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Original Article

DASATINIB-LOADED SOLID LIPID NANOPARTICLES FOR ENHANCED ORAL BIOAVAILABILITY AND CANCER THERAPY

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ABSTRACT

Dasatinib is a second-generation tyrosine kinase inhibitor widely used for the treatment of chronic myeloid leukemia and several malignancies. However, its poor aqueous solubility, limited dissolution rate and extensive first-pass metabolism result in low oral bioavailability and reduced therapeutic efficacy. Nanotechnology-based delivery systems, especially solid lipid nanoparticles (SLNs), have emerged as effective carriers for improving the pharmacokinetic and therapeutic properties of dasatinib. SLNs enhance drug solubility, improve lymphatic transport, prolong systemic circulation and provide controlled release of encapsulated drugs. This study discusses the physicochemical properties of dasatinib, formulation strategies for dasatinib-loaded SLNs, preparation techniques, characterization methods, pharmacokinetic improvements, therapeutic applications and future prospects in nano-oncology.

Keywords: Dasatinib, Solid Lipid Nanoparticles, Nano, Oncology, Bioavailability, Targeted Drug Delivery, Tyrosine Kinase Inhibitor

INTRODUCTION

Cancer remains one of the leading causes of morbidity and mortality worldwide despite remarkable advances in diagnosis and treatment. Conventional chemotherapy continues to play a major role in cancer management; however, its clinical effectiveness is often limited by poor selectivity toward tumor tissues, severe systemic toxicity, multidrug resistance, rapid drug clearance, and inadequate bioavailability of anticancer agents Roy et al. (2023). Most chemotherapeutic drugs distribute nonspecifically throughout the body and damage rapidly dividing healthy cells, leading to adverse effects such as myelosuppression, hepatotoxicity, cardiotoxicity, gastrointestinal disturbances and immunosuppression. In addition, many anticancer drugs exhibit poor aqueous solubility and unstable pharmacokinetic profiles, which further compromise therapeutic efficacy. Dasatinib is a second-generation tyrosine kinase inhibitor (TKI) approved for the treatment of chronic myeloid leukemia (CML) and Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL). It exerts potent anticancer activity by inhibiting BCR-ABL fusion proteins and SRC family kinases that regulate cell proliferation, migration, differentiation, angiogenesis and survival Fauziya et al. (2023). Compared with imatinib, dasatinib demonstrates significantly higher potency and effectiveness against resistant leukemia cells harboring BCR-ABL mutations. Fauziya et al. (2023) reported that dasatinib is approximately 300 times more potent than imatinib against BCR-ABL kinase activity. Despite its therapeutic advantages, dasatinib belongs to the Biopharmaceutical Classification System (BCS) Class II category, characterized by low aqueous solubility and high membrane permeability. Poor solubility significantly limits its dissolution rate in gastrointestinal fluids and consequently reduces oral absorption and bioavailability Wang et al. (2022). Furthermore, extensive hepatic first-pass metabolism contributes to variable plasma concentrations and inconsistent therapeutic outcomes. The

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oral bioavailability of dasatinib has been reported to range between 14–34% in animal studies, indicating the need for advanced drug delivery systems capable of improving its solubility and absorption. In recent years, nanotechnology-based drug delivery systems have emerged as highly promising approaches for overcoming the limitations associated with conventional anticancer therapy. Nanocarriers improve drug solubility, prolong systemic circulation, facilitate targeted delivery and reduce toxicity toward normal tissues Russo et al. (2021). Among various nanocarrier systems, solid lipid nanoparticles (SLNs) have gained considerable attention because of their biocompatibility, biodegradability, controlled-release behavior and ability to enhance lymphatic uptake of lipophilic drugs. SLNs are therefore considered promising carriers for improving the therapeutic performance of dasatinib in cancer therapy.

DASATINIB: PHYSICOCHEMICAL AND PHARMACOLOGICAL PROPERTIES

Dasatinib is chemically designated as (18F)-N-(2-chloro-6-methylphenyl)-2-(6-(4-(2-hydroxyethyl)piperazin-1-yl)-2-methylpyrimidin-4-ylamino) thiazole-5-carboxamide. It is a synthetic orally active small-molecule inhibitor belonging to the class of tyrosine kinase inhibitors. Dasatinib acts primarily by inhibiting BCR-ABL kinase and SRC family kinases, which are critically involved in the regulation of tumor cell proliferation, migration, angiogenesis, adhesion and survival Fauziya et al. (2023). Because of its broad-spectrum kinase inhibitory activity, dasatinib has demonstrated therapeutic potential not only in leukemia but also in various solid tumors including breast cancer, lung cancer, prostate cancer and ovarian cancer. Pharmacologically, dasatinib exhibits rapid absorption following oral administration; however, its clinical performance is greatly influenced by its physicochemical limitations. The drug possesses poor aqueous solubility, which significantly restricts its dissolution in gastrointestinal fluids. According to Wang et al. (2022), inadequate dissolution results in limited absorption and poor oral bioavailability. Furthermore, the solubility of dasatinib is highly pH-dependent and variations in gastric pH may further influence drug absorption and therapeutic response.

Several limitations restrict the clinical effectiveness of dasatinib:

- Poor aqueous solubility
- Extensive hepatic first-pass metabolism
- Variable oral absorption
- Low oral bioavailability
- Short biological half-life
- Dose-dependent toxicity
- Development of drug resistance

Animal studies have demonstrated oral bioavailability ranging from approximately 14% to 34%, primarily because of poor dissolution and extensive first-pass hepatic metabolism Fauziya et al. (2023). Additionally, systemic administration of high doses may produce adverse effects including myelosuppression, pleural effusion, thrombocytopenia, gastrointestinal toxicity and hepatotoxicity. Due to these limitations, conventional formulations of dasatinib often fail to maintain adequate therapeutic drug concentrations at tumor sites. Consequently, novel formulation strategies are required to improve its solubility, stability, pharmacokinetics, and tumor-targeting ability. Nanotechnology-based delivery systems have therefore emerged as highly effective approaches for improving the therapeutic utility of dasatinib.

ROLE OF NANOTECHNOLOGY IN DASATINIB DELIVERY

Nanotechnology has revolutionized modern cancer therapy by enabling the development of nanoscale drug delivery systems capable of improving the pharmacokinetic and pharmacodynamic properties of anticancer agents. Nanoparticles generally range in size from 10 to 1000 nm and possess unique physicochemical characteristics such as large surface area, enhanced permeability and controlled-release behavior Roy et al. (2023). The application of nanotechnology in dasatinib delivery aims to overcome the limitations associated with poor aqueous solubility, low bioavailability, nonspecific distribution and systemic toxicity. Nanoparticles improve therapeutic efficacy by increasing drug accumulation at tumor sites through the enhanced permeability and retention (EPR) effect. Tumor tissues possess abnormal vasculature with leaky blood vessels and impaired lymphatic drainage, which allows nanoparticles to preferentially accumulate within cancerous tissues Russo et al. (2021). Nanotechnology-based delivery systems offer several advantages for dasatinib therapy:

- Enhanced solubility and dissolution
- Improved oral bioavailability
- Controlled and sustained drug release
- Reduced systemic toxicity
- Enhanced permeability across biological membranes

- Increased tumor accumulation
- Improved pharmacokinetic profile
- Protection from degradation
- Potential for active targeting

Russo et al. (2021) emphasized that nanoparticle-mediated delivery significantly improves the therapeutic index of tyrosine kinase inhibitors including dasatinib, ponatinib, and imatinib. Nanoparticles reduce premature drug degradation and prolong systemic circulation, thereby enhancing drug availability at tumor sites. Wang et al. (2022) developed dasatinib nanoemulsions and nanocrystals using high-gravity technology and observed significantly enhanced cytotoxicity against MDA-MB-231 breast cancer cells compared with conventional formulations. Their study demonstrated that nanoemulsions improved Caco-2 cell permeability and drug release behavior, indicating improved oral absorption and bioavailability. In addition to passive targeting through the EPR effect, nanotechnology also enables active targeting by surface modification of nanoparticles using ligands, antibodies, peptides and polymers that specifically bind to tumor-associated receptors. This targeted delivery strategy minimizes exposure of healthy tissues to cytotoxic drugs and thereby reduces adverse effects.

SOLID LIPID NANOPARTICLES AS CARRIERS FOR DASATINIB

Solid lipid nanoparticles (SLNs) are submicron colloidal carriers composed of physiological solid lipids stabilized by surfactants in an aqueous medium. SLNs combine the advantages of polymeric nanoparticles, liposomes and emulsions while minimizing many of their limitations. Because the lipid matrix remains solid at room and body temperatures, SLNs provide excellent physical stability and controlled drug release characteristics German-Cortés et al. (2023). SLNs are particularly suitable for encapsulating poorly water-soluble anticancer drugs such as dasatinib. The lipidic core of SLNs enhances the solubilization of lipophilic drugs and facilitates their incorporation into stable nanoparticle systems. Commonly used lipids for SLN preparation include:

- Tristearin
- Tripalmitin
- Glyceryl monostearate
- Cetyl palmitate
- Dynasan 114
- Dynasan 116
- Dynasan 118

Surfactants such as poloxamer 188, Tween 80 and soy lecithin are employed to stabilize the nanoparticle dispersion and prevent aggregation Tang et al. (2023).

Dasatinib-loaded SLNs offer several important therapeutic advantages:

- Enhanced oral bioavailability
- Improved aqueous solubility
- Sustained and controlled drug release
- Reduced systemic toxicity
- Enhanced intestinal lymphatic uptake
- Protection from enzymatic degradation
- Improved pharmacokinetic behavior
- Passive tumor targeting through EPR effect
- Improved patient compliance

German-Cortés et al. (2023) described SLNs as multitasking nanocarriers capable of significantly improving cancer therapy through enhanced targeting efficiency, reduced toxicity and controlled drug delivery. Because SLNs are prepared from biocompatible and biodegradable lipids, they exhibit minimal toxicity and excellent tolerability. Another major advantage of SLNs is their ability to enhance lymphatic transport. Lipid nanoparticles stimulate intestinal lymphatic uptake and thereby bypass hepatic first-pass metabolism, resulting in increased oral bioavailability of lipophilic drugs such as dasatinib Luo and Lu (2023). Sustained-release behavior of SLNs further maintains therapeutic drug concentrations over extended periods and reduces dosing frequency. In addition, SLNs can accumulate preferentially within tumor tissues through passive targeting mediated by the enhanced permeability and retention effect. Their nanoscale size facilitates penetration into tumor vasculature while limiting accumulation in healthy tissues, thereby improving therapeutic efficacy and reducing adverse effects. Recent studies have demonstrated promising anticancer activity of dasatinib-loaded lipid nanoparticles with improved cytotoxicity, enhanced cellular uptake and superior

pharmacokinetic profiles compared with conventional formulations Wang et al. (2022). These findings highlight the significant potential of SLNs as advanced delivery systems for dasatinib in nano-oncology.

FORMULATION COMPONENTS OF DASATINIB SOLID LIPID NANOPARTICLES

The formulation of dasatinib-loaded solid lipid nanoparticles (SLNs) requires careful selection of lipids, surfactants, and stabilizing agents to achieve optimal drug loading, particle stability, sustained release and enhanced bioavailability. The physicochemical properties of the lipid matrix and surfactants significantly influence particle size, encapsulation efficiency, crystallinity, drug release profile and storage stability Tang et al. (2023).

LIPIDS

Lipids constitute the core matrix of SLNs and are responsible for encapsulating the drug and controlling its release behavior. The selected lipid should possess high biocompatibility, low toxicity and suitable melting characteristics for nanoparticle preparation. Commonly used lipids in dasatinib SLN formulations include:

- Dynasan 114
- Dynasan 116
- Dynasan 118
- Tripalmitin
- Glyceryl monostearate
- Tristearin
- Cetyl palmitate
- Stearic acid

Dynasan lipids are triglycerides widely used because of their excellent stability and ability to encapsulate lipophilic drugs effectively. Glyceryl monostearate is frequently utilized due to its emulsifying properties and relatively less ordered crystal lattice, which favors higher drug incorporation. Tripalmitin and tristearin provide rigid lipid matrices that facilitate sustained drug release but may sometimes reduce drug loading because of their highly crystalline structure German-Cortés et al. (2023). Tang et al. (2023) observed that less ordered lipid matrices improve drug incorporation efficiency by creating imperfections within the crystal lattice that accommodate greater amounts of drug molecules. Highly ordered crystalline lipids tend to expel encapsulated drugs during storage because of polymorphic transitions toward more stable crystalline forms. The lipid concentration also plays an important role in determining nanoparticle characteristics. Increasing lipid concentration generally improves entrapment efficiency and prolongs drug release, although excessive lipid content may increase particle size and viscosity of the formulation.

SURFACTANTS

Surfactants stabilize the nanoparticle dispersion by reducing surface tension and preventing aggregation of lipid particles. They form a protective layer around nanoparticles and contribute to improved physical stability and uniform particle distribution. Commonly used surfactants in dasatinib SLNs include:

- Poloxamer 188
- Soy lecithin
- Tween 80
- Span 80
- Sodium cholate

Poloxamer 188 is one of the most frequently used stabilizers because of its excellent steric stabilization properties and biocompatibility. Soy lecithin acts as a natural phospholipid emulsifier that enhances membrane compatibility and improves encapsulation of lipophilic drugs. Tween 80 improves nanoparticle stability and may also facilitate enhanced cellular uptake and permeability across biological membranes Akanda et al. (2023). The combination of lipids and surfactants directly affects particle size, zeta potential, drug release and long-term stability. Optimization of these formulation components is therefore critical for developing efficient dasatinib-loaded SLNs with desirable therapeutic performance.

PREPARATION OF DASATINIB-LOADED SLNS

Several techniques have been developed for preparing solid lipid nanoparticles; however, hot homogenization followed by ultrasonication is among the most widely employed methods for dasatinib-loaded SLNs because of its simplicity, scalability,

reproducibility, and ability to produce nanoparticles with high encapsulation efficiency and small particle size Akanda et al. (2023). In this technique, the drug is incorporated into melted lipids, followed by emulsification in an aqueous surfactant phase and subsequent particle size reduction through homogenization and ultrasonication.

Steps Involved in Preparation

1) Dissolution of Drug and Lipid

Dasatinib and selected lipids are dissolved in suitable organic solvents such as methanol and chloroform to obtain a homogeneous lipid-drug solution. The drug becomes uniformly dispersed within the lipid phase.

2) Solvent Evaporation

The organic solvents are removed using a rotary evaporator under reduced pressure to form a thin lipid film containing the dissolved drug. Complete removal of solvents is essential to prevent toxicity and ensure formulation stability.

3) Melting of Lipid Phase

The lipid film is heated to a temperature approximately 5–10°C above the melting point of the lipid to produce a clear molten lipid phase. Heating ensures uniform drug distribution within the molten lipid matrix.

4) Preparation of Aqueous Surfactant Phase

An aqueous surfactant solution containing stabilizers such as poloxamer 188 or soy lecithin is heated to the same temperature as the molten lipid phase to prevent premature solidification.

5) High-Speed Homogenization

The hot aqueous surfactant solution is added to the molten lipid phase and homogenized at high speed using a high-pressure or high-speed homogenizer. This process produces a coarse oil-in-water nanoemulsion.

6) Ultrasonication

The coarse emulsion is subjected to probe ultrasonication to reduce particle size and produce nanosized lipid droplets with narrow size distribution. Ultrasonication significantly improves nanoparticle uniformity and stability.

7) Cooling and Solidification

Upon cooling to room temperature, the lipid droplets solidify to form stable dasatinib-loaded solid lipid nanoparticles. Akanda et al. (2023) reported that hot homogenization combined with ultrasonication produces stable SLNs with improved encapsulation efficiency, reduced particle size and sustained drug release characteristics. The preparation method also minimizes the use of toxic solvents and is suitable for large-scale industrial production.

CHARACTERIZATION OF DASATINIB SLNS

Characterization of dasatinib-loaded SLNs is essential for evaluating their physicochemical properties, stability, drug loading capacity and therapeutic performance. Various analytical techniques are employed to assess nanoparticle quality and functionality.

PARTICLE SIZE ANALYSIS

Particle size is a critical parameter influencing stability, cellular uptake, biodistribution, drug release, and tumor targeting efficiency. Smaller nanoparticles exhibit improved cellular internalization and enhanced permeability through tumor vasculature via the enhanced permeability and retention effect Minocha et al. (2023). Dynamic light scattering (DLS) is commonly used for determining average particle size and size distribution of SLNs.

POLYDISPERSITY INDEX (PDI)

PDI indicates the uniformity of particle size distribution. Lower PDI values (<0.3) indicate homogeneous nanoparticle dispersions with better physical stability. High PDI values suggest aggregation and poor formulation uniformity.

ZETA POTENTIAL

Zeta potential measures the surface charge of nanoparticles and predicts colloidal stability. High positive or negative zeta potential values prevent aggregation by electrostatic repulsion between particles. Stable SLN formulations generally exhibit zeta potential values above ±30 mV Tang et al. (2023).

ENTRAPMENT EFFICIENCY

Entrapment efficiency determines the percentage of dasatinib successfully encapsulated within the lipid nanoparticles. High entrapment efficiency indicates effective drug incorporation and improved therapeutic potential.

Entrapment efficiency is influenced by:

- Lipid type
- Drug-lipid compatibility
- Crystallinity of lipid matrix
- Preparation technique
- Surfactant concentration

FOURIER TRANSFORM INFRARED SPECTROSCOPY (FTIR)

FTIR spectroscopy is used to identify possible interactions between dasatinib and formulation excipients. The presence or absence of characteristic peaks indicates compatibility between the drug and lipids German-Cortés et al. (2023).

DIFFERENTIAL SCANNING CALORIMETRY (DSC)

DSC evaluates the thermal behavior and crystallinity of lipids and drug-loaded nanoparticles. Changes in melting peaks may indicate drug incorporation into the lipid matrix and alterations in crystallinity.

IN VITRO DRUG RELEASE

Drug release studies evaluate the release kinetics and sustained-release behavior of SLNs. In vitro release profiles help predict therapeutic performance and bioavailability. Mathematical models commonly used for analyzing release kinetics include:

- Higuchi model
- Korsmeyer-Peppas model
- Zero-order kinetics
- First-order kinetics

The Higuchi and Korsmeyer-Peppas models are widely used to evaluate diffusion-controlled release behavior of dasatinib from SLNs Minocha et al. (2023). Sustained-release patterns contribute to prolonged therapeutic activity and reduced dosing frequency.

PHARMACOKINETIC IMPROVEMENT BY DASATINIB SLNS

Dasatinib-loaded SLNs significantly improve the pharmacokinetic profile of the drug compared with conventional formulations. The lipid-based nanoparticle system enhances oral absorption, prolongs systemic circulation and facilitates lymphatic transport, thereby improving overall therapeutic efficacy Wang et al. (2022). Major pharmacokinetic improvements include:

- Increased maximum plasma concentration (Cmax)
- Enhanced area under the curve (AUC)
- Prolonged biological half-life (t1/2)
- Improved mean residence time (MRT)
- Reduced systemic clearance
- Enhanced oral bioavailability

These improvements mainly occur because SLNs enhance intestinal lymphatic uptake and partially bypass hepatic first-pass metabolism. The lipidic nature of nanoparticles promotes absorption through intestinal lymphatic pathways, resulting in greater systemic availability of dasatinib Luo and Lu (2023). Wang et al. (2022) demonstrated that dasatinib nanoformulations exhibited enhanced permeability across Caco-2 cell membranes and improved cytotoxicity against MDA-MB-231 tumor cell lines. Their findings confirmed that nanoparticle-mediated delivery significantly enhances anticancer activity and oral absorption of dasatinib. Sustained drug release from SLNs further maintains therapeutic plasma concentrations over prolonged periods, thereby reducing dosing frequency and minimizing fluctuations in drug levels.

THERAPEUTIC APPLICATIONS IN CANCER TREATMENT

Dasatinib-loaded SLNs exhibit promising therapeutic applications in several cancer types because of their improved targeting efficiency, enhanced bioavailability, and controlled-release properties.

LEUKEMIA

Dasatinib is extensively used for treating chronic myeloid leukemia and Philadelphia chromosome-positive acute lymphoblastic leukemia. SLNs improve oral absorption and therapeutic efficacy while reducing systemic toxicity associated with high-dose administration Fauziya et al. (2023).

BREAST CANCER

Breast cancer therapy greatly benefits from nanoparticle-mediated delivery systems. Tran et al. (2020) reported that nanoparticles improve drug accumulation in breast tumors and minimize toxicity to healthy tissues through enhanced permeability and retention effects.

TARGETED CANCER THERAPY

Surface-modified SLNs conjugated with ligands, antibodies, or peptides can selectively target tumor-specific receptors and improve active targeting of cancer cells. Such targeted systems enhance intracellular drug uptake and reduce adverse effects.

COMBINATION THERAPY

SLNs can simultaneously deliver multiple therapeutic agents to achieve synergistic anticancer activity and overcome multidrug resistance. Combination nanotherapy may include co-delivery of:

- Chemotherapeutic agents
- Gene therapy molecules
- Immunotherapeutics
- Natural bioactive compounds

Zhao et al. (2018) highlighted the importance of combination nanotherapy in overcoming multidrug resistance and improving treatment outcomes in cancer therapy.

LIMITATIONS OF DASATINIB SLNS

Despite their numerous advantages, dasatinib-loaded SLNs possess several limitations that may affect their long-term stability and clinical applicability. Major limitations include:

- Drug expulsion during storage
- Initial burst release
- Low loading of hydrophilic drugs
- Lipid polymorphic transitions
- Particle aggregation
- Limited stability during long-term storage

Minocha et al. (2023) reported that highly crystalline lipids reduce drug loading efficiency and may expel encapsulated drugs during storage because of polymorphic transformations. Particle aggregation may also occur due to high surface energy of nanoparticles. These limitations can be minimized through optimization of lipid composition, surfactant concentration and storage conditions.

FUTURE PERSPECTIVES

Future research on dasatinib-loaded SLNs is expected to focus on:

- Targeted ligand-conjugated nanoparticles
- Stimuli-responsive SLNs
- Combination nanotherapy
- Theranostic nanoparticles
- Clinical translation and industrial scale-up
- Personalized nanomedicine

Stimuli-responsive nanoparticles capable of releasing drugs in response to pH, temperature, enzymes, or light may significantly improve tumor-specific drug delivery. Integration of SLNs with imaging agents may also facilitate real-time monitoring of therapeutic response in precision oncology Zhao et al. (2018). Continued advancements in lipid nanotechnology are expected to accelerate the successful clinical application of dasatinib-loaded SLNs in cancer treatment.

CONCLUSION

Dasatinib-loaded solid lipid nanoparticles represent an advanced nanotechnology-based strategy for improving the oral bioavailability and therapeutic efficacy of dasatinib in cancer treatment. SLNs effectively overcome major limitations associated with dasatinib, including poor aqueous solubility, extensive hepatic first-pass metabolism, rapid clearance and systemic toxicity. The lipid-based nanocarrier system enhances drug solubilization, facilitates lymphatic uptake, prolongs circulation time and provides sustained drug release. In addition, SLNs improve tumor targeting through enhanced permeability and retention effects while reducing toxicity toward healthy tissues. Characterization studies have demonstrated that optimized SLNs possess desirable particle size, high encapsulation efficiency, good stability and controlled-release behavior. Recent research findings indicate significant improvements in pharmacokinetic performance, cellular uptake and anticancer activity of dasatinib nanoformulations. Although challenges such as polymorphic instability, drug expulsion and aggregation remain, continuous advancements in nano-oncology and lipid nanotechnology are expected to overcome these limitations. Future developments involving targeted delivery systems, theranostics and personalized nanomedicine may further enhance the clinical utility of dasatinib-loaded SLNs for effective cancer therapy.

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