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SOLID LIPID NANOPARTICLES: AN INNOVATIVE APPROACH FOR IMPROVING THE BIOAVAILABILITY AND SOLUBILITY

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ABSTRACT

Now a day Solid lipid nanoparticles (SLN) are most developing formulations of nanotechnology with numerous applications including solubility enhancement in diverse fields like clinical medicine, drug delivery and research as well as in other different branches of sciences. SLN are the sphere-shaped particles of nanometer range which immersed in water or aqueous surfactant solution either using lipophilic and hydrophilic drug. It is equal to an oil-in-water emulsion for parenteral nutrition but the liquid lipid (oil) of the emulsion has been replaced by a solid lipid, i.e. producing SLN. Different production methods which are suitable for large scale production and applications of solid lipid nanoparticles are described in this review. Different analytical techniques are used for characterization of solid lipid nanoparticles such as scanning electron microscopy, differential scanning calorimetry, and photon correlation spectroscope. Aspects of solid lipid nanoparticles, route of administration and their bio distribution are also integrated. If appropriately investigated, solid lipid nanoparticles may open new scenes in therapy of complex diseases.

KEYWORDS

Solid lipid nanoparticles (SLN), Colloidal drug carriers and Homogenization.

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INTRODUCTION

Solid lipid nanoparticles (SLN) introduced firstly in 1991 characterise an alternative carrier system to custom colloidal carriers such as - liposomes, emulsions and polymeric microparticles and nanoparticles. Preparation of nanoparticles by using solid lipids is inviting key interest as novel colloidal drug carrier for intravenous applications as they have been recommended for an alternative particulate carrier system. SLN are sub-micron colloidal carriers ranging from 50 to 1000 nm,

which are composed of physiological lipid, dispersed in water or in aqueous surfactant solution. SLN deals with exclusive properties such as small size, large surface area, high drug loading and the interaction of phases at the interface and are attractive for their potential to improve performance of pharmaceuticals.

The underlying principle for the growing attention in lipid based system are

1. Lipids improve oral bioavailability and decrease plasma profile variability.
2. Enhanced interpretation of lipoid excipients.
3. An improved ability to address the issues of technology transfer and manufacture scale-up[1,2].

Advantages of SLN

1. Practice of biodegradable physiological lipids which decreases the risk of acute and chronic toxicity and evasion of organic solvents in production methods.
2. Enhanced bioavailability of poorly water soluble molecules.
3. Site specific delivery of drugs, enhanced drug penetration into the skin via dermal application.
4. Protection of chemically labile agents from degradation in the gut and sensitive molecules from outer environment.
5. Better stability as compared to liposomes.
6. Enhance the bioavailability of entrapped bioactive and chemical production of labile incorporated compound.
7. High concentration of functional compound achieved.
8. Possibility of lyophilization.
9. Ease of industrial scale production by hot dispersion technique.
10. Relatively cheaper and stable[3,4].

Disadvantages of SLN

1. Poor drug loading capacity.
2. Drug expulsion after polymeric transition during storage.
3. Comparatively high water content of the dispersions (70-99.9%).
4. Due to partitioning effects during production process hydrophilic drugs rarely loaded.
5. Particle growth may takes place.
6. Gelation tendency cannot be predicted[5,6].

Aims of Solid Lipid Nanoparticles

- Possibility of controlled drug release.
- Improved drug stability.
- High drug pay load
- No bio-toxicity of the carrier.
- Evasion of organic solvents.
- Incorporation of lipophilic and hydrophilic drugs[7].

PROPERTIES OF SLN AS COMPARED WITH OTHER FORMULATIONS: As shown in Table No.1.

Principle of Drug Release from SLN

The medication discharge from lipid nanoparticles are as per the following

1. Higher surface area because of little molecule measure in nanometre extent gives higher medication release.
2. Slow medication release can be accomplished when the medication is homogenously scattered in the lipid framework. It depends on type and medication entanglement model of SLN.
3. Crystallization conduct of the lipid carrier and high portability of the medication lead to quick medication release.
4. Fast initial drug release in the first 5 min in the drug –augmented shell model as a result of the outer layer of particle because of larger surface area of drug deposition on the particle surface.
5. The rupture of drug release is reduced with increasing particle size and sustained release could be obtained when the particles were sufficiently large, i.e., lipid macromolecules.
6. The type of surfactant and its concentration, which will interact with the outer shell and affect its structure, because a low surfactant concentration leads to a minimal burst and prolonged drug release.

7. The particle size distress drug release rate that directly depends on various parameters for instance composition of SLN formulation (such as surfactant, structural properties of lipid, drug) production method and conditions (such as production time, equipment, sterilization and lyophilisation[8].

COMPOSITION OF SLNs

Lipids

The solid lipid, itself, is the chief ingredient of lipid nanoparticles that influence their drug loading capacity, their stability, sustained release behaviour as well as bioavailability of the formulations.

Selection criteria for lipids

Important point to be considered in the selection of drug carrier system (lipid) is its loading capacity and also the intended use. Lipids that form highly crystalline particles with a perfect matrix cause drug exclusion. More complex lipids containing fatty acids of different chain length form less perfect crystals with many deformations. These deformations provide the space to assist the drugs.

Co-emulsifier

Role of co-emulsifier

Due to little movement of the phospholipid molecules, rapidnon-existence of emulsifier on the surface of the particle leads the particle aggregation and increase in the particle size of SLNs. To avoid this co-emulsifiers are incorporated[8].

PREPARATION OF SOLID LIPID NANOPARTICLES

The depiction of SLNs greatly depends on the method of preparation which in turn impacts on the particle size, drug loading capacity, drug release, drug stability etc. Different approaches exist for the production of finely discrete lipid nanoparticle dispersions.

Methods of preparation[8,11]

1. High pressure homogenization
   a. Hot homogenization
   b. Cold homogenization.
2. Ultrasonication/high speed homogenization.
   a. Probe ultrasonication.
   b. Bath ultrasonication.
3. Spray drying method.
4. Solvent evaporation method.
5. Solvent injection or solvent displacement method
6. Solvent emulsification-diffusion method.
7. Supercritical fluid method.
8. Membrane contactor method
9. Precipitation technique.
10. Film-ultrasound dispersion

High Pressure Homogenization (HPH)

HPH is a reliable and suitable method for the preparation of SLN, NLC and LDC and can be performed at elevated temperature (hot HPH technique) or at or below room temperature (cold HPH technique). SLNs made from solid lipids or lipid blends produced by high pressure homogenization of melted lipids disperse in an aqueous as outer phase stabilized by surfactant as tween80, SDS, lecithin etc. High pressure homogenization impulses a liquid with high pressure (100-2000 bar) over a narrow gap. The fluid accelerate on a very short distance to very high velocity (over 100 km / hr.)Very high shear stress and cavitation forces interrupt the particles down to the submicron range. Generally 5-10% lipid content is used but up to 40% lipid content has also been employed[9]. Difference between hot homogenization technique and cold homogenization technique is as shown in Table No.2.

Ultrasonication or high speed homogenization

Drug and Phospholipid are dissolved in methanol and mixed with an acetone solution containing a mixture of fatty acids. The mixture is then added drop wise into the Pluronic solution at 70°C. A pre-emulsion is gained by homogenization using an Ultra-Turrax T 25, at 15000 rpm for 10 minutes at 70°C. This pre-emulsion is ultrasonicated (20w) for 15 minutes to stop the crystallization of lipids. The o/w emulsion so formed is subsequently cooled down at the room temperature with continuous stirring, and the lipid is recrystallized to form SLN.

Spray drying method

It's a substitute technique to lyophilization in order to renovate an aqueous SLN dispersion into a drug product. It's a cheaper method than lyophilization. But the disadvantage of this method is particle aggregation due to high temperature, shear forces and partial melting of the particle.

Solvent evaporation- diffusion method

SLN can also be prepared from emulsion precursor, whose organic phase is established by a solvent, which can be either volatile or partially water miscible. O/W or W/O/W emulsions can be prepared: O/W emulsions are used for lipophilic drugs that are dissolved in the inner organic phase of the system, composed with the lipid. W/O/W emulsions are suitable for hydrophilic drugs that are dissolved or dispersed in the inner aqueous phase, while the lipid is dissolved in the intermediate organic phase of the multiple system. Nanoparticles are formed when the solvent is distant either by evaporation (solvent evaporation technique for volatile solvents) or by water dilution (solvent diffusion technique for partially water miscible solvents): due to solvent removal lipid precipitates as nanoparticles encapsulating the drug.

Solvent-injection method

In solvent injection (or solvent displacement) method the lipid and the drug are dissolved in a water-miscible organic solvent (e.g. ethanol, acetone, isopropanol) and this solution is injected through a syringe needle in water under stirring, lipid precipitates as nanoparticles while contacting with water, encapsulating the drug. Particle size can be influenced by type of lipid, surfactant and solvent used, and from the viscosity of the outer phase.

Double Emulsion Method

The double emulsion (w/o/w) method is built on the solvent emulsification–evaporation method. It is mainly used for the producing lipid nanoparticles loaded with hydrophilic drugs. The drug and emulsifier are encapsulated in the inner aqueous phase of w/o/w double emulsion in this case.

Supercritical Fluid Method

This is a marginal method of preparing SLNs using particles from gas-saturated solutions (PGSS). This technique has several advantages such as

a. Avoiding the use of solvents
b. Particles are obtained in the form of dry powder, instead of suspension
c. It required mild pressure and temperature conditions. The good choice of solvent for this method is Carbon dioxide.

Membrane contactor technique

The liquid phase was pressed at a temperature above the melting point of the lipid through the membrane pores which allows the formation of small droplets. SLNs were designed by the cooling of the preparation at the room temperature. Here both the aqueous and organic phases were placed in the thermo stated bath to maintain the required temperature and nitrogen was used to create the pressure for the liquid phase.

Basically, the process consists of three steps

1. Melting a pharmaceutically suitable matrix comprised of lipid(s), surfactant(s), polymer(s), and drug at 5570°C
2. Adding pre-heated water with stirring to form the o/w microemulsion,
3. Cooling to room temperature with stirring to produce the SLNs.

Precipitation technique

Solid lipid nanoparticles can also be produced by a precipitation method which is considered by the requisite for solvents. In an organic solvent (e.g. chloroform) the glycerides will be liquefied and the solution will be blended in an aqueous phase. The lipid will be precipitated after evaporation of organic solvent to yield nanoparticles.

Film ultrasound dispersion

The lipid and the drug were put into suitable organic solvents, after decompression, rotation and evaporation of the organic solvents, a lipid film is formed, and then the aqueous solution which comprising of the emulsions was added. By means of the ultrasound with the probe to diffuser at last, the SLN with the little and uniform particle size is formed[8].

SECONDARY METHODS

Freeze-drying

Water can be withdrawn in order to improve physical and chemical stability of these systems. Freeze drying is the most widely used in pharmaceutical field for solidification purpose of SLN that improves the stability for distribution and storage. Freeze-drying, also known as lyophilization, is an industrially scalable process, which removes frozen water by sublimation, and desorption under vacuum[10].

Sterilization

For parenteral administration, SLNs dispersions must be sterile. Aseptic production, filtration, gamma irradiation and autoclaving are commonly used to for sterilization. Aseptic conditions can be used during fabrication of sterile SLNs but requirements can be complex and expensive. Sterilization by autoclaving is popular and convenient but it has some disadvantages; that is the high temperatures encountered during autoclaving can cause coalescence, as there is no applied shear to prevent this.

Characterisation of Solid Lipid Nanoparticles[7]

Measurement of Particle Size and Zeta Potential

Photon correlation spectroscopy (PCS) and laser diffraction (LD) are the most powerful techniques for measurements of particle size. PCS also known as dynamic light scattering which measures the fluctuation of the intensity of the scattered light which is caused by particle movement. This method covers a size range from a few nanometres to about 3 microns. PCS is a good tool for characterize nanoparticles, but it is not able to detect larger micro particles. The physical stability of optimized SLN discrete is generally more than 12 months. ZP measurements consent predictions about the storage stability of colloidal dispersion.

Photon Correlation Spectroscopy (PCS)

It is a traditional method which is based on dynamic scattering of laser light due to Brownian motion of particles in solution or suspension. This method is suitable for the measuring particles in the range of 3 nm to 3 mm. The PCS method consists of laser source, a sample cell (temperature controlled) and a detector. Photomultiplier detector is used to detect the scattered light. The diameter of PCS is based on the intensity of the light scattering from the particles.

Electron Microscopy

Electron Microscopy methods such as Scanning Electron Microscopy (SEM) and Transmission Electron Microscopy (TEM) are used to measure the shape and morphological characteristics of lipid nanoparticles. It consist the determination of particle size and distributions. SEM uses electrons transmitted from the surface of the sample and in TEM uses electrons transmitted through the sample and capture image beneath the surface of particle.

Atomic Force Microscopy (AFM)

It is an advanced microscopic technique which is used as a novel tool to image the original unchanged shape and surface properties of the particles. AFM measures the force acting between surface of the sample and the tip of the probe, when the probe is kept close to the sample which results in a convincing resolution of up to 0.01nm for imaging.

Determination of Incorporated Drug

Amount of drug incorporated in SLNs affect the release characteristics hence it is very important to measure the amount of incorporated drug. The amount of drug encapsulated per unit wt. of nanoparticles is resolute after separation of the free drug and solid lipids from the aqueous medium and this separation can be done by ultracentrifugation, centrifugation, filtration or gel permeation chromatography and the drug separated can be assessed by standard analytical technique such as HPLC spectrophotometer, spectroflurophotometry etc.

In- Vitro Drug Release

Dialysis Tubing: In vitro drug release could be done by the use of dialysis tubing. The solid lipid nanoparticle dispersions placed in prewashed dialysis tubing which can be hermetically sealed. The dialysis sac then dialyzed against an appropriate dissolution medium at room temperature; then the samples are withdrawn from the dissolution medium at specific time intervals,

centrifuged and analysed for the drug content using a proper analytical method.

Reverse Dialysis

A number of small dialysis sacs containing 1ml of dissolution medium are placed in SLN dispersion in this technique. The SLNs are then displaced into the medium for measurement.

Rheology

Rheological measurement of formulation can carried out with help of Brookfield Viscometer, using suitable spindle number. The viscosity depend on dispersed lipid content. As it increases the flow becomes Nonnewtonion from Newtonian.

Nuclear Magnetic Resonance (NMR)

NMR used to determine size and qualitative nature of nanoparticles.

X-Ray Diffraction (Powder X-Ray Diffraction) and Differential Scanning Calorimetry (DSC)

The geometric scattering of radiation from crystal planes within a solid allow the presence or absence of the former to be determined thus permitting the degree of crystallinity to be measured. DSC can be used to determine the nature and speciation of crystallinity within nanoparticles. It also estimated by comparison between melting enthalpy/g of the bulk material and melting enthalpy/g of the dispersion.

ROUTES OF ADMINISTRATION[7]

Parenteral administration

Peptide and protein drugs are typically accessible for parenteral use in the market. Since their conventional oral administration is not probable due to enzymatic degradation in GI tract. Parenteral application of SLN diminishes the possible side effects of drug incorporated with the improved bioavailability. These systems are very suitable for drug targeting.

Oral administration

Controlled release behaviour of SLNs is reported to enable the bypass of gastric and intestinal degradation of the encapsulated drug, and their possible uptake and transport through the intestinal mucosa. However, the assessment of the stability of colloidal carriers in GI fluids is crucial in order to assume their suitability for oral administration.

Rectal administration

When rapid pharmacological effect is required, in some situation, parenteral or rectal administration is preferred. This route is used for paediatric patients due to easy application.

Nasal administration

Nasal route is preferred due to its fast absorption and rapid onset of drug action that also avoid degradation of labile drugs in the GIT and insufficient transport across epithelial cell layers.

Respiratory delivery

Nebulisation of solid lipid nanoparticles carrying anti-tubercular drugs, anti-asthmatic drugs and anticancer was observed to be successful in improving drug bioavailability and reducing the dosing frequency for better management of pulmonary action.

Ocular administration

To achieve ocular drug targeting, biocompatibility and muco-adhesive properties of SLN improve their interaction with ocular mucosa and prolong corneal residence time of the drug.

Topical administration

SLN are very attractive colloidal carrier systems for skin applications due to their various desirable effects on skin excluding the characteristics of a colloidal carrier system. Non-irritant and non-toxic lipids are employed in SLN formulation and because of that it is well suited for topical administration.

APPLICATIONS[8]

SLN as Potential new Adjuvant

Vaccines Adjuvants are used in vaccination to enhance the immune response. The benign new subunit vaccines are less effective in immunization and therefore current adjuvants are required. The oil-in-water emulsions rapidly destroy into body that mainly focus on adjuvant area now-a-days.

SLN in Cancer Chemotherapy

Consequences of these studies have been shown to improve the efficacy of chemotherapeutic drugs, concurrently reduction in side effects related with

them. Improved stability of drugs, encapsulation of chemotherapeutic agents of diversified physicochemical properties, enhanced drug efficacy, improved pharmacokinetics and less *in vitro* toxicity are the important characteristics of SLN which make them a suitable carrier for delivering chemotherapeutic drugs. Several obstacles frequently encountered with anticancer compounds, such as normal tissue toxicity, poor specificity and stability and a high incidence of drug resistant tumour cells, are at least partially overcome by delivering the cogitative SLN.

SLN for delivery of Peptides and Proteins

Proteins and antigens proposed for therapeutic resolutions may be incorporated or adsorbed onto SLN. Formulation in SLN convers improved protein stability, avoids proteolytic degradation, as well as sustained release of the incorporated molecules. Important peptides such as cyclosporine A, insulin, calcitonin and somtostatin have been incorporated into solid lipid particles and are presently under investigation. There are several local or systemic therapeutic.

SLN for Topical application

SLN and NLC are identical to attractive colloidal carrier systems for skin applications due to their various desirable effects on skin besides the characteristics of a colloidal carrier system. In the course of last few years, SLN and NLC have been deliberate with active compounds such as Vitamin E, tocopherol acetate, retinol, ascorbyl palmitate, clotrimazole, triptolide, phodphyllotoxin and a nonsteroidal antiandrogen RU 58841 for topical application.

SLN for potential agriculture application

Essential oil extracted from *Artemisia arborescens* L. when incorporated in SLN, able to reduce the rapid evaporation compared with emulsions and the systems have been used in agriculture as a suitable carrier of ecologically safe pesticide.

Stealth nanoparticles

These provide a novel and unique drug-delivery system they escape quick clearance by the immune system. Theoretically, such nanoparticles can target specific cells. Studies with antibody labelled stealth lipobodies have shown increased delivery to the target tissue in accessible sites.

SLNs as cosmeceuticals

The SLNs have been applied in the preparation of sunscreens and as an active carrier agent for molecular sunscreens and UV blockers. The in vivo study displayed that skin hydration will be increased by 31% after 4 weeks and by accumulation of 4% SLN to a conventional cream. SLN and NLCs have proved to be controlled release innovative occlusive in topical drug delivery systems.

Table No.1: Comparative properties of solid lipid nanoparticles, Polymeric nanoparticles, Liposomes, Lipid emulsions[7]

S.No	Property	SLN	Polymer Nanoparticle	Liposomes	Lipid Emulsions
1	Systemic toxicity	LOW	>= to SLN	Low	Low
2	Cytotoxicity	LOW	>=to SLN	Low	Low
3	Residue from organic solvent	NO	YES	May or May not	No
4	Large scale production	YES	NO	Yes	Yes
5	Sterilization by autoclaving	YES	NO	No	Yes
6	Sustained release	YES	YES	<or= to SLN	No
7	Avoidance of RES	Depend on size and coating	NO	YES	Yes

Table No.2: Hot Homogenization and Cold homogenization[8]

Steps	Hot Homogenization Technique	Cold Homogenization Technique
1	Melt lipid; dissolve or solubilize active ingredients in the lipid.	Melt lipid; dissolve or solubilize active ingredients in the lipid.
2	Disperse melted lipid in hot aqueous surfactant solution.	Cooling and recrystallization of the active lipid mixture using liquid nitrogen or dry ice.
3	Preparation of pre-emulsion by means of a rotostator homogenizer.	Milling of the active lipid mixture by means of a ball mill or a jet mill.
4	High pressure homogenization above the melting point of the lipid.	Disperse lipid microparticles in cold aqueous surfactant solution.
5	Cooling and recrystallization.	High pressure homogenization at or below room temperature.

Table No.3: Advantages and Disadvantages of different methods

S.No	Method	Advantages	Disadvantages
1a	Hot HPH	Versatile, avoid use of organic solvent, easy scalability, short production time, instruments easily available and no regulatory problems.	High temperature lead to degradation, conformational change in protein, coalescence of particles, burst release due to high emulsifiers.
1b	Cold HPH	Minimizes thermal exposure of the drug but does not avoid it completely. Useful in temperature labile drugs or hydrophilic drugs.	Higher Polydispersity index
2	Emulsification-solvent evaporation	Avoidance of heat during production thus useful for thermo labile drugs. Simple procedure	Solvent residues
3	Micro emulsion	No need for specialised equipment and energy for production	High concentrations of surfactants and co-surfactants, presence of large amounts of water in system
4	Membrane contractor	Simple method, control of particle size by selection of process parameters its scaling-up abilities	---

5	Solvent injection	No need for HPH ,easy handling, fast production process, No need for specialized equipment	Use of solvent surfactant
6	PGSS	One step procedure, no need of organic solvent, low processing temperature conditions	Frequent nozzle blockage with hydrophilic drugs, machinery is costly.
7	Multiple emulsion	No need to melt lipids, high loading of hydrophilic drugs, useful for protein loading	Use of solvent and surfactant
8	Solvent injection	No need for HPH, easy handling, fast production process, No need for specialized equipment	Use of solvent surfactant
9	Film Ultra sonication dispersion	Simple ,no need for specialised equipment	Metallic particle contamination, broader particle size
10	Phase inversion	Useful for thermo labile drugs, avoidance	---

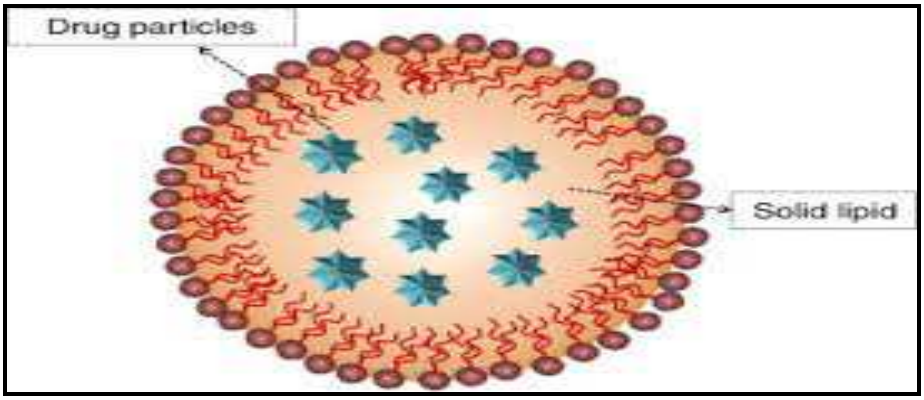

Figure No.1: Structure of solid lipid nanoparticle (SLN)

CONCLUSION

Solid lipid nanoparticles show a particulate system which can be formed with are cognised technique. The site specific and sustained release effect of drug can better achieved by use of SLNs. It acts as a carrier for the delivery of drug. Nanoparticles have been used widely for applications in drug discovery, drug delivery and diagnostics and for many others purposes in medical field. In future we can expect many formulations in the form of SLN.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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