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Review Article

Solid Lipid Nanoparticles: Revolutionizing Drug Delivery Through Lipid-Based Nanocarriers.

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ABSTRACT

Compared to traditional formulations, solid-lipid nanoparticles (SLNs) are a novel family of Nano systems that transport medications to their respective targets more effectively and bio availably. SLNs are easier to biodegrade, less harmful, and more biocompatible. SLNs can be loaded with lipophilic, hydrophilic, or hydrophobic medications to improve their chemical and physical stability in harsh conditions. This review contain information about SLNs likes roles of it in different drug delivery system, description about SLNs, drug incorporation methods, methods of preparation of SLNs, advantages and limitation in drug delivery. SLNs can be useful in several treatment of disease with different techniques like chemotherapy. Now a day it is widely use treatment of cancer cells.

INTRODUCTION

In the word nanotechnology, the prefix Nano stands for billionth (1 x $\log^{-9}$). Nanotechnology deals with various matter formations that have dimensions of the order of a billionth of a meter. Although the term" nanotechnology" is relatively new, functioning devices and structures with nanoscale dimensions are not; in fact, they have been on Earth for as long as life. By arranging calcium carbonate into robust nanostructured bricks held together by a glue composed of a mixture of proteins and carbohydrates, the abalone, a mollusc, creates extremely durable shells with iridescent interior surfaces. Because of the nanostructured bricks, cracks that start on the outside cannot pass through the shell. The shells are a natural example of how a structure made of nanoparticles can be significantly stronger(1).

Overview of nanotechnology in drug delivery:

Pharmaceutical scientists around the world are discovering new possibilities in medicine delivery

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because to nanotechnology. For localized or systemic purposes, it provides an appropriate way to deliver a wide range of agents, from small molecular drugs to macromolecules like proteins, peptides, or even genetic materials. Considerable effort has been made to develop the potential of nanotechnology in drug delivery. Drug delivery systems based on the nanotechnology platform have concentrated on creating therapeutically active agents in biocompatible nanostructures like nanoparticles, Nano capsules, micellar systems, Nano-conjugates, etc. to get around the pharmaceutical problems with traditional dosage forms (2).

Need for the controlled and targeted drug delivery:

- In order to reduce adverse effects, targeted medication delivery systems convey pharmacokinetic drugs to the site of action while avoiding needless interactions with other healthy tissue. Non-targeted drug delivery, such as chemotherapy treatments used to treat cancer, has undesirable effects on healthy cells. Targeted drug administration lowers the dosage and increases the consistency of the medicine's effect. The process of targeted drug release involves three steps:
- The drug Nano carrier attaches to the target cell's receptors through multivalent receptor–ligand interactions.
- The drug Nano carrier enters the cell through endocytosis.
- Drug release occurs in the final phase. By interacting with the lipid membrane, targeted drug delivery can occur in the cytosol and cell membrane(3).

Limitations of conventional drug delivery system:

Despite their widespread use, conventional drug delivery systems (CDDS) have a number of drawbacks that affect their therapeutic efficacy and patient compliance. One major drawback is decreased bioavailability, particularly for medications taken orally, where the rate of drug clearance and first-pass metabolism can significantly lower the drug's distribution to the systemic circulation. This frequently leads to less-than-ideal therapeutic effects, requiring larger dosages to get the intended response. Non-specific targeting, in which medications work throughout the body rather than only at the intended site, is another significant problem. This indiscriminate dispersion may limit the safety and precision of treatment by causing unwanted side effects and possible toxicity in tissues that are not the intended target(4).

1. SOLID LIPID NANOPARTICLES (SLNs)

Definition:

Solid biodegradable lipids make up the matrix of solid lipid nanoparticles (SLNs), which are aqueous colloidal dispersions. Physical stability, controlled release, high tolerability, and protection of integrated labile medicines from degradation are only a few of the benefits that SLNs combine with the disadvantages of other colloidal carriers in their class. SLNs formulas have been developed and comprehensively studied in vitro and in vivo for a variety of administration routes, including parenteral, oral, cutaneous, ophthalmic, pulmonar, and rectal(5).

History of SLNs:

Since their successful establishment in the early 19th century, SLNs, also known as NLCs, have emerged as a class of promising delivery systems with desired features. In contrast to traditional

pharmacological formulations, SLNs feature distinct assembly and arrangement structures. As a result, compared to traditional NPs without fatty acids, SLNs are more biocompatible and less harmful. Additionally, they exhibit the best loading capacity for both water-heating and water-loving drugs, making them a versatile and reliable substitute for liposomes. Additionally, SLNs provide site-specific drug delivery and enhanced drug stability while the drug is stored in bodily lipids, which can prolong release and prevent terrible medical problems. As a result, SLNs make lipophilic medications more bioavailable. Furthermore, the SLNs protect the medications against harsh environmental factors such as biocompatibility, biodegradability, and simple high-volume manufacture using a high-pressure homogenization technique (6).

2.Advantages and Disadvantages: -(7–9):

- Increase the stability of pharmaceuticals.
- They are less expensive than drug carriers based on polymers or surfactants.
- The product can be sterilized.
- Compared to other carriers, SLNs can retain more medication.
- The viability of transporting both hydrophilic and lipophilic medications.
- Target and/or control the release of drug.
- When processing, they don't use natural solvents.
- They are easier to obtain regulatory approval and validate.
- Lyophilization is possible.
- By using a technique known as “site specific distribution of medications”, it improves the penetration of drugs into the skin.
- It is possible to accomplish controlled dynamic medicine arrival over an extended period of time.

Disadvantages of solid lipid nanoparticles:

- Because the manufacturing method separates the drug delivery, they are unable to carry much hydrophilic (water-loving) medication.
- Gelation tendency.
- When the polymer shifts during storage, the drug may be forced out
- Their medication loading or stacking limit is low [poor sedate stacking limit].
- The propensity to become a gel is unpredictable.

2. Composition of SLNs

SLNs are composed of solid lipid, emulsifier, and water/solvent. Lipids include triglycerides (tri-stearin), partial glycerides (Imwitor), fatty acids (stearic acid, palmitic acid), steroids (cholesterol), and waxes (cetyl palmitate). A range of emulsifiers and their combinations have been used to stabilize the lipid dispersion (Pluronic F 68, F 127). The mixture of emulsifiers may be more efficient in preventing particle agglomeration(8).

2.1 Solid Lipids

The primary ingredient in the formulation, lipids control any API's stability, release, encapsulation, and loading (10). When greater melting lipids are utilized, the SLNs dispersion's average particle size rises. The dispersed phase's increased viscosity is the primary technical factor causing phenomena. The primary issue with SLNs is inadequate drug loading because to partitioning effects. Highly effective hydrophilic medications, however, can be appropriately added to solid lipid matrices at low doses. Lipid drug conjugates (LDCs) were used to get around this problem, and they showed a 33% increase in SLNs drug loading capabilities (11).

Table 1 lists a few of the lipids used to make SLNs

Table 1. Lipid utilized in the production of solid lipid nanoparticles (10,11)

Ingredients	Example
Lipids components	Triglycerides: Trilaurin, Tricaprin, Tripalmitin, medium-chain triglycerides [MCT] Fatty Acids: Lauric Acid, Myristic Acid, Palmitic Acid, Stearic Acid, Oleic Acid Waxes: Cetyl palmitate, Beeswax, Carnauba Wax. Hardened fat: (Witepsol E85, H5 And W35) Other lipid: Behenic Acid, Compritol 888, Castor oil, hydrogenated soybean oil.

2.2 Surfactant and Stabilizers:

Lipid nanoparticle quality and effectiveness are significantly impacted by surfactant characteristics and concentrations. Surfactants reduce the interfacial tension between the lipid and aqueous phases due to their amphiphilic properties. Emulsions are thermodynamically unfavorable because the water-lipid interfacial area grows as the size of the oil droplets decreases. A distinctive phase separation process takes place if surfactants are not used to stabilize the interface (12). However, in addition to ensuring the particles' steric stability in aqueous dispersion, the surrounding surfactants also Induces. Surface chemical characteristics and have the power to modify the biopharmaceutical profile. Based on their electrical charge, surfactants can be divided into three groups: amphoteric, non-ionic, and ionic. Non-ionic surfactants provide steric repulsion stability, whereas ionic surfactants provide electrostatic stability (10). The composition and manufacturing processes of SLNs and nano emulsions are very similar. SLNs, however, cannot be reduced to colloidal lipid dispersions with solidified droplets. For both carrier systems, there are issues related to the existence of extra colloidal structures (micelles, mixed micelles, liposomes). But, additional characteristics of SLNs (such as supercooled melts, various modifications, and non-spherical forms) are) are influencing or contributing to (13)

Table 2. Surfactants Utilized in the production of solid lipid nanoparticles(10)

Ingredient	Sub Type	Examples
	Amphoteric Surfactants	Phospholipids: Egg Phosphatidylcholine, soybean Phosphatidylcholine, hydrogenated egg Phosphatidylcholine, hydrogenated soybean Phosphatidylcholine Steroids: cholesterol, cholesteryl oleate

Surfactant	Non-ionic Surfactants	Polysorbate 60, polyethylene glycol, polysorbate85, polyethylene glyceryl monostearate, polysorbate 80.
	Cationic Surfactants	Chlorhexidine salts, DOTMA, Dimethyldioctadecylammoniumbromide, 1,2-dioleoyl-3-trimethylammonium-propane (DOTAP).
	Anionic Surfactants	Bile Salts: sodium cholate, sodium dihydrofolate, Sodium glycocholate. Sodium lauryl Sulphate (SLS).

Table 3. Other Agents utilized in the production of solid lipid nanoparticles (10,11)

Ingredient	**Examples**
Co-surfactant	Sodium oleate, Butanol, Taurocholate sodium salt, polyvinyl alcohol (PVA). Tyloxapol, Diethylene glycol monoethylether, Sodium dodecyl sulphate, Low molecular weight PEG.
Cryoprotectant	Glucose, Mannose, Maltose, polyvinyl alcohol, Gelatin, Lactose, Sorbitol, Mannitol.

4.3 Role of Excipients:

Formulation development may be facilitated by modifications in the qualitative and quantitative composition of excipients, such as optimized hydrophilic–lipophilic balance, lipids, and lipid/surfactant combinations. An overview of popular and potential excipients that can help with the creation of lipid nanoparticle formulations is covered (6). Two main excipients are required for the preparation of solid lipid nanoparticles: lipids and stabilizers (surfactants). The lipid used in the formulation should be biocompatible, biodegradable, and solid at room temperature. Different types of lipids can be used, such as fatty acids, fatty alcohols, triglycerides, waxes, fats, and mixtures of mono- and diglycerides. For stabilization of the nanoparticles, surfactants are added to the formulation. Among the various types of surfactants, non-ionic surfactants are commonly used because they are generally safer and more suitable for internal use (14).

5.3 Methods of Preparation

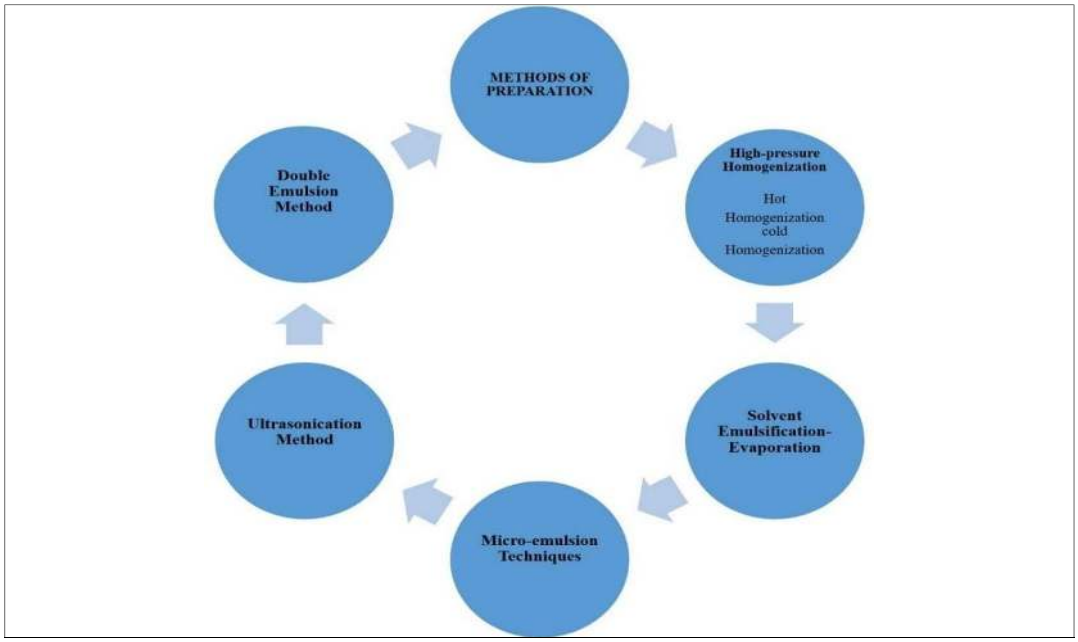

Fig. 1 Methods of Preparation

5.3 High-pressure Homogenization:

Based on the temperature at which SLN is created, this technique can be classified as either hot homogenization or cold homogenization. One advantage of this method is that it produces SLNs with small particle sizes and excellent entrapment efficacy. Melted lipid is quickly pumped through a narrow area at a pressure of 500–5000 bar during high-pressure homogenization. 5–10% lipid content is frequently used, even though up to 40% lipid content has been examined. For HPH, two popular techniques are hot homogenization and cold homogenization (10).

5.3 Hot homogenization:

Solid lipid nanoparticles (SLNs) they are prepared by the hot homogenization technique. In this approach, the process is conducted at a temperature higher than the melting point of the lipid material. Initially, the lipid is heated until it melts, and the drug is either dissolved or uniformly dispersed within the molten lipid phase. At the same time, the emulsifier is mixed in the aqueous phase to prepare the aqueous solution. After the preparation of both phases, the hot lipid phase is added to the aqueous phase and mixed using a high-shear mixer to produce a pre-emulsion. This step results in the formation of an oil-in-water (o/w) emulsion. The emulsion is then subjected to cooling. As the decreases in temperature, the lipid begins to crystallize, which further do to the formation of solid lipid nanoparticles. The high processing temperature decreases the viscosity of the lipid phase, which do the formation of nanoparticles which have smaller particle size. Even though its advantages, this technique also presents certain limitations. Exposure to elevated temperatures may take to decline of thermolabile drugs and lipid components. In addition, a portion of the drug may divide into the aqueous phase during the homogenization process, which decreases the drug loading efficiency. The SLN formulation is processed through nearly three to five homogenization cycles at pressures ranging from 500 to 1000 bar. In many cases, a high-pressure homogenizer operating for about five cycles is employed to obtain nanoparticles with the

desired properties (15). The complete procedure flow chart for hot homogenization is provided in Figure 2.

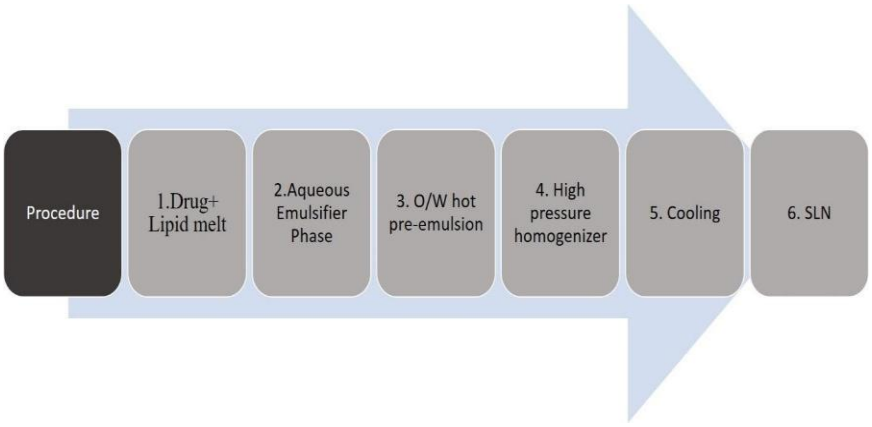

Fig.2 Hot Homogenization

5.3 Cold homogenization

The medication dissolves in the lipid melt during the cold homogenization procedure. The lipid melt is cooled using either liquid nitrogen or dry ice. A mortar mill is used to grind the resulting solid mass. The size range of the nanoparticles produced by this milling is 50–100 nm. These nanoparticles are then added to the cold emulsifier solution. This nanoparticle diffusion is applied to additional HPH at room temperature or low. SLNs loaded with vinorelbine were produced using the cold homogenization method(15). The complete procedure flow chart for Cold homogenization is provided in Figure 3.

5.2 Solvent Emulsification-evaporation

The solvent emulsification–evaporation (SEE) technique is commonly used to prepare nanoparticles and consists of three main stages. Initially, the lipid material is dissolved in a specific amount of organic solvent and mixed thoroughly to form a clear and uniform solution. In the next step, this lipid solution is slowly added to a suitable volume of water while the mixture is homogenized at a high speed, leading to the formation of a coarse emulsion. In the final stage, the coarse emulsion undergoes high-pressure homogenization. The pressure applied reduces the size of the droplets, transforming the coarse emulsion into a Nano emulsion by breaking down larger droplets into much smaller ones. Once the Nano emulsion is formed, the dispersion is continuously stirred using a magnetic stirrer overnight or left in a fume hood to allow the complete evaporation of the organic solvent during the solvent evaporation process, the lipid material precipitates into the aqueous phase, leading to the formation of a Nano dispersion. The precipitated lipid particles are then separated using a sintered disc filter funnel. Nanoparticles produced by this method are generally on a nanoscale, remain well dispersed without clumping, and demonstrate good drug delivery efficiency (11). The complete procedure flow chart for Solvent Emulsification-evaporation is provided in Figure 4

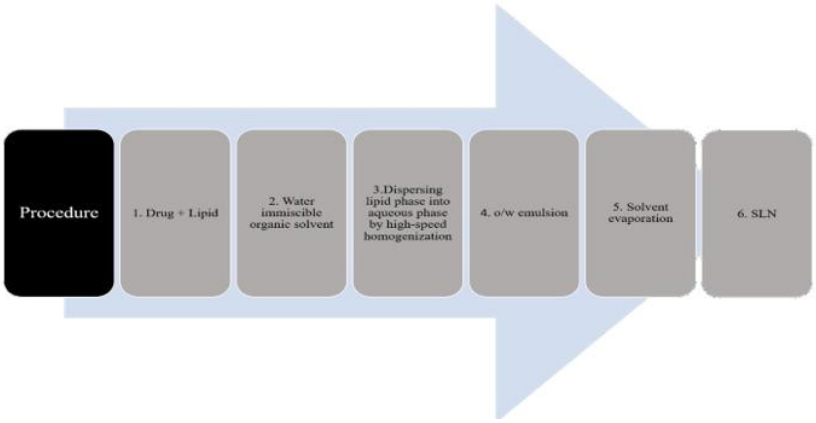

Fig.4 Solvent Emulsification-evaporation

5.3 Micro emulsion

There are two phases to micro emulsions: the aqueous phase and the lipid phase. The co-surfactant or surfactant phase makes up the aqueous phase. The lipid phase, which is made up of glycerides and fatty acids, is melted to create the SLN. The mixture of co-surfactant and aqueous surfactant is heated to the same temperature as the lipid melt. The lipid phase is slowly stirred while the aqueous phase is introduced. Following its formation, this micro emulsion is mechanically distributed in a cold aqueous medium (38°C±2). The SLN is created at last. The idea is that adding the micro emulsion to water causes the emulsion's lipid phase to precipitate. At the very end of the process, SLN fine particles are created (15). The complete procedure flow chart for micro emulsion is provided in Figure5.

5.4 Ultrasonication Method

The method involves heating a solid lipid above its melting point at a temperature of 5–10°C. The surfactant solution in the aqueous phase is also heated to the same temperature as the melted lipid. The lipid melt is then dispersed into the aqueous phase using high-speed homogenization, followed by an ultrasonication process using a probe sonicator. This results in the formation of an emulsion, which is cooled to room temperature to produce the solid lipid nanoparticles (SLNs). This technique relies on simple equipment and does not use organic solvents. However, the product may contain metal contaminants and micro particles, which are significant drawbacks of this method. Additionally, the use of a large amount of surfactant in the aqueous phase is a disadvantage, and this method is unable to produce SLNs with a narrow particle size distribution, leading to instability during storage (15). The complete procedure flow chart for ultrasonication or high-speed homogenization is provided in Figure 6.

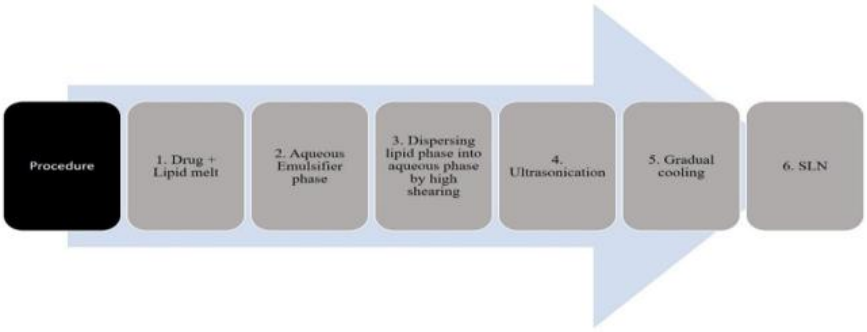

Fig.6 Ultra-sonication Method

5.5 Double Emulsion Method: (15)

One of the most popular methods for creating nanoparticles encapsulated with hydrophilic active substances using surfactants or stabilizers is the double emulsion technique. The three basic steps of this method, also called the multiple emulsion method, are as follows:

I. The water-in-oil emulsion or reverse emulsion is formed
II. The W1/O emulsion is added to the aqueous surfactant solution to form a W1/O/W2 emulsion with constant stirring (sonication or homogenization)
III. The solvent evaporates or the multiple emulsion is filtered to form the nanoparticles.

- **Drug Incorporation Models** (16)

The drug release pattern of Solid Lipid Nanoparticles (SLNs) is highly interrelated to the production and composition method of the same. And hence for assembling the drug release pattern of SLN the Drug Incorporation Model are considered very important. To illustrate, during the process of production of SLN by cold homogenization technique the drug-loaded lipid phase mainly abides in the form of solid. This is the case where the drug incorporation model is used. After the solid solution drug incorporation model is introduced the drug release is sustained for weeks. This happens due the limited dispersion of colloidal particles.

Solid Lipid Nanoparticles using three different drug incorporation model.

- Homogenous Matrix Model
- Drug-Enriched Shell Model
- Drug-Enriched Core Model

11 Homogenous Matrix Model:

In Homogenous matrix model the medication is uniformly distributed molecularly within the particles' lipid matrix. Therefore, the drug release happens either through the breakdown of the lipid matrix in the stomach or through diffusion from the solid lipid matrix (17).

It is believed that using the cold homogenization method and using the hot homogenization method to incorporate extremely lipophilic pharmaceuticals in SLN will result in the homogenous matrix with molecularly distributed drug or drug present in amorphous clusters. The bulk lipid in the cold homogenization method contains the dissolved drug in molecularly dispersed form; mechanical breaking by high pressure homogenization results in nanoparticles with homogenous matrix structure; similarly, when the oil droplet created by hot homogenization method cools, it crystalizes and

there is no phase separation between the drug and lipid.

For example, the medicine prednisolone, which has a release period of one day to several weeks, is thought to be compatible with this paradigm(18)

Fig.7 Homogenous Matrix Model

11 Drug-Enriched Shell Model:

The drug is concentrated on the nanoparticles' outer shell in the drug-enriched shell model (17). When phase separation takes place during the cooling process from the liquid oil droplet to the production of a solid lipid nanoparticle, an outer shell enriched in active chemical can be formed. The TX diagram indicates that the lipid can precipitate first, creating a lipid core that is essentially compound-free. While the lipid core is developing, the concentration of the active component in the residual liquid lipid keeps rising. Ultimately, the compound-enriched shell crystallizes similarly to the TX diagram's eutecticum. According to this concept, for instance, enrichment causes a very quick release of coenzyme Q10. When applying SLN topically to enhance medication penetration, a quick release can be highly desirable, particularly when utilizing SLN's occlusive action concurrently(18).

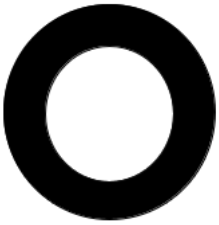

Fig.8 Drug-Enriched Shell Model

11 Drug-Enriched Core Model:

Drug-enriched core models, in contrast to drug-enriched shell models, are created when drug precipitated more quickly than lipid during Nano emulsion cooling. When the medication dissolves at its saturation's solubility in the lipid at production temperature, this effect is seen. During chilling, a super saturation and subsequent drug precipitation take place. These SLNs typically exhibit extended drug release(17).

It is evident that the chemical makeup of the active ingredient and excipients, as well as how they interact, determine the structure of SLN. Additionally the production conditions may have an impact on or dictate the structure(18).

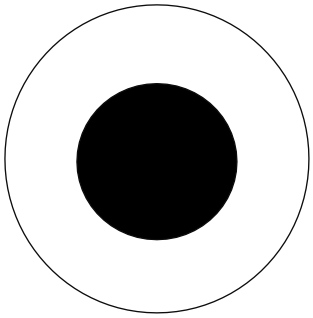

Fig.9 Drug-Enriched Core Model

- **Characterization of SLNs**

The primary purpose of SLN characterization is to regulate the manufactured SLNs' quality. The complexity of SLNs makes it difficult for researchers to describe them. Of the system, especially its tiny particle size. The few parameters that need to be evaluated are as follows: Their direct influence on the release kinetics and stability of included medications(19).

11 Particle Size and Polydispersity Index:

Particle size: The primary markers that the particles are nanoscale structures are their dimensional properties. The average hydrodynamic particle size and the size distribution of sub-micrometer-sized particles are commonly measured using dynamic light scattering (DLS), also known as "quasi-elastic light scattering (QELS)" and "photon correlation spectroscopy (PCS)." The mean, median, or mode diameter could also be used by the researchers to depict the particle size. The mean, median, and mode diameters are all the same for symmetric particle distributions, and all of the Centre values are equal. When there is a non-symmetric particle distribution, these three values are present. The various mean computations in terms of number, surface, and volume distribution are defined by a number of standard protocols(20).

Polydispersity Index: The "polydispersity index" (PDI) is a measure used in particle size distribution characterization that defines the size range of lipidic nanocarrier systems. The degree of non-uniformity of a particle size distribution is referred to as "polydispersity" (or "dispersity" as advised by IUPAC)(21).

7.2 Zeta Potential:

The effective electric charge on the surface that the NP acquires in dispersions is measured by the zeta potential. Both electrophoretic light scattering (ELS, laser Doppler electrophoresis) and phase analysis light scattering (PALS) techniques combined with laser Doppler velocimetry can be used to measure zeta potential. Zeta potential values are merely necessary for the dispersion to be stable. To draw a judgement about stability, stability studies must be conducted. The dispersion medium and particle composition determine the zeta potential value. The zeta potential value of SLN is influenced by variables like temperature, light, pH, ionic strength (conductivity), and solution components(20).

7.3 Entrapment Efficiency:(19)

After centrifuging the aqueous dispersion, the entrapment efficiency (EE) is calculated using the spectrophotometric technique. In short, the amount of free drug was found in the supernatant, and the amount of incorporated drug was

calculated by subtracting the free drug from the original drug.

The following formula can be used to determine the EE:

$$EE\ (\%) = \frac{W\ \text{initial drug} - W\ \text{free drug}}{W\ \text{initial drug}} \times 100$$

7.4 Thermal and Crystallinity Studies (DSC)(22)

To study the Thermal and crystalline properties of SLN, Differential Scanning Calorimetry (DSC) is used. For example, for the characterization of n-dodecyl-ferulate-loaded solid lipid nanoparticles A Mettler DSC 821e device (Mettler Toledo, Germany) was used to conduct DSC measurements. In 40-liter aluminium pans, an adequate quantity of active was precisely weighed. Using an empty pan as a reference, a DSC scan was obtained between 25 and 200 °C at a heating rate of 5 K/min.

A Mettler TG-DTA analyzer (Mettler Toledo, Germany) was used to conduct TGA measurements. Weighting was used to approximate the weight reduction.

7.5 Surface Morphology (SEM/TEM)(20)

The most popular methods for examining the surface morphology of NP are transmission electron microscopy (TEM) and scanning electron microscopy (SEM). While TEM offers two-dimensional imagery and information about the interior particle composition, SEM offers three-dimensional pictures of the particles and concentrates on their surface. While the electron cannon in the SEM creates a concentrated electron beam that scans the sample surface covered with a metal layer during the preparation process, electrons that have passed through the sample create the image in the TEM. The resolution that each method offers varies as well; for SEM, it is between 1 and 10 nm, while for TEM, it is between 0.1 and 0.5 nm.

7.6 In-Vitro Drug Release Studies (20)

An essential component of the SLN and NLC's characterization is the evaluation of their in vitro drug release. The physicochemical characteristics of the drug (such as its state and solubility in lipids and aqueous medium) and its distribution in the carrier, the selection of the lipid composition and its essential characteristics, such as the degree of crystallinity and lipid modification, the kind and quantity of the excipients used, and the parameters of the SLN and NLC production process all affect the drug release process and its kinetics. The selection of an analytical technique for measuring the amount of medication released in the acceptor environment is another crucial factor. These techniques must to be accurate and precise. Because UV/Vis spectrophotometry allows for quick and simple analysis, several writers favour it as an analytical technique. Although they are labor-intensive, techniques like HPLC with UV/Vis detection and HPLC-mass spectrometry (HPLC-MS) guarantee higher accuracy. It is crucial to select and carefully assess the in vitro release method and its parameters; the approach should be ideal for the specific formulation.

8. MECHANISM OF DRUG RELEASE:

The drug release profiles can be adjusted to provide either a slow release with no burst at all or a burst followed by a lengthy release [see fig. 1a, b]. The initial burst can be employed to

administer a first dosage as necessary. Particle size has very little effect on the release profiles. Production parameters, such as temperature and surfactant concentration, as well as the kind of lipid matrix utilized, are the primary factors that influence the profiles. * The partitioning effect is explained in Fig. 1, where the drug shifts during particle generation between the water-based surfactant phase and the melting lipid phase. The medication moves from the lipid [oil] phase to the water phase during the hot-homogenization process (23).

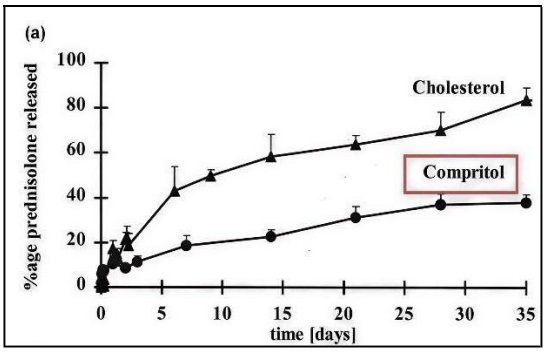

Fig.10.a Prednisolone is released in vitro from solid lipid nanoparticles (SLNs) containing various lipids (cholesterol, compritol), all of which are created by hot homogenization.

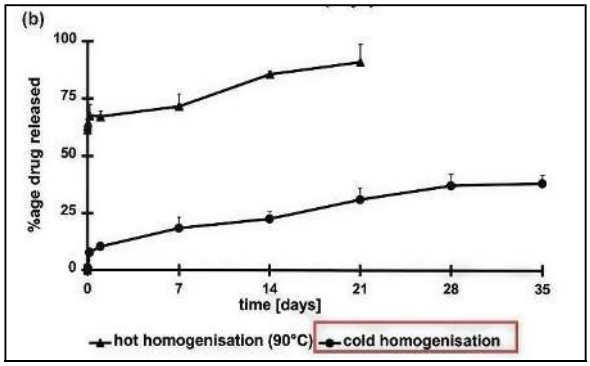

Fig.10.b Prednisolone in vitro release profiles from compritol SLN produced by cold homogenization [lower] and hot homogenization [upper].

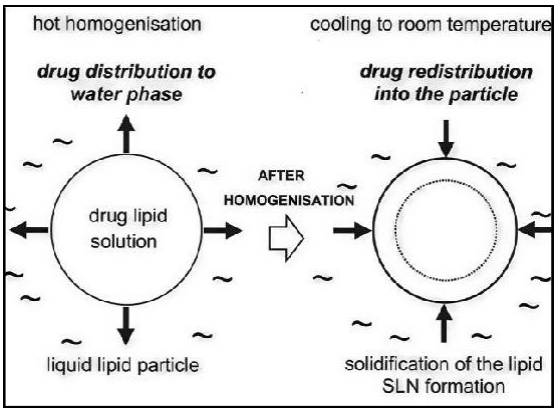

Fig.11 Drug partitioning effects during hot homogenization-based SLN synthesis

Left: When the temperature increases, the medication transitions from the lipid phase to the water phase. Right: As the oil-in-water nano emulsion cools, the right-drug re-particles back into the lipid phase(23)

Models of release:

1) Drug-Enriched Shell Model
2) Drug-Enriched Core Model
3) Homogeneous Matrix Model (24).

When the particles are made using the cold homogenization method without the use of a surfactant or a drug solubilizing surfactant, the SLNs (solid lipid nanoparticles) matrix is solid solution, meaning that the drug is molecularly distributed in the lipid matrix (23).

- **Roles of SLNs in drug delivery**

11 Oral Drug delivery:

Due to the maximum patient compliance, oral drug administration is the most popular method of drug delivery. A delivery method based on nanoparticles was thought to be an appropriate way to boost oral bioavailability. SLNs and other lipid nanoparticles offer the benefit of sustained drug release, which keeps plasma levels steady. Furthermore, nanoparticles with greater saturation solubility and specific area dissolve more quickly, which can hasten the start of a drug's activity. P-glycoprotein efflux pumps and chemical or enzymatic degradation are two more significant obstacles to oral medication administration. According to recent studies, certain lipids or surfactants utilized in lipid nanoparticles have the ability to block p-glycoprotein efflux pumps. In addition to avoiding the hepatic first pass effect and avoiding the liver, lipid nanoparticles may facilitate lymphatic transport (25).

SLNs can be administered orally as an aqueous dispersion or as an alternative after being converted into a conventional dosage form, such as tablets, pellets, capsules, or powders in sachets (23). Instead using a granulation fluid in the granulation process, the fluid SLNs scattering can be used to create tablets (7).An individual dose by volume of the reconstituted SLNs will be possible if the SLNs is packed in a sachet for redispersion in water or juice before administration. Aqueous SLNs dispersions can be utilized in place of a granulation fluid during the granulation process to produce tablets. As an alternative, SLNs can be lyophilized or spray-dried into a powder and added to the tableting powder mixture. A larger solid content is advantageous in both situations to prevent the need to remove excessive amounts of water. With the prior addition of a protectant, spray drying may be the most cost-effective way to turn SLNs dispersions into powders (26). The SLNs dispersion can be utilized as a wetting agent during the extrusion process to produce pellets.

Hard gelatin capsules can also be filled with SLNs granules. As an alternative, SLNs can be made directly in liquid PEG 600 and then placed into soft gelatine capsules. medication preservation from hydrolysis and potential increases in medication bioavailability are benefits of using SLNs for oral and peroral administration. In addition to the general adhesive qualities of tiny particles, prolonged plasma levels have also been hypothesized as a result of a controlled, optimized release (26).

Advantages:(25)

- Increased oral bioavailability.

- Avoiding an unwanted plasma peak.
- Controlled and adjusted the discharge of drug.

Disadvantages:(25)

- Drug ejection during storage is a drawback.
- Growth in particle size over storage.
- Transition to polymorphism.

11 Parenteral Drug Delivery:

Nanotechnology and nanomedicine are crucial for enhancing parenteral drug delivery. SLNs are often administered intravenously to animals. Lipid nanoparticles laden with drugs can be injected directly into target organs, subcutaneously, intramuscularly, or intravenously. Lipid nanoparticles can release drugs through diffusion, which may facilitate a prolonged drug release, or erosion, such as enzymatic destruction. The ability of lipid nanoparticles to incorporate peptides and proteins has been validated by recent studies. Due to their restricted drug loading capacity, SLNs are not a good carrier in this situation; instead, NLCs are a suitable substitute.

Peptides and proteins can be shielded from adverse environmental circumstances with this technique (25). In general, SLNs is appropriate for all parenteral applications using polymeric nanoparticles. Treatment of joint arthritis is one of many additional parenteral applications that seem promising and therapeutically beneficial (23).

The arrangement encouraged greater diffusion into the liver and kidneys, but conveyance of SLNs was found to have larger medicine fixations in the lung, spleen, and brain. for parenteral organization, SLNs scatterings need to be sterile (7).

Advantages:(25)

- Sustained and regulated medication release.
- Strong promise as adjuvants for vaccines.
- Increasing the bioavailability of drugs.
- Increase viability.

Disadvantages: (25)

- drug expulsion;
- reduced drug payload for hydrophilic medicines;
- Lipid buildup in the liver and spleen may result in pathological alternation, particularly when compritol containing SLNs is present.

11 Topical and transdermal delivery:

Topical, dermal, and transdermal administration must all be taken into account when using the skin as a medication delivery method. Only the transdermal formulations are intended to penetrate and reach systemic circulation, even though all are applied topically. Dermal drug delivery occurs when the medication reaches the skin's dermis, whereas topical drug delivery refers to the drug's action at the superficial layers (such as the epidermis). When treating skin conditions for which systemic absorption is not advised, topical medication distribution is a crucial component of the treatment plan. The topical approach is preferred over the parenteral and oral parenteral routes because to its advantages. It avoids both fluctuations in plasma medication levels and systemic negative effects. Additionally, it circumvents the first-pass metabolism and allows a higher medication concentration to be administered to the afflicted site. However, because the majority of medications used to treat skin conditions are hydrophobic in nature, passing through the stratum corneum presents a significant obstacle to the topical distribution of hydrophobic moieties(27).

Skin conditions are prevalent worldwide. Low medication efficacy due to inadequate skin

penetration or skin permeation of pharmaceuticals from the most traditional formulations is one of the main therapy limitations for these disorders.

To improve skin penetration or permeation, lipid nanoparticles like SLNs and NLCs have been created. SLNs or NLCs are combined with traditional formulations to create these particle formulations. For topical medication delivery, lipid nanoparticles offer numerous benefits, including biocompatibility and biodegradability, a regulated and prolonged drug release profile, intimate contact and strong skin adherence, skin hydration, and film formation to improve skin and dermal penetration (25).

For SLNs scatterings with low lipid content [up to 5%], the smallest particle sizes are monitored. poor clustering of the dispersed lipid and poor thickness are disadvantages of dermal organization. In order to achieve plan that can be controlled by the skin, it is crucial to join the SLNs scattering in a treatment or gel (7)

Table 4.Examples of drug used in topical and transdermal delivery: (27)

Drugs	Category	Purpose
Curcumin	Anti-inflammatory	Formulation and evaluation of curcumin SLNs (ceramide-palmitic acid complex) for physical features and ex vivo permeation
Amphotericin B	Antifungal	Design of amphotericin B SLNs for improvement of therapeutic antifungal activity
Benzoyl peroxide	Anti-acne	Benzoyl peroxide SLNs to reduce side effects associated with drug for acne treatment
Fluconazole	Antifungal	Design of fluconazole SLN for its topical delivery against candidiasis
Retinyl palmitate	Anti-wrinkle	Improvement of surface modified SLNs loaded gel for enhancement of skin distribution of retinyl palmitate for skin aging.

Terbinafine	Antifungal	Development of terbinafine hydrochloride SLNs for controlled release via topical application SLNs as a topical delivery technology to address the problems of more frequent delivery and longer treatment times.

Advantages: (25)

- Lengthen skin deposition and improve medication solubility.
- Enhance skin permeability and/or penetration.
- The potential for targeting particular follicles.

Disadvantages: (25)

- High drug loss.
- Limited transdermal medication administration.

11 Brain targeting:

Due to the existence of blood brain barriers [BBB], drug delivery to the brain is one of the most significant issues in pharmaceutical sciences. Over time, a number of methods have been developed to treat neurological illnesses by delivering active therapeutic substances to the brain. For the purpose of specifically targeting brain tissues, nanoparticles with the benefits of small particle size and high drug encapsulation effectiveness have been investigated. Nanoparticles can be used as a brain drug delivery technique since they can avoid the reticuloendothelial system [RES]. Drug efflux from the brain to the bloodstream and restricted drug penetration across the blood brain barrier are two of the main challenges in brain medication delivery. Lipophilic and hydrophilic medications that may be supplied through various methods can be incorporated into lipid nanoparticles. It is possible to select the right surfactants based on their packing parameter and HLB. Polysorbates, particularly polysorbate 80, have demonstrated the best outcomes for site specific brain medication delivery. Furthermore, the findings demonstrated that positively charged lipid nanoparticles improve medication accumulation in the brain (25).

The most researched and widely accepted method of delivering the medication to the brain to date is the systemic delivery route. They avoid systemic clearance by using the nose brain route or intravenous techniques with better encapsulation, which enables greater drug concentration, improved therapeutic efficacy for CNS illnesses, and decreased toxicity. After entering the nasal cavity, the active medication is put into a nanocarrier system and travels straight to the brain via the trigeminal and olfactory pathways. However, the primary barrier to this kind of medication delivery approach is BBB. It is necessary to develop a design that allows the active medication to be put into permeable, nontoxic nanoparticles that can pass through the blood brain barriers. Additionally, a number of methods have been devised to improve the blood brain barriers' permeability, including the injection of hyperosmolar mannitol. either by delivering ultrasound as a physical stimulation or by producing reversible disturbance. In any case, the rupture of the blood brain barrier caused an inevitable inflow of neurotoxins that seriously damaged the brain. Therefore, sophisticated drug modification techniques may be useful in treating neurological illnesses caused by the breakdown of blood brain boundaries by improving

themedications' capacity to penetrate these barriers. Blood brain barriers can be safely and successfully crossed by lipid-based nanoparticles (24).

A number of variables affect a substance's capacity to pass across the blood-brain barrier and enter the brain:

1. Drug related factors at the BBB include concentration at the BBB, the drug's size, flexibility, conformation, ionization (non-ionized) form penetrates the BBB), and lipophilicity; its cellular enzyme stability and cellular sequestration; affinity for efflux mechanisms (like P-glycoprotein); hydrogen bonding potential (like charge); affinity for carrier mechanisms; and the impact of the current pathological conditions on all of the aforementioned.

2. The physicochemical properties, such as log One of the most informative parameters is the therapeutic agent's Po/w. In this context, the rule of 2 is widely acknowledged, meaning that a log Po/w number that is close to 2 is seen ideal. On the other hand, increasing lipophilicity with the goal of increasing permeability would increase both the rate of oxidative metabolism by cytochrome P450 and the volume of distribution (Vd). Systemic enzymatic stability, plasma protein binding affinity, drug absorption into other tissues, clearance rate, and the impact of pre-existing pathological states are examples of peripheral variables (28).

Function of blood brain barrier:

The BBB carries out numerous tasks. First, in order for neurons to carry out their intricate integrative functions, the internal environment of the brain that is, the composition of the brain's interstitial fluid (ISF) and cerebrospinal fluid (CSF)must be kept within incredibly fine bounds, far more so than the somatic extracellular fluid. The CNS's integrative neuronal activity is almost entirely dependent on precise synaptic transmission as well as temporal and spatial summation. Second, neuroprotection is one of the BBB's primary roles. The CNS will be exposed to a variety of neurotoxic metabolites and acquired xenobiotics during the course of a lifetime, which may result in cell death or injury.

Since mammals are a phylogenetic class of animals with very long lifespans and essentially no neuronal replacement in their central nervous systems, any increase in neuronal death will accelerate degenerative diseases and worsen age-related natural debilitation. The blood-brain barrier (BBB) shields the brain from changes in ionic composition that may follow a meal or physical activity, which may interfere with synaptic and axonal Signaling. The barrier aids in maintaining the separation of neurotransmitters that act centrally and peripherally. Lastly, the continuous bulk flow turnover and drainage of ISF and CSF aids in the removal of bigger molecules and brain metabolites, preserving the brain microenvironment(28).

Techniques for getting around the BBB Despite their effectiveness, invasive systems are not always appropriate due to their intrusive character. Therefore, the use of innovative drug delivery systems (NDDS) would be the main method of attaining noninvasive delivery. A novel method to drug delivery systems Drug transport to the brain fails for two basic reasons:

1) The medication molecule's poor BBB penetration.
2) Drug efflux, or back transport, from the brain to the blood(28).

Advantages: (25)

- A notable rise in medication absorption in the brain.

- Extended stability in storage.
- Bypassing blood brain barrier
- Opening tight junction.
- The potential for both hydrophilic and lipophilic drug encapsulation.

Disadvantages: (25)

- Quick removal of drug loaded SLNs from the systemic circulation following IV delivery is a draw back.
- The potential for reticuloendothelial system [RES] cells to identify lipid nanoparticles.

9.5 Anticancer drug delivery: Uncontrolled cell division, resistance to cell death, and the capacity of these cells to infiltrate other tissues are all characteristics of the group of disorders known as cancer. It is one of the main causes of death in the globe. Chemotherapy administered through traditional drug administration is the most prolonged cancer treatment, but it has several drawbacks, such as low drug solubility, low specificity, high toxicity, and low therapeutic index.

The resistance of cancer cells to medication therapies is another challenge associated with chemotherapy. The development of resistance to a wide range of medications is referred to as multidrug resistance (MDR). Furthermore, because anticancer medications are primarily provided intravenously or by injections rather than orally, they cause significant discomfort for patients. Chemotherapy is still the primary cancer treatment today, despite all of these drawbacks. In addition to the aforementioned benefits, the use of SLNs in anticancer treatments may enable oral drug administration and extend the duration that cancer cells are exposed to medications compared to the most common administration techniques. This would suggest using more straightforward and practical treatments for patients (29).

SLNs has recently surfaced as a unique DDS for cancer research, encompassing targeting, diagnostics, and medication delivery. SLNs is widely utilized in pharmaceuticals, biomedical applications, bio-imaging, and photothermal therapy, either alone or in combination with other compounds. When anticancer drugs are administered via innovative SLNs, their activity is increased and their selectivity is improved. By modifying cellular signaling and gene expression, the SLNs based delivery system also offers the possibility of cellular-based drug guiding (30).

When loaded in SLNs with their traditional therapeutic forms, the cytotoxicity of numerous chemotherapeutic drugs was compared. The human colorectal cancer cell line HT28 was used in one investigation to assess the cytotoxicity of SLNs formulations containing paclitaxel (PTX), doxorubicin (Dox), or cholesteryl butyrate. The findings demonstrated that SLNs of dox and cholesteryl butyrate showed noticeably greater cytotoxicities than the corresponding quantity of free drug. Both SLNs drug formulations' 50% inhibitory concentration (IC50) values for HT28 cell growth were lower than those of the equivalent traditional drug solutions (butyrate: 0.3 mM versus 0.6 mM; Dox: 81.87 nM versus 126.57 nM, respectively). However, when compared to the same quantity of medication in a free solution including Cremophor EL, PTX loaded SLN demonstrated nearly identical cytotoxicity. This was explained by the reduced drug release from the SLN caused by PTX's poor water solubility. It was thought to be advantageous to replace the hazardous Cremophor EL with SLNs (31).

11 Comparison with other Nanocarriers

Drugs and other bio actives used in diagnosis, therapy, and treatment processes are delivered via solid-lipid nanoparticles and nanostructured lipid carriers(32). SLNs are made of solid lipids at 20–28°C, whereas nanostructured lipid carriers (NLC) are a mixture of liquid and solid at room temperature. Gelatin propensity, high diffused water volume, reduced drug packing capacity, high polymeric transition movement, polymeric variation that results in drug elimination, optimization challenges, and sometimes a challenging preparation process are some of the drawbacks of SLNs. To get around the drawbacks of SLNs, NLCs are becoming the second generation of lipid nanoparticles (33).

Solid lipids, liquid lipids, surfactants, and cosurfactants are typically used in the formulation of NLCs. Stearic acid, cetyl alcohol, glyceryl monostearate, and glyceryl behenate are examples of common solid lipids. Oleic acid and isopropyl myristate are examples of liquid lipids that can be utilized. Polysorbate 80 and Poloxamer 188 are two common surfactants. Cosurfactants like ethanol, propylene glycol, glycerin, and sucrose stearate are frequently utilized (34).

11 Recent Advances and Future Perspectives

remedies for a number of disorders. Conventional drugs can be harmful to healthy cells. In order to create models that would reduce detrimental side effects in their applications, research is currently concentrated on the cell toxicity and inflammatory reactions brought on by SLNs. In the near future, researchers hope to optimize and modify the use of stealth SLNs and NLCs into forms like targeted SLNs and Nano particulate lipid carriers. These are anticipated to increase the nanoparticles' efficacy in anticancer treatments while reducing negative effects (35)

The future direction of research can be done on administration routes of Solid Lipid Nanoparticles (SLN).

- This field of rectal route of administration appears to be quite open to research, particularly when the advantages of the rectal route are taken into account. PEG coating appears to be a viable method for improving bioavailability through rectal administration.
- In respiratory delivery the nebulization of SLNs is an emerging field of study. SLNs may be used as carriers of peptide medications to enhance their effects or anticancer medications in the treatment of lung cancer.
- For the parenteral route researchers have shown that SLNs coated with hydrophilic molecules containing anticancer medications can more successfully penetrate solid tumour cancer cells than healthy tissues.
- In oral administration pharmaceutical companies have shown a great deal of interest in the use of submicron-size systems for oral drug delivery, particularly for peptide medicines.
- The effective integration of active chemicals and the associated benefits make SLNs an appealing colloidal drug carrier technology. They continue to show their benefits, and new strategies are being presented. SLNs coating with hydrophilic materials has great promise for treating a variety of illnesses, including tuberculosis and cancer (16).

CONCLUSION

Solid lipid nanoparticles are a viable and adaptable drug delivery method that has great promise for pharmaceutical advancement in the

future. They are a significant topic of study in contemporary nanomedicine because of their capacity to improve medication stability, bioavailability, and controlled delivery. Conclusion A sustained release profile of the drug must be attained in order to maintain steady concentrations within its therapeutic concentration and avoid suboptimal levels that might promote the selection of resistant bacteria. Because encapsulation lessens the medication's toxicity, higher dosages and/or longer therapy periods are possible.an increase in BA systemically. Allowing for pulmonary delivery with little scattering. promoting accumulation in target cells by using active targeting. Lowering bacterial strains' minimum inhibitory concentrations (MICs).

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