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Solid Lipid Nanoparticles: Formulation, Evaluation, and Future Prospects

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Abstract: Solid lipid nanoparticles (SLNs) have gained considerable attention as advanced nanocarrier systems due to their ability to overcome major limitations associated with conventional drug delivery, particularly poor drug solubility, instability, and low bioavailability. SLNs are composed of physiologically acceptable solid lipids stabilized by surfactants, offering a biocompatible, safe, and versatile platform for pharmaceutical applications. This review provides a comprehensive overview of SLNs, focusing on their composition, preparation techniques, characterization methods, and critical formulation challenges. Widely employed preparation approaches, including high-pressure homogenization, solvent evaporation, microemulsion, solvent injection, and ultrasonication methods, are systematically discussed with emphasis on their advantages and limitations. Furthermore, key evaluation parameters such as particle size, zeta potential, drug loading, crystallinity, in vitro release behavior, stability, and sterility are summarized. The review highlights recent advances in SLN applications across multiple administration routes, including oral, parenteral, transdermal, and intranasal delivery, demonstrating their potential to enhance drug bioavailability, targeting efficiency, and therapeutic outcomes. Despite their promising attributes, challenges related to large-scale production, polymorphic transitions, and long-term stability remain. Overall, this review concludes that SLNs represent a promising and adaptable drug delivery system, with ongoing technological advancements expected to facilitate their successful translation into clinical and industrial applications.

Keywords: Solid Lipid Nanoparticles, Lipid-Bases, Formulation, Evaluation, Nanotechnology, Controlled Release.

Review Paper

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1. INTRODUCTION

Nanotechnology has markedly advanced modern drug delivery by enabling the development of nanoscale carrier systems capable of improving drug solubility, stability, targeting efficiency, and therapeutic performance. Among these systems, solid lipid nanoparticles (SLNs) have received sustained scientific interest over the past three decades as lipid-based nanocarriers composed of biocompatible and physiologically acceptable excipients. Their ability to enhance the bioavailability of poorly water-soluble drugs addresses a persistent challenge in pharmaceutical development, as it is estimated that more than 40% of marketed drugs and nearly 90% of drug candidates in development exhibit low aqueous solubility [1, 2].

SLNs were introduced in the early 1990s as an alternative to polymeric nanoparticles, with the aim of overcoming limitations associated with polymer-related toxicity, degradation byproducts, and regulatory complexity. By combining advantages of polymeric nanoparticles (controlled release) and liposomes (biocompatibility), while reducing their respective drawbacks, SLNs have emerged as a promising delivery platform suitable for a broad range of therapeutic agents [3, 4]. Consequently, research on SLNs has expanded significantly, with continuous growth in publications focusing on formulation strategies, route-specific delivery, and therapeutic applications.

Structurally, SLNs are composed of solid lipids such as triglycerides, fatty acids, waxes, and glyceride mixtures that remain solid at both room and physiological temperatures. This solid-state lipid matrix enhances nanoparticle stability and protects encapsulated drugs from chemical and enzymatic degradation. Typically ranging from 50 to 1000 nm in size, SLNs facilitate controlled drug release and improved interaction with biological membranes, enabling enhanced transport across physiological barriers compared with conventional dosage forms [5].

A key advantage of SLNs is their adaptability to multiple routes of administration, including oral, parenteral, transdermal, ocular, and pulmonary delivery. This versatility allows SLNs to be tailored for site-specific, sustained, or targeted drug delivery, expanding their potential applications across diverse therapeutic areas [6]. In oral delivery, for example, SLNs may improve drug absorption through lymphatic uptake, endocytosis, and paracellular transport, while certain lipid components and surfactants can modulate efflux transporters such as P-glycoprotein. Surface modification with polymers such as chitosan further enhances mucoadhesion and oral bioavailability [7–10].

Despite extensive preclinical research and promising therapeutic outcomes, the successful clinical and industrial translation of SLNs remains limited. Several critical challenges persist, including lipid polymorphism, phase separation, sterilization difficulties, long-term stability, and batch-to-batch variability. These factors directly influence drug loading, release behavior, safety, and reproducibility. In addition, large-scale production of SLNs requires precise control of process parameters to ensure consistent particle size distribution, drug encapsulation efficiency, and regulatory compliance. Although techniques such as high-pressure homogenization have demonstrated scalability, standardized manufacturing protocols and quality-control frameworks remain insufficiently established [11, 12].

In light of these challenges, there is a clear need for a focused and up-to-date review that not only summarizes recent advances in SLN formulation and applications but also critically examines the translational barriers limiting their clinical adoption. Therefore, the purpose of this article is to comprehensively review the composition, preparation methods, characterization techniques, and pharmaceutical applications of solid lipid nanoparticles, while explicitly identifying current knowledge gaps and future directions related to formulation optimization, scale-up, and clinical translation. By addressing both technological progress and unresolved challenges, this review aims to provide a practical and scientifically grounded resource for researchers and formulation scientists working toward the development of clinically viable SLN-based drug delivery systems.

2. Composition of SLNs

The major ingredients include solid lipids, which serve as the structural backbone of the nanoparticles. Examples of these solid lipids are glyceryl behenate (known commercially as Compritol® 888 ATO), glyceryl palmitostearate (marketed as Precirol® ATO 5), as well as common lipids like stearic acid, cetyl palmitate, and tripalmitin [13]. In addition to solid lipids, surfactants and co-surfactants play a critical role in stabilizing the dispersion of nanoparticles. Widely used surfactants include Poloxamer 188, Tween 80, Span 80, lecithin, and sodium cholate, all of which help to reduce surface tension and prevent aggregation. Finally, the aqueous phase, serves as the dispersion medium, facilitating the overall formulation and stability of the SLNs. Together, these components work synergistically to enhance the delivery and bioavailability of encapsulated active substances [14].

3. METHODS OF PREPARATION

SNLs were prepared by the following techniques:

3.1 High-Pressure Homogenization (HPH)

One of the most common and scalable techniques. The lipid phase containing the drug is melted and mixed with an aqueous surfactant phase, then homogenized under high pressure to form nanoparticles.

Elevated temperatures beyond the lipid's melting point are chosen for this method and can later be regarded as the homogenization process employing emulsifiers. A high shear mixing device is utilized resulting in an oil-in-water type emulsion. The mixture is then allowed to cool, initiating the crystallization of lipids, which leads to the formation of SLNs. To achieve optimal SLN production, 3 to 5 cycles of homogenization at elevated pressures are demanded. It’s important to note that high-pressure homogenization (HPH) causes a temperature increase. As the frequence of cycles or pressure increases, there is an increase in particle size, which occurs due to the attractive forces stemming from kinetic energy. then, the nanoemulsion is cooled prompting the recrystallization of lipids and resulting in the formation of nanoparticles [15].

Cold homogenization is a technique designed to address the issues associated with hot homogenization, such as rapid degradation from high temperatures, loss of drug during the process, and unpredictable changes in the lipid's polymorphic form due to the complexities involved in crystallization. The initial step of the process—dissolving the drug in the lipid melt—remains the same as in hot homogenization. However, subsequent steps differ significantly. The drug-lipid mixture is quickly cooled to ensure an even distribution of the drug within the lipid matrix. After cooling, the mixture is finely ground using a ball mill, resulting in particles that typically range from 50 to 100 µm in size. It is important to note that cold homogenization typically yields larger particle sizes compared to the hot method [16].

3.2 Solvent Evaporation

In this technique, the lipophilic materials and hydrophobic drug are dissolved in organic solvents that do not mix with water, such as cyclohexane. Then, the mixture is emulsified in an aqueous phase employing high-speed homogenization. The coarse emulsion is then promptly passed through a microfluidizer. A rotary evaporator with functioned at room temperature and

reduced pressure, is employed to evaporate the organic solvent [16].

3.3 Microemulsion Technique

A microemulsion is assembled by fusing a medicine liquefied in molten lipids with an aqueous phase that comprises emulsifier, all heated then introduced into cold water at temperatures ranging from 2 to 10 °C while being stirred, which leads to the formation of lipid nanostructures that crystallize [17]. This technique was used to create nanostructured lipid carriers (NLCs) employinga phagocytic role to target oligonucleotides within atherosclerosis. This showcases an effective and favorably selective formulation for atherosclerosis therapy. The method is reproducible appropriate for thermolabile drugs. Nevertheless, it necessitates a significant quantity of surfactant and requires the evaporation of excess water after the preparation is complete [1].

3.4 Solvent Injection Method

In this approach, a miscible solvent is utilized to solubilize both the lipid and the medicine, and the aqueous phase mixed with an emulsifier. The lyophilic phase is introduced into the aqueous phase via a needle, creating smaller droplets, which increases the concentration of lipids. These emulsifiers help lessen the interfacial tension, facilitating the creation of tiny solvent droplets that contain lipids. The quick speed at which the solvent is injected drives these droplets to fragment into even more undersized droplets. The energy liberated during the solvent's redistribution provides the essential energy required for lipid precipitation [19].

3.5 Ultrasonication or High-Shear Homogenization

SLN was also assembled by high-speed stirring or sonication. The gear utilized for this procedure is prevailing. The foremost weakness of this technique is a broader particle size distribution, which is the leading reason for physical instability. Particle gain on storage is an acute problem in this approach. After multiple investigations, it was proven that high-speed stirring and ultrasonication, when utilized combinedly at elevated temperatures, generate a unchanging formula [20].

Preparation Method	Principle / Process	Key Conditions	Advantages	Limitations	Typical Particle Characteristics
High-Pressure Homogenization (Hot HPH)	Drug-loaded lipid is melted and emulsified in a hot aqueous surfactant phase, followed by high-pressure homogenization and cooling-induced lipid crystallization	Temperature above lipid melting point; 3–5 homogenization cycles at high pressure	Scalable; solvent-free; suitable for industrial production	Elevated temperature may cause drug degradation; increased pressure/cycles may increase particle size due to aggregation	Small nanoparticles with good homogeneity; possible size increase at high energy input
High-Pressure Homogenization (Cold HPH)	Drug is dissolved in lipid melt, rapidly cooled, ground into microparticles, then homogenized at low temperature	Rapid cooling; ball milling (50–100 μm); room or low temperature homogenization	Suitable for thermolabile drugs; reduces drug loss and polymorphic transitions	Larger particle sizes compared to hot HPH; more complex process	Larger SLNs with broader size distribution
Solvent Evaporation Method	Lipid and drug dissolved in water-immiscible organic solvent, emulsified in aqueous phase, followed by solvent removal	Organic solvent use; homogenization or microfluidization; reduced pressure evaporation	Good for hydrophobic drugs; controlled particle formation	Residual solvent risk; environmental and safety concerns; less scalable	Uniform nanoparticles with high drug entrapment
Microemulsion Technique	Hot microemulsion (lipid, drug, surfactant, water) is rapidly	High surfactant concentration; rapid cooling (2–10 °C)	Reproducible; suitable for thermolabile drugs; narrow	Requires large amounts of surfactant; dilution and	Small particles with narrow size distribution

Preparation Method	Principle / Process	Key Conditions	Advantages	Limitations	Typical Particle Characteristics
	dispersed into cold water causing lipid crystallization		size distribution	water removal steps needed	
Solvent Injection Method	Lipid–drug solution in water-miscible solvent injected into aqueous emulsifier phase causing lipid precipitation	Rapid injection; solvent diffusion; emulsifier presence	Simple; no high energy required; fast process	Limited lipid solubility; solvent-related toxicity; scale-up challenges	Small nanoparticles dependent on injection rate
Ultrasonication / High-Shear Homogenization	Lipid phase dispersed into aqueous phase using mechanical shear or ultrasound	High-speed stirring; sonication; elevated temperature improves stability	Simple equipment; low cost; easy laboratory-scale preparation	Broad particle size distribution; poor long-term stability; particle growth on storage	Heterogeneous particle sizes; improved uniformity with combined methods

4. Characterization and Evaluation of SLNs [21].

4.1 Particle Size and Zeta Potential

Measured by Dynamic Light Scattering. Particle size affects drug release and bio-distribution, while zeta potential indicates surface charge and colloidal stability.

4.2 Drug Loading and Entrapment Efficiency

Determined by separating free drug from nanoparticles (via ultracentrifugation or filtration) and quantifying using HPLC or UV spectroscopy.

4.3 Morphological Studies

Transmission Electron Microscopy (TEM) and Scanning Electron Microscopy (SEM) are employed to study particle shape and surface characteristics.

4.4 Crystallinity and Polymorphism

Differential Scanning Calorimetry (DSC) and X-Ray Diffraction (XRD) assess the crystalline nature of lipids and potential drug–lipid interactions.

4.5 In Vitro Drug Release

Usually performed employing diffusion methods in suitable media. The release pattern (burst, sustained, or biphasic) depends on lipid composition and drug localization.

4.6 Stability Studies

Assessed under various temperature and humidity conditions to evaluate aggregation, polymorphic transitions, and drug degradation over time.

4.7 Sterility and Toxicity Testing

Essential for parenteral applications. Cytotoxicity is tested using cell lines such as Caco-2 or HepG2.

The composition and evaluation parameters of SNP are demonstrated in Figure 1 and table 1.

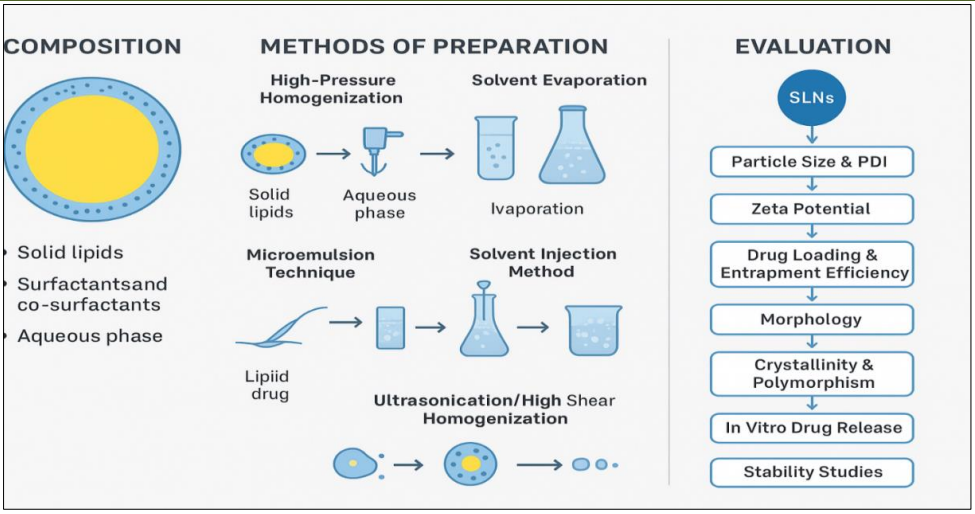

Figure 1: The composition, preparation and evaluation

Table 1: The evaluation parameters of SNP

Parameter	Purpose and Description
Particle size and PDI	Determined using DLS. Smaller particles (<200 nm) ensure enhanced bioavailability and stability. Low PDI (<0.3) indicates uniformity.
Zeta potential	Measures surface charge; values above ±30 mV indicate good colloidal stability by preventing aggregation.
Drug loading and entrapment efficiency	High entrapment efficiency (>80%) ensures effective loading.
Morphological analysis	Conducted using TEM or SEM assess the shape.
Crystallinity and polymorphism	Analyzed using DSC and XRD to assess lipid modification and drug incorporation into the lipid matrix.
In vitro release	Performed employing diffusion techniques in physiological media. The release profile (burst, sustained, or biphasic) reflects lipid composition and particle structure.
Stability studies	Conducted at various storage conditions (25°C/60% RH and 40°C/75% RH) for 3–6 months to evaluate aggregation, polymorphic transitions, and degradation.
Sterility and cytotoxicity testing	For parenteral use, sterility testing (membrane filtration method) and cytotoxicity assays

5. Applications of SLNs

5.1 Oral Delivery

After being taken orally, drug-loaded solid lipid nanoparticles penetrate the bloodstream via miscellaneous mechanisms, including lymphatic absorption, transport, and endocytosis. Furthermore, SLNs can be coated with distinct polymers (such as chitosan) to enhance their mucoadhesion and increase drug absorption. Numerous studies revealed that SLNs significantly enhance absorption, and oral bioavailability [22].

5.2. Parenteral Delivery

After injection, solid lipid nanoparticles (SLNs) can enhance bioavailability. For instance, SLNs comprising 5-fluorouracil enhanced bioavailability, when administered via the intraperitoneal route, compared to free 5-fluorouracil. These SLNs exhibited more profitable tumor growth inhibition subcutaneously corresponded to the free form of 5-fluorouracil. Ondansetron-loaded SLNs demonstrated sustained-release properties in rats following subcutaneous administration. In a separate study focused on resveratrol-loaded SLNs, the formulation enhanced the cellular uptake of resveratrol, revealing improved efficacy in treating breast cancer compared to free resveratrol [23].

5.3. Transdermal Delivery

SLNs effectively facilitate the transdermal penetration of drugs. They are regarded as safe for physiological use and can help to hydrate the skin. Various studies have performed evaluations of SLNs or SLN gels through in vitro or in vivo methods. For instance, SLNs loaded with tacrolimus achieved skin permeation levels of 25–40%, although the SLN gel resulted in a decrease in skin permeation. Nevertheless, SLN gels enhance drug retention in the skin, making them appropriate for the cure of atopic dermatitis. In a prior investigation, quercetin and resveratrol were co-encapsulated in SLN gel to enhance drug distribution within the epidermis, revealing improved release from

the SLN gel effectively than from a standard gel, signifying its potential for skin cancer treatment. In a similar investigation, SLNs that contained isotretinoin exhibited prolonged drug release over 24 hours and notable anti-acne effects. Additionally, a thermosensitive SLN gel loaded with tacrolimus demonstrated deeper skin penetration than a reference product [24].

5.4. Intranasal Delivery

SLNs possess the capability to deliver medications directly to the brain, improving their bioavailability in that area. This enhancement is due to better drug solubility, permeation, and stability. A gel formulation containing both levofloxacin and doxycycline loaded into SLNs exhibited superior brain targeting when compared to pure drug as evidenced by efficiency exceeding 100% [25].

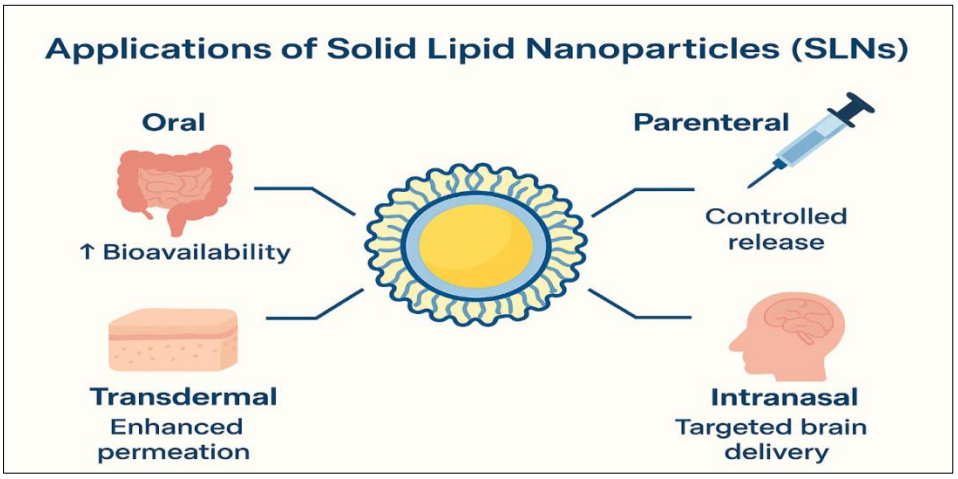

Figure 2: Application of SNP

6. Future Prospects

The future of SLNs in drug delivery retains great potential, particularly as advancements in nanotechnology and pharmaceutical sciences enhance their design and usage. Nevertheless, numerous challenges persist in scaling up SLN production. These challenges encompass inconsistencies between batches, cost-effective manufacturing processes, and the complexities involved in formulation. To address the expenses linked to these innovative delivery systems, researchers are investigating more streamlined approaches for creating SLNs. This involves utilizing standardized, scalable, and efficient development techniques that leverage readily available and affordable materials. Innovations in HPH, solvent emulsification, and microemulsion methods are being refined to boost production efficiency while maintaining the quality and stability of the SLNs [26].

7. CONCLUSION

SLNs have emerged as a versatile and promising nanocarrier system capable of addressing long-standing challenges in drug delivery, particularly for poorly water-soluble and unstable therapeutic agents. Their unique features such as the use of physiologically acceptable lipids, the ability to protect encapsulated drugs, controlled release behavior, and compatibility with multiple administration routes have positioned them as an attractive alternative to conventional delivery systems, including polymeric nanoparticles and liposomes. Extensive research has demonstrated their potential in improving drug solubility, bioavailability, targeting efficiency, and therapeutic outcomes across diverse treatment areas.

Despite these advantages, the successful translation of SLNs from laboratory to industrial and clinical settings is hindered by key formulation and manufacturing challenges. Issues such as polymorphic transitions, limited drug loading, particle aggregation, sterilization difficulties, and batch-to-batch variability remain significant obstacles. Moreover, the scale-up of SLN production requires robust optimization of processing parameters, stabilization strategies, and quality-control measures to ensure reproducibility and cost-effectiveness. Innovations in high-pressure homogenization, solvent based methods, microemulsion techniques, and continuous manufacturing show promise in overcoming these barriers.

The future of SLNs is bright, with ongoing advancements in nanotechnology, surface modification, and targeted delivery opening new avenues for precision medicine. The integration of SLNs with biodegradable polymers, ligands for active targeting, and stimuli-responsive materials may further enhance their therapeutic potential. As research progresses toward more stable, scalable, and patient-friendly formulations, SLNs are expected to play an increasingly influential role in improving drug delivery and shaping the next generation of pharmaceutical technologies.

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