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Review Article

An Overview Of Niosomes- Novel Strategies For Drug Delivery

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ABSTRACT

For novel drug delivery of drug is required basic appropriate component like carrier which are protecting the drug and enhancing the drug concentration in targeted tissue and reduced the rapid degradation or clearance of drug. The number of articles, review and research have been published on niosomes in the last one decade. The niosomes are carrier which show the several advantages for drug delivery. Niosomes are formed by non-ionic surfactant vesicles which are assembled by themselves. Niosomes carried the drug and release the drug on targeted site and it can be reduced side effect of drug and enhance the therapeutic effect on various disease.

INTRODUCTION

Since earlier, the medicament of acute or chronic disease effectively administered of drugs to the patient through different type of dosage form like creams, tablets, capsules, ointments, pills and suppositories. To keep the concentration of drug and reach the therapeutic effective range, need to administered of drug in many times a day. So, the drug concentration is fluctuated and cause unwanted toxicity. To reduce the fluctuation of drug concentration, then the novel drug delivery system has been come out. Niosomes, liposomes, microcapsules, microspheres, micro-emulsions and nanoparticles are novel drug delivery system [3]. The drug delivery in a control rate and targeted site are achieved and much observe in the recent year. The nanoparticles are act as the carrier of drug which can be loaded with the various drug. Nanocarrier have best approach to delivery of drug with various features like protect the drug from degradation, drug release in controlled manner and the drug molecules are delivered to the specific targeted site. Niosomes are non-ionic carriers of drug which are bilayer structure, contain non-ionic surfactant, cholesterol or its derivative and charged molecules. Niosomes formed by self-assemble and prepared by hydration of synthetic non-ionic surfactant and cholesterol [1].

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Niosomes are the microscopic vesicle, novel drug delivery system. It is used for the controlled, sustained and specific targeting of drug. Liposomes are the earlier vesicular system of drug delivery, but there are some drawbacks like stability problem at different pH, toxicity and cheap cost. Due to the drawback of the liposomes, the research transfer in niosomes. Niosomes are contain non-ionic surfactant so these are called by niosomes and it is non-toxic due to these non-ionic surfactants. Since the structure of niosomes, it can be used for the loading of drug and delivering both hydrophobic and hydrophilic drugs [2]. Niosomes are the greatest carrier system. Niosomes are structurally alike to liposomes, but the niosomes are more economically and chemically stable than liposomes. Liposomes and niosomes both are consisting of bilayer but noisome are composed by non-ionic surfactant and the liposome with phospholipid. Size range of noisome from 10 to 1000 nm, microscopic lamellar structure. The nature of noisome are amphiphilic, the both hydrophilic and hydrophobic drugs are embraced into the noisome. The hydrophilic drug enclosed in the core cavity and hydrophobic drug in non-polar area inside the bilayer [3,4]. The niosomes are a hollow structure similar to the liposome and used as a secondary carrier of amphipathic and lipotropic drug. The niosomes are favorable carriers for delivering of drug and it is a quite cytotoxic and enhance the drug therapeutic index though the cells targeting. Niosomes including of decomposable, non-immunogenic and biocompatible wetting agent [5]. The niosomes rare widely used in the area of topical delivery due to their excellence properties like improve the permeation of drug, sustain release of drug of drug and its potential to contain both hydrophilic and hydrophobic drugs. The niosomes can be manufactured by different type of non-ionic surfactant like ester-linked surfactant, crown ether, polyglycerol alkyl ether, polyoxyethylene alkyl ethers [12]. The niosomes are carrier which are carry and transfer different type of pharmacological compound such as therapeutic drugs, gene, hormones, antigens and peptides. The niosomes have best affinity to delivery of drug in cancer research and it is used to transfer the drug at the targeted sites of cancer cells [13].

Merits of niosomes: [6,7,8]

1. The niosomes are structurally amphiphilic in nature so it gives a wide array of solubility for drug.
2. The drug can be protected from enzymatic breakdown.
3. Minimum quantity of dose required to get desire effect.
4. Niosomes not need favorable condition for storage due to their chemical stability and structural composition.
5. The niosomes are safer because it is composed of biodegradable, biocompatible and non-ionic substance.
6. Due to hydrophilic structure the niosomes are stable and it can be osmotically active.
7. The niosomes improve the drug permeation through the skin.
8. The vesicle can behave like depot and drug can be release steadily.
9. The vesicles of aqueous based suspension have more patient compliance than the oil based.
10. It is more cost effective for wide range of production.

Demerits of niosomes: [9,10]

1. Shelf life of encapsulated drugs can be reduced by hydrolysis.
2. The drug molecules are aggregated.
3. Physical instability.
4. The entrapped drug can be leaked.
5. Requirement of specialized equipment for some formulation.

Types of niosomes:

Based on the size and number of lamellar the niosomes are divided into three parts are: -

1. SUVs- Small-unilamellar vesicles (10-100 nm)
2. LUVs- Large-unilamellar vesicles (100-3000 nm)
3. MLVs-Multilamellar vesicles (500-10000 nm). [11]

Composition of niosomes:

The potency of drug delivery is depended on the components and it should be specified in the label of clinical, chemical and physical properties required to the preparation of niosomal system. Basically, niosomes are formulated by appropriate available raw material. The non-ionic surfactant and cholesterol are the basic compound of niosomes.

1. Non-ionic surfactant:

The non-ionic surfactant is amphipathic in nature, it has two definite zone in their chemical structure, the one has hydrophilic (water-soluble) in nature and the another one has hydrophobic (organic-soluble) in nature. The both part of the molecules may be connected with ether, amide or ester bond. It has contained hydrophilic head and hydrophobic tail. The hydrophobic part is formed by fluorocarbon, alkane, aromatic or other non-polar group chain. Non-ionic surfactant is entirely one of the perfect polymeric nano-carriers with major role in sustain, controlled, continuous and targeted drug delivery. The head group more solvating the hydrophilic part. Due to their polar head group the surfactant is classified. There is no charge in the head portion of non-ionic surfactant (14,15). The non-ionic surfactant is less toxic, more stable and biocompatible than the cationic, anionic or amphoteric counterparts. So, they can highly selected to made up of stable niosomes for in-vivo and in-vitro implementation. For the niosomes preparation the alkyl ether, alkyl amide, alkyl ester, fatty acids classes are basically used. In the choosing of surfactant molecule for the niosomes formation the hydrophilic-lipophilic balance (HLB) and critical packing parameter (CPP) value play important roles. The entanglement efficiency of niosomes affected by the HLB of surfactant, the length of alkyl chain increase when the value of HLB are increases. The range of HLB from 14-17 are not preferable for the formation of niosomes surfactant. To the hydrophilic surfactant the higher HLB and for lipophilic surfactant the lower HLB are suitable. Surfactant with the range between 4 to 8 HLB are used for the formation of vesicles. The CPP (critical packing parameter) value of surfactant measured from polar head group area and volume and the length of non-polar group. By the using CPP values assuming and determined which type of vesicles are formed (1,2,5).

2. Cholesterol:

The cholesterol is applied in the formation of niosomes and it is a derivative of waxy steroid which are found within the cell membrane. Proper shape and rigidity produce by the cholesterol. The cholesterol is generally added on non-ionic surfactant to provide correct adjustment and hardness to the niosomal bilayer (3,5). Cholesterol provides other effect like permeability, membrane rigidity and ease of hydration. The releasing action of content is differed due to change cholesterol in different niosomes. Cholesterol can be influencing the drug loading capacity. The release of drug is delayed due to addition of cholesterol and it terminate gel to liquid phase transition and increase the hydrophilic drug loading (17).

3. Charge molecules:

Introduction of charge molecule in bilayer of vesicles, increase the stability of vesicles and to prevent vesicles aggregation by increasing the density of surface charge. The most commonly negatively charge ionic molecule like Dicetyl phosphate and phosphatidic, the positively charge ionic compound such as stearyl amine and stearyl pyridinium chloride are used to formation of niosomes. The amount of charge molecule used in

the niosomal preparation are 2.5-5 mol %. Noisome formation can be prevented by increasing the amount of charge molecules (1,17).

Method of preparation:

1. Ether injection method:

This method is used to formation of niosomes by the solution of cholesterol and surfactant dissolved in diethyl ether in specific amount. The solution was taken in the syringe and then solution is injected slowly in warm aqueous solution through 14-gauge needle and regulate temperature 600C. Due to temperature difference among phase ether led to vaporized and single layer of niosomes vesicles are formed (20,28).

2. Sonication:

Sonication is a technique which are also used in the formation of niosomes. The drug, cholesterol and surfactant are mixed with the buffer in 10 ml glass vial. The mixture is sonicated through probe for 3 min at 600C by using a sonicator. Then the result, small unilamillar vesicles are produce. On the basis of need of niosomes there are two types of sonicator used are bath and probe type. The sonication techniques are most extensively used in the formation of small vesicles (18,19).

3. Thin film hydration technique:

The thin film hydration technique is also known as hand shaking method. In round bottom flask drug, cholesterol and non-ionic surfactant dissolved in volatile organic solvent (chloroform or methanol). Then using rotatory evaporator, the volatile organic solvent evaporated under vacuum pressure at 400C and the formation of thin layer of solid mixture on the wall of flask then stay under room temperature for overnight. Then hydration of thin surfactant film with aqueous phase carry drug normal temperature with gentle agitation. By the using this process multilamellar niosomes is formed (24,26,27).

4. Reverse phase evaporation technique:

Basically, the volatile organic solvent is carrying away in this system by the process of solvent evaporation. The cholesterol and surfactant are dissolved in the mixture of chloroform and ether. An aqueous phase which are carry the drug is added on the organic solution and the resulting two phases are sonicated at 4-50C. then it produces clear gel and they are further sonicated after the addition of PBS (Phosphate buffer saline) in small amount. Then evaporation of organic solvent under low pressure at 400C. The resulting, suspension of viscous niosomes is diluted with phosphate-buffer saline. Then, at 600C it heated on water bath for 10 min the final product of niosomes is obtained (21,25).

5. Emulsion method:

It is another process for the formation of niosomes. By the using of emulsion method the oil-in-water emulsion are formed from the aqueous solution of drug and the organic solution of cholesterol and surfactant. The evaporation of organic solvent leads to obtained final product of niosomes (22).

6. The bubble method:

The bubble method is a technique which is used to formation of liposomes and niosomes in one step without any requirement of volatile organic solvent. The bubbling unit contain round bottom flask with three neck and the flask is put in water bath for regulating temperature. The cooled water reflux through the first neck of flask and thermometer is positioned to the second neck of flask and the nitrogen is passes through the third neck of flask. In buffer solution (pH 7.4) cholesterol and surfactant dissolved together, and flask is heated at 700C. the solution is homogenized for 15 second through high shear homogenization and then nitrogen gas moved through solution which show the formation of niosomes (23).

7. Multiple membrane extrusion method:

This method also used in the formation of niosomes by using mixture of surfactant, cholesterol and dicetyl phosphate in chloroform, and solution is evaporated and formed a thin film.

Then hydration of thin film with aqueous drug solution, the suspension is produces and it extruded through polycarbonate membrane, which are placed in series up to 8 passages. This method is good for controlling the size of niosomes (21,23,25).

Factor affecting the formulation of niosomes:

1. Drug:

The characters of drug play major role in encapsulation of drug. The entrapment of niosomes is influenced by various factors like-chemical structure molecular weight interaction between niosomal membrane and drug, and the drug hydrophilicity and lipophilicity. The inflexibility and charge of bilayer niosomes are directly influence by the physical and chemical properties of encapsulated drug. The drug hydrophilic-lipophilic balance are influenced the degree of encapsulation (2,47).

2. Nature and type of surfactant:

Surfactant is the most important constituent of niosomal preparation. The surfactant are amphiphilic in nature which contains hydrophilic head and lipophilic tail. The lipophilic tail may contain aromatic, alkanes, and other non-polar groups. The size of niosomes id directly depend on HLB of surfactant it means when increase in the HLB of surfactant the size of niosomes will be increase due to increasing the surfactant hydrophobicity and decrease in the free energy of surfactant (8,45).

3. Cholesterol content:

The hydrodynamic diameter and entrapment efficacy of niosomes improved by insertion of cholesterol. The nature of bilayer in liquid state are enhanced and the nature of bilayer in gel state are decrease by the cholesterol. The cholesterol decreases the leakiness of membrane and increase and increase the membrane steady activity. The release rate of entrapped substance are decrease and the rigidity of bilayers are increase by increasing the amount of cholesterol in bilayer. The presence of charge which can be leads to increase the interlamellar distance between successive bilayers in multilamellar vesicle structure and leads to greater overall entrapped volume (5,43).

4. Temperature & pH of hydration medium:

The drug entrapment efficiency can be influence by one more factor is pH of the hydration medium and the temperature of hydration medium also play important role for the formulation of vesicles. The temperature influences the shape and size of vesicles (44,48).

5. Resistance to osmotic stress:

The diameter of vesicles decreases due to addition of hypertonic salt solution in niosomal suspension and when the addition of hypertonic salt solution in the suspension of niosomes the structure of vesicles swell and the release rate of substance are slow due to the eluting fluid from vesicles are inhibited, the fastest release occurs due to the vesicles under osmotic stress mechanically loosing their structure (7,46).

EVALUATION:

1. Morphology:

The niosomes morphology analysis was examine through the transmission electron microscopy (TEM). The vesicular preparation was put a drop on carbon-coated grid and stay for 1 min to attach a drop of vesicular on the carbon substrate. The excess of formulation was wipe off by a piece of filter paper. On the carbon grid a drop of 2% phosphotungustic acid (PTA) solution was stratified and then the excess of solution was wipe off by tip of filter paper and stay for 2 min. Air dried the sample and detect at an accelerating 80 KV under a ZEISS EM 10 electron microscope (33,37,38).

2. Size & size distribution:

The determination of size and size distribution of niosomal preparation by Dynamic Light Scattering (DLS) technique using Malvern instrument. The determination of homogeneity was measured by

the Polydispersity Index (PDI). Large value of PDI (>0.3) show high heterogeneity and small value of PDI (<0.1) show a homogenous population. After 24h of preparation the sample were analysed. Before the measurement of sample, the formulation was diluted with distilled water. Dilution of each 50µL of vesicle dispersion with 10ml of distilled water. The measurement of each sample was taken in triplet time (30,31).

3. Entrapment efficiency:

The niosomes entrapment efficiency of drug was specified after free drug segregation through dialysis. As per this method, drug-loaded niosomal dispersion (2ml) was put into a dialysis sac (cellulose tubing) which are incubated for 4h into 100ml of 30% v/v ethanol. Due to employing ethanolic dialysis it ensures sink condition. From the drug concentration in the dialysate solution the free drug amount was calculated. The entrapment efficiency was calculating by using formula-

Entrapment efficiency (%) = [(Ct-Cf)/Ct].100

Where, Ct is the total amount of loaded drug in dialysis bag and Cf is the amount of free drug in dialysate (29,32,36).

4. Stability study:

The drug molecule may be exuded from the niosomes on storage due to fusion and aggregation. So, the niosomes stability study was performed. The niosomes exposed in several temperature condition (40C, room temperature, 450C) for several month and the preparation are also exposed in different light and humidity condition. Before the storage of niosomal preparation was determine and evaluated the vesicle size, size distribution and entrapment efficiency. The sample which are stored in different temperature were checked and compare with different temperature stability of size and entrapment efficiency (2,34,41).

5. In-vitro release study:

The in-vitro drug release study of niosomes is performed under sink condition. The method which are used in the study of in-vitro release is dialysis tubing. The dialysis sac was clean and immersed in distilled water. The drug loaded niosomal suspension was moved in the dialysis after 30 min of immersing and suspended in phosphate buffer saline at 370C. the bag are gently stirring through magnetic stirrer. After some time interval some amount of sample withdraws and then volume of compartment was maintained by fresh phosphate buffer saline. Analysing the withdraw sample for drug content by any suitable assay method (1,35,40).

6. Statistical analysis:

On the dependent variable the effect of independent variable were determined by ANOVA – one way analysis of variable with Dunnet's comparison test. The result were expressed by the mean standard deviation (SD) for their independent run. The analysis of data on In-vitro release through repeated measures test by two-way analysis of variance statistically significant difference of level was $p<0.05$ (39,42).

Application of Niosomes:

1. Niosomes used as a drug carrier.
2. It is used in drug targeting.
3. It is used in delivery of anticancer drug.
4. It is used in protein and peptide drug delivery.
5. It is used in immune response study.
6. It is used to antigen and vaccine delivery.
7. It is used as a carrier of haemoglobin.
8. It is used in the gene therapy for delivery of gene.
9. It is used in the Leishmaniasis treatment.
10. It is also used in the brain targeting.

CONCLUSION:

Niosomes are novel drug delivery system which is used as a carrier for drug delivery and it is used for sustained, controlled and targeted drug delivery. The niosomes carrier loaded with hydrophilic or lipophilic or both drugs together and targeted the drug at appropriate site. It can be used to entrapment of variety of drug like vaccine,

enzyme, peptide, gene, anticancer drug. The niosomes enhance the stability of encapsulated drug and reduce the dose frequency. They are less toxic and more stable than liposomes. For large production the researcher are developing the suitable technology because it has encouraging targeting drug delivery system.

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