample was observed with a Hitachi 7500 Transmission Electron Microscopy at having different magnification of 60000x, 100000x, 120000x, and 200000x of 80kV [20].

Stability Studies:

Stability studies can be carried out by storing the prepared proniosomes at various temperature conditions like refrigeration temperature (2°-8°C), room temperature (25°± 0.5°C) and elevated temperature (45º± 0.5°C) from a period of one month to three months. Drug content and variation in the average vesicle diameter is periodically monitored [21].

Release rate profiles of drug:

One of the important characteristic of proniosomal formulation is their sustained release characteristics. The release rate profile of drugs can be performed using Franz-diffusion cell, Keshary chin cell or cellophane dialyzing membrane or U.S.P dissolution apparatus type I [22].

Application:

Drug Targeting:

One of the most useful aspects of proniosomes is their ability to target drugs. Proniosomes can be used to target drugs to the reticulo-endothelial system. The reticulo-endothelial system (RES) preferentially takes up proniosome vesicles [23].

The uptake of proniosomes is controlled by circulating serum factors called opsonins. These opsonins mark the Proniosome for clearance. Such localization of drugs is utilized to treat tumors in animals known to metastasize to the liver and spleen. This localization of drugs can also be used for treating parasitic infections of the liver. Proniosomes can also be utilized for targeting drugs to organs other than the RES. A carrier system (such as antibodies) can be attached to proniosomes (as immunoglobulin bind readily to the lipid surface of the niosome) to target them to specific organs [24].

Anti-neoplastic treatment:

Most antineoplastic drugs cause severe side effects. Proniosomes can alter the metabolism; prolong circulation and half-life of the drug, thus decreasing the side effects of the drugs. Proniosomal entrapment of Doxorubicin and Methotrexate (in two separate studies) showed beneficial effects over the unentrapped drugs, such as decreased rate of proliferation of the tumor and higher plasma levels accompanied by slower elimination [25].

Antiparasitic Treatment:

A leishmania parasite commonly infects liver and spleen and derivatives of antimony (antimonial) are primarily used for the treatment but higher concentrations of these are always harmful for our sensitive organs like heart, liver, kidney etc. Hunter et al., (1988) reported that the Proniosome containing sodium stibogluconate showed greater efficacy in treatment as well as lower the side effects [26].

Delivery of peptide drugs:

Oral peptide drug delivery has long been faced with a challenge of bypassing the enzymes which would breakdown the peptide. Use of proniosomes to successfully protect the peptides from gastrointestinal peptide breakdown is being investigated. In an in-vitro study, oral delivery of a Vasopressin derivative entrapped in proniosomes showed that entrapment of the drug significantly increased the stability of the peptide [27].

Proniosomes as Carriers for Hemoglobin:

(Moser P. and Marchand Arvier M. in 1989) reported that niosomes can be used as carriers for hemoglobin within the blood. The niosomal vesicle is permeable to oxygen and hence can act as a carrier for hemoglobin in anemic patients [28].

Hormonal Therapy:

A proniosome based transdermal drug delivery system of levonorgestrel (LN) was developed and extensively characterized both in vitro and in vivo. The proniosomal structure was liquid crystallinecompact niosomes hybrid which could be converted into niosomes upon hydration. The system was evaluated in vitro for drug loading, rate of hydration (spontaneity), vesicle size, polydispersity, entrapment efficiency and drug diffusion across rat skin. The effect of composition of formulation, amount of drug, type of Spans, alcohols and sonication time on transdermal permeation profile was observed. The stability studies were performed at 4°C and at room temperature. The biological assay for progestational activity included endometrial assay and inhibition with the formation of corpora lutea. The study demonstrated the utility of proniosomal transdermal patch bearing levonorgestrel for effective contraception [29].

Hypertension:

Thakur *et al.* fabricated proniosomes using different nonionic surfactants, such as Span 20, Span 40, Span 60, Span 80, Tween 20, Tween 40, and Tween 80 for transdermal drug delivery system of losartan potassium. HPMC and carbopol 940 were used and HPMC gel was selected as a suitable base for incorporation of optimized PNG. The best *in vitro* skin permeation profile was obtained with proniosomal formulation prepared using span 40 in 24 h [30].

Anti-Inflamatory drug: Non-Steroidal:

Ketorolac, a potent non-steroidal anti-inflammatory drug, is formulated as a proniosome gel using spans, tweens, lecithin and cholesterol with ethanol as a solvent. Each of prepared proniosomes formulation shows significantly improved drug permeation [31].

Antibacterial treapy:

Amphotericin-b proliposomes could be stored for 9 months without significant changes in distribution of vesicle size and for 6 months without loss of pharmacological activity.Even though physical stability of the preparation can be increased, a vacuum or nitrogen atmosphere is still required during preparation and storage to prevent oxidation of phospholipid [32].

Uses in Studying Immune Response:

Proniosomes are used in studying immune response due to their immunological selectivity, low toxicity and greater stability. Niosomes are being used to study the nature of the immune response provoked by antigens [33].

CONCLUSION

From the above article it is concluded that proniosomes are better candidates of drug delivery when compare to the liposome and niosome due to these factors like cost, stability and possibility to encapsulate lipophilic as well as hydrophilic drug molecule. One of the most important advantages of proniosomes is drug targeting. Proniosomes have one advantageous effect of nontoxicity and penetration enhancing effect of surfactants and effective modification of drug release. Proniosomes are having a great attractiveness in the delivery of drugs through transdermal route. The study of proniosomes is helpful in future for different carrier, materials with bio-compatibility and suitability in the preparation of proniosomes.

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How to cite this article:

Ankit Kumar et al.,: Proniosome: A Preferable Carrier for Novel Drug Delivery System, J. Pharm. Res., 2015; 4(8): 300-303.

Conflict of interest: The authors have declared that no conflict of interest exists.

Source of support: Nil