



SOLID LIPID NANOPARTICLES: A REVIEW ON FORMULATION METHODS, EVALUATION PARAMETERS AND PHARMACEUTICAL APPLICATIONS

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DOI: <https://doi.org/10.5281/zenodo.18803284>

How to cite this Article: Christopher Vimalson D. *, Alagaraja M., Jeevan Nithish S., Naveen Ram R., Aishwarya T., Rimshad K., Selvaragavan R., Tulashiha K., Valaparameshwari T. (2026). Solid Lipid Nanoparticles: A Review on Formulation Methods, Evaluation Parameters and Pharmaceutical Applications. World Journal of Pharmaceutical and Life Science, 12(3), 01-08.

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Article Received on 16/01/2026

Article Revised on 06/02/2026

Article Published on 01/03/2026

ABSTRACT

Solid lipid nanoparticles are advanced lipid-based nanocarrier systems designed to address the major drawbacks of conventional dosage forms, including low bioavailability, poor stability and lack of controlled drug release. These nanocarriers consist of biocompatible solid lipids stabilised by appropriate surfactants and remain in the solid state at both ambient and physiological temperatures. Solid lipid nanoparticles can efficiently incorporate hydrophilic as well as lipophilic drugs while maintaining low toxicity and excellent biocompatibility. By integrating the beneficial properties of polymeric nanoparticles and lipid emulsions, these systems offer enhanced physical stability, sustained and controlled drug release and improved therapeutic performance. In addition, solid lipid nanoparticles protect incorporated drugs from chemical degradation, thereby extending shelf life compared with conventional delivery systems. Their compatibility with large-scale manufacturing processes and ability to enhance patient compliance have contributed to their growing significance in pharmaceutical research. The use of biodegradable lipids and the elimination of harmful organic solvents further improve the safety of these nanocarriers for clinical use. In recent years, solid lipid nanoparticles have been widely explored for the delivery of poorly soluble drugs, peptides, proteins and macromolecules owing to their adaptability and favourable safety characteristics. Moreover, these systems exhibit promising potential in targeted drug delivery, sustained release formulations and enhanced drug absorption. This review focuses on the formulation aspects, methods of preparation, advantages, disadvantages, limitations and pharmaceutical applications of solid lipid nanoparticles.

1. INTRODUCTION

Solid lipid nanoparticles are submicron colloidal drug delivery systems with particle sizes typically ranging between 10 and 1000 nm and are formulated using lipids that remain solid under physiological conditions. These nanocarriers were developed as an alternative to conventional colloidal systems such as emulsions, liposomes and polymeric nanoparticles in order to overcome challenges including physical instability, drug leakage and toxicity. Owing to their ability to enhance

drug stability, provide prolonged and controlled drug release and improve bioavailability, solid lipid nanoparticles have gained considerable importance in pharmaceutical research. Their suitability for large-scale manufacturing processes further enhances their potential for industrial production and clinical use. In recent years, solid lipid nanoparticles have been widely investigated for the delivery of poorly soluble drugs, peptides, proteins and macromolecules due to their versatility, biocompatibility and favourable safety profile.^[1]

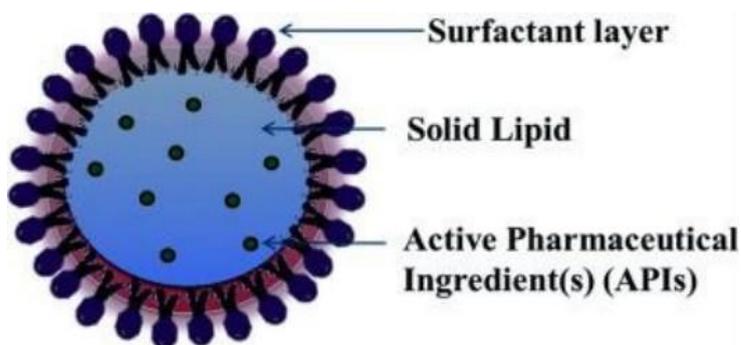


Figure 1: Schematic representation of Solid Lipid Nanoparticle showing surfactant layer, solid lipid core and encapsulated API(s).

1.1. SOLID LIPID NANO PARTICLES (SLNs)

SLNs are a better alternative to the other nano drug delivery carriers such as emulsion, polymeric nanoparticles and liposomes. Biocompatibility, stability during storage and preventing the degradation of a drug are the major advantages of SLNs which emerged in 1991. SLNs are colloidal drug carriers of sub micron size made up of solid lipid and having 50–1000 nm.^[6]

1.2. LIPID DRUG CONJUGATE NANO PARTICLES (LDCs)

The lipids are conjugated also be changed with LDC.

Enhanced oral bioavailability, lymphatic system targeting, tumor targeting and less toxicity are a few of the advantages of LDCs.^[7]

1.3. NANOSTRUCTURED LIPID CARRIERS NLCs)

NLCs are the colloidal drug carriers like the SLNs. The solid lipid of SLN is partly replaced with a liquid lipid or a mixture of liquid lipids. The major disadvantage of SLN is the drug expulsion from the lipid matrix. The lipid solidification and subsequent crystallization in the SLN lead to the expulsion of the drug from the SLN.^[8]

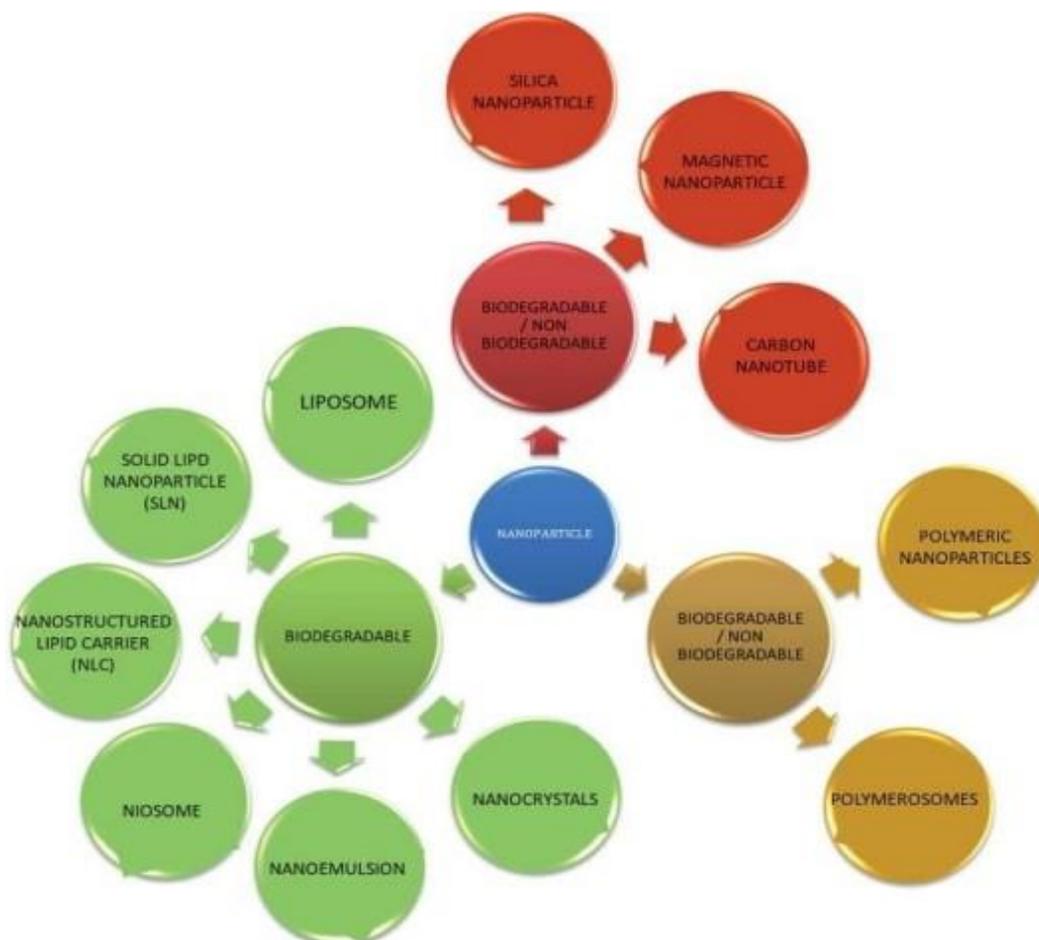


Figure 2: Classification of nanoparticles highlighting lipid-based systems (SLN, NLC, liposomes, etc.).

2. ADVANTAGE OF SOLID LIPID NANO PARTICLES

- Solid lipid nanoparticles are formulated using biodegradable and biocompatible lipids, which significantly reduce the risk of toxicity and improve safety profiles.
- These carrier systems enhance both the physical and chemical stability of incorporated drugs by protecting them within a solid lipid matrix.
- Solid lipid nanoparticles are capable of providing controlled as well as sustained drug release, thereby maintaining prolonged therapeutic drug levels.
- Encapsulation within the lipid matrix protects drugs from degradation caused by hydrolysis, oxidation and photodegradation.
- The solubility and oral bioavailability of poorly water-soluble drugs are significantly improved when delivered using solid lipid nanoparticles.
- Formulation of solid lipid nanoparticles reduces or eliminates the need for toxic organic solvents, making the process safer and more environmentally acceptable.
- These systems are compatible with large-scale pharmaceutical manufacturing techniques such as high-pressure homogenisation.
- Improved therapeutic efficiency and sustained release characteristics lead to reduced dosing frequency, thereby enhancing patient compliance.^[9]

3. DISADVANTAGES OF SOLID LIPID NANO PARTICLES

- Solid lipid nanoparticles often exhibit low drug entrapment efficiency for hydrophilic drugs, as these drugs tend to partition into the aqueous phase during formulation.
- Certain formulations of solid lipid nanoparticles may show an initial burst release, particularly when the drug is concentrated near or on the surface of the lipid matrix.
- Particle aggregation and instability can occur if the type or concentration of surfactant used for stabilisation is not properly optimised.
- Solid lipid nanoparticles offer limited flexibility in tailoring drug release profiles due to the highly ordered crystalline structure of the solid lipid matrix.
- Successful formulation of solid lipid nanoparticles requires careful optimisation of formulation and process parameters, including lipid type, surfactant concentration and preparation method, to ensure stability and reproducibility.^[10]

4. PHARMACEUTICAL APPLICATIONS OF SOLID LIPID NANO PARTICLES

- Solid lipid nanoparticles have been widely investigated for ocular drug delivery, as they enhance corneal penetration and prolong pre corneal residence time, thereby improving ocular bioavailability.
- In oral drug delivery, solid lipid nanoparticles improve the bioavailability of drugs by enhancing

solubility and reducing degradation as well as first-pass hepatic metabolism.

- Solid lipid nanoparticles are extensively explored for the targeted delivery of anticancer drugs, resulting in improved therapeutic efficacy and reduced systemic toxicity.^[11]
- These carrier systems are also suitable for the delivery of peptides, proteins and macromolecules, providing protection from enzymatic degradation and improving stability.
- Solid lipid nanoparticles facilitate lymphatic targeting, which helps in reducing systemic side effects and enhances drug concentration at the target site.
- In addition, solid lipid nanoparticles are effectively used in topical and trans dermal drug delivery systems, where they enhance skin penetration and provide controlled drug release.^[12]

5. LIPIDS AND SURFACTANTS USED IN SOLID LIPID NANO PARTICLES

The selection of lipid plays a critical role in determining the physicochemical characteristics of solid lipid nanoparticles. Commonly used lipids include stearic acid, glyceryl monostearate, glyceryl monooleate, tri stearin and other physiological lipids, which remain solid at room and body temperature.^[13] These lipids provide structural integrity to nanoparticles and influence crystallinity, particle size, entrapment efficiency and drug release behaviour. The nature of the lipid also affects long-term stability and polymorphic transitions of the formulation.^[14]

Surfactants are essential for stabilizing the nanoparticle dispersion by reducing interfacial tension between the lipid and aqueous phases. Nonionic surfactants such as Tween 80, Span 20, Span 60 and Span 80 are widely employed due to their low toxicity and good stabilizing efficiency.^[15] The type and concentration of surfactant significantly influence particle size distribution, zeta potential, drug entrapment and physical stability of solid lipid nanoparticles. A combination of surfactants is often employed to achieve optimum stabilization and smaller particle size.^[16]

6. METHODS OF PREPARATION OF SOLID LIPID NANO PARTICLES

6.1. HOT HOMOGENISATION METHOD

Hot homogenisation is among the most commonly employed methods for the preparation of solid lipid nanoparticles and is well suited for large-scale industrial production. In this technique, the selected lipid is heated to a temperature about 5–10 °C above its melting point to achieve complete liquefaction. The drug is then either dissolved or uniformly dispersed in the molten lipid depending on its solubility properties. Separately, an aqueous surfactant solution is prepared and maintained at the same temperature as the lipid phase in order to prevent premature lipid solidification. The molten lipid phase is subsequently emulsified into the heated aqueous

surfactant solution using high-speed homogenisation, leading to the formation of a coarse oil-in-water emulsion. The intense shear forces generated during homogenisation effectively reduce the size of the lipid droplets. Upon cooling the emulsion to room temperature, recrystallisation of the lipid occurs, resulting in the formation of solid lipid nanoparticles. The

final particle size and stability of the nanoparticles are influenced by factors such as lipid concentration, type of surfactant, homogenisation speed and cooling rate. Despite its advantages, this method is not suitable for thermolabile drugs due to prolonged exposure to elevated temperatures during processing.^[16]



6.2. COLD HOMOGENISATION METHOD

Cold homogenisation was introduced to reduce the thermal stress encountered during the hot homogenisation process. In this method, the drug is first incorporated into the molten lipid in a manner similar to hot homogenisation. The drug-loaded lipid melt is then rapidly cooled using liquid nitrogen or dry ice to obtain a solid lipid mass. Rapid solidification restricts drug migration and minimises drug loss during processing.

The solidified lipid mass is subsequently ground to form lipid microparticles, which are dispersed in a cold

aqueous surfactant solution. This dispersion is subjected to high-pressure homogenisation at or below room temperature to reduce particle size. As the lipid remains in the solid state throughout the homogenisation process, degradation of thermolabile drugs is significantly minimised. Although cold homogenisation generally produces nanoparticles with comparatively larger particle size than hot homogenisation, it offers enhanced drug stability and improved retention of heat-sensitive compounds.^[17]



6.3. ULTRA SONICATION OR HIGH-SPEED HOMOGENISATION METHOD

In the ultra sonication method, the lipid is melted above its melting point and the drug is incorporated into the molten lipid phase. The lipid melt is emulsified into an aqueous surfactant solution using high-speed stirring to form a coarse emulsion. This emulsion is then subjected to ultra sonication, where cavitation forces generated by ultrasonic waves reduce droplet size to the nanometer range.

After ultrasonication, the system is cooled to room temperature, resulting in lipid solidification and nanoparticle formation. Although this method is simple and economical, prolonged ultrasonication may cause metal contamination from the probe and can result in a broad particle size distribution if processing conditions are not optimized.^[18]



6.4. SOLVENT EMULSIFICATION-EVAPORATION METHOD

The solvent emulsification–evaporation method is suitable for the preparation of solid lipid nanoparticles containing thermolabile drugs. In this technique, the lipid and drug are dissolved in a water-immiscible organic solvent such as chloroform or dichloromethane. This organic phase is emulsified into an aqueous phase containing surfactant using mechanical stirring or homogenisation, forming an oil-in-water emulsion.

The organic solvent is subsequently removed by evaporation under reduced pressure or continuous stirring. As the solvent evaporates, the lipid precipitates, resulting in the formation of solid lipid nanoparticles. Although this method provides good control over particle size and entrapment efficiency, complete removal of organic solvent is essential to ensure formulation safety.^[19]

6.5. DOUBLE EMULSION METHOD (W/O/W)

The double emulsion method is mainly employed for the incorporation of hydrophilic drugs into solid lipid nanoparticles. Initially, an aqueous drug solution is emulsified into a molten lipid phase containing a lipophilic surfactant to form a primary water-in-oil emulsion. This primary emulsion is then further emulsified into an external aqueous phase containing hydrophilic surfactant, resulting in a water-in-oil-in-water system.

Subsequent cooling or solvent removal leads to solidification of the lipid phase and formation of solid

lipid nanoparticles encapsulating the hydrophilic drug. Although this method improves entrapment efficiency for hydrophilic drugs, it involves multiple processing steps that may affect reproducibility.^[20]

6.6. MICRO EMULSION – BASED METHOD

In the micro emulsion-based method, a transparent and thermodynamically stable micro emulsion is prepared by mixing molten lipid, surfactant, co-surfactant and water at elevated temperature. The formation of micro emulsion ensures uniform dispersion of lipid droplets at the nanoscale.

The hot micro emulsion is then rapidly dispersed into excess cold water under mild stirring, causing a sudden reduction in lipid solubility. This leads to precipitation of the lipid and formation of solid lipid nanoparticles.^[16] This method produces nanoparticles with small particle size and narrow size distribution; however, high surfactant concentrations are usually required.^[21]

6.7. HIGH – PRESSURE HOMOGENISATION METHOD

High-pressure homogenisation is a robust and scalable technique commonly used for industrial-scale production of solid lipid nanoparticles. In this method, the lipid dispersion is forced through a narrow homogenisation gap under extremely high pressure. The intense shear stress and cavitation forces generated during this process reduce particle size and result in uniform nanoparticle formation.



This technique can be applied using either hot or cold homogenisation approaches depending on drug and lipid characteristics. High-pressure homogenisation offers

excellent reproducibility and scalability but requires specialized equipment and high energy input.^[22]

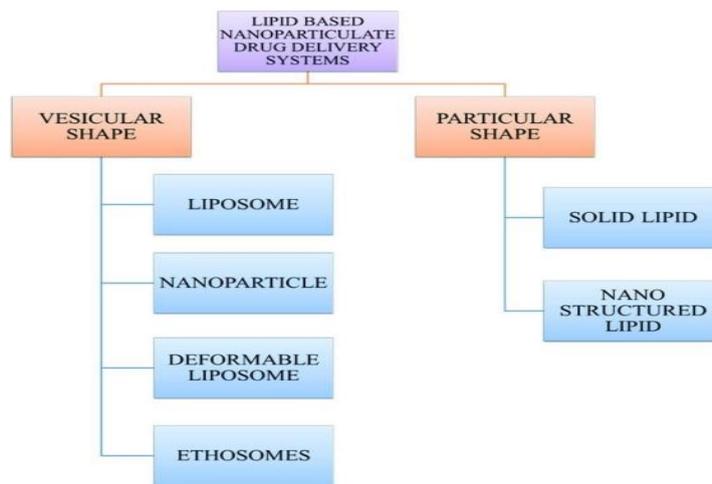


Figure 3: Classification of lipid based nanoparticulate drug delivery systems.

7. CHARACTERISATION OF SOLID LIPID NANO PARTICLES

Characterisation of solid lipid nanoparticles is an essential step to evaluate their physicochemical properties, stability, drug release behaviour, and in vivo performance. Proper characterisation helps in understanding the suitability of the formulation for pharmaceutical applications.^[23]

7.1. PARTICLE SIZE AND POLYDISPERSITY INDEX (PDI)

Particle size is one of the most important parameters influencing the stability, biodistribution, cellular uptake, and drug release behaviour of solid lipid nanoparticles. SLNs generally possess particle sizes in the nanometre range, which enables enhanced absorption and improved bioavailability. Smaller particle size provides a larger surface area, leading to better interaction with biological membranes and improved cellular uptake.

The polydispersity index indicates the uniformity of particle size distribution within the formulation. A low PDI value represents a narrow and homogeneous particle size distribution, which is desirable for better physical stability and reproducibility of the formulation. Particle size and PDI of solid lipid nanoparticles are commonly measured using dynamic light scattering techniques.^[23]

7.2. ZETA POTENTIAL AND STABILITY

Zeta potential is an indicator of the surface charge present on solid lipid nanoparticles and plays a crucial role in determining their physical stability. Nanoparticles with higher absolute zeta potential values exhibit strong electrostatic repulsion, which prevents particle aggregation and enhances dispersion stability.

A stable zeta potential ensures long-term stability of solid lipid nanoparticles during storage by reducing the chances of particle agglomeration. The type and concentration of surfactant used in the formulation significantly influence the zeta potential of SLNs.^[24]

7.3. ENTRAPMENT EFFICIENCY AND DRUG LOADING

Entrapment efficiency refers to the percentage of drug successfully incorporated within the lipid matrix of solid lipid nanoparticles. It is an important parameter that determines the effectiveness of the delivery system. Entrapment efficiency is influenced by factors such as lipid type, surfactant concentration, drug solubility, and method of preparation.

High entrapment efficiency ensures sustained drug release and reduces drug loss during formulation. Drug loading capacity indicates the amount of drug present relative to the lipid content and is essential for achieving therapeutic drug concentrations.^[25]

7.4. CRYSTALLINITY AND POLYMORPHIC BEHAVIOUR

The crystalline nature of the lipid matrix affects drug incorporation, stability, and release behaviour of solid lipid nanoparticles. Differential scanning calorimetry is used to study melting behaviour and crystallinity of the lipid matrix, while X-ray diffraction analysis helps in identifying polymorphic transitions.

Polymorphic transitions of lipids during storage may lead to drug expulsion from the lipid matrix. Therefore, evaluation of crystallinity is essential to ensure formulation stability and consistent drug release.^[25]

7.5. MORPHOLOGICAL CHARACTERISTICS

Morphological evaluation provides information regarding the shape, surface characteristics, and structural integrity of solid lipid nanoparticles. Scanning electron microscopy and transmission electron microscopy are commonly used techniques to study morphology.

Solid lipid nanoparticles typically exhibit spherical shape with smooth surface characteristics. Uniform morphology confirms successful formulation and contributes to improved stability and reproducibility.^[26]

7.6. IN-VITRO DRUG RELEASE STUDIES

In vitro drug release studies are conducted to evaluate the release kinetics and sustained release behaviour of solid lipid nanoparticles. These studies help in understanding the mechanism of drug release from the lipid matrix, such as diffusion-controlled or erosion-controlled release.

Controlled and prolonged drug release from solid lipid nanoparticles is advantageous in maintaining therapeutic drug levels for extended periods and reducing dosing frequency.^[27]

7.7. BIO-DISTRIBUTION STUDIES

Biodistribution studies provide information about the in vivo fate of solid lipid nanoparticles after administration. These studies help in understanding tissue distribution, organ targeting, and accumulation behaviour of nanoparticles.

Particle size, surface charge, and lipid composition significantly influence the biodistribution pattern of solid lipid nanoparticles. Proper biodistribution ensures targeted drug delivery, reduced systemic toxicity, and enhanced therapeutic efficacy.^[28]

7.8. STABILITY STUDIES

Stability studies are performed to evaluate the physical and chemical stability of solid lipid nanoparticles during storage. Parameters such as particle size, zeta potential, entrapment efficiency, and drug content are monitored over time.

Stability studies ensure that the formulation maintains its quality, safety, and efficacy throughout its shelf life. Lipid polymorphism and surfactant concentration play an important role in determining long-term stability of SLNs.^[29]

8. RECENT ADVANCES AND FUTURE PERSPECTIVE

Recent advances in solid lipid nanoparticle research include surface modification, ligand-based targeting and incorporation of multiple drugs within a single carrier system. Development of nanostructured lipid carriers has further improved drug loading capacity and stability by reducing lipid crystallinity. Future research is expected to focus on clinical translation, scale-up, regulatory acceptance and development of patient-friendly dosage forms based on solid lipid nanoparticles. Integration of solid lipid nanoparticles with novel therapeutic agents such as genes, peptides and vaccines may further expand their pharmaceutical applications.^[30]

9. CONCLUSION

Solid lipid nanoparticles have emerged as a highly promising and flexible nanocarrier platform with the ability to enhance drug stability, improve bioavailability, and provide controlled drug release. Their favourable characteristics, including biocompatibility, ease of scale-

up, and formulation versatility, support their application across a broad range of pharmaceutical drug delivery systems. Although certain challenges such as limited drug loading capacity and lipid polymorphic transitions remain, ongoing research efforts and formulation optimization strategies, together with recent technological advancements, are expected to significantly strengthen the clinical applicability and industrial feasibility of solid lipid nanoparticle-based drug delivery systems.

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