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Nano Lipid Carrier System in Cosmetic Dermal Preparation: A Review

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Abstract

Since the beginning of the 1990s the nano-lipid carriers (NLCs) have been attracting a growing interest from the pharmaceutical technology research groups worldwide. NLCs appeared as consumer products first on the cosmetic market. The article gives an overview of the cosmetic benefits including enhancement of chemical stability of actives, film formation, controlled occlusion, skin hydration, skin bioavailability, and physical stability of the lipid nanoparticles. Solid-lipid nanoparticle as topical formulations. List of the cosmetic products currently available in the market, and bioequivalence protocol, excipients, improvement of the benefit/risk ratio of the topical therapy is shown. Lipid based drug delivery systems are nowadays popular as they are expected to be the promising carriers because of their potential to increase solubility and improve bioavailability of poorly water soluble and/or lipophilic drugs.

Key words: Cosmetics, Dermal, Nano lipid

Introduction

Pharmaceutical breakthrough new technologies have leads to find numerous new mighty therapeutic compounds. To assure progress in drug therapy, the development of new drugs merely is not sufficient. Poor water solubility and insufficient bioavailability of the new drug substances are very extensive issues encountered. Thus, there is an expanding need to develop a pharmaceutical carrier scheme that overcomes these matters, such a carrier should have an adequate pharmaceutical loading capability, free from cytotoxicity and the possibility of possessing pharmaceutical targeting and controlled release characteristics. The system should provide chemical steadiness to incorporate pharmaceuticals. Lipid nanoparticle different categories

A wide range of nano-lipid carrier (NLC) can be used for topical application of drug. To illustrate, several problems have been reported with the conventional topical preparations, e.g., low uptake due to the barrier function of the stratum corneum and unwanted absorption to the systemic circulation.

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The literature review provides several systems that can deliver an active pharmaceutical ingredients across the skin presenting advantages in systemic treatment with minimal side effects, the absence of first-pass metabolism, and in topical treatment allowing targetingspecificskinappendages.[2].Among the carriers, solid-lipid nanoparticle (SLN) and NLC have emerged as novel systems composed of physiological lipid materials suitable for topical, dermal, and transdermal administrations. Many features, these carrier systems exhibit suggest for dermal application including cosmetics and pharmaceuticals.

NLCs are the new generation of lipid nanoparticles, attracting major attention as novel colloidal drug carriers for topical use. NLC has been developed to overwhelm the drawbacks affiliated with SLN.[3] SLN is produced by replacing the oil of an o/w emulsion by a solid lipid or a blend of solid lipid, i.e., the lipid particle matrix being solid at both room and body temperature. While NLC consists of a mixture of specially blended solid lipid (long chain) with liquid lipid (short chain), preferably in a ratio of 70:30 up to a ratio of 99.9:0.1. The resulting matrix of the lipid particle shows a melting point depression compared to the original solid lipid, however, the matrix remains solid at body temperature. However, some limitation of the SLN system regarding drug expulsion during storage,

NOVELGENERATIONOFLIPIDNANOCARRIER
Solidlipidnanoparticle(SLN)

Solid lipid nanoparticles (SLNTM) were developed at t he midlines of the 1990s as an alternative carrier syste m to the existing traditional carriers, such as emulsions, liposomes and polymeric nanoparticles 9. Solid lipid nanoparticles (SLN) prepared either with physiologi cal lipids or lipid molecules with an history of safe use in human medicine, which attract increasing atte ntion as colloidal drug carriers. Under optimized con ditions they can be produced to incorporate lipophil ic or hydrophilic drugs and seem to fulfill the requir ements for an optimum particulate carrier system10. Advantages of SLN are the use of physiological lipids, the avoidance of organic solvents, a potential wide app lication spectrum (dermal, per os, intravenous) and the high pressure homogenization as an established production method. Additionally, improved bioavailability, protection of sensitive drug molecules from the outer environment (water, light) and even controlled release characteristics were claimed by incorporation of poorly water soluble drugs in the solid lipid matrix[4]

Nanostructured lipid carriers (NLC)

A new generation of nanostructured lipid carriers (NLC s) consisting of a lipid matrix with a special nanostruct ure has been developed This nanostructure improves drug loading and firmly incorporates the drug dispersions with solid contents from 30–80%.Carrier system. However, the pressure homogenization and the process can be modified to yield lipid particle NLC system minimizes or avoids some potential problems associated with SLN. The review by Mehnert and Mader14 high lights these aspects:

1. Pay-load for a number of drugs too low
2. Drug expulsion during storage
3. High water content of SLN dispersion[5,6]

Lipid drug conjugates (LDC) nanoparticle

A major problem of SLNs is the low capacity to loa d hydrophilic drugs due to partitioning effects durin g the production process. Only highly potent low d ose hydrophilic drugs may be suitably incorporated in the solid lipid matrix15. In order to overcome this limitation, the so called LDC nanopa rticles with drug loading capacities of up to 33% h ave been developed[10]. An insoluble drug-lipid conjugate bulk is first prepared either by salt formation (e.g. with a fatty acid) or by covalen t linking (e.g. to ester or ethers). The obtained LDC is then processed with an aqueous surfactant sol ution (such as Tweens) to a nanoparticle formulatio n using high pressure homogenization (HPH). Such matrices may have potential application in braintargeting of hydrophilic drugs in serious prot ozoal infections.[7]

Drug incorporation model of NLC

SLN modified by incorporation of liquid lipid into the solid lipid has been proposed to NLC to overcome the some limitation of old generation SLN. There are three types: [5]

Type I (highly imperfect matrix) In Type I NLC, low liquid lipid (oil) concentration is used compared to solid lipid. Solid lipid and oil are blended to o/w nano-emulsion that when cooled from molten state to room temperature, forms solid particle, due to crystallization process, leads to highly disordered, imperfect lipid matrix offering space for drug molecules and amorphous structure of drug.

Type II multiple types In Type II NLC, there is a high oil concentration. During crystallization process, phase separation of the two lipids occurs. At certain temperature, they have miscibility gapleading to precipitation of tiny oily nano-compartment. When lipids lack drug solubilities, the addition of higher amount of liquid lipid to the lipophilic phase display the advantages of the solid matrix which prevented drug leakages while liquid lipid shows high solubility for lipophilic drug.

Type III amorphous type

In this type of NLC, by controlled mixture of lipids, particles were created which were solid, not crystalline but in an amorphous state. This amorphous state needs to be preserved [6]

INTENTION OF TOPICAL PREPARATION

To formulate an effective and efficient topical preparation, i.e., directly concerned with the site of action and the desired effect of the preparation, this preparation may be used for;

Transepidermal water loss (TEWL)

Bioactives penetration into the stratum corneum can be enhanced by occlusion caused by the product, which enhances hydration of the stratum corneum due to the inhibition of water evaporation. Application of NLCs on the skin helped to reduce water loss from the skin when compared to the untreated control. This could be due to the small size of particles in NLCs having larger surface area, which give greater adhesive properties. They form a uniform compact layer on the skin surface, thus preventing water evaporation from the skin[(7)]

Increase of skin occlusion

The occlusion effect was reported for lipid nanoparticles. By using very small lipid particles,

which are produced from highly crystalline and low melting point lipids, the highest occlusion will be reached. Particles smaller than 400 nm containing at least 35% lipid of high crystallinity have been most effective. Comparing NLC with different oil contentshowed that an increase in oil content leads to a decrease of the occlusive factor [8,9]

Enhancement of skin permeation and drug targeting

The stratum corneum in healthy skin has typically a water content of 20% and provides relatively an effective barrier against percutaneous absorption of exogenous substances skin hydration after applying SLN or NLC leads to a reduction of corneocytes packing and an increase in the size of the corneocytes gaps. This will facilitate the percutaneous absorption and drug penetration to the deeper skin layers. [10]

Enhancement of ultraviolet (UV) blocking activity

Some side effects of organic UV blockers were reported due to the penetration of these compounds into the skin causing skin irritation and allergic reaction. This penetration can be reduced by incorporating these compounds in lipid nanoparticles; furthermore, a significant increase in sun protection factor (SPF) up to about 50 was reported after the encapsulation of titanium dioxide into NLC. Encapsulation of inorganic sunscreens into NLC is, therefore, a promising approach to obtain well tolerable sunscreens with high SPF. [11]

IMPROVE BENEFITS/SKIN RATIO

Skin atrophy and systemic side effect occurred after applying conventional prednicarbate cream could be avoided when this drug was formulated as SLN. Prednicarbate uptake was enhanced and it was accumulated in the epidermis with a low concentration in the dermis.

Methods of preparation for SLN and NLC[12,13]

1. Homogenization method
   - Hot homogenization
   - Cold homogenization.
2. Solvent evaporation method
3. Solvent emulsification-diffusion method
4. Microemulsion-based method
5. Supercritical fluid method
6. Spray drying method
7. Double emulsion method
8. Precipitation technique
9. Film-ultrasound dispersion
10. High-speed homogenization followed by ultrasonication

TECHNIQUES FOR SLN PRODUCTION General ingredients and the emulsifiers The matrixes of SLN are the natural or the synthetic lipids which can be degradated, including triglyceride (tri-stearic acid, tri-palmitic acid, tri-lauric acid etc. long- chain fatty acid), steroid (e. g. cholesterin) waxes (e. g., microcrystal paraffin wax, whale ester wax). The choice of the emulsifiers depends on the administration of the drug, to the parenteral system, there are limits to choose the emulsifiers16] including the phospholipids [e. g. , soybean phospholipids(LS 75, LS loo), yolk phospholipids (L E80) lecithin(epikuron ~ooo)], nonionic wetting agent (e. g. , poloxamer 188, 182, 407, 9081, chleolate (e. g. , sodium cholate) lecithin(epikuron ~ooo)], nonionic wetting agent (e. g. , poloxamer 188, 182, 407, 9081, chleolate (e. g. , sodium cholate, sodium glycocholate sodium taurocholate ,deoxy-sodium taurocholate 1 short-chain spirits (e. g. ,butanol, butanoic acid 1. Amphipathicity materials (e.g.,ionic and nonionic type) can stabilize the dispersion of SLN, on the surface of SLN,hydrophobic parts stretch to the core, hydrophilic parts stretch to the disperse medium, so drug with low water-solubility can be entrapped in the SLN to form the colloidal drug system. [51,52,53, 54)

High pressure homogenization

HPH is a 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)

Film ultrasound dispersion

The term lipid and the drug were put into suitable organic solutions, decompression, rotation and evaporation theorganic solutions, a lipid film is formed, then the aqueous solution which includes the emulsions was added. Using the ultrasound with the probe to diffuser at last, the SLN with the little and uniform particle size is formed. Wang et al use the soybean phospholipids as carrier and the film-ultrasound dispersion method to prepare the Olea nane solid lipid nanoparticles (OA-SLN)

SLNpreparedbysolventemulsification/evaporation

For the production of nanoparticle dispersions by precipitation in o/w emulsions24 the lipophilic material is dissolved in water-immiscible organic solvent (cyclohexane) that is emulsifed in an aqueous phase. Upon evaporation of solvent nanoparticle dispersion is formed by precipitation of the lipid in the aqueous medium. The mean diameter of the obtained particles was 25 nm with cholesterol acetate as model drug and lecithin/sodium glycocholate blend as emulsifer. The reproducibility of the result was confirmed by Siekmann and Westesen, who produced the cholesterol acetate nanoparticles of mean size 29 nm25.

Modulation of drug release

The common principles of drug release from lipid nanoparticles can be explained below; drug release is inversely proportional to the partition coefficient of the drug. Surface area increases due to smaller particle size in nanometer range which results in higher drug release. Slow release of the drug could be accomplished when the drug is equally dispersed in the lipid matrix.

Drug release from lipid particles occurs by diffusion and simultaneously by lipid particle degradation in the body. In some cases, it might be desirable to have a controlled fast release going beyond diffusion and degradation. Ideally, this release should be triggered by an impulse when the particles are administered. NLCs accommodate the drug because of their highly unordered lipid structures. By applying the trigger impulse to the matrix to convert into a more ordered structure, such a desired burst drug release can be initiated. NLCs of certain structures can be triggered this way for example, when applying the particles to the skin incorporated in cream. Increase in temperature and water evaporation leads to an increase in drug release rate [Figure 1][1. (14,15,)]and some of the polymers used in topical are show in Table 4

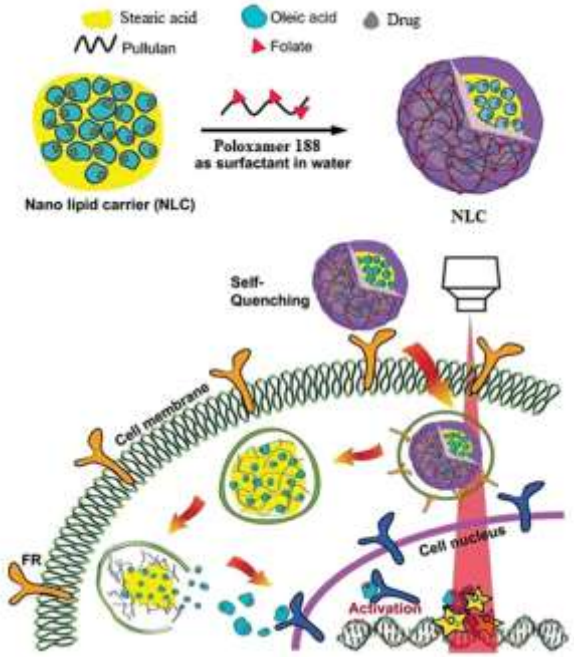

Figure: 1Modulation of drug release**Factors affecting drug release**

Many factors that could affect the release profile of the drug from the NLC system.

Stability
Particle size
Lipid matrix
Surfactant
Drug loading
Drug type

Stability

During long-term storage of dispersions, element aggregation can happen. Aggregation and case formation were described for SLNs. In the highly intensified, NLC dispersions the particles pattern a "pearl-like network," thus the particles are in a repaired place and will not undergo collision and perikinetic flocculation [Figure 2][1. (16,17)]

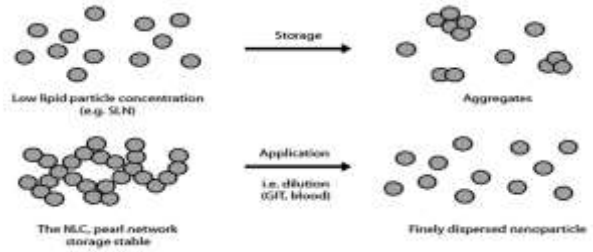

Figure 2: Aggregation process in low concentrated dispersions (upper) and pearl-like network in nano-lipid carriers dispersions with stabilizing effect

Characterization of NLC dispersion

- Particle size
- Zeta potential
- Scanning electron microscope
- Determined % drug entrapment efficiency
- % $EE = Wa - Ws/Wa \times 100$

Where, *EE* is entrapment efficiency, *Wa* stands for the mass of drug added to the formulation and *Ws* is the analyzed weight of the supernatant.

- Differential scanning calorimetry.

Characterization of topical[42-44]

Parameters	**Method**
Diffusion	Franz diffusion cell
Viscosity	Brookfield viscometer
Refractive index	Abbe's refractometer
Spreadibility	Glass plate method
pH	Digital pH meter

REGULATORY CONSIDERATION OF TOPICAL

Bioavailability and bioequivalence issues

The issues of bioavailability and bioequivalence were given considerable, since the target organ for topical products is skin, it seems logical that determining drug concentrations in the skin layers should provide an assessment of topical bioavailability. More work in this area is needed to establish procedures for assessing bioavailability of topical dermatological products. Using the skin stripping technique, only stratum corneum is readily accessible and the deeper tissues. At present, there are no accepted non-clinical models or approaches to predict or determine the bioavailability

and bioequivalence of dermatological drugs. Consequently, bioequivalence assessment of test and reference product is based on studies with clinical end points or pharmacodynamics measurements.

Quality control issues

At present, no recognized quality control procedure is available for assessing batch-to-batch uniformity of dermatological products in terms of drug release. A simple procedure to determine the drug release rate from the cream formulations using commercially available diffusion cell and the synthetic membrane has been suggested as a means of accomplishing this, but it is clear that this approach needs to be carefully validated before it can be recommended and widely implemented. Since drug must first be released from the formulation and then permeate through the stratum corneum for therapeutic effect, it may be appropriate to use drug release properties employing synthetic membrane techniques as a quality control test to ensure batch-to-batch uniformity. The quality control test should be able to detect formulation or process factors which may affect the bioavailability and bioequivalence of the drug product.[45]

STUDIES OF TOPICAL BIOEQUIVALENCE

***In vitro* release testing (IVRT)[48,49]**

IVRT utilizes widely accepted Franz diffusion cells to estimate rate of drug release from drug products. It involves the application of a drug product onto a membrane (synthetic membrane, excised animal skin, or excised human skin) that separates the donor and receiver chambers. The receiver chamber simulates sink conditions *in vivo*. The rate of delivery obtained from these studies is assumed to be similar to the *in vivo* situation. The method has been widely employed in discovery research for screening formulations and understanding mechanism of cutaneous drug transport.

Tape stripping (TS)

TS provides information on drug uptake, apparent steady-state levels, and drug elimination from the stratum corneum based on a stratum corneum concentration time curve (FDA's Draft Guidance, 1998). This method is also known as the dermatopharmacokinetic approach similar to blood, plasma, and urine analysis for drug concentrations as a function of time.

Microdialysis (MD)

MD is a continuous sampling technique in which the molecule of interest is collected from the target tissue; thus providing insight into the time course of drug action or biochemical monitoring of the tissue. The technique can be imagined as an artificial capillary, in which a hollow semipermeable probe is carefully inserted into the site of interest: Brain, muscle, eye, and skin. Therefore, it provides valuable information of unbound drug concentration or biomarkers at the site closer to the pharmacological action compared to the conventional plasma/blood drug concentration versus time.[50]

TEWL

TEWL measurements (the rate at which water vapor is lost from the body through the skin) are of great importance in evaluating barrier functionality. Often normal rates of TEWL are compromised due to injury, infection and/or severe damage as in the case of burns. Damage to the stratum corneum and superficial skin layers not only results in physical vulnerability but also results in an excess rate of water loss. TEWL is also affected by variations in sweatgland activity, temperature, and metabolism. Therefore, TEWL becomes a significant factor in dehydration associated with several major disease states. Some Cosmetic products containing lipid nanoparticles are currently available in the market are shown in table1

Table1:Cosmeticproductscontaininglipidnanoparticles are currently available in the market [38, 39]

Product name	Active ingredients	
Nano-lipid restore CLR	Black currant seed oil containing 3 and 6 unsaturated fatty acids	
Nano-lipid basic CLR	Caprylic/CT	
NLC deep effect eye serum	Coenzyme Q10, highly active oligo saccharides	
Extra moist softener	Coenzyme Q10, 3 und 6 unsaturated fatty acids	
Olivenöl anti-falten	*O. europaea* oil, panthenol, acacia senegal, tocopherylacetate	

Conclusion

Lipid based nanocarriers have the greater importance in the developing field of nanotechnology with several advantages apart from various carriers. Lipid based carriers are a promising nanoscaler delivery system for the pharmceutical industry due to the fact that: • Large scale production possible, no organic solvents ne eded High concentrations of functional compounds can be achieved Lyophilization possible Spray drying for l ipids with T > 70ºC to yield powders. the concept of surface modification is further increasing the importance of SLN and NLC among traditional

colloidal drug carrier system. SLN and NLC delivery are promising candidates that will enable efficient and targeted delivery of novel drug compound. Lipid carriers have bright future, because of their intrinsic property to improve the bioavailability of lipophilic drugs with low aqueous solubility. SLN and NLC offer an economical and patient-friendly device for administration of drugs by topical routes.

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